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MAPPING DISASTERS

The Application of a Disaster-Sociological 'Theoretical Superstructure' and Methodology in a Prima Facie Case for Investigating the Role of Hepatitis B Vaccines in the Contamination of the Canadian Blood Supply with Human Immunodeficiency (AIDS) Virus (HIV) and Hepatitis C Virus (HCV)

By

OLAF KRASSNITZKY, MD (VIENNA), BA (CARLETON), MA (CARLETON)

**A thesis submitted to
the Faculty of Graduate Studies and Research
in partial fulfillment of
the requirements for the degree of**

Doctor of Philosophy

Department of Sociology and Anthropology

**Carleton University
Ottawa, Ontario
May 25, 2000
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Mapping Disasters

**The Application of a Disaster-Sociological 'Theoretical Superstructure' and
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submitted by Olaf Krassnitzky, MD, B.A., M.A.

in partial fulfilment of the requirements for
the degree of Doctor of Philosophy

Chair, Department of Sociology and Anthropology

Thesis Supervisor

External Examiner

Carleton University
May 15, 2000

“ Sometimes things get so bad, you can’t fix them anymore.” (A major player in the events following the contamination of the Canadian Blood supply with HIV-1 and HCV, 1999. Name withheld).

“Capitalism may be wicked, it may be oppressive, it may be exploitative, it may be vulgarizing culture and destroying moral values, but there is more freedom in it, more variety, more self expression.” (Isaiah Berlin, quoted by John Alemang in *The Globe and Mail*, on the occasion of receiving an honorary doctorate from the University of Toronto on November 24, 1994.)

“Our own times have inherited a dilemma: Is reasoning a natural component or datum of our species, or is it a painfully arrived at objective that does violence to some of our natural tendencies?” (Massimo Piatelli-Palmarini, 1994. *Inevitable Illusions*. p.4. Center for Cognitive Science, M.I.T.; and Department of Cognitive Science at the Institute of San Raffaele, Milan, Italy).

“From the conclusion of this war we shall be going downhill. It will not then be necessary to resort every moment to the people for support. They will be forgotten, therefore, and their rights disregarded. They will forget themselves but the sole faculty of making money, and will never think of uniting to effect a due respect for their rights. The shackles, therefore, which shall not be knocked off at the conclusion of this war, will remain on us long, will be made heavier and heavier, 'til our rights shall revive or expire in a convulsion.” (Thomas Jefferson, quoted by Carl Sagan, 1996: *The Demon-Haunted World: Science as a Candle in the Dark*. Pages 433-4)

Abstract

Building on advances and difficulties encountered in disaster sociology (compiled in Quarantelli (ed.), 1998) and following Quarantelli's suggestion of a 'theoretical superstructure', a methodology for the analysis of disasters was developed and applied to an exploration of the genesis of the contamination of the Canadian blood supply with human immuno-deficiency virus (HIV) and hepatitis C virus (HCV). The superstructure is grounded in concepts of general and human ecology, such as phenomena of organization and disorganization. Two classes of ecological contingencies are mapped: 1) material contingencies and their spatio-temporal relationships; 2) the social constructions of such contingencies. The methodology employs a technique for the modeling of critical paths, which are constituted by key decisions (milestone decisions) and practices concerning a specific technology through all its phases of development and operation. The application of the methodology to the analysis of the contamination of the Canadian blood supply yielded 'a prima facie case for investigating the role of trial and commercial hepatitis B vaccines in the contamination of the Canadian blood supply with HIV and HCV.' The evidence for the case is circumstantial as most of the critical direct evidence can be assumed to have been concealed or destroyed. The indirect evidence suggests that at least one of the experimental hepatitis B vaccines developed during the seventies in the US and in Europe may have been contaminated with HIV-1 of chimpanzee origin. The outbreak of the AIDS pandemic may have been related to the experimental use of such vaccines in the US, and possibly on Haitians, Africans and Europeans. Alternatively, contaminated needles and syringes used for hepatitis and vaccine research on chimpanzees in African facilities (e.g. Liberia) may have found their way into black markets for 'injectionists,' and thus may have played a role in the spread of HIV in Africa. The Canadian evidence

suggests that a HCV contamination of one or more of the Merck hepatitis B vaccines cannot be excluded; and that, alternatively/additionally, specific and non-specific gammaglobulin preparations from human plasma, (e.g. HBIG - hepatitis B immunserum used for passive immunization, such as provided by Connaught Laboratories, Toronto), were contaminated with HCV. The vaccines and the HB immunesera were licensed for experimental and/or routine use by (then) Health and Welfare Canada, while the Canadian Food and Drugs Act specifically prohibits the use of plasma from individuals with a history of a disease transmissible by blood (such as hepatitis B surface antigen and antibody positive donors, as a source of raw material). The case study also points to two deficiencies in the standards (codes of ethics) for research on side-effects: 1) an unresolved conflict between corporate proprietary privileges and 'informed consent'; 2) the lack of unequivocal rules for the investigation of side-effects and their remedies. The discussion of the case explores the risks associated with the capitalist mode of competitive, secretive development of technology; and with the techniques of disinformation employed by government, business, and scientific institutions whenever technological mishaps or 'socio-technical disasters' occur as a result of flawed technology development. Traditional sociology is focused on conditions of production, consumption and related discourses. The case study demonstrates the need for a sociology of the capitalist mode of technological development; and for a sociology of the 'genesis of disasters' arising from technological development. Without such an understanding of technological development, the public, in Western industrialized and developing nations alike, cannot seek and be assured of effective protection from adverse outcomes of relentless, competitive technological development: from the 'tragedy of capitalism.'

Dedication

This dissertation is dedicated to my late wife Rosina Puopolo and our children Sonja and Claudio. From Rosina's favorite prayer: *Oh! Signore, fa di me un istrumento della tua Pace: Dove e errore, Ch'io porti la Verita*. S. Francesco d'Assisi. She also knew Max Weber's last words: *The only thing that really matters is the truth*. Over the years, she had incurred 'collateral damage' from the strategies and tactics of those who needed to hide the 'whole truth' of the contamination of the Canadian blood supply. It was her last wish that I persevere in finding the 'whole truth' and make it known as best as I know how. Whereas the 'whole truth' may have been destroyed, or remains hidden in the vaults and specimen stores of institutions engaged in various phases of the contamination of the blood supply, and in the memories of the involved scientists and decision-makers, I believe that this study comes close enough to meeting her wishes. Rosina also gave me the idea that truth, as best as it can be known, and **when it matters**, still is the most extensively violated, yet undeclared, of all human rights. Its violations, like all other violations of human rights, are usually justified by some *higher good*, while their underlying motivations are as *banal* as they can be. They create 'virtual' gulags and concentration camps, 'gulags of the mind' as it were, which hold the inmates as well as their guards in perpetual captivity.

Acknowledgements

The author wishes to acknowledge the help and contribution of the following: **Dr. Michele Brill-Edwards** for 6 years of discussing the issues with me and providing me with invaluable information and interpretations; **Gabe and Lynn Kampf** for their help with documenting the hepatitis C case; **Dr. Alan Powell** for his support over the years; **Prof. C. Laughlin and Prof. C. Gordon** for their sustained support in an, at times very frustrating, undertaking; **Prof. F. Kellner** for pointing me in directions which I would have missed otherwise; **Prof. Terry Nosanchuk** for pragmatic advice on the politically sensitive issues; **Prof. Alan Hunt** for encouragement on the methodological approaches developed for this kind of inquiry; **Prof. Janet Siltanen** for her encouragement of keeping the moral issues alive in this endeavor; **Wayne Bissett** from Environment Canada, for his encouragements to develop the investigational methodology; **Prof. Joseph Scanlon** for putting me on the right track of the debate on disaster definitions and classifications; my colleagues **Lynda Bertrand and Alex Ipe**, who very patiently provided me with opportunities for 'talking the thesis' throughout its development, for reading and editing drafts, and for providing me with several valuable references; **the Canadian Social Sciences and the Humanities Research Council** for the award of a doctoral fellowship.

Contents

	Page
Abstract.....	i
Dedication.....	iii
Acknowledgments.....	iv
Table of Contents.....	v
List of Tables.....	vi
List of Figures.....	vii
1. Introduction.....	1
1.1 What caused the outbreak of AIDS and the spread of hepatitis C in the Canadian donor population? <u>Research questions</u>	2
1.2 Disaster sociology.....	10
1.3 A realist approach to a 'theoretical superstructure' for the investigation of disasters.....	23
2. Methodology.....	38
2.1 Characterization and identification of a disastrous occurrence.....	39
2.2 Realism and the mapping of contingencies in the space-time continuum.....	45
2.3 Spatial coordinates for the mapping of contingencies.....	55
2.4 Adding the time dimension; critical path(s) construction.....	63
2.5 Levels of knowledge construction; explaining a disaster sociologically.....	70
2.6 Models: mediating between data (maps) and theories (concepts).....	76
2.7 Contingency accounting and critical path construction in practice.....	78
3. The case of the contamination of the Canadian blood supply with HIV and HCV.....	105
3.1 Introduction	107
3.2 Critical paths and their confounded contingencies: models.....	112
3.3 The bushmeat model, the injectionist model, and the experimental hepatitis B vaccine model of the outbreak of the AIDS pandemic	129
3.4 The critical path of hepatitis B vaccines and the AIDS pandemic	202
3.5 The critical path of hepatitis B vaccines/HBIG and the spread of HCV in Canada.....	246
3.6 The critical path of Factor VIII concentrate and other blood products.....	262
3.7 The critical path of surrogate testing of blood donors for hepatitis non-A,non-B.....	271
3.8 Synopsis	296
4. Discussion: The need for a sociology of technological development and the genesis of disasters.....	300
4.1 'Dysinformation' ('dys' = bad, defective): The political economy of truth and falsity, disclosure and secrecy.....	301
4.2 The case of the contamination of the blood supply: unique or a paradigm of strategy? A comparison with the Challenger incident.	341
4.3 The need for a sociology of technological development; the need for a sociology of disaster genesis.....	368
5. Conclusions	388
5.1 The prima facie case for the role of hepatitis B trial vaccines on the outbreak of the AIDS pandemic and the spread of hepatitis C.	389
5.2 Dysinformation.....	405
5.3 'Normal business': The 'tragedy of capitalism'.....	411
5.4 The case study and disaster sociology.....	416
5.5 What kind of inquiry?.....	422
Appendix 1.....	428
Appendix 2.....	438
Appendix 3.....	452
Glossary.....	454
Bibliography.....	462
Author's Bibliography.....	481

List of Tables

Table 1	Characterization of the Challenger case and the hepatitis B vaccine case.....	40
Table 2	Equivalencies between axial coordination of contingencies and DSM axes.....	61
Table 3	Critical path prototypes for the Challenger case and the case of Factor VIII concentrate contaminated with HIV-1 and HCV.....	66
Table 4	Comparison of complete methodology and actual use in the case study of the contamination of the blood supply.....	79
Table 5	Data matrix for the Mexico City earthquake.....	82
Table 6	Data matrix for the Chernobyl disaster.....	88
Table 7	Similarities and differences between the Chernobyl disaster and the Mexico City earthquake (based on Gary Kreps's reports).....	93
Table 8	Commercial interest in the 'blood product market'	114
Table 9	Similarities in the characteristics of the hepatitis B vaccine and factor VIII concentrate ventures.....	120
Table 10	AIDS cases reported from a number of countries (from Mann et al., 1992.).....	142
Table 11	Comparative HIV-1 and HIV-2 prevalence in Guinea-Bissau, Senegal and Tanzania in 1988 (after Garrett, 1994, 692-3).....	167
Table 12	Difference in ratio between homosexual and non-homosexual infections in Belgium, compared with other European countries.....	175
Table 13	Overview of inactivation protocols for hepatitis B vaccines.....	210
Table 14	Markers of infectious disease in hepatitis B vaccine recipients.....	226
Table 15	Hepatitis ABC.....	251
Table 16	Knowledge of serious consequences of hepatitis non-A,non-B before 1981.....	257
Table 17	Relative risks of blood from voluntary and paid blood donors, known before and after HCV (HIV) testing became available.	265
Table 18	Comparison of surrogate test studies.....	294
Table 19	Similarities between the contingencies of the Challenger incident and the contamination of hepatitis B vaccines.	359
Table 20	Milestones in blood group serology.....	429
Table 21	The most important blood components.....	431
Table 22	Some important products from plasma fractionation.....	431
Table 23	Abbreviations for types of viruses and hepatitis.....	433
Table 24	Abbreviations used for post-transfusion hepatitis.....	434
Table 25	Recovery <i>in vivo</i> of different Factor VIII preparations.	442
Table 26	Recovery rates for the three Factor VIII preparations.	442
Table 27	Advantages of Factor VIII concentrate over cryoprecipitate.....	443

List of Figures

Figure 1	Fields of contingencies (simple case).....	55
Figure 2	Fields of contingencies: the multi-organizational case.....	57
Figure 3	Axial (dimensional) representation of fields of contingencies	58
Figure 4	Mapping of DSM axes onto axial diagram for disaster analysis. (For equivalencies see Table 2).....	62
Figure 5	Critical path: Sequential arrangement of time-slices with the contingency field diagram and the axial diagram: trajectories.....	63
Figure 6	Critical path (simplified version, field diagram) built with time slices	63
Figure 7	The fractal nature of critical paths.....	69
Figure 8	The position of sociological explanation vis-à-vis other modes of knowledge construction.....	70
Figure 9	Mapping of contingencies into data matrices. A 3-page organization of contingency maps for the Chernobyl disaster and the Mexico City earthquake.....	80
Figure 10	Comparative mapping of the Mexico City and Chernobyl Disasters.....	95
Figure 11	Schematic map of Equatorial African countries	139
Figure 12	Distribution of MNO types of HIV-1, chimpanzee subspecies, high density of urban HIV-1 seropositivity and research sites of the International Agency for Research on Cancer (IARC).	140
Figure 13	Hypothetical curves of vaccine cohorts and secondarily infected individuals..	142
Figure 14	Hepatitis B markers in Hepatitis B vaccine trials.	225
Figure 15	Sketches of global distributions of HIV-1 infection, hepatitis B, hepatitis C, primary cancer of the liver and schistosomiasis.	249
Figure 16	Critical paths and major milestones of the hepatitis B vaccine-related contamination of the Canadian blood supply.....	296
Figure 17	Synopsis of all major contingencies of the contamination of the Canadian blood supply with HIV-1 and HCV.....	298
Figure 18	Simplified diagrams of the cross-sections of the booster rocket field joints.....	343
Figure 19	'Incident' charts of the orbiter program.....	350
Figure 20	Separation of blood and extraction of plasma.....	430

1. INTRODUCTION

1.1 What caused the outbreak of AIDS and the spread of hepatitis C in the Canadian donor population? Research questions

1.2 Disaster sociology

1.3 A realist approach to a 'theoretical superstructure' for the investigation of disasters

Overview: The case of the contamination of the Canadian Blood supply with human immunodeficiency virus (HIV) and hepatitis C virus (HCV) is introduced. The Commission of Inquiry on the Future of the Canadian Blood System (also known as the 'Krever Inquiry') dealt with both kinds of contamination. While the final report of the Commission (referred to as the '*Krever Report*' in this dissertation) identifies many instances of 'mismanagement' of the contamination of the Canadian blood supply, it gives no indication of how voluntary and paid blood or plasma donors had acquired these infections. The report refers to certain 'high risk blood and plasma donors', but not to the epidemiological history of the two disease states in blood donors. To this day, this question has been left unanswered in the medical-scientific literature, in particular with respect to HIV-1.

Some key facts led the author to suggest that at least one of various experimental hepatitis B vaccines under development during the seventies may be linked to the contamination of the blood supply with HIV-1 in North America and in Europe. In the earlier drafts of this thesis, the author attempted to address the reasons for the 'mismanagement of the contamination of the blood supply', without including the possible role of hepatitis B vaccines. However, the author had some awareness of this possibility. For this study, the research questions had to account for such a possibility: whether or not the hepatitis vaccines had a role in the contamination of the blood supply; and if so, in what ways this circumstance may have influenced or generated the events and decisions which were characterized as 'mismanagement of the contamination crisis' in the *Krever Report*.

The HIV- and HCV-contamination of the blood supply can be viewed as 'chronic, complex socio-technical disasters'. Accordingly, the author consulted the disaster-sociological literature to find methodological approaches to this kind of inquiry. However, most of the disaster-sociological literature is focused on social responses to a disastrous occurrence, and, with few exceptions, not on the social processes leading to a disaster. It became necessary, therefore, to generate some theoretical foundations and a methodology for investigating socio-technological development. In keeping with Quarantelli's terminology, the theoretical foundation is referred to as a '**theoretical superstructure**'. (Quarantelli is a prominent US disaster sociologist). The methodology is referred to as '**mapping disasters**.'

1.1 WHAT CAUSED THE OUTBREAK OF AIDS AND THE SPREAD OF HEPATITIS C IN THE CANADIAN DONOR POPULATION? RESEARCH QUESTIONS

On October 27, 1993, Judge Horace Krever was commissioned by the Government of Canada, per Order in Council, to conduct an inquiry on the safety of the blood system in Canada (Krever, 1997:1079-1084). The inquiry had been triggered by preliminary hearings of a subcommittee of the Standing Committee on Health and Social Services of the House. Over a period of 4 years, Krever's team compiled hundreds of thousands of pages of documentary and testimonial evidence and produced a thousand page report published in late 1997, at a cost of well over 10 million dollars, with a support staff of 64.

The report has some quotes, no citations, no subject index, no bibliography, no document index. It goes to great lengths to demonstrate a series of bad management decisions by the Canadian Red Cross Society, the Bureau of Biologics of the Health Protection Branch of Health and Welfare Canada, provincial health departments and suppliers of fractionation products (specifically those who supplied Canada with Factor VIII concentrate for the treatment of hemophilia A, and notably Connaught Laboratories and Armour). The report does not explain why these 'bad' decisions, which at times appeared to be outright absurd, were made.

The report also does not explain how blood donors were infected with HIV-1 and/or hepatitis C. Infected donors are merely categorized as 'high risk populations' (such as gay men, intravenous drug users, transfused people, Haitians). Products other than fresh blood components and Factor VIII concentrate were tacitly assumed not to be

contaminated, even if collected from donor populations known to include carriers of hepatitis B, C or HIV. Two blood products (plasma derivatives), which were distributed in Canada in the late seventies and early eighties, were ignored by Horace Krever: 1) hepatitis B vaccines manufactured from human plasma of donors with a manifest hepatitis B infection; and 2) hepatitis B immuneserum for passive immunization (HBIG) derived from plasma of donors with a history of hepatitis B infection. Some of these donors could have been carriers of hepatitis C virus (HCV) also, some even of HIV-1, the virus of the AIDS pandemic.

At the outset, this study tried to explain the bad management decisions, which led to the infection of tens of thousands of Canadian hospital patients, of hemophiliacs and of some of their spouses. Because of the way in which the evidence is presented in the *Krever Report*, one is left with the impression that governmental and medical administrators did everything in their power to save the plasma fractionation industry (the suppliers of Factor VIII concentrate for hemophiliacs) from ruin as a possible consequence of the contamination of their products. If appropriate action had been taken by the government, and safety measures such as product recall and destruction of raw material had been implemented, the entire industry might have been shut down, at least temporarily.

A puzzle remained, however, as to why those of the non-hemophilic Canadian population, who required blood transfusions, had to rely on an unscreened, partially contaminated blood supply. One possible interpretation might have been that there could not be two standards in Canada, one for the source material of Factor VIII concentrate and one for blood and blood components. This kind of argument was used by the author in his

masters thesis (Krassnitzky, 1994), and the *Krever Report* (Krever, 1997) does little to correct this impression. However, in view of the compensation settlements for infected persons, in the range of billions of dollars in Canada alone, this does not appear to have been a 'judgement call to save the plasma fractionation industry from ruin.' If all products had been withdrawn, when the contamination crisis was at its height between 1981 and 1985, the loss of revenue (in Canada) to the plasma fractionation industry would have been merely in the order of a quarter billion dollars. Thus the argument put forward by the author in his masters thesis cannot be viewed as a sufficient explanation for the contamination of the Canadian blood supply with HCV and HIV.

During the early nineties, the author was alerted by some individuals in the US (whose names must remain confidential) that AIDS may have resulted from the use of a contaminated vaccine (but they did not specify which vaccine). The author was also aware that hepatitis B vaccines had been used in New York on gay men. However, there was no confirmed evidence at the time of the writing of the masters thesis which could be used to show that these vaccines could have contained live HIV-1. Chimpanzees became known in the nineties to be a possible natural reservoir of HIV-1. This was confirmed as late as 1999.

Chimpanzees were extensively used in hepatitis research and in hepatitis B vaccine research. In late 1998, the author came across documentary evidence from the US FDA (Food and Drug Administration) which linked the contamination of the blood supply to hepatitis B vaccine developers.

In the spring of 1999, these two observations prompted the author to revise his concentration on the contamination of the blood supply, and to ask the question whether

there was, at the very least, a *prima facie* case for investigating hepatitis vaccines, developed in the seventies and early eighties, as to possible HCV and HIV-1 infectivity.

Subsequently, the 'hepatitis B vaccine model of the AIDS pandemic and the spread of hepatitis C' helped explain many of the 'bad decisions' and solve the puzzles mentioned earlier. Without the help of this model, one is left with the impression that some scientists and health administrators had turned into irrational sociopaths, and that the 'saving of the plasma fractionation industry' was one of the most bizarre business decisions ever made. This is not a believable scenario. The vaccine model, on the other hand, provides a context in which the decisions, bizarre from an economic as well as from a humanitarian perspective, make at least some rational/economic – but not humanitarian - sense. The possible involvement of vaccines and other mechanisms for the entry of HIV-1 into human populations does not change the fact that known contaminated blood products were sold everywhere in the world, while other options providing a safer blood supply and transfusion practices were available, but not used. However, these commercial objectives behind these practices do not appear to have been the driving force for the unmitigated contamination of the blood supply between 1981 and 1985. The vaccine model suggests that the actions and decisions concerning the contamination of the blood supply first exploited an already bad situation (*'hemophiliacs were infected already anyway'*); and then, as exemplified by the *Krever Report*, they served, by chance, not necessarily by intention, as a smoke screen or decoy during inquiries and court cases, to divert attention away from the far more serious and far-reaching consequences of the possible use of contaminated hepatitis B vaccines in Africa and elsewhere.

In addition to the discrepancy between the potential loss of revenue for the plasma fractionation industry and the cost of settlements, other facts, which led the author to include the vaccine model of the AIDS pandemic in this dissertation, are as follows:

1) The very individuals who, in the US and in Europe, argued against the surrogate testing of blood donors for hepatitis non-A, non-B were also leaders in the development of hepatitis B vaccines.

Results from surrogate testing to screen out blood donors potentially infected with HIV-1 or HCV could have led to the suspicion of a linkage between vaccinations and infections with HIV/HCV. The recommendations against such blood donor screening tests were not made by a group of people whom one would consider representative of blood banking in the United States or in Europe.

2) The latest studies by Gao et al. (1999) revealed that the epicenter of the African AIDS epidemic (Rwanda, Uganda, Tanzania) was almost a thousand miles away from the habitat of the chimpanzee subspecies which is the natural reservoir for HIV-1, the virus of the AIDS pandemic.

3) None of the experimental vaccines were ever tested as to their freedom from HIV-1 or HCV contamination and the results published.

At least three different trial vaccines (Merck, Sharp & Dohme, vaccine developed by Hilleman; National Institutes of Health (NIH), vaccine developed by Purcell; and the New York Blood Center, vaccine developed by Prince) were tested on gay populations in New York around 1978. The only hepatitis B vaccine that was ever tested with publication of results was also the only one that was ever licensed by the US FDA: the commercial hepatitis B vaccine produced by Merck, Sharp & Dohme, licensed in 1981, available for distribution 1982. The tests were not carried out by independent laboratories and thus have little credibility – but that does not necessarily mean that the results were falsified.

These findings arose from a systematic search for contingencies of the contamination of the Canadian blood supply, which would explain not only the contamination itself, but also the decisions and actions taken by those responsible for the safety of the blood supply in the US, Canada and Europe. While the vaccine model does not make their decisions and actions any less objectionable, at least they no longer appear to be irrational, but rather very ‘rational’ and strategic. As this study progressed, it

became impossible to address the contamination of the Canadian Blood supply without accounting for the possible role of hepatitis B vaccines.

These findings led to questions as to how it was possible that, to this day, the outbreak of the AIDS pandemic can be claimed to be a 'mystery'. The following comment on the AIDS pandemic is taken from Laurie Garrett's book *The Coming Plague* (1994). Garrett studied the outbreaks of new epidemics as a fellow at Harvard University.

Though it had been the focus of attention of some of the greatest minds in contemporary biomedical science on at least four continents, nobody by 1994 had yet pinpointed a time, place, or key event responsible for the emergence of HIV-1. (Garrett, 1994:389)

Some of the greatest minds whose focus of attention had been on HIV, had also been involved in the development of Hepatitis B vaccines. Given the circumstances described above, one can hardly expect them to do much 'pin-pointing'. One of these 'greatest minds' involved in the early stages of the outbreak of AIDS was Don Francis of the US CDC (Centers for Disease Control in Atlanta, Georgia). He appears to have been a key informant of Randy Shilts, the author of *"And the Band Played on"* (1987), and judging from his remarks and descriptions, he was also a key informant for Laurie Garrett. Don Francis testified before the Krever Commission and responded to cross-examination by Allen Powell regarding the origins of HCV as follows (Powell, 1996:45):

Most of these viruses have always existed, but an ecological change in humans picks them up out of whatever ecology they are circulating in either

human or non-human. They then enter the human population (Ref.: Krever Inquiry, transcript, Exhibits, Volume 102, March 9, 1995, at 22004).

Laurie Garrett tries to demonstrate such ecological changes. Her account is consistent with the position taken by Harvard University (also Don Francis's alma mater), that AIDS arose from ecological conditions and changes in Africa, such as the butchering of chimpanzees and the consumption of HIV-infected chimpanzee meat (the 'bushmeat model of the origins of AIDS), and hence the spread of HIV in human (African) populations. By early 1999, the research questions for this dissertation were reformulated as follows:

- 1) Did the hepatitis B vaccines, developed in the US and in Europe during the seventies and early eighties, play a role in the genesis of the AIDS pandemic, and in the sudden increase in post-transfusion hepatitis in Canada (doubling over a period of two years)?**
- 2) If so, how did that influence the handling of the contamination of the Canadian blood supply with HIV and HCV; and how was it possible that, to this day, that**
  - a) the outbreak the AIDS pandemic; and**
  - b) the spread of hepatitis C in the Canadian donor population remain 'mysteries'?**

As the author found more and more 'needles' in more and more 'haystacks', the inquiry moved from initial ambiguity and uncertainty to increasing certainty. However, caution required the author to re-read sources consulted earlier, and to be on the lookout for evidence that would contradict the vaccine model. This has not happened. On the contrary, the cumulative evidence supported the vaccine model. The author was aware that even 'cautious modeling' can lead to false, invalid, or incomplete models and

conclusions, in particular when the modeling has to rely on circumstantial evidence, and when this evidence is mixed with what will be referred to as ‘dysinformation’. For this reason, and for additional reasons given below, this inquiry presents a ‘prima facie case’ for a full investigation. This caution also led to the inclusion of additional plausible models for explaining the outbreak of AIDS in Africa.

During the final writing of this dissertation, the author was still discovering additional evidence. By aiming for a ‘prima facie’ case, what seemed to be never-ending ‘work-in-progress’ could be brought to some kind of preliminary closure. The more advanced the ‘critical paths’ of various models constructed for this study became, the more time-consuming became the integration of every additional piece evidence: since all evidence is linked somehow to a vast evidentiary network, its relevance and significance needed be checked in the context of all other contingencies and pieces of evidence already accumulated, often with very little additional ‘value added’ – relative to the effort.

At the close of this study, the prima facie case for a vaccine model of the origins of AIDS and the spread of hepatitis C has remained unchallenged. However, the accumulation of indirect evidence alone cannot lead to definite conclusions: those can only be reached if specimens and lab records are released and if relevant tests are performed. So far, there is no indication that this is going to happen.

1.2 DISASTER SOCIOLOGY

IN MEMORIAM SAMUEL HENRY PRINCE

In 1917, a Canadian named Samuel Henry Prince began the formal study of Sociology of Disaster with his dissertation on Canada's worst catastrophe, the 1917 Halifax explosion. However, it wasn't until after the Second World War that scholars began to concentrate on this area and produce perceptive studies, such as Charles Fritz and J.H. Mathewson's Convergence Behavior in Disaster, readers such as George Baker and Dwight Chapman's Man and Society in Disaster, and books such as Allen Barton's Communities in Disaster (1969) and Russel Dynes's Organized Behavior in Disasters (1970).

In the same era, Dyne's long-time colleague, Henry Quarantelli, started pressing for a world-wide organization of disaster scholars and insisting that this body must have a journal. Quarantelli's efforts led to the creation of the Research Committee on Disasters, International Sociological Association, and publication of the International Journal of Mass Emergencies and Disasters." (Joseph Scanlon, Director, Emergency Communications Research Unit, Carleton University, Ottawa, Canada. President, Research Committee on Disasters. in Quarantelli, 1998:xi, Foreword.)

Note: Since 1973, Carleton University School of Journalism in Ottawa has a research capacity for disasters. (Scanlon, Joseph and Taylor, Brian 1977, 'A Stand-By Research Capacity.' *Mass-Emergencies*, 2,1:35-41).

SHIFTS IN SOCIOLOGICAL PERSPECTIVES ON DISASTERS (for the most part, based on, Gilbert's summary in Quarantelli, ed., 1998:11-18)

Following World War II, and in the wake of the Cold War, disaster sociology emerged from efforts by the US government to prepare for possible attacks on US territory and citizens. (Fritz, 1961; 1968; Gilbert; 1998 in Quarantelli, ed., 1998:11-18). In Europe, as for instance in France, the development of disaster sociology proceeded on

the basis of similar premises and conditions, such as civil defense and security built up during the two world wars. Disaster was characterized as the intervention of a **'destructive external agent'**. Ever since, disaster sociology has remained 'market-driven', i.e. prioritized and funded according to the purposes and agenda of institutions involved in disaster response, relief and reconstruction in the face of effects of such specific 'agents'.

In the seventies, sociological interest in disasters expanded into theoretical aspects (e.g. Quarantelli 1970; Wenger, 1978; Dynes, 1970; Kreps, 1978). This reorientation shifted the characterization of disasters from the notion of 'intruding agents' to the human groups involved in it, and to **'social vulnerability'**. In the 1980s much of disaster research moved in this direction, mostly in Europe, less in the United States (Jaeger, reported in Schorr, 1987; Dombrowski, 1981; Gilbert, 1991; Pelanda, 1981; Perrow, 1984: disaster as result of communal and organizational complexity; disasters as 'normal accidents'). Actual damages to the material and social order remained foci of such research.

In the 1990s, another shift occurred towards risk and uncertainty, meanings and constructions of risk and uncertainty (**'disaster as uncertainty'**; Lagadec, 1988; Gilbert 1991, Rosenthal, 1989). The notion of uncertainty is seen as generated by communities and organizations, and this sense-making and construction of reality is seen to be the result of the disastrous occurrence itself, not the result of external factors. Gilbert voices some concerns that the overemphasis on risk, uncertainty and meaning may divert attention away from actual human losses and other damages. (Gilbert in Quarantelli ed., 1998:17); and that, through relentless reinterpretation of uncertainties, human

communities may end up accepting anything (*'nothing is without risk'; 'life is a dangerous place'*). Conversely, communities may not accept anything, when people cannot be informed about the danger. This sequence of shifts parallels or follows similar trends in the management of industrial enterprises, from the management of threats and opportunities (war-like *'strategic management'*), to the management of *'liabilities'*, (management of *'damages to the community'*, i.e. the enterprise); to *'risk management'*; and *'risk perception management'* (management of meanings). Indeed, knowingly or unknowingly, disaster sociology may not only have reacted to institutional market trends, but also to shifts in business management paradigms (e.g. insurance) and their influence on funding agencies.

Extrapolating from Quarantelli's proposed expansion of potentially applicable paradigms (Quarantelli, 1998), which includes ecological and related concepts, one could predict that the next shift is going to be in the direction of *'ecology'* and related *'ethics'* (and absence thereof); and that this shift will accelerate (or be slow in coming) in correspondence with the rate at which business begins to develop ethical and ecological formulations of its conduct (if it does at all). However, as will be argued in the discussion of the vaccine case, under current conditions of competitive capitalism, which includes developmental secrecy as a key strategy for attaining global or regional market position, and the resulting lack of public participation in developmental decisions, this is not going to be an easy road ahead. However, as will be shown with the example of the analysis of the vaccine trials, research in this direction can at least accumulate a body of knowledge as a basis for adapting capitalism towards more benign developmental practices (if such research is going to receive any funding at all).

LACK OF A HUMAN-ECOLOGICAL CONTINUUM IN DISASTER-SOCIOLOGICAL PERSPECTIVES

The four perspectives:

- ❖ 'disaster as agent'
- ❖ 'disaster as vulnerable community'
- ❖ 'disaster as interpretation of reality'
- ❖ 'disaster as lack of ecological ethics'

are not mutually exclusive. An ecological scheme may well encompass the other three perspectives and provide a basis for an accounting for all of them. Unreconciled 'multiple perspectives,' on the other hand, are discontinuous representations of reality and have led to epistemological problems, as manifest in the struggle of disaster sociologists with definitions and the classification of disasters. The epistemological problems are manifest in two ways:

1) Discontinuities are assumed or constructed where there are not any. For instance, today all disaster affecting humans have some kind of technological component, and a sharp distinction between natural and human-made disasters is not possible.

2) Error in logical types (see below), i.e. definitions of phenomena without superordinated genus (such as may arise from a recognized phenomenal continuum).

In 1989, a series of articles in a special issue of the *International Journal of Mass Emergencies and Disasters* (7,3; 1989), which dealt with the problem of disaster definition and classification, could not report a consensus. There were voices for an ecological construction of disasters (e.g. Porfiriev, 1995; Kroll-Smith and Couch, 1989;

Shrivastava (1994)) and for a 'genotypal' construction of disasters' (Quarantelli, 1987). There was no better agreement in Quarantelli's 1998 collection of essays on disaster definitions (Quarantelli (ed.), 1998).

Related to the ecological perspective is the issue of **social problems theory** (or perspective). The '*social problem*' in '*social problems theory*' is a moral evaluation of people's behavior which is seen as requiring intervention. Drabek's (1987; 1989) call for integrating disasters into social problems theory ('problematizing') is just another way of saying that ultimately '*blame should be laid, leading to policy and social change*'.

There are two opposing schools of thought in disaster sociology. One supports the view that disasters are not routine social problems (Quarantelli); the other sees them as part of routine social problems (Kreps) and as part of social historical/developmental change. Extreme views of disasters as routine social problems were developed by Charles Perrow, who interpreted disasters, in particular technological disasters, as '*normal accidents*' arising under conditions of organizational and technological complexity; and by Diane Vaughan (1996), in her description of the Challenger incident, as '*inevitable mistake*' and '*normalization of deviance*'.

Assuming continuity between social processes and the uses of technologies, it seems that the distinction between social and technical problems, and whether disasters should be socially problematized as exceptional or routine social problems, may not be particularly helpful. It may not be clear, a priori, whether social policy changes or technical design changes are of primary concern. In particular during the early stages of the development of a technology, techno-scientific knowledge may indeed be such that '*mistakes are inevitable*': in this case we are dealing with a 'technical problem'. On the

other hand, when techno-scientific knowledge is substantial and design decisions are made which tolerate a high probability of failure or in the life-cycle of that technology, then we have a 'social problem'.

For instance: A 'technological problem' was encountered when manufacturers of Factor VIII concentrate realized, the latest in 1981, that probably all of their products, in-process-materials and raw materials, were contaminated with a virus causing AIDS. Their subsequent decision to sell all that contaminated material anyway, not to put a moratorium on the product, and not switch back to the safer cryoprecipitate, was a 'social problem'.

This dissertation suggests that disasters may arise from the very same conditions which lead to what is perceived as successful practices and projects. As Zygmunt Bauman (1989) pointed out, modernity has produced both destructive and productive consequences, with exactly the same norms, values, practices, etc. An explanation of this apparent paradox will be sought with the aid of notions of 'disorganizing effects' (or 'side effects') of all organizing processes (an ecological explanation).

ELIMINATING 'SPATIAL' DISCONTINUITIES IN THE SOCIO-TECHNICAL CONTINUUM

The distinction between natural and human-made disasters is 'fuzzy'. If an earthquake were to hit a large city along the San Andreas fault system, at some level of analysis, it would be difficult to say whether this should be classified as a natural disaster, or as a human-made disaster: people knowingly built their cities there. The same can be said about tornadoes, hurricanes, volcanoes, droughts, forest fires, and some epidemics.

Technological warning and prevention systems for natural disasters are growing (and are operated by socio-technical organizations). Any particular occurrence may eventually be characterized as 'socio-technical'. For instance, massive Mississippi River floodings can be attributed to both, unusual rainfall – contingency ('natural disaster'), but also to flaws in the design of the regulated river bed - structural flaw ('socio-technical disaster'). It may be prudent to drop the distinction between natural and human-made disasters, and technological and non-technological disasters, and to view all disasters on a socio-technical continuum (and continuities between social processes and the use of technologies, Drabek, 1986). Disasters without technology involvement would be placed at one default end of the continuum, and those without natural intervention at the other default end. The continuum viewpoint would diminish concerns raised regarding the neglect of physical (natural and technological) conditions in the classifying disasters on the basis of predominantly social conditions (Kroll-Smith and Couch (1889; Quarantelli, 1989): the analysis of both aspects would be obligatory.

ELIMINATING TEMPORAL DISCONTINUITIES

A review of the disaster literature showed that the emphasis of disaster sociology is on disastrous occurrences, consequences and response, not so much on the genesis of disasters. For practical purposes of disaster preparedness, response, mitigation and reconstruction, definition and classification of disasters according to consequences of a disastrous occurrence may well be sufficient. For purposes of understanding the genesis

of disasters and for thinking about approaches to prevention, they are inadequate (**Note:** ‘Preparedness’ is preparedness for disaster intervention, and just that. It must not be mistaken as true ‘prevention’).

This bias may be linked to funding priorities. In addition to competitive and security considerations, governmental and business organizations may not be inclined to have their developmental practices and failures exposed. Also, disaster response, mitigation, rescue, reconstruction have political payoffs. Exposure of failures in prevention is a political liability and will not find funding easily.

The danger of placing blame and the possible suppression of truth (and thus insight) have been pointed out by Pidgeon (1997). Furthermore, in the author’s own experience, it is easier to get the public involved in relief operations of limited duration, than in sustained prevention efforts. Prevention has no perceptible effect other than what is predicted in the analyst’s tables and writings. It is therefore ‘unrewarding’: the results of prevention are ‘non-events’. Interventions have visible effects, and are therefore experienced as ‘rewarding’ events. Accordingly, one cannot blame disaster sociologists entirely for this ‘neglect’ of disaster genesis.

On the other hand, it is difficult to envision any analysis of technical, social and ‘socio-technical’ problems without a full understanding of the genesis of disasters. The analysis of genesis cannot merely be an examination of the state of vulnerabilities, agents, and contingencies at or just before the time of the disastrous occurrence. The decisions which lead to these states must be tracked as far into the past as necessary. (**Note:** This will be referred to in this dissertation as ‘critical path construction’.)

ERROR IN 'LOGICAL TYPING' OF DISASTERS

This problem ('theory of logical types') is summed up by Gregory Bateson (1972:280), in reference to A.N. Whitehead and B. Russell (1910-13):

First, it is appropriate to indicate the subject matter of the Theory of Logical Types: the theory asserts that no class can, in formal logical or mathematical discourse, be a member of itself; that a class of classes cannot be one of the classes which are its members; that a name is not the thing named; ..... These assertions may seem trivial and even obvious, but we shall see later that it is not at all unusual for the theorists of behavioral science to commit errors which are precisely analogous to the error of classifying the name with the thing named - or eating the menu instead of the dinner - an error of logical typing.

Discussants in the sociological disaster taxonomy debate of 1989, and again in Quarantelli's 1998 publication, made the logical mistake of collapsing two levels of classes of phenomena into one, which made definition and classification inherently impossible. Disasters are defined as a class of phenomena as well as the (higher order) genus. The introduction of a 'genus' implies, however, that disaster sociologists would have to have knowledge of phenomena which are not normally classified as disasters. In all classification systems, things are defined by what they are as much as by what they are not. Until there is a consensus what should be used as 'genus' for disastrous occurrences, it will not be possible to agree on a definition of 'disaster'.

In the absence of an agreed upon definition, there may be a continuing preoccupation with ontological categories as substitute genera, i.e. with genera which are based on fundamental assumptions on our life-world, which cannot be defined with higher categories and cannot be 'proven'. 'Event', 'process', 'contingency,' 'structure.'

'class,' 'social problem,' 'mistake' are such categories. They are expressions of how our perceptions and thinking are organized, not necessarily representations of that which is being perceived and thought about. The exclusive use of this or that ontology tends to straightjacket the way we make sense of our surroundings. In the closing chapter of his 1998 collection of essays, Quarantelli points to this problem as being pervasive in theoretical disaster sociology and a major barrier to reaching consensus. (He refers to 'constructing the elephant', i.e. the metaphor of various blind individuals touching and examining different parts of the elephant and then coming to very different conclusions as to what 'it' is; hence his call for a '**theoretical superstructure**'). His publications suggest that there is no consensus as to what a disaster is; that there is no consensus whether there is a consensus; and there is no consensus whether there ought to be a consensus.

Quarantelli (1998:234-73: the closing chapter: 'Where we have been and where we might go. Putting the elephant together, blowing soap bubbles, and having singular insights'), points to a need for some new perspectives:

- 1) **Chaos theory;**
- 2) **Ecofeminism;**
- 3) **Cultural theories;**
- 4) **Risk theory;**
- 5) **Stress, emotional-affective factors, in addition to cognitive perspectives.**

All of these perspectives can be integrated in a human-ecological framework, as is attempted in this dissertation:

Chaos theory corresponds to the discussion of thermodynamics and 'fractals';

Ecofeminism is unnecessarily restrictive; an ecological perspective, consistent with chaos theory has been taken in the development of the superstructure.

Risk theory is part of the cognitive and 'social construction' dimension of disaster genesis;

Stress and emotional factors in addition to cognitive factors have been addressed as part of the cognitive and social construction dimension (the three modes of decision making: moral, rational and 'aesthetic'). The dichotomy between affect and cognition is an artificial one: psychologists have not been able to separate emotion from cognition as two separate or separable phenomena.

Anthropological (cultural) perspectives have been used by Diane Vaughan in her analysis of the Challenger incident. Anthropology can be viewed as 'human ecology.'

Quarantelli voices some concerns that radical new concepts such as those mentioned above might destroy the older ones. He concedes, on the other hand, that revolutions succeed once in while. But perhaps his concern is overstated, and is too much influenced by Kuhnian thinking. New paradigms rarely displace older ones entirely, but rather they tend to elaborate existing paradigms, or occupy domains for which the old ones were insufficient, or inadequate. Einsteinian physics did not replace classical physics, nor did thermodynamics replace time reversible characterizations of the physical world (including the Theory of Relativity).

The most serious concerns on the subject of multiple ontologies are expressed by Quarantelli in his concluding thoughts:

"A LAST WORD.

I started this chapter by noting that disaster researchers are operating with different assumptions about the nature of reality and knowledge. As such they are bound to come up with and use different conceptions of disasters. Probably most readers will have noted that much of what has been discussed in this chapter often implicitly rested on these fundamental differences in basic starting point. I am not sure that such implicit bedrock differences can be reconciled. In contrast, at least in principle, it seems to me that many, although not all, of the explicit questions and issues in this chapter can be discussed and relative agreement or consensus reached. But axiomatic disagreements would seem to be of a different order. That is one reason why, although I raised these philosophical matters, I did not address them directly. We may all have to live with them. At a personal level this is certainly possible. I was trained an elephant hunter. Because of being infected during my professional training with the Thomas virus of "if people define a situation as real, it is real insofar as consequences are concerned," I also have come to believe in being a social constructionist. And the more I have lived, the more I have wondered that my unique insights about the world are not as equally obvious to others, including what I have written in this chapter." Quarantelli, in Quarantelli, ed., 1998:273).

Overall it appears that the theoretical and methodological strategies of this dissertation come close to what Quarantelli referred to as a necessary 'theoretical superstructure.' Perhaps more importantly, these strategies do not appear to exclude any of the perspectives brought forward by disaster sociologists and Quarantelli. The approach taken may well accommodate Quarantelli's 'mixed feelings':

In saying this I should stress that in no way am I arguing for agreement on a single, all purpose, view of disaster. As noted in some of my writings of several decades ago, for legal, operational, and different organizational purposes, there is a need for and there necessarily will always continue to be different definitions/conceptions of when a 'disaster' is present. I have no problem with such different views about what constitutes a 'disaster'.

However, in my view, for research purposes, aimed at developing a theoretical superstructure for the field, we need greater clarity and relative consensus. For example, some disputes about what appear to be empirical findings mostly stem from different usages of the basic concepts in the field. (Quarantelli, in Quarantelli (ed.), 1998:3).

Given this state of affairs in disaster sociology, the author felt justified to develop a theoretical superstructure and methodology for the modeling of disasters which would overcome some of the problems mentioned. For the case study at hand, this was done in reference to 'socio-technical disasters', i.e. disasters arising from the development, production, operation or consumption of technologies – for the time being, since such a classification of phenomena may not be sustainable in the near future.

1.3 A REALIST APPROACH TO A 'THEORETICAL SUPERSTRUCTURE' FOR THE INVESTIGATION OF DISASTERS

SOCIOLOGICAL ANALYSIS AS DUAL ACCOUNTING: MATERIAL REALITY AND SOCIAL CONSTRUCTIONS OF IT

'Disasters' are entities which do not exist independently of their anthropocentric, cultural and purposive meanings. (Note: For pre-hominid occurrences of this kind the term 'catastrophe' is in use). Their nature, their presumed causes, their experienced consequences, the human responses to them, are 'socially constructed', i.e. they are analogously bounded, coded and interpreted according to their situatedness in the cultural nexus of codes and meanings. The specific meaning of 'disaster' depends on groups or individuals, their position, status, role in society, their experiences, their instrumental or moral presuppositions and intentions. (Wagman, 1997: 'conventional analogies,' 'shared cognitive maps,' 'semantic isomorphisms'; Berger and Luckman, 1966; Gruber and Voneche, 1977; Chalmers, 1991: 146-50.) In the U.S. a disaster does not really exist until the president or governor says so, and the affected communities gain access to federal aid.

However, underneath all this 'social construction' there are aspects which are accessible to natural-scientific inquiry, i.e. that which is being socially constructed can be accessed by scientific method independently of social construction (which does not necessarily mean that it is done). On the other hand, that which is scientifically constructed does not necessarily find its way into a social construction of it – and remains ignored. As Laughlin (1992) points out, scientific knowledge and meaning (social and/or cosmological) are always, at least to some degree, confounded in one-another:

We must be cautious here. Observations of dials, mazes, the behavior of chimpanzees, chemical reactions and icebergs are also life-world experiences for the scientists having them. The real question is to what extent these experiences, and the cycles of meanings of which they are a phase, are integrated into the everyday life-world of people, including the scientists themselves? I would suggest that there are very few people for whom these disparate domains of experience are integrated within a single cycle of meaning, including very few scientists (Laughlin, 1992:46)

One can turn the problematic around and suggest that there are very few non-scientists that can integrate their socially constructed meanings into scientific knowledge, and if they do, they may well contribute to corrupted scientific knowledge (in the extreme, eugenics in Nazi Germany).

Despite this 'bifurcation of knowledge' (Laughlin, 1990; 1992), people pursue projects, investigate, make decisions, use certain practices or avoid others and so forth, without being confused, most of the time. Which is to say that most people's decisions and actions are more or less singular, integrated paths, sometimes guided by scientific rationality (or equivalents), sometimes '*because the boss says so,*' or because '*everybody else does it,*' or because '*it is the moral thing to do.*' This integration in practical life does not come from either prong of the bifurcation, but from a third principle or dimension of our experience, which is neither moral nor rational, but mainly moral sometimes and mainly rational at other times: the past or anticipated experience of satisfaction (e.g. reward) and dissatisfaction (punishment or sanctions) associated with either a moral or rational response to a situation. The satisfaction/dissatisfaction can come from a purely scientific context (e.g. scientific problem and puzzles solved); or it may come from a social/cosmological context (conformance or deviations from cosmological/social beliefs). In an unpublished account of the nature of these decision processes (Krassnitzky,

1997), the author referred to this third dimension of human cognition as the 'aesthetic dimension,' i.e. a broad application of the Greek root meaning of the word: **aisthanesthai** = **to perceive**. The satisfaction of rational aesthetics comes from the solution or the performance of a material and instrumental practice (for instance 'competence'); the satisfaction of social aesthetics comes from social approval. Aesthetics then becomes that 'experiential glue' that reunites the bifurcation, but not by a higher order algorithm or logic, but simply by that which is part of our 'human nature' and made us reach the point in evolution at which we are finding ourselves today.

In some instances the instrumentally satisfying is also socially approved, in which case we may become highly committed to what we are doing (for instance being a pilot of a fighter bomber). This theme surfaces in various places in this dissertation. It lies at the heart of how power works, and no level of detail and no number of similar cases can provide the answer to the question: accepting that the power uses this or that mechanism, as for instance outlined by Michel Foucault, why and how does it work? Until we address this question, no law, political philosophy or social movement can prevent abusive social control – bearing in mind that those who believe in the need for social control may not be too eager to have such knowledge widely integrated in the knowledge and awareness of those to be controlled. Marketing strategies are designed to manipulate perception (e.g. 'risk perception management') and thus mainly the positive and negative aesthetic dimension of our life-world constructions and evaluations of our actions, be they of a moral or rational instrumental nature.

The need for science to at least approximate what it is that is being socially constructed. Accepting that all knowledge is 'socially constructed', i.e. embedded in and

emanating from social relations, in particular power relations, there is still a need to construct reality as independently as possible from such social relations and related meanings. The importance of at least trying such a construction of reality can be exemplified with the notion that AIDS came out of Africa:

As will be discussed, during the eighties it became fashionable to suggest that AIDS was the result of Africans having contact with monkeys, initially by having sex with them, and later, by butchering and eating them. This 'social construction of the origins of AIDS' conveniently placed the origins and the blame into Africa, away from Europe and the US. Africans do not have sex with monkeys, but some do eat monkey meat (e.g. the sooty mangabey). However, none of the pygmies of Central Africa, who regularly eat monkey meat, showed signs of infections. The social construction of the origins of AIDS was kept alive by two lab accidents in the US, where animal handlers, who looked after monkeys used in scientific tests in the US, were infected with HIV-2 through scratches, blood sample taking and bites. Thus it is suggested that poachers who trade in monkey meat get infected when they capture and butcher chimpanzees (the natural reservoir of HIV-1, the virus of the AIDS pandemic). Poachers could then pass it on to women, including prostitutes, and the virus would then spread through human populations. This social construction of AIDS is maintained despite the fact that the HIV-1 carrying chimpanzees live a thousand miles away from the main epicenter of the epidemic around Lake Victoria. In the area of the epicenter itself, there are hardly any chimpanzees. The chimpanzees that do live close to the epicenter carry a different, HIV-related virus, and so far there has been no evidence whatsoever that the immunodeficiency virus for which they are the natural reservoir, has entered into human populations – while this subspecies is no less suitable for bushmeat than the other.

Thus the scientific evidence on AIDS, HIV-1 and chimpanzees does not arise from any particular social construction, nor has it led to one. It is observed evidence that is apparently independent of socially meaningful construction of knowledge. It is aimed at establishing which chimpanzees carry virus and its epidemiology, and the coevolution of chimpanzees and simian retroviruses. The scientific evidence does undermine the prevalent social construction of the origins of AIDS.

Definitions and taxonomies may serve specific human interests, not 'humanity as such'. In principle, scientific constructions of disasters are not much different from social constructions in this respect, with three important differences:

- 1) Science uses unique methods of validation in its constructions of reality and in ascribing levels of certainty to generalizations derived from observations;
- 2) Science uses relatively fixed schemata of classification, which other constructions of reality do not;
- 3) Science of one field of inquiry seeks validation from other, contingent fields of inquiry (not always).

Nonetheless, in analyzing the origins of AIDS, we cannot discard the social construction of it. If we assume, with Foucault, that social construction is purposive and that the purposes are often linked to regimes of power in the near or distant past, the contradiction between the scientific evidence and the social construction raises the question why the origins of AIDS were constructed in particular ways. Neither the scientific evidence by itself, nor the social construction of 'AIDS out of Africa' by itself, can get us nearer to the origins of AIDS. However in combination, questions arise that otherwise would not be asked.

Foucault suggested that science independent of power relations is impossible, as knowledge itself becomes a source of power, and while different regimes may take their turn, power and associated privileged knowledge construction are, by implication, historical constants (Foucault 1980:133). The 'way out' cannot be, as Foucault, and also Norbert Wiener, (1967) suggest, *"to detach a regime of truth from the current conditions*

of hegemony, power, oppression,” as the detached regime of truth inevitably generates its own conditions of hegemony, power, and oppression. The problem of truth then is not whether it can be produced or not (it can be, to some extent), but whether the discovered truth is allowed to make a difference.

ACCOUNTING OF CONTINGENCIES.

As will be discussed in the review of the Challenger case, there was a fundamental flaw in the design of the booster rockets of the orbiter space craft, which by itself did not ‘cause’ the craft to explode. The explosion became reality in the presence of one or more ‘contingencies’, i.e. conditions within and around the craft which set in motion a process which was already inherent (‘latent’) in the structure of the booster rocket. Thus the cold temperature did not ‘cause’ the rocket, as designed, to explode. It created conditions under which the rocket could and would explode.

In the case of the Peruvian earthquake (May 31, 1970; also recently in the earthquake at Izmit, Turkey, 1999), the building design and the layout of villages was such that it inevitably led to serious harm to humans during an earthquake. Thus the earthquake was a contingency of the disaster referred to as ‘earthquake’. the design of houses and buildings was a ‘structural weakness’. The earthquake did not cause the people to die, but it was a condition or contingency in the presence of which the buildings would collapse and kill people. (Oliver-Smith, in Quarantelli ed., 1998:177-94). In the case of the hepatitis B vaccine discussed in this study, the HIV-1 virus is not seen as the

cause of the pandemic, but the contingencies of vaccination, scientific curiosity, and competition for vaccine markets created conditions and conduits are interpreted as permitting the virus to jump from an animal species to humans.

The relationship between properties of structures, or better, 'organization' on one hand, and conditions under which such properties became manifest on the other, has been addressed by realists (Bhaskar, 1978; 1979; 1986; 1989; Sayer, 1992). This viewpoint opposes simplistic positivist and empiricist constructions which isolate cause and effect relationships from the field of structures (organization) and their contingencies. The realist viewpoint generates a necessity for a dual accounting: the accounting for material realities (to the extent that this is feasible and possible); and the accounting of social constructions of material reality, because they are as real (in their consequences) as any material reality. To live in an unsafe house in an earthquake-prone area and believing that an earthquake is not going to happen, is as 'real' a contingency as the earthquake itself. If we look at the four main trends in disaster sociology:

- ❖ 'agent,'
- ❖ 'vulnerable community,'
- ❖ 'interpretation of reality,'
- ❖ 'ecological ethics' (or lack thereof);

it becomes clear that disaster sociology has been dealing with different sets of contingencies, but not with fundamental structural weaknesses other than those of a 'communal' nature, and their origins. Perrow's 'normal accidents' and Diane Vaughan's 'inevitable mistakes' allude to such structural weaknesses, but do not acknowledge the possibility that some may be neither 'normal' nor 'inevitable'.

SOCIOLOGICAL PERSPECTIVES

A realist position and contingency accounting render social theory and sociological perspectives problematic as analytical tools: they are liable to be social constructions of reality themselves, some more obviously so (feminism, Marxism, Parsonian functionalism) than others (postmodernism). From a realist perspective they cannot be accepted as sufficient explanatory tools, nor can they be rejected, because any one perspective contributes knowledge of contingencies, either by emphasizing them or conspicuously excluding them. The feminist perspective has made far-reaching contributions by exploring the contingency of sex (physical realities, health and illness) and gender (social construction of sex, social inequality). By excluding other contingencies (male sex, male gender) it has also created a field of which we know less than we thought, namely the contingency of male sex and male gender. Similarly, Marxism has elaborated the contingencies of capitalist production (and its liabilities for humankind), but that focus has left a void with respect to contingencies of technological development. Accordingly, in this study, some sociological perspectives will be used, but at the same level as any other social construction of material reality.

A WORKING DEFINITION

Definitions show the limits of classifications. Thus definitions are to classifications roughly as maps to geographical territory. The usefulness of classifications depends in part upon the precision of the definitions involved. In

explanatory classifications fuzzy definitions can conceal the truth you are seeking. The word or class which is being defined (the definiendum) is put into the larger class (the genus) and then differentiated from all other members of the genus. (Moore, 1967:83-190; 190-8).

Accepting as given:

The dual nature of construction of reality (scientific, material; social, purposive and meaningful);

The need for the dual accounting of contingencies (material and social construction accounting);

That there is currently no approach to identifying a 'genus' for the class of phenomena referred to as 'disasters', let alone consensus on such a genus;

A lack of understanding of the genesis of disasters beyond technical analysis;

it is probably premature to come up with a specific definition of disasters. Instead, a broad encompassing definition (i.e. a broad genus of classes of phenomena), which recognizes that a disaster is not a disaster until it so called by some social interest was accepted by the author as sufficient for the purpose of this study.

Accordingly, the working definition for disaster is a dual definition, as follows:

(a) "Any disturbance which adversely affects human life and well-being."

(b) "Any such disturbance which is perceived as serious and individually or socially constructed as a 'disaster' ".

THE MATERIAL ANALYSIS OF A DISASTER

The disturbance in question may be acute or chronic, massive or limited, noticeable or invisible, communal or regional, affect an individual, group, nation or even the entire human population. Rather than starting with some ontological assumptions and deriving classes of disasters thereof, it may be more appropriate to accumulate cases and case studies, and to derive, at some point, a classification (or continuum) thereof. This in turn cannot happen until there is an agreed-upon accounting system for structures in question and the contingencies which may affect them.

Disturbance. Usually it is the damage to an existing order which is recognized as a disturbance, regardless how it may be socially constructed. Such disturbances may or may not affect human life and well-being. The near extinction of the American buffalo was obviously a disturbance which affected the species, it was a disaster in terms of the livelihood of the Plains Indians. It was definitely of benefit to the colonizers.

From the broadest possible perspective of thermodynamics, all disturbances in existing organizations are the consequences of other organizing processes. Even when a large meteor hits the earth, and creates a disaster, or catastrophe, it is still the outcome of the effect of the sun's gravitational field organizing matter.

This concept of 'disorganizing organization' is vastly underrated in human pursuit of organizing processes, in particular with respect to technological development. Technological development, as an organizing process, inevitably disorganizes existing natural, technological, social, and psychological organization. To believe otherwise

constitutes a kind of ecological fallacy. Only the most obvious disorganizing effects are normally accounted for. Even then they may be discounted under some ideological justification such as '*cost of progress*', '*science and technology can solve all problems*', '*political expediency*', and so forth. The most insidious ideology is the notion that nothing is 'risk-free', which belittles the disorganizing, damaging effects. The notion of 'risk' implies that the bad effects may not happen, when it is known that with the presence of certain contingencies, and given enough time, they will happen.

Some authors have sought to escape the definitional and taxonomic conundrum and suggested a 'dimensional approach' to disaster classification, which can accommodate a number of continua, rather than using potentially false boundaries or thresholds. (Kreps, 1989). Kreps in particular suggested three dimensions of measurement: time, technical, and organizational. His approach was critiqued by others as overly conceptual. However, these three dimensions provided a useful starting point for this dissertation in the development of a 'dimensional' or 'axial' accounting for contingencies i.e. a system which, for the time being, designates dimensional characteristics to a specific event, but does not construct 'classes of disasters'.

SOCIAL CONSTRUCTIONS OF DISASTERS IN TIME-SPACE

'Causes' may be referred to as *tragedies* (inducing a sense of loss and compassion plus '*force majeure*', a quasi-natural catastrophic event, rather than one of human failure with potential for blame; e.g. the contamination of the blood supply with HIV).

inevitability of mistakes (Diane Vaughan's 1996 analysis of the Challenger disaster); *bureaucratic bungling*' (implying a kind of benevolent incompetence, also used in the publicity of the contamination of the blood supply with HIV); *uncertainties in requisite knowledge* before the disaster happened; in the extreme, as proposed by Charles Perrow (1984), as *normal occurrences*, the inevitable products of complex socio-technical operations (which is not too far away from notions of '*cost of progress*').

The social construction of such occurrences includes human purposive action (or lack of action) and human error; and distinctions between '*accidents*,' '*mistakes*' and '*negligence*', or worse. Even for disasters of the acute type, such as the Challenger disaster, this latter kind of distinction is not an easy one to make. When damaging effects are widely spread out in time and space, like the contamination of the Canadian blood supply, the distinction becomes even more difficult.

Today, victims of disasters, no matter how constructed, tend to become informed enough, and some at least may have the political will and determination to seek '*clarification*', in order that '*it may never happen again*' (other motives such as compensatory or retributive justice may also play a significant role - in particular compensatory justice). On the other hand, those at risk of being blamed, and who may refer to it as '*tragedy*', prefer constructions of the disaster as '*normal accident*' (a kind of natural occurrence of chance) over '*mistake*' ('*an honest error*'). '*Mistake*' is preferred over '*negligence*': '*negligence*' inevitably invokes notions responsibility, acceptability, and ultimately, sanctions.

With such '*contingencies of explanatory preferences*,' not only the social construction of a disaster is inevitably shaped by relations and differentials in power, but

also by the allocation of blame: the least powerful actors, and thus the ones least empowered to effect prevention, are likely to be blamed ('scape-goated'); while the most powerful actors tend to be exonerated. This is not to say that 'true accidents', 'honest errors' and 'operator negligence' do not happen. But, as will be discussed, the odds are that true failure in the prevention of disasters is one of higher levels of control (those with the most power to prevent them).

Note: It is a rule of thumb in quality assurance management circles that the vast majority of quality problems is due to human failure, and of that, the vast majority is due to management failure. (The author is holder of a quality assurance certificate from the Ryerson Polytechnical Institute in Toronto; for several years he was regional councilor (Canada) for the Biomedical Division of the ASQC - American Society for Quality Control).

Note: A 'scientific' approach to disaster research will increase exposure to liability, and ultimately only be possible at the expense of culpability (Pidgeon, 1997). During the parliamentary inquiry into AIDS and Blood transfusion in 1993, the author expressed these concerns to a parliamentary subcommittee. A similar approach was taken by President Mandela in his inquiries into the wrong-doings of former South-African governments. The biggest problem with this approach is that, while outright punitive sanctions would be excluded, public revelations still lead to loss of reputation, trust, power, etc., and such processes are thus inherently punitive. However, a reduced risk from failure in personal responsibility may not lead to conditions conducive for prevention, and the end result may be a lack of clarification as well as deterrent. Nonetheless, it may be necessary to rethink processes of justice which may have had some effectiveness under conditions of minimal technology. They may be inadequate under conditions of high-risk technology.

Time dimension and the life history of a disaster. Berren et al. (1980) mention that duration of a disaster and control over future impact are significant characteristics of disasters. This notion was further elaborated by LaPlante and Kroll-Smith (1989) for chronic disasters. Drabek (1986) refers to a 'life-history' of disasters and later (1989), to a disaster 'life-cycle.' Bailey (1989) points to the need for time accounting. A characteristic

of disasters reported by Turner (1976; 1978; Turner and Pidgeon, 1997) is that warning signs are not being reacted to before a disaster happens; and that emergency responses, inquiries and corrective actions tend to take place after the disaster. Time is obviously an essential dimension for the analysis of disasters. These considerations led the author to the concept and methodology of constructing 'critical paths' of decisions and contingencies.

Chronic disasters. For the most part, so-called *chronic technological disasters* have escaped disaster classification. There is a lack of the 'emergency aspect' associated with acute disasters; and the complexities and diffusion of material and social processes and responsibilities over protracted periods of time tend to leave 'allocation of blame' out of reach. Indeed, chronic disasters (such as the contamination of the Canadian blood supply with hepatitis virus) are hardly ever declared. There is also comparatively little public communication associated with them; and there are few action responses. Disastrous occurrences like the *ozone-hole* ('disastrous' with respect to the extent of increase in the incidence of skin cancer) get the occasional attention when pictures of the hole, conference communiqués or epidemiological data are released. Otherwise, it seems, the hole is now 'culturally accommodated' and taken for granted along with UV readings, sunscreens, and some degree of avoidance of exposure to sun, and not at all perceived as a disaster (except, perhaps, by those with a "*green*" outlook).

CONCLUSIONS

Accepting that there will not be an agreed upon definition of disasters and a classification system in the near future, disaster sociology could profit from an agreed upon accounting system, which is based on some 'superstructural theoretical assumptions' and thermodynamic concepts such as the disorganizing effects of organization. The accounting system could be constructed to serve the clarification of structural weaknesses (which are 'already there' at the time of the disaster, but nonetheless have a genesis of their own) and relevant fields of contingency which may arise within or outside such a structure and turn the latent structural weaknesses into a 'disturbance'. The structural weakness and fields of contingency need to include material conditions, as well as social constructions of those conditions, as both kinds of contingencies can be 'real' in their consequences. The accounting for multiple social constructions (including multiple sociological perspectives) helps to arrive at a comprehensive accounting of contingencies to an occurrence, which material accounting alone (such as technical analysis) cannot achieve.

2. METHODOLOGY

- 2.1 Characterization and identification of a disastrous occurrence
- 2.2 Realism and the mapping of contingencies in the space-time continuum
- 2.3 Spatial coordinates for the mapping of contingencies
- 2.4 Adding the time dimension; critical path(s) construction
- 2.5 Levels of knowledge construction; explaining a disaster sociologically
- 2.6 Maps, models, theories
- 2.7 Contingency accounting and critical path construction in practice

Overview. The methodology is proposed as a standardized characterization of a disastrous occurrences, in line with the concepts outlined in the *Introduction*, which is then applied to the potential role of hepatitis B vaccines in the genesis of the AIDS pandemic. The sources used in the development of 'contingency maps' are briefly reviewed. '**Fields of contingencies**' and axial schemas derived thereof were developed to represent the informal logics used for spatio-temporal contingency accounting. Two disasters documented by Gary Kreps (the Mexico City earthquake of 1985, and the Chernobyl nuclear power plant explosion of 1986) are used as examples to demonstrate the contingency accounting approach. The legitimacy of this methodological approach is supported by showing similarities between the axial schema developed for disaster analysis and the axial schema used in psychiatry (DSM).

By adding a time dimension to the field of contingencies, one or more '**critical paths**' can be constructed, which are arrays of critical decisions or events ('**milestones**') and '**phases**' of practices and processes in between. The critical paths of two technologies (the space shuttle and Factor VIII concentrate) are shown as prototypes for critical path construction. While these prototypes may not be universally applicable, they are prototypical of the life-cycle of commercial technologies and show structural similarities.

Sociological analysis is presented as a critical synthesis of the social and material contingencies of disasters captured in models mediating between maps (data) and theories (high level abstractions). A combination of an extension of Foucault's concept of **power/knowledge** to '**power/falsity**,' with an extension of Marxist analysis from the '**capitalist mode of production**' to the '**capitalist mode of technology development**' is suggested as a suitable conceptual (theoretical) basis for a critical synthesis for material and social constructions of socio-technical disasters. The section closes with a description of problems encountered in the contingency analysis of the Challenger incident and the contamination of the blood supply.

2.1 CHARACTERIZATION AND IDENTIFICATION OF A DISASTROUS OCCURRENCE

Note: The suggested first step in analyzing a disaster is a general identification or characterization of the occurrence. In the case of the contamination of the blood supply, what was first thought to be 'the disaster,' i.e. the contamination of the Canadian blood supply with HIV and HCV, turned out to be a possible secondary effect of a different kind of disaster, i.e. the spread of pathogens through contaminated vaccines.

Accordingly, the 'disaster' addressed in this study is the possible spread of HIV-1 and HCV through vaccines amongst American gay men, intravenous drug users, possibly foreign aid workers working in Africa including Haitians and Europeans, and Africans in the region of Northern Tanzania, Southern Uganda and Rwanda (the 'epicenter' of the African AIDS epidemic). Under such assumptions, the epidemic would then have spread through other possible routes of transmission, such as sexual contact, intravenous drug use, blood transfusion, blood product treatment, perinatal transmission. Each transmission route would have generated a 'secondary disaster' (such as the contamination of the blood supply), with its own, peculiar disaster responses (such as the suppression of the use of surrogate testing for the screening of blood donors).

It must be borne in mind, that the hepatitis B vaccine case is built on circumstantial evidence only, and that direct evidence for the vaccine model of the origins of AIDS and the spread of hepatitis C, or for refutations, ought to exist, but is not accessible. Therefore, all references to the vaccine model must be viewed as a *prima facie* case and 'model to be tested,' not as proof of viral contamination of the hepatitis B vaccine.

Disaster identification is not a classification, but merely a description of the occurrence, allowing it to be catalogued, and providing the essential information for considering it to be a 'disaster' or a 'disaster-like' occurrence. The following table provides the descriptors, their explanation, and their application to the case of the contaminated trial vaccines and the Challenger incident:

Table 1: Characterization of the Challenger case and the hepatitis B vaccine case.

CHARACTERISTIC	ORBITER	HEPATITIS B VACCINES
Technology Developmental or operational product which is involved or directly related to the occurrence	Booster rockets, seals, O-rings	Vaccines from human source
Operators/users Individuals who are directly involved in the operation of the technology or make decisions concerning its operation	Launch engineers (involved)	Distributors of vaccines (involved)
Product/technology cycle at occurrence Distinction whether the technology was developmental (in any one of its test stages) or operational, i.e. commissioned, licensed, implemented, commercially sold	Operational	Phase 1, 2, 3 clinical trial of vaccines; perhaps licensed vaccine.
Damage Should include all primary and secondary damages	Loss of crew, spacecraft and cargo; moratorium on orbiter program. Loss of some confidence in space technology and the US's dominance; boost for competition with specialized cargo rockets.	Tens of millions infected with HIV-1; hundreds of thousands infected with HCV; millions dead from AIDS; premature death from chronic liver diseases for perhaps tens of thousands; billions of dollars in compensation payments; unknown cost of patient care and prevention programs; devastation to some African economies.
Spatial dimensions Refers to the fields of contingency affected involved in the genesis of the occurrence	Shuttle, launch site, NASA, Morton Thiokol (Utah)	HIV: global HCV: Canada, perhaps UK, others unknown
Temporal dimension: Characterization of the occurrence itself	Minutes	Chronic, no end in sight; lethal consequences with increasing delay
Date Date of occurrence, or in the case of chronic disasters, date of likely start	1986 Kennedy Space Center, Florida	HIV: 1971/2 (US); 1975 (Africa); 1978 (US, Haiti, Africa)
Central disturbance This should refer to the 'structural weakness' realized by whatever contingency at the time of the occurrence. For instance, in a case of an earthquake, the central disturbance would be the collapse of building structures	Leaking joint of booster rocket	Transmission of live HBV, HCV and/or HIV-1 in hepatitis B trial vaccines; some HCV infections, AIDS.
CHARACTERISTIC	ORBITER	HEPATITIS B VACCINES

Structural condition making the disturbance possible This is the structural weakness which may not become manifest without additional contingencies	Flawed design of rocket joints, (lack of redundancy); possible irregularities in contract award to the Morton Thiokol Company (design specifications)	Product possibly derived from human donors infected with hepatitis B; possibly with hepatitis C; use of chimpanzee plasma for the isolation and reproduction of specific subtypes of hepatitis B surface antigen (the 'immunogen'). Insufficient viral inactivation
Proximate contingency This refers to the contingency which is the closest to the structural weakness and sets of the disastrous occurrence	Cold Temperature on launch date	Use of vaccines on trial populations
Proximate contingent decision This is the decision or series of decisions which makes it possible for the proximate contingency to act on the structural weakness.	Launch decision	To use trial vaccine on trial populations
Remote structural (design) decisions Can be any number of contingencies and decisions which are either linked to the structural weakness or the precipitating proximate contingency.	Design specifications of booster rocket; contract award; launch of first orbiter flight.	To develop vaccine from human source; possibly to try chimpanzee-derived immunogenic material
Warning signs Warning signs almost always precede a disaster. They are the most important clues for preliminary identification of structural weaknesses, proximate contingencies and proximate contingent decisions.	Yes: 'incidents' (burnt O-rings, 'blow-bys')	Yes, the Cutter vaccine incident which contained live polio vaccine; SV40 contamination of Salk-type vaccines and transmission to humans;
Public classifications These construction provide some clues as to whether there is strategic intent in the handling of the communications on the occurrence, or whether the public is reacting spontaneously. If these constructs are strategic, they may provide some clues as to the 'structural weaknesses.'	Disaster, incident	Tragedy, mystery, bureaucratic misconduct, (not a disaster); 'ecological disturbance.'

Note: The identification of proximate contingency (sometimes referred to as 'cause'), plays a significant role in litigation. For instance, the criminal charges against the managers of the Westray Mine in Nova Scotia were dismissed because the court ruled that it had not been clearly enough established what the cause (proximate contingency) of the mine explosion had been. The 'structural weaknesses', i.e. the mining of a coal field with a high risk from a combination of methane and coal dust accumulation and inadequate safety conditions of the mine, as well as the management of these conditions, were not considered as sufficient 'causes' calling for a criminal prosecution.

The courts treat organizations and individuals differently in this respect. Firstly, individuals can be charged with 'criminal omission' (i.e. criminal neglect, which in effect is equivalent to 'structural weakness'). Most industrial disasters are the consequences of 'omissions' (neglect); however, this statute is hardly ever applied to industrial organizations. Another reason for non-prosecution of organizational neglect is that most plaintiffs settle out of court, in which case the evidence is usually sealed and the plaintiff obliged to confidentiality as a condition of settlement. A third reason is that evidence of developmental and design decisions, which are inherently risky and logically and materially linked to 'structural weaknesses,' are difficult to access by plaintiffs, because companies can assert proprietary privileges. Fourthly, when accountabilities are threatened to be enforced, companies can use relocation of the business to a location with lower 'social costs' as leverage (threat of unemployment in the regions of their operations). Overall, business enterprises are not accountable to the public in the same way as we understand accountability of individual citizens.

Neither the Challenger incident nor the contamination of the Canadian blood supply were disasters by public definition. In the case of the contamination of the blood supply, this may have been due to the absence of an understood origin of the contamination. In the Challenger case, the reason may have been the limited scope of damage. On the other hand, despite a limited number of deaths, under conditions somewhat comparable to the Challenger incident, the Westray Mine explosion was readily referred to as 'disaster'. The 1918/19 flu epidemic, which killed around 20 million people (including the author's grandfather), and thus more people than had been killed in the war, is still not referred to as a disaster.

Thus public social constructions are unreliable references for disaster definition and classification. Sayer would probably consider 'disaster' to be a 'chaotic conception', i.e. a generalization which divides one or more wholes or amalgamates unrelated parts. (Sayer, 1992). Even if a case could be made for both occurrences to be some kind of disastrous occurrences, it may be pointless if the public does not think so. In this dissertation the issue of definition will be side-stepped. Both cases are assumed to belong to a continuum of occurrences, within the scope of which we can locate the majority of 'disasters', publicly, or otherwise defined as such. The vaccine case will be referred to as the 'outbreak of the AIDS pandemic and the spread of hepatitis C'; the specific occurrences related to blood and blood products as the 'contamination of the Canadian blood supply'; the Challenger explosion as 'the Challenger incident'.

The kind of disaster characterization and identification used here does not claim to be sufficient to cover all possible occurrences which may be viewed as disasters. It does cover, however, a wide range of occurrences, including those affecting individuals, as, for instance, the death or injury of a driver in a car crash, breaks of dams and levees, airplane crashes, mine explosions, famines and so forth. The identification is constructed to identify what will be referred to as the 'ring of techno-scientific controls', e.g. technologies and their human handlers and users, which are organized to prevent the intrusion of adverse contingencies. The ring of techno-scientific control is a special subset of the organizational and technological fields of contingencies in socio-technical organizations.

In the case of the Challenger incident, this included engineers of the launch preparations, the procedures, and information used to make such decisions (manuals,

cameras, thermometers, checklists, etc.). In the case of the vaccine, this set of contingencies includes the vaccine developers and the test systems which they used to ascertain the safety of the product. In the case of the contamination of the blood supply it was, amongst other systems, the various tests used to screen donors blood (such as surrogate tests), the organization of the respective laboratory operations and testing policies. The structural weakness may be present in the technology itself, in its operators, or users. For instance, an alcoholic driver of a car would constitute a structural weakness in the total set of controls of the car being driven.

2.2 REALISM AND THE MAPPING OF CONTINGENCIES IN THE SPACE-TIME CONTINUUM

LOCATING A DISASTROUS EVENT AMONGST CONTINGENCIES IN SPACE-TIME; SPACE-TIME COORDINATES FOR CONTINGENCY MAPS

In keeping with a realist approach to knowledge construction, a disastrous occurrence is assumed to arise from certain properties (structural weaknesses) of a structure, or 'organization,' and from the presence or absence of contingent conditions, which make a structural weakness manifest. Structure, organization, contingencies, conditions, occurrences, are, and can be located and **mapped in a space-time continuum.**

Sources: The space-time continuum is of interest to a realist philosophy of science as well as to a realist practice of research. Giddens, for instance, emphasized the space-time 'distantiation of social phenomena' (Giddens, 1976, 1981, 1984). Bhaskar addressed the space-time dependency of social practices and structures (Bhaskar, 1986:129-31). Urry (1985) suggested that social entities (actors, groups, populations) effect certain outcomes ('*have certain powers*') depending on spatio-temporal relations between them.

The author generalized this realist concept of knowledge construction, by including all contingencies and structures, social and otherwise, in the space-time continuum. This includes material conditions, ideas, practices (extending contextual knowledge construction beyond social contexts into 'human-ecological contexts').

Accordingly, at the outset of an investigation, if nothing is known as to its causes, no set of contingencies should be seen as privileged over any other set of contingencies. Social outcomes may arise from non-social processes, and non-social outcomes may arise from social processes.

When there is already substantial knowledge on an outcome and its likely origins, some assumptions as to the relevance contingencies can be used - with

some caveats: always to include all fields of contingencies in the search for information; to redirect, if the evidence contradicts the original assumptions.

Comprehensive representation (modeling) the human life-world must include consideration of human sense-making as relevant contingencies for outcomes. Therefore, as discussed in the *Introduction*, social and individual construction (beliefs, dispositions, intentions, meanings, etc.) not only need to be mapped onto the space-time continuum, but also in relation to the material realities of which they are constructions. For instance, if the people of Mexico City believed God makes earthquakes ('Act of God'), and this is why people get killed, the Mexican government may not feel particularly pressured to do something about building codes and their enforcement. If the people believed that the government has failed to develop or enforce certain building codes, the government may feel politically compelled to develop and implement certain building codes. Thus beliefs and ideas are as real in their consequences as are material conditions ('Thomas principle').

Mapping of elements and their space-time relationships have been developed by geographers and have been enhanced by satellite imaging. There is, however, a dimensional problem with mapping of events, individuals and contingencies in the space-time continuum. Space occupies three dimensions, and time is thus a fourth dimension. Mapping can be done, at the most, in three dimensions. Most maps, however, are usually two dimensional.

There are representational strategies that can cope with this problem. For instance, (as is done for this methodology), one of the spatial dimensions can be dropped or amalgamated with one of the others. This makes room for time as one of three representational dimensions. To account for time, a series of two-dimensional, spatial maps can be used ('time slices', such as, for instance, 'before and after the warming of climate at the end of the ice-age'). A series of time-slices can then give us information on temporal changes in contingencies and their relationships.

Hunt's and Wickham's (1994) book on *'Foucault and the Law'* presents a 'toolkit for mapping' contingencies. The authors' approach de-emphasizes the mapping of material realities in favor of social constructions by informants. Jane Azevedo's (1997) naturalist realist approach to *'Mapping Reality'* and to using 'multiple (sociological) perspectives' considers social theories and concepts as maps. Of course they are not, because theories are not made up of data points, but are abstractions of their relationships. She neglects to include in her mapping approach the relationships between material realities and their social (non-sociological) interpretations, which exist independently of sociological concepts. She also misses the time dimension, and thus the time-space continuum. Also, her concept of mapping appears to be rather close to Denzin's concept of 'triangulation' (Denzin, 1970).

Realist representational techniques do not elaborate the need for 'coordinates for mapping', i.e. certain structural constants or fixed concepts, which are either self-evident (such as fences, seashores, landmarks) or are agreed upon (such as longitude and latitude). Without such coordinates, mapping yields a

rather chaotic network of contingencies, the relevance, veracity and reliability cannot be tested.

The science philosophers Shrader-Frechette and McCoy (1994) argue in favor of case study for applied ecological studies, and make reference to the US Academy of Sciences' recommendation to use case study and 'informal logics' instead of theoretical models for applied ecology. Sociology and anthropology can be viewed as 'human ecology'. Ecological theoretical models had not worked in the past (yielding only weak correlations, not unlike those produced by multivariate sociological analysis).

The combined use of mapping, mechanism discovery, using multiple perspectives, including social constructions of reality, truthful or misleading, are consistent with the informal approach suggested by Schrader-Frechette and McCoy. The informal approach also supports realism's antipositivistic stance. Positivism emphasizes generalizability (in time and space, i.e. for the future and elsewhere), and would not attempt generalization from a single case. Case studies as discussed may acknowledge findings in a single case, can be sufficient to warrant social action, at least within the boundaries of the case.

Positivism is not 'realistic' in the sense that those instances which do not fit a generalization tend to be ignored (in theory as well as bureaucratic-technocratic practice). The common positivist assumption of 'closed systems' is the reason for positivism's failure to represent reality validly. The opposing view is that all systems are open and thus not predictable (post-modernism). The author departs from both positions: all systems in our life-world and their subsystems are more or less open or more or less closed; or they have properties of open and closed systems in different mixes. For instance, the military is a relatively closed system. However, soldiers also take leave, and are influenced by beliefs prevalent outside of the military. Houses of representatives are (or at least are supposed to be) open systems, i.e. receptive to the ideas and beliefs of their constituencies. But they are also constrained by respective party doctrines and caucus decisions ('caucus' from Algonquian 'caucwasu', advisor).

Thus some 'conjunctions of contingencies' are relatively constant, others are highly variable. Dominance hierarchies are a relatively constant characteristic of human organizations. The size and shape of the hierarchies, on the other hand, are highly variable and contingent in historical space-time. From a practical viewpoint, and thus consistent with Shrader-Frechette's and McCoy's elaboration of the use of case study and informal logic instead of theoretical models, the question of constant or variable relationships of contingencies may be of interest only for a limited time period. From a theoretical viewpoint, constant and variable relationships (such as dominance hierarchies), become questions of (constant) human nature and its variable adaptations ('epigenesis': Wilson 1998). This dissertation confines itself to the practical viewpoint. However, the issues of competitive enterprising, communicative social control, and their inherent risks, which appear to pervade the case of the hepatitis vaccines, do beg questions concerning some invariable (and thus predictable and exploitable) structures of human nature and social behavior.

After the author had developed the contingency schema, he found what could be considered a precursor. The issues of a 'space-time' sociology have been summarized by Thrift (1983). Hägerstrand (1973, 1976, 1984), the Lund school', and his 'time-geography' need to be recognized here.

Time-geography contains an equivalent of a critical path. Hägerstrand described a web of social interactions situated in different contexts, in different places, at different times. However, he constructed his model in the basis of individual life histories (and thus individual 'life-paths'). He did not focus his model on particular 'outcomes', as is attempted in this dissertation, which seeks to identify 'critical paths', i.e. those paths which have a particular significance for the outcome in question. His contingency categories differ from the categories used in this thesis. He uses kinds of resources/capabilities and constraints. This methodology uses physical and ideational contingencies, related to four specific domains: environment, community, organization and technology.

While Hägerstrand's time-geography and the 'theoretical superstructure' differ in many characteristics (perhaps mainly because Hägerstrand's model ultimately seeks to serve demography, whereas the 'superstructure' seeks to serve 'outcome analysis'), they are nonetheless grounded in very similar fundamental ideas and conceptualizations of relationships between time, place, cause and material contingency. If these sets of material contingencies are complemented with ideational contingencies, the resulting framework could go a long way in helping to avoid human-ecologically fallacious arguments and explanations of social phenomena.

THE USE OF GRAPHICS IN CONTINGENCY MAPPING AND RELATED TECHNIQUES.

The title of this dissertation refers to the process of 'mapping' and an attempt to visualize data, their relationships and related concepts. Mapping in a realist application, is a technique, not just a 'metaphor'.

Originally, the author had considered an alternative title '*An Anatomy of Socio-Technical Disasters*'. Human anatomy (the Greek word '*anatomy*' meaning '*cutting up*') uses the format of an 'atlas', i.e. a collection of maps of the human body. Because of the limited scope of this dissertation, this idea was far too ambitious and thus not pursued. Instead, only a few maps of the 'atlas' were produced. However, the idea of the eventual production of such an atlas of disasters may not be one to be rejected out of hand as a standard of documenting disasters.

Maps are meant to be representations of physical phenomena (e.g. by aerial photography), but they may also be 'schematized', i.e. abstracted, usually with the intent to show some important features, such as spatial relationships; or, in sequential mapping, such as used for the ozone hole, temporal relationships ('animated maps'). Methods of this kind are widely used, for instance, for weather, physiological and neurological maps.

Further abstractions are possible which show only the functional relationships of some key elements of the phenomena observed (e.g. in physiology). They are commonly referred to as 'cartoons.' Functional relationships are usually reversible, reciprocal ('feedback'). When the time dimension is ignored (assumed reversibility), cyclical interactions can be collapsed into time-reversible functional 'feedback' diagrams.

All of these maps have in common that they depict sets of things, boundaries, flows and functional relationships amongst them, and if possible, transformational relationships. Therefore, 'maps' are fundamentally mathematical (derivatives of Venn diagrams). The characterization of sets makes possible an organization of variables and observations, which can be examined and abstracted logically, statistically or mathematically as set and probability relationships (contingency tables, analysis of variance, etc.)

Sociology tends to use either variable sets or theoretical concepts in its work. There is a lack of continuity between the two forms of sociological knowledge production. Many sociological concepts are arrived at through logical processes of deduction, or they may be avoided altogether (e.g. Hunt and Wickham, 1994). If theoretical concepts are tested directly with data, difficulties arise because of the absence of valid testable models mediating between data and theories/concepts.

Most data sets can be represented visually. In particular in complicated, complex, diverse or very rich data sets, visual representation provides a means of communicating these data in ways that cannot be substituted in any other way. (Stephen Hawking's mathematical physics is visualized mathematics. It has been acknowledged that this method of representation allows him to gain insights that would not be possible in any other way).

Most of the publications in science journals and magazines make ample use of mapping techniques, except sociological publications. Sociologists are entrained in theoretical discourses on high-level abstractions; or they observe with as little abstraction as possible (e.g. ethnomethodology); or they use statistical models which, of course, are

not maps or renderings of the operational environment, but simply stochastic characteristics of relationships of variables. A statistical model can indicate that the elements represented by the variables may be associated or interacting, but no statistical model can say how they may interact. Statistics can confirm functional relationships discovered by other means, or it can induce the search for such relationships.

MAPPING WHEN THE PROBABLE CAUSE OF A DISASTER IS KNOWN OR NOT KNOWN.

When a disaster occurs and the 'causes' are unknown, the observer deals with the total field of contingencies, which, at the outset, is spatially and temporally undifferentiated in relationship to the occurrence. Without some preliminary investigations or models of the occurrence, which at least provide a range of possible causes and contingencies, it is impossible to conduct an inquiry. However, even when such knowledge is available, this can be a daunting task, if this is the first occurrence of its kind. On the other hand, if there had been warning signals, or if certain risk factors were known beforehand, then the selection of relevant contingencies becomes a lot easier.

In the case of the Challenger incident, the Thiokol engineers probably knew immediately what the cause had been. Evidently, Richard Feynman (Feynman, 1988) was not asked to serve on the presidential commission to 'discover the causes' of the explosion, but he was being coached by at least one (military) member of the Commission to 'discover' for the public the properties of the O-rings, and their malfunction in cold temperature on the morning of the launch.

In the case of the AIDS pandemic, the field of possibly related contingencies remains (officially) vast, and hence the reference to the origins of the pandemic as a ‘mystery’. To narrow down the field, the author searched for organizational contingencies (who worked with whom, in what institution, on what projects); for communal contingencies (what were the patterns of infection, how did they differ from region to region, which ones looked similar); and for contingencies of social construction in the post-outbreak period (which public announcements did not make sense; which theories were too obvious in their scape-goating intents). The search led to the identification of the US/European ‘vaccine developer club’; a recognition that decisions against surrogate testing could not be satisfactorily explained with ‘saving the fractionation industry’: something else was hidden behind the obvious. The timing of the confirmation by Gao that chimpanzees are the natural reservoir for HIV-1, however, was pure luck. Had it appeared a year later, this dissertation might have been very different.

COORDINATES FOR MAPPING

Thus searches for the contingencies engaged in the genesis of a disaster can be systematically carried out by exploring the total field of contingencies and certain subsets. The search was carried out in the following subfields of contingencies:

- a) Material contingencies** (natural and technological);
- b) Social contingencies** (organizational and communal);
- c) Cognitive contingencies**, which come to bear in human decision-making and practices, and **'social constructions' of reality**;
- d) A trajectory of critical practices and decisions** (dimension of time, 'critical path'), contingent on one or more of the other three fields.

These fields and arrays of contingencies can be converted into 'axial' or 'dimensional' systems of accounting for contingencies. The following sections discuss the logic and use of these coordinates in detail. It will be shown that a similar schema has been developed for the classification and diagnosis of psychiatric illnesses, for very similar reasons: the causes of mental disorders are by and large not known. Therefore the discipline of psychiatry relies on the mapping of symptoms ('disturbances', 'structural/behavioral weaknesses') and their contingencies. The main differences between the two fields of inquiry is that in the case of disasters, when they involve technologies, the structure and functions of that technology are known, and far less emphasis is placed on social and related contingencies. In the case of psychiatric illnesses, since the structures and functions are not really known (or only very superficially), the emphasis has been on social and environmental, or surface (behavioral) characteristics. With respect to responses to disasters (and psychiatric illnesses, respectively), however, the patterns of knowledge construction and application are very similar: mostly 'symptomatic', with little or no reference to genesis and underlying conditions.

These discontinuities exist in our knowledge of mental illness because we do not know the causal mechanisms. In our knowledge of socio-technical disasters they may exist, to a large extent, because of efforts 'not to make the causes known'.

2.3 SPATIAL COORDINATES FOR THE MAPPING OF CONTINGENCIES

FIELDS OF SPATIAL CONTINGENCIES, BOUNDARIES (THE SIMPLE CASE)

Fig.1: Fields of contingencies (simple case)

The total field of contingencies is divided into subfields: **Communal environment, general natural environment, organizational environment, technology**. At the center of it is a field representing a specific **event, occurrence, decision, practice, set of ideas, beliefs etc. at a point in time**. For technological disasters (at least those considered in this dissertation), the event is situated at the organizational/technological boundary. However, events (and, as discussed, 'critical paths', or 'disturbances') can be situated at other boundaries, or within any of the contingency fields. The **'ring of techno-scientific control'** is a subset of combined organizational and technological contingencies. The field of decisions (in this diagram a singular element in the trajectory of the critical path of decisions and practices), and field of **contingencies of 'sense-making'**, i.e. cognitive, communicative and social construction contingencies is represented by a small, white circular field. It cannot be adequately represented with contingency field modeling. It is better reprinted in the 'axial diagram.' Decision, and practices and sense-making fields may exist elsewhere.

Fields of critical decision and practices may be situated in a subfield of contingencies, or they may be situated on a boundary. Boundaries exist amongst all fields of contingencies. In the case of the contaminated vaccine, for instance, the spread of AIDS in the gay community resulted in a critical path in that community, which led to partial voluntary abstention from donating blood and to the reduction in bathhouse activities.

Within fields or along boundaries, we may find 'loci of control', which are of particular interest for identifying 'structural weaknesses' and proximate contingencies (which the controls are meant to 'keep out'). Special technologies are being developed to maintain and secure such boundaries (vaccines, dams, walls, vessels, borders, fences, houses built with concrete shells, bunkers, prisons, quarantines, etc.) Breaches in boundaries are common contingencies of disasters (breaking dams, tornadoes breaking down houses, forest fires destroying buildings, prisoners escaping, and so forth).

For instance, in the case of the contaminated hepatitis vaccines, the boundary between natural environment (chimpanzees) and technology was broken. The injection of the HIV-1 via the vaccine then broke another boundary (the human skin barrier between technology and natural environment-human organism), and allowed the virus to organize its reproduction in humans, and to disorganize human organisms.

The subfields of contingencies presented and arranged in this diagram cover most, if not all, possible subsets of contingencies which may have a bearing on a disastrous occurrence, before, during and after the occurrence. It must be borne in mind that this is a two-dimensional projection of a three-dimensional reality, at a particular point in time. This diagram forms the basis for broad spatial accounting categories for the investigation of a disaster and other social outcomes. It can also serve to spatially locate the occurrence

ocate the occurrence (and its characteristics in the total field of contingencies. The diagram represents a 'time slice'.

FIELDS OF SPATIAL CONTINGENCIES, BOUNDARIES (THE MULTI-ORGANIZATIONAL CASE)

This diagram is a recursive map of fields of contingencies related to specific socio-technical organizations and their linkages. It shows organizational linkages as well as technology linkages and examples of transgression of boundaries, such as viruses entering into donor populations (not specified here as to how); from there they enter into technologies (blood products); and finally into patient populations. The field represents the field of decisions and practices relative to these transgressions. Note: This diagram serves as an example, as the vaccines have been omitted. Also, the field of cognition and social construction has been omitted, because in this form of representation, its contingency with all other fields cannot be depicted (see axial diagram below).

This diagram is an extension of the 'simple case.' Each segment in the graph is equivalent to a complete set of fields of contingencies of the simple case. In multi-organizational cases, each

individual organization may have its own technology, communal environment, and natural environment. The linear array is a simplification, as organizations tend to be networked in more complicated ways. The arrows in the communal field point to this circumstance.

Multiplicity may not arise only from technologies and socio-technical organizations. For instance, chimpanzees exist in two different kinds of environments: in the wild and in captivity (laboratories, circus, zoos). There are bridges between these environments (quarantines, holding facilities, trans-portion); and their specific habitat may be related to specific scientific organizations (e.g. cancer research laboratories in the US and in Africa). The two chimpanzee ecologies form the basis for two models of the outbreak of the AIDS pandemic: the bushmeat model, which postulates contact between humans and wild-living chimpanzees; and the vaccine model, which postulates a viral transmission from captive chimpanzees to humans.

AN AXIAL VERSION OF THE FIELDS OF CONTINGENCIES

The contingency diagrams are useful for a quick orientations, (and for an understanding of the principles underlying this methodology). However, they are not suitable tools for the detailed accounting of contingencies.

Fig.3: Axial (dimensional) representation of fields of contingency

The diagram shows the field of decisions and practices embedded in material contingencies, in their spatial relationships and the social construction of them. The social material axis consists of a communal and an organizational portion. The non-social material axis consists of a technological and a natural portion. The technological and the organizational portions form the contingencies of socio-technical organizations. The axial diagram is a complete set of 'spatial coordinates' for any given 'time-slice' in the space-time continuum.

This axial version is equivalent to the contingency field diagram: the fields have been projected on two coordinating axes: the axis of social material contingencies and the axis of non-social material contingencies, with the decision/practice field in the center. There are trade-offs between the two forms of representation:

- 1) The field diagram can show boundaries between subfields, but not the contingencies between material realities and their social constructions.
- 2) The axial diagram can show the contingencies between material realities and their social constructions, but not boundaries between the subfields.

SIMILARITIES BETWEEN THE AXIAL SCHEMA FOR DISASTERS IN THE AXIAL SCHEMA UTILIZED BY THE DSM SYSTEM (Diagnostic and Statistical Manual) FOR PSYCHIATRIC ILLNESSES.

The first psychiatric classification system dates back to Hippocrates (500 BC). The first American system was introduced in 1869. The first DSM edition of the American Psychiatric Association was published in 1952. Multiaxial systems of classification are used when there is uncertainty as to the etiology of a particular class of phenomena. Psychiatric disorders fall into this category, and DSM (Diagnostic and Statistical Manual of Mental Disorders) is such a system. It converges with the European system of International Classification of Diseases and Related Health Problems (ICD; WHO). All DSM categories are in the ICD; not all ICD categories are in the DSM (After Kaplan and Sadock 1997; Kaplan, Sadock and Grebb, 1994).

DSM describes disorders atheoretically, i.e. without reference to causal explanations. However, not entirely: for instance, 'vascular dementia' makes assumptions

as to a change in the blood supply to the brain being the causative principle. But no attempt is made in the manuals to elaborate such causal relationships inherent in the classification as detailed causal models.

Note: Similarly, in the case of disasters, an 'earthquake' is both a category plus a self-evident causal relationship between movement of the ground and disturbances and destruction of life-conditions. A brief schematic comparison with the axial system for contingency accounting is provide here. It should be noted that the axial system for disaster analysis was developed independently of the DMS, of which the author had only a vague recollection, at the time when the schemata were developed.

DSM uses five axes (Kaplan and Sadock, 1994):

Axis I	Clinical features ('characteristics')
Axis II	Personality features ('contingencies'; including mental retardation)
Axis III	Somatic conditions ('contingencies') in addition to 1) and 2)
Axis IV	Psychosocial and environmental problems (contingencies)
Axis V	'Global function'

There is a phenomenal similarity between mental disorders (and many other 'disorders' for that matter) and 'disasters': mental disorders can be viewed as 'disturbances' in the organism - equivalent to disturbances in a socio-technical organization (without inferring an 'organismic' explanation of social organizations). All social collectives and technological organizations are extensions of the organization and activities of the (sentient, cognizing and acting) individual human organism. Accordingly,

the schemata developed for the study of socio-technical disasters can be examined as to their relevance for psychiatric disorders. Such an examination would support the validity of the schemata of the proposed 'theoretical superstructure' and methodology developed here. In the diagram in Fig. 4, the axes of the DSM are mapped onto the axial diagram. There is an (albeit incomplete) match between the coordinates of the two mapping systems.

Note: DSM Axis 2 is an interesting one, since it contains all personality disorders, and also so-called 'defense mechanisms'. However, it is not clear whether the personality disorders themselves are not in part defense mechanisms, while others may be primary disorders of the nervous systems (for instance obsessive-compulsive disorders). If it was possible to separate the two, then it may well be possible to allocate some disorders to Axis I, and others as Axis II as 'defense mechanism' (i.e. secondary to a primary condition). In this case there would even be an equivalent to the 'techno-scientific ring of control.'

The equivalencies between the psychiatric axis schema and the schema developed for disasters would be as follows:

AXIS #	AXIS	FIELD OF CONTINGENCY
I	Clinical (neurological organization)	Organization
II	(Defense mechanism)	'Ring of techno-scientific controls'
III	Organism ('somatic' organization)	Technology
IV	Social and natural environments	Communal and natural environments
V	'Functioning'	Decisions, practices, etc.

Table 2: Equivalencies between axial coordination of contingencies and DSM axes

Fig. 4: Mapping of DSM axes onto the axial diagram for disaster analysis. For equivalences see Table 2.

Both, the multi-organizational schema and the 'time-dimension' schema (discussed below, including a 'critical path for a mental disturbance), can be applied to the DSM axial schema. It should be noted that the 'functional axis' is not considered a

'temporal axis' in the DSM. In practice, however, observations on change in function inevitably invoke questions of onset and duration, therefore the time dimension can be considered implicit in that axis.

It is proposed then that the theoretical schemata of coordinates and the axis schema are a valid system of organizing data describing disturbances affecting humans in general, and socio-technical disasters specifically. It is further suggested, that this general applicability of the schema and the axes system allows a partial investigation into disasters, and comparison amongst disasters, as specific information can be mapped into the coordinates provided, including detailed coordinates as suggested in the temporal schema and the multi-organizational schema.

2.4 ADDING THE TIME DIMENSION; CRITICAL PATH(S) CONSTRUCTION

Fig. 5: Critical path: Sequential arrangement of time-slices with the contingency field diagram and the axial diagram; trajectories. This diagrams illustrates 'complexity' (transformation). A schema of steady-states, transformations and relational views of occurrences is included in the author's **masters thesis** (Krassnitzky, 1994). This diagram of 'multiple time slices' was built with elements from the Challenger disaster. The **cognitive dimension** is sketched into the first time slice of trajectories diagram as a white circle (equivalent to the 'sphere' in the axial diagram).

Fig. 6: Critical path (simplified version, field diagram) built with time slices

CRITICAL PATH

The critical path of an outcome is a mapping of the trajectory of critical decision and actions of developers and operators of a technology. Contingencies in the various fields are analyzed relative to that critical path.

More than one critical path (more than one technology) may be involved: Any contingency in any of the fields may have its own critical path. It is not possible to trace all possible trajectories of all contingencies. There are a few trajectories, however, which appear critical in the life-cycle of disasters. Going back to the assumption that disasters are not only socially constructed, but also, in a number of cases socially produced, the decisions and practices which lead up the central occurrence are of particular interests. This path is nested in a longer path which extends into what Turner (1978) would have considered as an 'incubation period' of the two disasters.' Critical decisions are referred to as 'milestones', with 'phases' in between. In the case of the contaminated vaccine the term 'phase' will be avoided, because it is also in use for the classification of 'clinical trials' taking place in the course of a drug or vaccine development.

In both cases (vaccines, Challenger), a series of decisions preceded the critical decision prior to the disaster. At those decision points, the same scientific evidence was available at the critical decision point. However, the nature of these 'warning signals' was such that the precipitating contingencies were not intrusive enough to cause a large scale disaster. In both instances, following the disaster, a review of the disaster took place and new decisions were taken to prevent or reduce the probability of such a disaster in the future.

Even without knowing the specifics of the technology in question and the disaster and its causes, some general assumptions can be made concerning the critical path of that technology. This critical path is usually located within a socio-technical organization. Technologies have forerunners, which are being replaced by the new technology; they have a design and development phase; and they have an operational phase, during which

the technology is produced, used and operated. If a disaster occurs, there is usually a moratorium on its use, some kind of inquiry (internal and/or public) and some decisions to modify the technology and/or its operations. This may include a decision to discontinue a technology (such as certain fluorocarbons for refrigeration). Thus one can usually identify phases of specific activities, bounded by specific decisions or events which, when they are of particular importance, are referred to as milestones.

In the inquiry into a disaster then, such phases and milestone decisions can be assumed to have existed. Most of the critical path may be 'blank' at the outset, but questions specific to the path segments and milestones can be asked. From this point of view, the *Krever Report*, which is almost entirely focused on operational issues, is incomplete and thus unacceptable.

A CRITICAL PATH PROTOTYPE

The following prototype for a critical path was assembled in reference to Feynman's and Vaughan's analyses of the Challenger incident, and the author's own familiarity with the contamination of the blood supply. It should be noted that the length of phases between milestones may vary considerably, depending on a wide variety of contingencies (this is an example of what may be referred to as 'social time').

Multiple paths. The prototype critical path for Factor VIII concentrate is really a collapsed composite of several paths. The parallel technological paths contribute their

Critical path	General	Challenger	Factor VIII conc.
Phase 7	Implementation	Orbiter program continued	( )
Milestone 7	Approval of new design	Approval of changes	( )
Phase 6	Design development and testing	Design changes and testing of changes	<i>Transitional period</i>
Milestone 6	Decision to implement recommendations: discontinuation or redesign	Orbiter program continued	<i>Decision to reorganize blood system</i>
Phase 5	Internal or external investigation	Inquires, civil suits	<i>Inquiry, lawsuits, criminal investigation</i>
Milestone 5	Decision to hold inquiry	Decision to have Presidential Commission, House Committee.	<i>Decision to hold blood inquiry (Krever inquiry)</i>
Phase 4	Disaster; assessment	Challenger explosion; preliminary exploration of what happened (NASA)	<i>Contamination of blood supply with HIV and hepatitis Virus</i>
Milestone 4	Decision to ignore critical conditions	Challenger Launch decision	<i>Decision to ignore contamination blood supply with hepatitis and HIV</i>
Phase 3	Operation of technology	Orbiter flights	<i>Program operation</i>
Milestone 3	Implementation approval	Approval and certification of orbiter design	<i>Decision to implement program</i>
Phase 2	Development and testing	Development and testing of design components	<i>Development of program</i>
Milestone 2	Design approval	Decision on orbiter program	<i>Approval of Factor VIII concentrate program</i>
Phase 1	Conceptualization	Concepts: shuttle, space station and flight to Mars	<i>Design of program</i>
Milestone 1	Decision to launch new technology	Decision to develop new programs for NASA	<i>Decision to introduce Factor VIII concentrate</i>
Phase 0	Phasing out of old technology	Apollo program terminated	<i>Phasing out of cryoprecipitate</i>
Milestone 0	Decision to discontinue old technology	Decision to terminate Apollo progr.	<i>Decision to discontinue cryoprecipitate</i>

Table 3: Critical path prototypes for the Challenger case and the case of Factor VIII concentrate contaminated with HIV-1 and HCV. The leftmost column shows the prototype of a critical path, the middle column the decisions and phases of the Challenger disaster trajectory, and the right-most column the corresponding milestone decisions and phases of the contamination of the blood supply.

peculiar social/organizational and natural/technological contingencies to the total field to be considered in the analysis. For instance, hemophiliacs are using the product (Factor VIII concentrate) but also visit hemophilia clinics for clinical checks on effects and side-effects of treatments. In the other case, the shuttle-launch technology was associated with the production technology of Morton-Thiokol. For detailed analysis, it may be necessary to identify 'networks of critical paths', and the respective contingencies of each and the interactions amongst the paths. This kind of analysis can be very extensive and complicated. Unfortunately, this is the 'nature of the beast'. The proposed 'theoretical superstructure' and the methodology derived thereof attempt to provide some orientation to cope with this complexity. Diane Vaughan describes her encounter with 'complexity' as follows:

It was now February 1987, and I had been involved in the project for a year. My hypothesis that the decision to launch was a case of organizational misconduct hinged on NASA's rule violations, and I had not yet found any. Where I expected rule violations, I found conformity. The tidy introduction to the chapter "Rule violations" that I had written went into the waste basket. As is often the case when we begin to learn the complexities of a situation, some of these issues that had seemed very clear at the outset had become more confused. Only much later would I fully understand the extent to which oversimplification obfuscates and complexity brings understanding. (Vaughan, 1996:58; emphasis by the author).

Disasters can be viewed as thermodynamic processes manifest as 'organization' causing 'disorganization'. In both cases under study, there is a 'product launch decision', i.e. a decision to introduce technological change into our life practices: i.e. the organization of a new social practice around a new technology. Such organizing processes inevitably lead to (and indeed depend on) corresponding processes of disorganization, not

just of an existing technology and its associated practices, but of the organization of any number of contingent fields. The ongoing 'environmental debate' testifies to that.

In addition, while the 'traditional contingencies' have been tested and are known for an existing technology, any new organization (technology) encounters contingencies which were no longer 'disturbing' for the technology being replaced. In other words, any new organization may encounter 'organizing processes' in the fields which are not anticipated, for which no or no adequate controls have been designed, and which intrude in a 'disorganizing manner' on the new technology and its associated practices. Thus 'organization' has two potential effects (produces a 'double jeopardy'):

- 1) Exposure of the new technology to disturbances from contingencies which are independent of the technology;**
- 2) Exposure to disturbances from contingencies which are induced by the new technology.**

The Challenger incident was the outcome of the first kind of jeopardy. The contamination of the blood supply was the outcome of both jeopardies.

CONTINGENCY ANALYSIS AS FRACTAL ANALYSIS

The following diagram illustrates the way in which 'small space/short time' and associated social construction may be nested recursively in larger spans of time and space. It suggests that the coordinates remain the same regardless of space and time span, and that therefore, the micro-macro-dichotomy sometimes used in sociology

should be replaced with a micro-macro continuum. It also suggests a 'fractal

Fig. 7: The fractal nature of critical paths

nature' of social phenomena, meaning that the dimensional characteristics are recursive (not necessarily entirely identical) at successive levels of organization, in a time-space continuum. In other words, society is represented in the individual and his or her life-world organization, and similarly, individuals are represented in society and its life-world organization. The diagrams could be extended further by including multi-organizational variations and their implications. The resulting complexity could be such that the visual effect would reach its limits of usefulness and become confusing rather than 'enlightening'.

2.5 LEVELS OF KNOWLEDGE CONSTRUCTION; EXPLAINING A DISASTER SOCIOLOGICALLY

LEVELS OF KNOWLEDGE CONSTRUCTION

Fig. 8: The position of sociological explanation vis-a-vis other modes of knowledge construction. The diagram describes four levels of knowledge construction: material construction, social construction of material reality, sociological explanation and ontologies. **Material construction:** Essentially what can be found in the 'fields of contingencies', including social systems of power and control. **Social construction:** social interpretation of material reality, 'sense-making' of material and social phenomena; communications by regimes of power, truth and falsity, disclosure and secrecy, 'decoys'. **Sociological explanation:** critical analysis of outcomes, synthesis: analysis of material knowledge and social constructions of material and social realities, and interactions between the two constructions. **Ontologies** underlie social, material and sociological constructions. **Sociological concepts** and theories can be found at all three levels (e.g. dialectal materialism, knowledge control by regimes of power, and Giddens's 'structuration'). The levels of knowledge construction can be expressed in 'three questions'. They are as confounded as the questions: the 'how' cannot be addressed without the 'why' and so forth.

The diagram shows epistemological difficulties which are similar to those of general ecology: different modes of knowledge construction are confounded in another. One might agree with Hunt and Wickham that sociological knowledge construction can be little more than '*mapping and careful generalization*' (Hunt and Wickham, 1994), not

unlike ethnography. On the other hand, the schema presented implies some kind of general model of human-ecological knowledge, applicable to micro- and macro-social processes, disasters and achievements, preliterate societies and large civilizations alike.

(Note: The author has shown elsewhere that the two main categories (social and material construction) used in the schema are valid constructs, but also confounded: Krassnitzky 1997, unpublished observations).

The schema begs the question of human nature, or, in ecological terms, of the '*natural history of the human species*'. At some level of analysis it appears to make no difference whether humans are wielding stone axes or are flying stealth bombers, whether they are producing vaccines or space shuttles, whether they are Christians or Communists, whether they are living in democratic or totalitarian systems.

This is not of mere philosophical interest, but it has very practical implications. We are in bad need of this kind of knowledge, which explains how it is possible that, despite their ability to have far-reaching insights, humans find it so difficult to act on them. We need to explain how it is possible that, despite warning signals and knowledge of serious risk, these signals and known risks are ignored over and over again. We need to explain how it is possible that, again and again, human lives and well-being are so easily sacrificed for the achievement of an established material goal. We need to explain how it is possible that regimes of power never seem to be able to act in the interest of the population over which they have power, and always choose self-preservation strategies over strategies for the common good. We need to explain how it is possible that the '*tragedy of the commons*' (Hardin, 1968), elaborated in this study as the '*tragedy of capitalism*,' is such an intractable problem.

It is beyond the scope of this dissertation to address these questions, and its findings must, therefore, remain unsatisfactory. No amount of detailed documentation of material or social construction contingencies and of 'structural weaknesses' leading to a disaster can explain how it is possible that disasters continue to happen, in the fashion described. The answers must be sought in some kind of model of human nature and, as part of it, in our social and rational/instrumental cognitive faculties and dispositions, which produce these contingencies and structural weaknesses. They cannot be found in the structural weaknesses and contingencies themselves. Such are the limitations of this study.

EXPLAINING DISASTERS SOCIOLOGICALLY

Complex inquiries of the kind carried out in this study do not fall within the boundaries of any particular discipline. Usually, one or more of several possible 'disciplinary perspectives' are used for disaster analysis, which may be disaster-sociological (addressing social consequences, responses and adaptations); political (public inquiries); medical (inquests); legal (civil, rarely criminal litigation); technological (engineering); scientific (e.g. for natural disasters); psychological (e.g. post-traumatic stress disorder). None of these perspectives by themselves, however, can deliver a comprehensive description and analysis of all relevant contingencies. All of them, including contemporary disaster-sociological explanations, are constituted by elements shown in the diagram (Fig. 8), in a selective manner.

Apart from anthropology (which as whole discipline does deal with the 'natural history of the human species'), sociology would be the only other discipline which could be epistemically positioned to come close to a comprehensive, human-ecological inquiry.

But there is a problem with ecology itself. The prevailing view of ecology is still one of viewing human existence external to the rest of the ecology, which is seen as impacting on humans or as humans impacting on it. While some disaster sociologists may be attempting to move in an ecological direction, the project is liable to encounter serious difficulties: ecological accounting is resource intensive, time consuming, and in conflict with 'disciplinary' knowledge construction. Judging from Diane Vaughan's experience with the Challenger incident; from the Krever inquiry and its resourcing; and from the author's own experience with this study (which only utilized already available information), such projects cannot be carried out by one or two sociologists. Fairly large teams would be required to carry out such projects, as the events unfold, within meaningful time frames. The production of this study took place 20 years after the onset of the AIDS pandemic. Only the fact that some individuals infected with hepatitis C in the early eighties (before 1986) are still fighting for compensation from the federal government of Canada gives the study some current relevance.

Given the degree of technologization which humankind has embarked on, it may be time to establish a discipline of human ecology, to be practiced in advance of policy decisions and decisions on technological development, not merely in response to the aftermath of failures, as a matter of historical interest. The current practice of 'social sciences' seems obsolete, as there is a lack of connectivity amongst the disciplines and purposes, which results in the failure of representing our life-world in its continuity.

Few, if any, sociological concepts, theories and perspectives, are free of a political agenda. Therefore, they tend to be 'partial' (in both senses of the term) and programmatic, and suffer from credibility problems found in all knowledge construction grounded in purposive social (political) values and interests. This does not mean that they have nothing to contribute to ecological analysis. But which ones, or which parts of them?

Disasters are complex occurrences and affect almost all aspects of our life-world. Once their genesis is properly accounted for, there is probably not a single concept that would not find some application. The case at hand has features of Marxist theory, of Weber's 'iron cage of bureaucracy' and officialdom, functionalist explanations of capitalist enterprising, of discourses controlled and propagated by regimes of power, of world-systems-theoretical views of Third World exploitation, of cultural differences in the interpretation of material and natural phenomena, of deviance, of role playing, of coercive and manipulative-ideological social control, and so forth.

Since questions of 'human nature' are not to be addressed in this study, what remains to be done is to select those sociological concepts which point to the potentially most effective course of inquiry and interpretations of disasters, i.e. the kind of concepts which have the best chance of contributing to a knowledge base that can eventually be used in policy development towards disaster prevention (other than purely administrative, technological or scientific). For the case at hand, there are two concepts which appear highly relevant:

- Marxism, in a form which traditional Marxism has neglected: the capitalist mode of technological development.

- Strategic knowledge construction and dissemination by regimes of power as described by Foucault. However, Foucault's concepts were not sufficient for the case at hand, as they do not adequately address the strategic use of 'dysinformation:' information that is false or defective, and is designed to redirect attention - mislead.

There is a functional relationship between the two concepts, as the capitalist mode of technological development and the strategic use of dysinformation go hand in hand, regardless whether such ventures are successful or fail. They also fit the schema of knowledge construction presented above. The political goals of the two theoretical positions are ignored, as they are utopian (at the very least inconsistent with the little we know about human nature), and therefore inherently destructive.

2.6 MODELS: MEDIATING BETWEEN DATA (MAPS) AND THEORIES (CONCEPTS)

The system of contingency accounting described here and concepts of sociological knowledge construction alone are not sufficient for the practical conduct of sociological projects. It is suggested that '**models**' are required to **mediate** between data (maps) and theories (concepts). Models, however preliminary, are necessary to organize data collection, or to convert concepts into testable constructs.

For instance: Einstein's relativity theory could not be tested without the construction of a model. The model was the bending of light from a star around the sun by the sun's gravitational field. Once this model was identified, data could be collected, the predictions of the model could be tested, and the verified model could then be used as the proof for the theory.

Three types or stages of models are commonly in use:

- 1) **Contingency models**, which predict associations, correlations, factor influences and the likes. They can be used to hypothesize:
- 2) **Causal models**, which predict and measure the effect of one or one set of variables on one or more variables through intervention studies. Such causal models can then form the basis for the construction of:
- 3) **Mechanism models** which elaborate the systems of structures and interactions of which contingent causally related variables were representative.

Contingency models, to be meaningful at all, make assumptions on causal relationships and mechanisms. Causal models make assumptions on mechanisms. Critical

for all of these modeling procedures are the most fundamental (ontological) assumptions. If, for instance, the world is seen as steady-state system (as seen by some environmentalists), then such models will encounter contradictions with transformative processes. If the worldview is one of 'transformation and flow' (as seen by some postmodernists), then the model will encounter contradictions with structural immutabilities. Such selective ontologies will lead to different causal arguments and mechanisms constructions. A steady-state orientation will emphasize recurrent variation ('oscillations') in functional variables, but not in its structures (e.g. structural functionalism). A transformational orientation will emphasize structural changes, and miss cyclical and controlled functional processes which are predicated on immutabilities in structure.

The models used in this dissertation are fundamentally contingency models, establishing associations, with no means of testing causal relationships. However, there are definite assumptions on causality and mechanisms (such hepatitis B vaccines having been contaminated with HIV-1 from chimpanzees by using hepatitis B positive chimpanzee blood as raw material for the production of hepatitis B vaccines.) Data are used to test plausibility and testability of the models. Because the direct evidence (specimens and lab records) are not accessible, the certainty of the validity of the models examined has to remain at the level of 'plausibility' ('prima facie case').

2.7 CONTINGENCY ACCOUNTING AND CRITICAL PATH CONSTRUCTION IN PRACTICE

PRELIMINARY (EXPLORATORY) AND FULL INQUIRY

The steps described in this section for 'mapping the genesis of a disaster' represents a full documentation procedure – if the evidence is accessible. If the evidence is not accessible, or deliberately concealed, destroyed, or falsified, as was the case in the Challenger disaster and the case of the contamination of the Canadian blood supply, different strategies have to be followed. The full sequence of steps is described here for completeness. The steps are presented together with exemplary material based on cases discussed by Kreps in Quarantelli (ed.; 1998).

At the outset of this study, the author tried to follow it, until the inquiry took a turn that diminished its feasibility and efficiency, and a modified, more efficient modification of the methodology had to be used. This dissertation addresses whether there is a *prima facie* case for the investigation of the role of hepatitis B vaccines in the outbreak of the AIDS pandemic and the spread of hepatitis C. The less elaborate and comprehensive modified methodology may well be suitable for such restricted purposes. A full inquiry, however, should follow the complete sequence of steps. The proposed methodology and its actual use for this study compares as follows: Steps 3), 4), 5) had to be discontinued, for reasons discussed in section 2.7.

Table 4: Comparison of complete methodology and actual use in the case study of the contamination of the blood supply.

Full sequence of contingency accounting	Accounting used in this study (modified methodology)
1) Characterization and identification of a disastrous occurrence	See section 2.1. Secondary occurrences (contamination of blood supply were added in the study)
2) Preliminary critical paths	Constructed for AIDS-related vaccine trials, hepatitis C-related vaccines, factor VIII concentrate, blood components, surrogate testing for hepatitis non-A,non-B
3) Construction of spatio-temporal grid	Discontinued
4) Material contingencies database reference codes of fields of reference	Discontinued
5) Social construction database by reference established in 4)	Discontinued
6) Detailed critical path construction	For items listed under 2)
7) Social construction details	For items listed under 2)

CHARACTERIZATION AND IDENTIFICATION OF A DISASTROUS OCCURRENCE

(See section 2.1)

CONSTRUCTION OF PRELIMINARY CRITICAL PATH

(See section 2.4)

CONSTRUCTION OF A SPATIO-TEMPORAL GRID ('DATA MATRIX'). MAPPING OF MATERIAL AND SOCIAL CONSTRUCTION CON- TINGENCIES.

The preliminary critical paths (and possibly more than one) can be combined with the 'fields of contingencies' (or spatial dimensions) to form a spatio-temporal grid, into which structures, contingencies and events can be 'mapped'. The following is an application of the construction of such grids to two 'pilot cases': the Mexico City Earth quake; and the Chernobyl disaster, as outlined by Gary Kreps (1998; Kreps: 'Disaster as systemic event and social catalyst;' in Quarantelli, E.L. (ed.), 1998: *What is a Disaster?* pp. 31-55; Hewitt: 'Excluded perspectives in the social construction of disasters.' pp. 75-91; Kreps: 'A reply to Hewitt's critique.' Pp. 101-103).

Fig. 9: Mapping contingencies into data matrices. A 3-page organization of contingency maps for the Chernobyl disaster and the Mexico City earthquake. The 'grid' is organized as three pages as a data matrix according to spatial and temporal dimensions of the axial coordinate system. The temporal dimension includes phases preceding the occurrence i.e. immediate causes, and genesis. The time dimension has been arranged in three pages for purposes of this exercise only. However, the 'pages' do represent a logical grouping of events leading up to an following the occurrence.

The main purposes of this exercise are as follows:

- 1) To demonstrate a continuity between the theoretical considerations discussed in the *Introduction* of this dissertation and methodology;
- 2) To look at the practicalities of charting disasters (and occurrences which might not be classified as disasters).

MEXICO CITY EARTHQUAKE, 19 SEPTEMBER 1985.

This case report is mapped in its entirety into a space/time schema derived from the diagrams discussed throughout the previous chapters. It differs from the mapping of the Chernobyl example, because the technology involved there needed more extensive descriptions of the events leading up to and becoming manifest in the course of the incident. The corresponding technologies of the Mexico City earthquake, which were not part of Kreps's report, would have to include: seismic warning systems, emergency and rescue technology, building codes and designs, layout of city.

The spatial category 'boundaries' remains empty in both cases, simply because it has not been Kreps's focus. The boundary issue is implicit, for instance, in the observation that buildings above ground were toppled by the earthquake, but that the subway system remained virtually unharmed: obviously, the boundary conditions between the earth and the underground structures and above-ground structures are very different. Boundary conditions were significant in the Chernobyl reactor explosion, as there was containment at the level of the reactor core, but not above the reactor core. What was described as the 'techno-scientific ring of controls' in the fields-of-contingencies schema

was isolated as a special case of boundary conditions and is carried together with the technology portion of the grid.

The temporal and spatial dimension contain all the major elements shown in the contingency diagrams. Temporal characteristics were given capital letters, spatial categories were given Arabic numerals. The dimension of social construction/cognition is marked with a bold frame, referenced with the alphabetic and numeral coordinates.

Contingencies of social construction are not mapped into the grid, but are referenced with coordinates used in the grid. However, there is nothing to prevent such contingencies from being entered into the grid. The examples use a very limited information base (Kreps's reports). In a true investigation, the grid could become very large. However, the principles of its organization would remain the same. For better data handling, one would use a database format, where every information entry would be referenced with grid location code (see section on 'database' below).

The specifications for a database of this sort would not be very different from a 'chart of accounts' used in financial accounting (except that the consolidation process is very different).

Table 5: Datamatrix for the Mexico City earthquake.

MEXICO	Temporal dimension: genesis and occurrence		
Spatial dimension	(A) Genesis	(B) Immediate causes	(C) Occurrence
(1) Natural environment	History: av. 90 quakes a year over 4 on Richter. Major quakes: 1460; 1637; 1845; 1859; 1911; 1932; 1957 (Epictr. at the Pacific coast, 170 miles away; killed 160, thousands of buildings damaged; property losses \$ 25 M).		Earthquake (Richter 8.1) without warning. Major aftershock (Richter 7.5) 36 hours later.
(2) Technology	Built on Lake Texcoco, old city on insecure ground, quakes register 5 to 6 times stronger there.		
(3) Techno-scientific controls			
(4) Organizations Federal government, military Public works and subway system (federal) Metropolitan Public Institutions World Bank	With exception of federal district, no formal emergency planning. Federal disaster responsibility assigned to military (upon declaration by president). Some plans to handle disruptions prepared by some federal departments. Civil protection unit created in 1984 under mayors's office for the metropolitan level. Small, no resources, no credibility.		
(5) Communal environment Citizen groups, NGO's, businesses, private groups PEMEX	1970: 7M inhabitants. Tripled in last 20ys. 20% of population lives there; 50% of GNP; 25 % of federal budget; 33% of government investments.		Impact regional, but mostly Mexico City.
(6) Boundary conditions			

MEXICO	Temporal dimension: damages and immediate response.	
Spatial dimension	(D) Consequences (short-term)	(E) Responses
(1) Natural environment		
(2) Technology		
(3) Techno-scientific controls		
(4) Organizations Federal government, military Public works and subway system (federal) Metropolitan Public institutions World Bank	400K residents without water; 8 power stations damaged; > 1M electr. installations defunct; teleph. inop. for days (partial collapse of cent. tel. bldg.); little highway damage, debris; subway restored in 6 hrs.; buses 40% interrupted, restored quickly. 4260 hospital beds lost (25 % of total capacity); 761 (3%) public schools damaged, 15 collapsed; 904 (90%) private schools damaged, 9 collapsed.	Military (federal plans) active only outside the capital, inside they only provided security and crowd control at search and rescue sites. Lifeline organizations: 1) initially autonomy, massive, multi-jurisdictional response; coordination in pockets of common activities; 2) initially, damage assessment, info gathering, rapid restoration; 3) less affected assisted more affected. 100s of sites. Mayor's office center, national, federal district and 16 subdivisions activated fast yto restore public service. In the absence of planning not organized for several days. But needs were met rapidly. 16 subdivision operating independently.
(5) Communal environment Citizen groups, NGO's, businesses, private groups PEMEX	4,287 killed; 5,748 badly inj.; 10,188 min. inj. 5,728 bldgs. badly damaged (70% in housing sector; 15% collapsed; 38% struct. dam., 47% non-struct.); severe for high-rise; less in low-rise. 1M bldgs. damaged; most serious for low and mod. income fam.	Despite a lack of planning community response remained intact. Response corresponded to predisaster structure. 4096 persons rescued alive. Millions of individual and group volunteers organized for search and rescue, casualty care, food and shelter. PEMEX (Mexico's largest oil company) organized rescue and shelter and other services in 24 major sites. Extracted 1000 dead, 400 alive;
(6) Boundary conditions		

MEXICO	Temp. dimension: long-term reconstr. preparedness preventn.			
Spatial dimension	(F) Reorg: reconstruction	(G) Cons. (H) Re- (I.- term) sponse	(I) Reorg: preparedn.	(J) Reorg: prevent.
(1) Natural environment				
(2) Technology				
(3) Techno-scientific controls				
(4) Organizations Federal government, military Public works and subway system (federal) Metropolitan Public institutions World Bank	None Federal: Housing and Reconstruction Program (HRP) Half of \$ 373 M . 48K dwellings rebuilt in 18 months. HRP: half of \$ 373M			
(5) Communal environment Citizen groups, NGO's, businesses, private groups PEMEX	Within 2y 100K families had housing restored or repaired 175K jobs created. repayment monthly, direct cost only , percentage of min. wage. Mexic., Am. and other Red Cross Societies helped; 1200 companies helped			
(6) Boundary conditions				

Dimension of cognition/social construction.

(1)(A) **The frequency of earth quakes**, the extent of the growth and the city, and the building on the 'soft' old lake bed raise questions as to how this high-risk situation is experienced and 'rationalized' by the population and by the different levels of government. It seems that, on average, a major earthquake is due every thirty years, and any one could be far more devastating than all the previous taken together. In the same vein, one would have to ask why there has not been more extensive emergency planning, and why public buildings like schools and hospitals were so 'fragile' and built on the soft ground of the old lake bed.

(4)(A) One could question why the **military** was the key intervener in the case of a disaster. There are several possibilities: 1) Armed forces, which are not likely to be engaged in warfare, may find a 'purposive 'outlet' in disaster assistance (e.g. in Austria, the military provided voluntary ambulance drivers to the Red Cross). Alternatively, the military may have been the only organized entity that could deal with a regional disaster (given the autonomy of the 'districts'). And thirdly, there may be a persisting 'construction' of disasters similar to bombing raids (and physically, there may not be a great difference). Actually, all three 'rationalizations' may be operative. Kreps's account does not address this.

(5)(D) Social disruption considered 'severe' (socially defined as such).

(5)(E) Millions of volunteers were mobilized. Altruistic behavior under crisis conditions has been of sociological interest. Associated with it is the question why this behavior does not extend into non-disaster situations, such as appalling conditions of extreme poverty.

(5)(E) The role PEMEX is of interest, because corporate organizations normally do not make available their resources and managerial staff. However, a petroleum company may have some expertise in this area. Other motivations are possible, but are not explicated in the Kreps's report. PEMEX responded within 2-3 hrs.; established headquarters and a map of damaged area; divided the city into 4 sectors with a supervisor and coordinator; made decision to focus on 24 sites, including 2 collapsed hospitals.

(4)(G) The response to the earthquake legitimated the political structure of Mexico. Obviously the contributing factors to genesis (such as 'fragile' schools and hospitals) were not given much attention, and the emphasis of reporting is on the damages, the response, and the reconstruction. It is not surprising that the political system came out of this 'smelling like roses'.

THE CHERNOBYL NUCLEAR POWER PLANT ACCIDENT. 26 APRIL, 1986

Description of operating conditions

Nuclear power, produced by 43 reactors, contributed 11 % to the Soviet Union's power supply in 1986. (In other European countries it is around 50%). This represented 10% (27 billion watts) of the world's nuclear power. 34 more reactors were planned in 1986 for an additional 36 billion watts. The RBMK ('Great Power Channel type') design was to be abandoned and replaced with more efficient pressure vessel-type designs.

Chernobyl was a town of 12 500 inhabitants, in the Ukrainian Republic of the former Soviet Union. It is located 100 km from Kiev (2 million inhabitants, capital of the Ukraine). The countryside consists of marshlands, dairy farming, rivers and lakes. These water reservoirs were an attraction for vacationers and an important source of water for Kiev and much of the Ukraine.

The Chernobyl nuclear power plant is located 15 km northwest of Chernobyl. At the time of the disaster, it contained 4 RBMK reactors, delivering nominally 1 million kilowatts each. Reactors are cooled by water and graphite. Construction started in 1971, by 1983 the four reactors were commissioned.

The city of Prypyat was located 3 km from the power station, and had a population of 50 000 people. It was the main place of residence for power station construction workers and operating personnel.

The basic fuel is uranium. A chain reaction is achieved by bombardment of uranium with neutrons, releasing more neutrons. The speed is regulated by graphite. The level of activity of such a reactor activity is a function of the number of neutrons produced. The heat produced by the chain reaction turns water into (radioactive) steam. The hot steam powers a turbine, which in turn powers a generator.

Containment: The radioactive hot steam is contained in 1600 pressure tubes. Below the reactor core, the tubes were contained inside leak-tight boxes, connected to a huge pool of water underneath the building. If a pipe or box broke, radioactive particles would be trapped in the water. Above the reactor core, the pipes were contained merely by ordinary industrial buildings. If a pipe broke there, radioactive steam would have been released. Containment of contamination would then have depended on emergency systems (reactor-shutdown and emergency core cooling).

Description of immediate causes and occurrence

The immediate causes were linked to an efficiency test on the day of the incident. This was an efficiency test on a turbogenerator at the time of the a regularly scheduled shutdown for internal maintenance. The test served to test safety conditions in the following scenario:

- There is an accident
- Reactor is shut down - and cannot generate electricity for safety systems
- There is a simultaneous loss of external electricity to run the safety systems

Emergency response of unit:

- The turbogenerator being shut down supplies energy for a few minutes from residual energy, long enough to power the safety systems until - a diesel generator kicks in within 20-50 seconds of reactor shutdown.

Operator error and inadequate documentation led to a power surge which overheated the uranium fuel, initiating the following sequence:

- Pressure tubes burst
- The metal housing around the graphite burst
- The concrete shield above the reactor was lifted
- All pipes burst
- The building above the reactor core was destroyed
- Flying burning fragments of fuel and graphite caused fires in unit 4 and some damage on the roof of the building of unit 3.

The immediate containment: Units 1-3 kept working for 4-22 hours. Then they were shut down because of increasing contamination. Fires were extinguished within 3.5 hours after they started. Monitoring equipment was installed. To contain the release of radioactive material, 5000 metric tons of sand and gravel were dropped on the reactor. Release rates fell over the following 3-5 days. Underneath the dropped material, the reactor heated up again for another 3-4 days. On day 9 the smoldering graphite cooled, and release rates declined thereafter.

Description of extent of damage

Several hundred people were working at the site during the first hours of the incident. Several thousands of workers, military personnel (from Kiev, Moscow and Donbass) were mobilized during the first few days.

300 - 500 people were admitted during first several days with acute radiation sickness. Confirmed for 237 people. Milder cases received 200 rems, severe cases received 600 - 1600 rems (lethal). This included 25 powerplant personnel and 6 firefighters who had been unprotected against lethal doses. Thirty marrow transplant operations were carried out.

50% of radioactive material was deposited within a 30 km radius with uneven distribution. Prypyat was within 3 km, Chernobyl was within 18 km. Several hundred small towns and villages were within a 60 km radius.

In socio-technical disasters reports and investigations tend to focus on immediate causes, the occurrence, and the extent of damages. There is a tendency to view such occurrences as 'technological problems or failures'. Such occurrences then tend to catalyze technological change or abandonment of the implicated technology (Russia discontinued the reactor design). The reorganizational response of socio-technical disasters tends to be of a preventive nature (Chernobyl).

Table 6: Datamatrix for the Chernobyl disaster.

CHERNOBYL Temporal dimension: genesis and occurrence			
Spatial dimension	(A) Genesis	(B) Immediate causes	(C) Occurrence
(1) Natural environment			50 tons of radioactive material released (10x Hiroshima)
(2) Technology	Design: (See design notes.)	April 26, 1986: Unintended power surge, sudden heating of uranium fuel; rapid boiling of cooling water in pressure tubes; bursting.	Reactor melt-down' Destruction of generator building; 30 fires caused by flying graphite; contamination of compound and beyond. Adjacent Unit 3 affect minimally (See notes on occurrence)
(3) Techno-scientific controls	Inadequate operator manuals and safety standards.		
(4) Organizations Chernobyl complex USSR nuclear power program USSR government Fire departments of Chernobyl and Prypyat	Human error in efficiency test of turbo-generator		
(5) Communal environment 30km radius: the zone Chernobyl 18km 12K Prypyat 3km, 50K Several hundred towns and villages within 60km Kiev 100km, 2M Europe			
(6) Boundary conditions			

CHERNOBYL	Temporal dimension: damages and immediate responses	
Spatial dimension	(D) Consequences (short-term)	(E) Responses
(1) Natural environment		
(2) Technology	Major damage to unit-4 reactor; units 1,2,3 had to be shut down because of contamination complex. Destruction of containment of unit 4. Substantial release of radioactive contaminants for 9 days. (For detail see narrative)	Fires put out; dropping of containment material; radiation monitoring; sarcophagus for nuclear reactor (340 000 tons of concrete; 3000 tons of metal housing). 74 meters high. Finished in December 1986.
(3) Techno-scientific controls		Radiation monitoring improvised;
(4) Organizations Chernobyl complex USSR nuclear power program USSR government Fire departments of Chernobyl and Prypyat	Lethal effects on personnel; effects during first 24-48 lethal. 237 cases of acute rad. sickness. 25 personnel died. Several 100 people were working in the complex during	Decontamination (5% of the 'zone') : 600 000 people involved, more than a billion rubels spent. Sept. 1986 500 M rubles for assistance for 12 K new houses. Completed by end of year. In total 30 000 constructed
(5) Communal environment 30km radius: the 'zone' Chernobyl 18km 12K Prypyat 3km, 50K Several hundred towns and villages within 60km Kiev 100km, 2M Europe	50% of radioactive material deposited in a 30km radius. 6 firefighters died.	4/27/1986 evacuation of 135 000 people; took 1 or 2 weeks (official); close to Chernobyl (minimal logistics, familiar agricultural environment) Milk products removed Destruction of cattle, milk, vegetables etc.
(6) Boundary conditions		

CHERNOBYL	
L	Temp. dimension: long-term, reconstr., preparedness, prevention
Spatial dimension	(F) Reorg: reconstruction (G) Consequ. (long-term) (H) Re-spon (I) Reorg: preparedness (J) Reorg: prevention
(1) Natural environment	Spring 1987 back-ground radiation reduced, normal living conditions by end of year. Radionuclids still spread in the environment in Russia
(2) Technology	Power plant continues to operate. Units 1,2,3 were restarted Oct. 1, 1986.
(3) Techno-scientific controls	Since 1987, single diagnostic system (4 computers) monitors temp., rad. inentombed reactor.
(4) Organizations Chernobyl complex USSR nuclear power program USSR government Fire departments of Chernobyl and Prypyat	Signs of wear on the sarcophagus reported by press by early 1991. 1989 Plans for units 5, 6 shelved. 1988 Russian nuclear progr. modified.
(5) Communal environment 30km radius: the 'zone' Chernobyl 18km 12K Prypyat 3km, 50K Several hundred towns and villages within 60km. Kiev 100km, 2M Europe	Evacuees in 30 K new housing units within 1y Since 1987 thousands returned; working in plant Ghost town in 1992. New city planned for 30K inh., 45 km from old city. Difficulties in implementation
(6) Boundary conditions	

Contingencies of cognition/social construction.

(A)(3) Inadequate operator manuals and safety standards may say something about the Soviet nuclear industry and its construction of safety, risk and hazards.

(B)(4) The same goes for operator error.

(E)(2) Of considerable interest are the fire and containment crews who put out the fire and did the initial earth-moving and were exposed to lethal doses of radiation. Did they know? Were they told? (Kreps asks that question).

(D)(5) Was the extent of Europe's destruction of food stuff justified, or was there an over-reaction?

(D)(5) There is uncertainty in Kreps's report. whether the inhabitants of Prypyat (3km from the reactors) were told anything before the evacuation started on the day of the explosion and the day after. There are reports that the inhabitants went about their business usual.

(E)(5) In Kiev, only some children, including those of party officials were evacuated. Children were seen running around with stick's as pretend dosimeters. playing 'radiation'.

(G)(2) In his memoirs, which were published after his death in April 1988, the head of the Soviet delegation to the International Atomic Energy Agency hearings on Chernobyl expressed serious concerns regarding the design and construction of Soviet nuclear reactors.

(G)(5) Official estimates by the Soviets of consequences have always been on the low side estimates in the increase of cancer rates for evacuees was 0.6% and 0.03-0.15% for the rest of the European part of the Soviet Union. However, this has been challenged by many other nations. The necessary systematic evidence is very likely never going to be revealed. (But even the lower estimates would lead to a far greater number, thousands, perhaps tens of thousands of deaths due to radiation-related cancer, and thus far exceeding the number of deaths due to the immediate exposure. In the author's opinion, that would be the 'true' extent of the disaster.)

COMPARISON BETWEEN THE TWO DISASTERS (ACCORDING TO KREPS)

	Mexico City earthquake	Chernobyl incident
Similarities:		
Physical harm and social disruption	✓	✓
Community and regional level	✓	✓
Catalysts on a massive scale for collective actions to meet immediate needs	✓	✓
Differences:		
Precedence:	Historical and cultural precedence	No precedence
Scope of threat:	Threat direct, invisible, immediate, regional	Threat direct, invisible, immediate, regional and international
Removal of threat:	N/A	Still incomplete
Evacuation:	None necessary	Partially permanent, different from evacuations during natural disasters.
Future of communities:	Never in question	Still uncertain
Disaster prevention:	Disaster seen as "Acts of God"	Disaster seen as "preventable."

Table 7: Similarities and differences between the Chernobyl disaster and the Mexico City earthquake (based on Gary Kreps's reports).

Kreps characterizes disasters, implicitly or explicitly, by:

'Agent' and 'material and social disruption' (consequent 'crisis'):

- o Environmental
- o Technological
- o Socio-political

Spatio-temporal dimensions and scopes (geographic and duration)

- o Organizations
- o Communities
- o Regions.
- o 'Before', contributing contingencies.
- o Critical event, destruction
- o 'After' ('Catalysis'): response and reconstruction

Social construction

- o Of genesis ('human-made', 'act of God') and prevention
- o Of response and preparedness

Kreps's organization of the data field is almost identical with the organization of the field presented in the *Introduction*. The comparative 'maps' of the two disasters show that Kreps steps outside the more conventional disaster research specification ('community' and 'response to crisis') producing the social phenomenon of a 'disaster'. Specifically, there is far more information on the genesis of disasters than conventional constraints on disaster research would consider.

COMPARATIVE MAPPING

The following observations are made concerning the comparative maps (see next page):

- 1) The intersection of the temporal and spatial dimensions is well covered for both disasters (Intersection of (D,E,F) with (4,5). These fields also show the highest density of issues of social construction.
- 2) As expected, the technology dimension is empty in the case of the earthquake and has numerous entries for the Chernobyl disasters.
- 3) There are more entries for the Chernobyl disaster for long-term consequences, and matters of prevention.
- 5) An immediate cause is identified, for both disasters. (In the case of the earthquake it is a social/cultural construction, an 'act of God', in the case of Chernobyl, it is 'operator error'.)
- 4) There is a fairly extensive disclosure of communal/organizational contingencies contributing to the damages in the case of the earthquake. This appears to be associated with the construction of the earthquake as an 'act of God'. In reality, a substantial loss of human life may have been due more to poor city planning and construction practices and standards, than to the earthquake itself. In contrast, in the case of the Chernobyl disasters, where the construction of blame was the prevailing social construction, we learn hardly anything about the contribution of organizational/ communal contingencies to the genesis of the disaster. (This social construction pattern may be referred to as 'cover-up'.)

In both cases, analysis extends beyond immediate responses to the disaster, into technological and social design of warning, prevention and preparedness systems. Human failure tends to be looked for in 'immediate causes' (such as operator error, or lack of preparedness in Mexico City), but not in more remote causes and contingencies (such as government policies, decisions, or non-decisions). Central in both cases are the occurrence, the originating disturbance, and the extent of damages. Disaster agency remains an important discriminant .

Fig. 10: Comparative mapping of the Mexico City and Chernobyl Disasters. The following graph maps observations made by Gary Kreps onto the grid without specific information entries. This gives a quick overview which fields have been covered and which ones have remained empty. The entries show a concentration of disaster-sociological interest at the intersection of communal consequences and observations and the disastrous occurrence. However, there are some entries on the genesis as well. Entries for 'social construction' are relatively sparse. Overall it appears that disaster sociologists fill the time-space continuum.

MEXICO		Temporal dimension							
Spatial dimensions	(A) Genesis	(B) Immediate causes	(C) Occurrence		(G) Consequ. (long-term)	(H) Responses	(I) Reorg: preparedness	(J) Reorg: prevention	
(1) Natural environment									
(2) Technology									
(3) Techno-scientific controls									
(6) Boundary conditions									
		Information at intersection of temporal and spatial dimensions of disaster sociology				Band of spatial or temporal dimensions of disaster sociology			
Information re: cognitive dimension		Information in spatial or temporal dimension of disaster sociology				Information outside of disaster-sociological domains			
CHERNOBYL		Temporal dimension				Immediate causes			
Spatial dimensions	(A) Genesis	(B) Immediate causes	(C) Occurrence		(G) Consequ. (long-term)	(H) Responses	(I) Reorg: preparedness	(J) Reorg: prevention	
(1) Natural environment									
(2) Technology									
(3) Techno-scientific controls									
(6) Boundary conditions									

CONSTRUCTION OF DATABASE (DATA MATRIX)

The 'grid' provides only a preliminary orientation on a coding system for a contingency inventory, which can be built up cumulatively over time by several investigators. The specification for individual pieces of information ('fexels') are as follows:

- 1) Information identification:** unique identifier; information on source: author, publication, date, institution, grant reference, etc.
- 2) Information element;** direct quote or summary, paraphrase; fact or interpretation;
- 3) Path identification (if necessary, because of multiple paths to be examined)**
- 4) Position on grid**
- 5) Material or interpretive contingency**

The author started out to organize information in this fashion. In the Challenger case, the lack of developmental information led to a discontinuation. In the case of the contaminated vaccines, the sheer vastness of the grid (multiple paths, global distribution of locations, multiple institutions) vis-à-vis the sparseness of relevant information, made continuation of the comprehensive accounting unfeasible and led to the discontinuation of this kind of documentation.

UNEXPECTED FINDINGS

The case of the contamination of the Canadian blood supply was familiar to the author. Therefore, some critical paths could be constructed without creating extensive inventories and accounts of contingencies. Also, the paths of Factor VIII concentrate, surrogate testing, and hepatitis non-A,non-B were documented in the Krever report, at least as of 1981. The case of the Challenger incident had been reported by Richard Feynman and Diane Vaughan, and again did not require the creation of extensive contingency inventories.

However, in both cases there were surprises. In the case of the contamination of the blood supply, the critical path of Factor VIII, originally assumed to be the controlling, dominant path, turned out to be secondary, as the path of hepatitis B trial vaccines (i.e. vaccines under development) and their side-effects were found to be the controlling path. In the case of the Challenger incident, the emphasis shifted from a misjudged temperature problem and a bad decision on the eve before the Challenger launch, to a fundamental flaw in the design of the rocket (i.e. a rocket development problem).

In both cases, what had appeared to be an operational problem at the outset (contamination of an established, licensed product with HIV-1; operational problems with the rocket segment joints), turned out to be major developmental problems (lack of redundancy in the design of the rocket seals, inadequate virus inactivation of trial vaccines, contamination with HIV and HCV). As a result of these observations, new contingencies had to be sought: for vaccine development and trials; and for rocket development and contracting.

DYSINFORMATION

For the case of the Challenger disaster, it became quickly obvious that such contingencies could not be accessed. In response to an allegation that Thiokol's contract had been 'fixed' through Mormon connections, Diane Vaughan did ask for documentation of the contract competition on the booster rockets. She was shown the management evaluation, but not the technical and operational specification portions. They can be expected to fall under proprietary privileges. Thus the critical path segment for the development phase of the orbiter could not be constructed. However, in the absence of or lack of access to critical information is 'a kind of information' which provides clue as to where the evidence for the genesis of the incident could be found. Nonetheless, the available evidence was sufficient for some comparisons with the vaccine case, and for a discussion of the capitalist mode of technological development.

In the case of the vaccines, the development process was far more public and published, at least in part, in scientific journals and symposia reports. The most critical evidence, however, which would have proven or disproven contamination of the trial vaccines, was, and still is, missing. As in the case of the orbiter, the lack of information provides a kind of circumstantial evidence as to where and what kind of evidence has been hidden.

There was a critical difference between the Challenger disaster and the vaccine case. In the Challenger case, the public's attention was diverted away from design, development, and contractual problems by an exclusive focus on the temperature problem (with the inadvertent and at times resisting co-operation of Richard Feynman, who may

have fully realized at some point that he had been manipulated by NASA and the military.)

In the case of the vaccines, the dysinformation strategies were so extensive, and at times resorted to misrepresentations, that it is now difficult to trust any evidence, in particular the evidence produced after 1980, the year when the first cases with AIDS-like symptoms were publicized. This circumstance, in addition to other circumstantial evidence, led the author to suggest that the contamination of the blood supply cannot be conclusively explained, but that there is a **prima facie case** for an investigation of the role of hepatitis B vaccines in the contamination of the blood supply, in the outbreak of the AIDS pandemic and the spread of hepatitis C, at very least, in Canada.

This was not anticipated when the methodology was written. It sheds a peculiar light on what was referred to as 'social construction' and the construction of truth about reality. Clearly, a separate accounting on the construction of falsities about reality became necessary. It also puts into serious question postmodern philosophies of science, according to which 'anything goes' (Feyerabend), and according to which any proposition must be taken seriously. Some went so far to suggest that abstract scientific truths are not the goals of research, and that sociologists should not 'explain' (Hunt and Wickham, 1994).

Dysinformation has been used by military and other security forces. It has now become pervasive in strategic management of commercial interests, not just vis-à-vis competitors, but also vis-à-vis the consuming public. It does not require, normally, outright lies, but the strategic selection and presentation of truths which can be expected to be misleading. Postmodernism aids in this dysinformation, as, according to its tenets,

an endless stream of propositions, right or wrong, needs to be accepted a priori as possibly truthful. The possible truth becomes buried underneath a thick sheet of white noise of propositions and opinions, and counter-positions and counter-opinions. Instead of getting at the possible truth, time is spent (in accepting all propositions as valid and worthy of consideration) in refuting them. It is suggested here that the postmodern mode of thinking is an effective addition to the arsenal of strategic disinformation tools in possible use by political and commercial interests.

While some of the disinformation propagated in the HIV case may have been random speculation, some of it appears to have been a professionally managed campaign, with substantial participation of the US military experts, (and by affiliation, the Centers for Disease Control in Atlanta and the Office of the Surgeon General); in Canada by ex-military personnel working for the Canadian Red Cross Society, and possibly some government departments. Thus, in both cases, the US military played an important role in the management of public communications on serious consequences from bad technological development decisions.

*At the heart of the story is the betrayal of the Swains by the very country of which they were proud citizens. Orville, a paradigm of the dedicated American pioneer spirit, was a devoted Republican. His elected leader, Ronald Reagan, could never find the will to confront AIDS. The President failed to understand his duty as chief executive to control epidemics. His neglect of the AIDS epidemic, throughout his two terms in office, set the stage for today's huge AIDS epidemic which is in the process of consuming more than a million Americans – including the old greasewood from Lapoint Utah, his wife, and his brother's grandchild. Donald P. Francis, MD, D.Sc. Centers for Disease Control (retired 1992); from his foreword to *The Blood Conspiracy*, by Joleen Swain Ottosen, 1993. Aspenleaf Press.*

This is the kind of reasonable- and compassionate-sounding communication which contributed to dysinformation. Don Francis was an employee of the CDC and as such a member of the US military (in the chain of command of the Surgeon General). It focuses attention on the spread of AIDS and the US Administration, and diverts attention away from the question where AIDS came from in the first place. Leonard Horowitz (1996) and one of his main informants (Robert Strecker) speculated that HIV-1 was the product of American biological weapons development and that HIV-1 was tested by adding it to various vaccines. Was it naïve speculation, sensationalist speculation, or deliberate dysinformation? We do not know. But Horowitz also pointed to hepatitis B vaccines, and then suppressed critical evidence from sources, which he quoted, on the vaccine most likely involved. Was that deliberate or just sloppy?

These 'cyber-weapons' had been in use for thousands of years by all regimes of power (even by 'micro-regimes' within families). They were developed as a political control system by Bolshevism and perfected by the Nazi propaganda machine. Much of that German expertise found its way into the US 'Cold War machinery'. The machine-like, relentless execution of 'cyber-strategies', its disregard of 'collateral damage' (unnecessarily infected people) resembles characteristics of the execution of military strategy. During the early eighties, the US and Europe were under some kind of undeclared 'war measures' due to Cold War conditions.

While the management of dysinformation was most likely controlled by military and other security experts, the flawed development was situated in business interests (or individuals interested in commercial benefits of their research) and under conditions of competition for market position and market share.

All of this informed the critical path construction: competitive conditions in development, warning signals, disaster, and dysinformation management following the disaster appear to be characteristics of both occurrences. The post-disaster information management was linked to flawed development and/or contractual decisions. Apart from proprietary secrecy, this made the discovery of development problems particularly difficult. As a result of these observations, rather than looking at the two disasters as socio-technical disasters occurring under the contingencies of capitalist production, the contingencies of capitalist development, including the concealment of bad development decision in cases of developmental or operational failure, took the front stage.

LOOKING FOR THE FEW ACCESSIBLE NEEDLES IN MORE HAYSTACKS THAN NEEDLES

While the author had to accept that developmental information of the orbiter program would not be accessible, the task of finding supporting (or contrary) evidence for the vaccine model posed a different kind of problem. There is no shortage of information on vaccination, AIDS, hepatitis and the contamination of the blood supply. In fact the information was so massive that it was beyond the feasibility of this study to accumulate databases from which the critical information could be extracted. The efficacy of such an approach would have been extremely poor. Instead, it became necessary to scan vast volumes of documents and literature to find relevant information, sometimes a single note or brief comment in several hundred pages scanned.

Three examples:

1) In the entire 1000 page '*Global Report on AIDS in the World*' prepared by Harvard University (Mann et al. (eds.), 1992) there were only a few statistics, tucked away in an appendix, which contained some information relevant to the vaccine question.

2) In the references on hepatitis compiled by the Krever Commission (Exhibits, Volume 135; 300 pages) there is only one abstract and one line in one article, which provide evidence that the results of anti-HBc surrogate testing had been suppressed as of 1981, until the end of 1984.

3) The Peace Corps as possible target for the use of trial vaccines appears in one table in a 700 page symposium report on viral hepatitis (Vyas et al. (eds.), 1978).

There are dozens of such haystacks yet to be examined. Rather than assembling a comprehensive database, the author had to rely on intuition and networking of clues to find relevant evidence within a reasonable time. This, in combination with the aforementioned managed disinformation, made definite conclusions impossible, and hence the goal for this study needed to be limited, "*to explore whether there is a prima facie case for an inquiry on the role of hepatitis B vaccines in the origins of the AIDS pandemic and the spread of hepatitis C.*"

3. THE CONTAMINATION OF THE CANADIAN BLOOD SUPPLY WITH HIV-1 AND HCV

3.1 Introduction

3.2 Critical paths and their confounded contingencies; models

3.3 The bushmeat model, the experimental hepatitis B vaccine model and the injectionist model of the outbreak of the AIDS pandemic; the hepatitis B vaccine/HBIG model of the spread of hepatitis C

3.4 The critical path of hepatitis B vaccines and the AIDS pandemic

3.5 The critical path of hepatitis B vaccines/HBIG and the spread of HCV in Canada

3.6 The critical path of Factor VIII concentrate and blood components

3.7 The critical path of surrogate testing of blood donors for hepatitis non-A,non-B

3.8 Synopsis

Overview. This section contains the documentation of the prima facie case and its construction. Four separate interacting paths are constructed for four technologies:

- 1) The hepatitis B trial vaccines and their relationship to AIDS;**
- 2) The Merck hepatitis B vaccines and their relationship to hepatitis C;**
- 3) Factor VIII concentrates and their contamination with HBV, HCV and HIV;**
- 4) Surrogate tests for the transmission of hepatitis non-A,non-B.**

The four paths are shown to be embedded in complex institutional networks. There are three models of the outbreak of the AIDS pandemic to be considered: the '**bushmeat model**', which assumes multiple transmissions of HIV-1 from wild living chimpanzees; the '**hepatitis B vaccine model**', which assumes the use of hepatitis B immunogenic material derived from hepatitis B infected chimpanzees for vaccine production; and the '**injectionist model**' which assumes that HIV-contaminated injection equipment found its way into black markets of the injectionist trade. This study shows that the bushmeat model is fraught with several implausibilities, and fails to explain some major features of the pandemic, including the simultaneous outbreaks of AIDS in the US, Haiti, Europe and Africa. The injectionist model is plausible, but not verifiable and falsifiable. The vaccine model, on the other hand, is plausible, and it can explain the major features of the pandemic. It is also verifiable or falsifiable. The

available evidence suggests that one or more of the trial vaccines used in and around 1978 on gay men in New York and on African populations are the most likely source of the AIDS pandemic, not including the licensed Merck vaccine.

There is cause to assume that the possible link between AIDS and vaccines was recognized by vaccine developers as early as late 1979, and definitely in 1980. The vaccine developers then took charge of the debate on surrogate-testing for hepatitis non-A, non-B and suppressed it in 1981. US research into the AIDS pandemic and the development of tests was delayed with very flimsy excuses (such as Gallo being homophobic), but may well have gone on secretly. By the time HIV-testing was introduced in the US, many of the primary victims would have died, and probably all of them by the time surrogate testing was introduced in the US in 1986. The plasma fractionation industry benefited from these strategies, as it created conditions under which their inventories of HIV-contaminated, non-heat-treated product could be sold, while heat-treated product was being developed. By February 1984, all major fractionators had a licensed, heat-treated Factor VIII concentrate. Also, by 1984, Merck, Sharp and Dohme had sold in the order of 5,000,000 doses of its commercial hepatitis B vaccine. In April 1984, 12 months after Barre-Sinoussi in Montagnier's lab in Paris, it is alleged that Gallo at the National Cancer Institute of the NIH isolated the HIV virus (according to Randy Shilts, Gallo knew that it was a lymphotoxic retrovirus at the end of 1982.) Shortly after April 1984, the first test kit became available, which required large quantities of viral materials. Apparently, the NIH already had gone into raw material production before the announcement.

Canada followed the US strategies in the early eighties, but in 1986 it still did not introduce surrogate testing. By then neither the primary HIV-infected nor the heat-treatment of plasma products were still at issue. The only conceivable issue that might have led to the Canadian decision was vaccine-related HCV transmission. The Merck vaccines had been licensed for use in Canada despite that fact that this violated the Food and Drug Act. This model also can explain the fact that surrogate testing was never used in Canada; that large specimen collections from blood donors were kept in Toronto from 1984 onward; that rigorous donor screening procedures were not implemented in Canada until 1988; and that patients infected with HIV via transfusions before 1986 are still denied compensation. The use of surrogate testing could have uncovered possible connections between vaccination and HCV and HIV infections. Europe followed the strategies of the US and did not use surrogate testing. The fact that particular emphasis was placed on ALT testing suggests that, in Europe, as in Canada, distribution of HCV contaminated hepatitis B vaccines would have been a major worry of responsible individuals and institutions.

The concealment of the vaccine problem apparently was accompanied by a misinformation campaign, shredding of documents, and destruction of physical evidence (specimens). For the same reason, the 'bushmeat model' may be the only model that is still considered in the medical scientific community and consistently promoted by Harvard University. Iatrogenic epidemics of this sort have not been unusual in the past, as the so-called 'endemicity' of both hepatitis B and hepatitis C is most likely the result of contaminated vaccines or contaminated needles and syringes. Socio-cultural conditions, such as sexual practices, accelerated the spread of some of these diseases. The handling of the crisis, the extent and effectiveness of 'dysinformation', and the large military contingent involved in vaccine development and in the decisions concerning surrogate testing suggest that this was an operation managed in a military fashion, including all necessary strategies of deception ('cognitive warfare').

3.1 INTRODUCTION

MODELS, CRITICAL PATHS AND CONTINGENCY MAPS

This case study 'maps' the critical paths and their contingencies, which led to the Canadian decision not to use surrogate testing of blood and plasma donors, and eventually to the Canadian clinical trial on surrogate testing of donated blood for hepatitis non-A,non-B. The mapping of the contingencies and critical path construction is based on models which link trials of hepatitis B vaccines in the US and elsewhere to:

- 1) The AIDS pandemic and the spread of hepatitis C in Canada;**
- 2) The avoidance of surrogate testing of blood donors in the US, Europe and Canada, to prevent discovery of possible links between HIV and non-A,non-B hepatitis from 1981 to 1986;**
- 3) The persistent avoidance of surrogate testing in Canada as of 1986, where the spread of hepatitis C via vaccines may have been more extensive than elsewhere;**
- 4) The contamination of the blood supply and of Factor VIII concentrate with HCV and HIV-1.**

The call for a clinical trial and the small trial that was eventually conducted in Canada can be shown to be part of a strategy to conceal evidence of possible linkages between the vaccines and HIV-1 and HCV transmissions.

The mapping of contingencies is based on the methodologies outlined in the *Introduction* and *Methodology* section, such the exploration of critical paths and decision milestones; fields of contingencies and the transgression of boundaries between them; levels of knowledge construction (material, scientific; social interpretive, sociological/ human ecological); models of viral transmission; and the thermodynamic model of organization/disorganization, which predicts that all human organization, including technological organization, come at the expense of the disorganization of some existing order – to differing degrees.

CREDITS

Horowitz. In Horowitz, 1996:247, a reproduction of the 1977/78 grant proposal by Robert Purcell (NIH) and Gerin's hepatitis B vaccine development is presented, which contains the names of some key actors: those who were primarily blood and blood products specialists; who participated in the development of the NIH hepatitis B vaccine; and who took the lead in the suppression of surrogate testing as of 1981 (NIH: Alter, Holland; FDA: Barker, and Gerety - facsimile of the US Department for Health Education and Welfare, Public Health Services, intramural grant proposal #Z01 A1 00026-11 LID (Laboratory for Infectious Diseases, National Institute of Allergies and Infectious Diseases, National Institutes of Health, Bethesda, Maryland). The author believes that this document was provided by Horowitz's mentor W.J. Martin, former director of the Viral Oncology Branch of the FDA.

The vaccine model advanced in this dissertation was arrived at by excluding another model which is still being supported by the scientific community: the bushmeat model of AIDS (African poachers selling chimpanzee meat to local villagers). The hepatitis B vaccine model of AIDS was rejected by the medical-scientific community in 1984/5. It was resurrected by Leonard Horowitz (1996). However, Horowitz did not appear to be aware of the links to the blood industry, and the links to hepatitis C and surrogate testing. Also, at the time of writing of his book, it had not been clarified with certainty that chimpanzees are the natural reservoir of HIV-1. His conclusion that the hepatitis B vaccine was the most likely route for the initial propagation of AIDS is intuitive, based on innuendo, and not systematically modeled. He packaged his proposition into sensational accounts of Fort Deterick and US biological weapons development; his belief that HIV was a virus engineered in the course of such developments, aimed at reducing overpopulation in Africa, and also perhaps at striking a blow against gay men diminish the credibility of his contribution. Nonetheless, in 1996, he probably was the only author still willing to advance the notion that hepatitis B vaccines developed in the seventies were contaminated with HIV. Despite all of these weaknesses, the author must credit Leonard Horowitz and John Martin for keeping the hepatitis B vaccine model alive. Without the key document mentioned earlier, which is reproduced in Horowitz's book, the author might have been discouraged from investigating the vaccine trail.

Gao et al. confirmed that chimpanzees are the natural reservoir for HIV-1; (Gao et al., in *Nature*, 397:436-441, 1999). He also showed that chimpanzee subspecies

carrying HIV-1 are not present in the epicenter of the African pandemic in Rwanda, Tanzania and Uganda, nor in the southern Sudan, where early cases of HIV cases were discovered in the mid-seventies. Without the findings of Gao et al., the vaccine model of AIDS would have remained little more than speculation; the field of natural environmental contingencies would have remained blank; and speculations on intentional or unintentional effects of retroviral engineering would have been the only other explanation besides the bushmeat model in support of the vaccine model. Gao's findings still await further confirmation by investigating wild-living chimpanzees and the natural history of HIV-1. However, the recognition of chimpanzees as the natural reservoir of HIV-1 make the use of plasma of chimpanzees infected with hepatitis B for trial vaccines a possible and plausible route for the virus to 'jump' from chimpanzees into human populations. The vaccine model of AIDS is closer to the conditions of *Occam's razor* than any other model ever was: *All else being equal, the simplest explanation is probably the right one.* This can be augmented with another investigative principle: *Follow the money and the politics.* The economic stakes (and possible gains) in developing a vaccine were in the billion dollar range, quite irresistible, and had led indeed to a fierce competition between American and European vaccine developers. The economic stakes (and avoidance of possible losses) in concealing a vaccine contamination were in a similar, but much higher range. The leading political stakes in concealment were most likely related to possible threats of expansion of Soviet Communism in Africa (a national security stake for the US). There were probably other political stakes in not revealing a link between hepatitis vaccines and the AIDS pandemic, which are not difficult to spot, but which cannot be discussed here for reasons of 'political correctness.'

A PRIMA FACIE CASE ?

All direct evidence for the role of hepatitis B trial vaccines in the outbreak of the AIDS pandemic and the spread of hepatitis C has been concealed or has been destroyed. In particular, there is no direct evidence that any or all of the trial vaccines were contaminated with HIV-1 of chimpanzee origin. But there is also no evidence which proves the opposite, something that could have been done easily. In the absence of direct evidence, at some stage of this study, the question became whether the circumstantial evidence is sufficient to warrant an investigation of all hepatitis vaccines of human origin injected into humans during the seventies and early eighties as to their possible contamination with HIV-1 and HCV. In other words, is there a prima facie case for such an investigation?

3.2 CRITICAL PATHS AND THEIR CONFOUNDED CONTINGENCIES; MODELS

CONTINGENCIES OF ORGANIZATIONAL AND TECHNOLOGICAL COMPLEXITY

Four critical paths. The decisions to suppress surrogate testing were made along four mutually confounded critical paths:

- 1) The critical path of **hepatitis B vaccine-related AIDS**
- 2) The critical path of **hepatitis B vaccine-related hepatitis C**
- 3) The critical path of **surrogate testing for hepatitis non-A,non-B and AIDS**
- 4) The critical path of **Factor VIII preparations** for the treatment of hemophilia A (and for blood and blood components, as a side-path)

A more extensive inquiry into the vaccines would have to unbundle each path into various subpaths. For instance, the paths for AIDS were different in different countries; there are several blood components and derivatives that were contaminated with different severity; there were two surrogate tests, which sometimes were considered separate, sometimes together. For the 'prima facie case' only the main paths are explored.

'Epidemiological companions.' The two surrogate tests (ALT and anti-HBc) were effective screening tests that could detect blood donors with three different virus

infections: hepatitis B, hepatitis C and HIV. At some point in the unfolding contamination crisis, all three infections were related, in varying degrees and different ways, to high risk life-styles and contingencies (sexual practices, intravenous drug use, vaccination, blood transfusion, perinatal transmission, 'traveling abroad'). They were 'traveling together', so to speak, as 'epidemiological companions'. Thus each specific test (anti-HIV-1, anti-HCV, HBsAg and anti-HBc) was also a surrogate test for the other two kinds of infection. ALT was a non-specific test for damages to the liver, which could detect possible cases of all three kinds of infections and others.

Note: In 1981, when the US and Canadian decisions were made not to use surrogate testing, testing for HbsAg was not sensitive enough to exclude all donors with transmissible hepatitis B infection. This is not a small matter, considering that a single hepatitis B positive donors could contaminate an entire pool of thousands of units of plasma used in the production of Factor VIII concentrate. The test was perfected in the 1980s. Thus, in the early eighties, surrogate testing would indeed have been useful for the screening of donors for all three viruses (HBV, HCV, HIV), not just for the donors suspected of transmitting hepatitis non-A,non-B. Similarly, during the early stages of test development for the detection of HIV and HCV positive donors, the test systems were not very sensitive. Thus, between 1986 and 1996, the US used both surrogate tests, and in 1996 dropped only ALT-testing. In comparison, Canada never used surrogate testing.

The two surrogate tests, together with stringent donor selection procedures could have prevented close to 100% of transfusion-related HIV infections, and in the order of 75% of transfusion-related hepatitis C infections amongst transfusion recipients before 1986. In Canada, compensation has been paid for blood and plasma-related HIV infections, but for blood-related hepatitis C infections only after 1986. Yet, neither the US nor the Canadian Government have offered a good explanation for not using surrogate

tests before 1986 and after 1981, when the studies on the efficacy of surrogate testing had been shown in major studies.

Multiple commercial interests. Three groups of commercial interests intersected at human blood product- related infections.

Technology	Organization
Diagnostic tests (ALT, HBV, HIV, HCV)	Abbott - US
	Pasteur Productions - France
Hepatitis B vaccines (development)	Merck, Sharp & Dohme - US
	Pasteur Productions - France
	NIH/Union Carbide - US
	New York Blood Center - US
Plasma fractionation (production of plasma derivatives, such as factor VIII concentrate)	Dutch Red Cross - Netherlands
	Cutter/Bayer - Germany
	Armour - France
	Baxter - US
	Alpha - US/Japanese;
	The New York Blood Center - US
	Connaught Laboratories- Toronto, Canada
	Armand Frappier - Montreal, Canada
	Winnipeg Rhesus Institute - Canada

Table 8: Commercial interest in the 'blood product market'

Note: The combined world market interests for these products was in the order of 5 -10 billion dollars in sales annually. Even in the worst case scenario, the annual compensation cost for patients infected with HIV and/or HVC via blood and blood products would have been in the order 1 billion dollars annually. In comparison, compensation cost from hepatitis B vaccine-related infections could be in the hundreds of billions of dollars.

Commercial interests were interrelated with activities in government institutions, such as the US National Institutes of Health (NIH), the US Food and Drug Administration (FDA) and universities (such as Harvard and Yale, George Washington

University, SUNY, UC, etc.). Particularly problematic was the active participation of the US Food and Drug Administration (FDA) and the US Center for Disease Control (CDC) in vaccine development. The Canadian government also participated by allowing such vaccines to be used in Canada in violation of the Food and Drugs Act. Since these institutions did not remain at arm's length from these industrial projects, they were caught in a conflict of interest in their role as industry regulators and public health watchdogs, and jeopardized their integrity. With the role as regulators thus compromised (in the US and elsewhere), the possible 'truth' of contaminated vaccines could not be told. Instead, governments surrendered control of the operational and safety aspects of the crisis to commercial interests; and the information control aspects to specialists, presumably of the U.S. military and other defense organizations. To this day the origins of AIDS are claimed to be a mystery. Lack of knowledge, by withholding key information, has led to 'unsolved mysteries' and transcendental speculation.

Though it had been the focus of attention of some of the greatest minds in contemporary biomedical science on at least four continents, nobody by 1994 had yet pinpointed a time, place, or key event responsible for the emergence of HIV-1. (Garrett, 1996:389)

Until recently, the origins of increases in hepatitis C infections has remained shrouded in mystery. Hepatitis A and B, on the other hand have been recognized as diseases of antiquity. Hepatitis vaccine development was an attractive proposition because of huge potential markets in Mediterranean, Asian and African countries. Hepatitis B is a prominent cause of primary liver cancer in Africa and Asia (it is one of the 'oncogenic', i.e. cancer-causing viruses.) The network of scientists working in this

field in the U.S. and in France were connected to a larger global cancer research network, with major centers in Bethesda and Lyon, and research stations on every continent. They were also part of the United Nations health programs (World Health Organization, WHO). During the sixties, the WHO had carried out extensive vaccination programs and trials in Africa, which led to the eradication of smallpox. In 1976 the WHO reactivated and expanded its vaccination program. Thus the hepatitis vaccination researchers could work with an established infrastructure for field trials and laboratory studies in Africa.

Hepatitis (and later HIV)-related research was and is still connected to and funded by the US military which, apart from its own immunization programs for military personnel, built up a biological weapons research facility at Fort Deterick during the Cold War (with consideration given to immune system destroying and oncogenic viruses). The WHO and NATO connections are of further interest, because scientists in NATO member states (in particular US, Canada, France, Belgium, Germany) went along, tacitly or explicitly, with the US recommendation not to use surrogate tests for the screening of blood donors between 1981 and 1985. Besides vaccines, military establishments had an interest in blood collection and preservation. Finally, the reality of biological weapons generated major interests within the military establishment not only in biological weapons manufacturing, but also in defense systems, such as protective and containment equipment, vaccinations, quarantines, isolation, investigations of 'outbreaks.' The US CDC (Centers for Disease Control in Atlanta, Georgia) are part of the US military organization.

These networks must now be viewed as the 'global industrial/military/government/medical complex' (**GIMGM**). In the US, the network of scientists,

with members from the diagnostic/therapeutic medical industry, the US military (e.g. Navy's Biomedical Research Facilities - NBRL, various VA health facilities), the 'regulator' (Food and Drugs Administration - FDA, and its Bureau of Biologics, BoB), public health (Center for Disease Control - CDC), the National Institutes of Health (NIH) and its subunits (National Cancer Institute - NCI; National Institute for Allergies and Infectious Diseases, NIAID; National Heart, Lung and Blood Institute, NHLBI); the American Red Cross and its blood program; and the New York Blood Center; various medical centers and university departments interacted freely, and no clear boundaries existed. The NIH was a common link, source of funding and intelligence center to all of them.

Note: These multiple networks were significant for Canada: Roger Perrault is the former National Director of the Canadian Red Cross Society blood program between 1974 and 1991, also a former medical Canadian naval lieutenant commander, and was trained by the US Navy in the freezing of blood for long-term storage. During the critical years 1975-1983, the staff organization of the Canadian Red Cross Society was headed by a retired Major General, Henri Tellier; and the chief administrator and financial staff officer of The Canadian Red Cross Society between 1981 and 1987, Ian Morgan, was also a reserve officer of the Canadian Navy. The late Dr. John Derrick, who was in charge of the development of the Canadian Red Cross Society Factor VIII concentrate development program as of 1975, and later its AIDS communications program, had been working for many years at the New York Blood Center, at a time when preparations for vaccine trials on gay men were already underway in New York. The medical transfusion specialists were linked globally through the International Society of Blood Transfusion (ISBT) and the less powerful committee of transfusion experts of the League of Cross Societies (one-time Chairman Dr. Perrault). In the plasma fractionation field, the Germany-based Cutter/Miles Canada, which operated in the US as a subsidiary of Bayer, had 'monopolistic understandings' with the Canadian federal (liberal) government during the seventies, to build a single fractionation plant in Canada. Dr. Perrault was the development manager for this project inside the Red Cross. The connections between the Canadian Red Cross and the American Red Cross are self-evident. President Reagan appointed Richard Schubert, former CEO of Bethlehem Steel as President of the American Red Cross, and Lewellys Barker was appointed Vice-

president Health services under Schubert. Barker formerly had been working for the Bureau of Biologics of the US Food and Drug Administration; he was directly involved in the hepatitis B vaccine trials (US Department of Health, Education and Welfare Grant proposal by the NIH. Number Z01 AI 00026-11; displayed by Horowitz 1996:247); he together with his former colleague at the FDA. Gerety, was the first to call for the non-use of surrogate testing in mid-1981 (Barker, Memo June 22, 1981). Given these circumstances, the relationship between the two 'sister-Red Cross Societies' is of special interest for Canada.

ORGANIZATIONAL COMPLEXITY AND CONFOUNDEDNESS: SOURCE OF MISTAKES AND ACCIDENTS, OR SOURCE OF PROTECTION FROM LIABILITIES ARISING FROM TECHNOLOGICAL FAILURE?

The author is taking the view that true accidents may happen in complex organizations, but they are not necessarily 'normal occurrences'. Complex organizations are quite capable of avoiding and preventing them. The most serious mishaps arise from strategies and decisions that should not have occurred, but which were pursued in the face of high and obvious risks, because of potentially large, mostly economic, gains associated with them. Networks of cooperating organizations tend to further such endeavors, allow for a pooling of resources, and safeguard against error through networks of experts and scientists. A continuous flow of formal and informal information keeps those individuals informed, up-to-date and on track. The best example for such extensive teamworks is the Manhattan Project. Notwithstanding its security problems, a very large team developed the A-bomb in a very short time, and at the same time developed the foundations for the nuclear industry.

The same network, however, once potential risks and damages become evident, can diffuse responsibility, ensure secrecy, and make possible concerted defensive action, even when defensive action is liable to generate new damages.

It is not the complexity of organizations which makes them vulnerable to mishaps, accidents or even disasters. Rather it is the simplicity of high-stakes gambles on highly profitable ventures; and the simplicity of concealment strategies and adjustment strategies, once side-effects become evident. These 'simplicities' intervene in a disordering, disruptive manner in a complex organizational, environmental or communal environment. Under such conditions, secrecy, guesswork and actions based on guesswork abound, generating more disturbances: complexity becomes 'chaotic'. Chaos thus generated is easily mistaken as complexity, and the mistaken complexity is mistaken as the cause of 'accidents' and 'inevitable mistakes.'

The 'simplicity' of two high risk ventures: hepatitis B vaccine and factor VIII concentrate; and the simplicity of the strategies used in concealing their damaging effects are summarized in the following table (see page 121). Neither product should ever have been licensed or sold, except perhaps with the most stringent virus inactivation and safety measures, which may well have reduced biological potency to the point of non-profitability. In the case of factor VIII concentrate, a cheaper, safer, and somewhat less convenient product was available. In the case of the hepatitis vaccine, more development time was required until smaller subunits of the antigen used for the vaccine could be mass-produced and perhaps more easily heat-inactivated. The use of more cautious approaches was most likely inhibited by European and American manufactures competing for global market position (the French had the market advantage in Sub-

Saharan Africa). The hurried, simplistic approach in vaccine development created conditions for viruses to enter into the complexity of medical/technological and social human-ecological interactions and to create havoc.

There are striking similarities between the development of the factor VIII concentrate and of hepatitis B vaccines from human origins. The origins of this similarity are in part reducible to the facts that: both were derivatives of human blood; both were developed at the same time, with the same kind of contingencies of a rapidly expanding biomedical industry; and viral transmissions from vaccines (including those occurring during and after World War II) were bound to find their way into the blood supply. The infectivity of blood and blood products had been partially contingent on vaccines for many decades. The transmission of hepatitis B was a more obvious phenomenon, because many infected patients become visibly jaundiced. The transmission of hepatitis C was far less obvious, as many cases remain 'anicteric', i.e. they do not become jaundiced during the acute stages ('subclinical hepatitis').

Table 9: Similarities in the characteristics of the hepatitis B vaccine and factor VIII concentrate ventures

	Hepatitis B vaccine	Factor VIII concentrate
Before contamination crisis	Human blood derivative from multiple donors Donors known to be potentially infected with unknown hepatitis virus Minimal virus inactivation Clinical trials suspect of transmission of live virus Licensed despite being an illegal product	Human blood derivative from multiple donors Donors known to be potentially infected with unknown hepatitis virus No virus inactivation Clinical trials suspect of transmission virus Licensed despite known risk
	Revenues expected: \$1-2 B ann. world-wide American/European competition for market share	Revenues expected: \$1-2 B ann. world-wide American/European competition for market share
During contamination crisis	Sale of unsafe stocks? High risk donor groups (except Hbe positive) not excluded (preservation of source of raw material) Avoidance of surrogate testing of vaccinated persons donating blood	Sale of unsafe stocks High-risk donor group exclusion delayed (preservation of source of raw material) Avoidance of surrogate testing of all blood donors (including vaccinated persons)
	'Vaccine is safe' propaganda	'Blood is safe' propaganda Risk accepted in America and Europe
Meanwhile	Upgrading of viral inactivation Development of new recombinant DNA product	Viral inactivation (heat treatment) Development of new recombinant DNA product
Later	'Scientific proof' that vaccine did not contain HIV No comment on hepatitis C	Origins of AIDS is a 'mystery' The increase of hepatitis C is a mystery
Consequences	Perhaps thousands dead from primary HIV- infections Perhaps tens of thousands primarily infected with HCV Tens of millions secondarily infected with HIV Perhaps hundreds of thousands secondarily infected with hepatitis C (via transfusion)	Thousands of hemophiliacs died from AIDS; Tens of thousands were infected with HCV;

HOW COULD THE HIV-1 VIRUS HAVE ENTERED INTO A VACCINE? HOW COULD A TRIAL VACCINE HAVE BECOME CONTAMINATED WITH HEPATITIS C VIRUS (HCV)?

It must be stressed that there is no direct evidence (or published evidence) of either kind of contamination of hepatitis B trial vaccines. It would have required the addition of hepatitis B immunogenic material from a chimpanzee infected experimentally or otherwise to vaccine raw material derived from human plasma. There was one vaccine, which, in contrast to all other hepatitis B viral vaccines, deliberately used hepatitis B antigenic material which included full viruses.

*At the New York Blood Center we have been working for the past 8 years on the development of an HB vaccine. Our approach has been guided by two major considerations: first, the purification procedure should be a type conventionally employed in manufacture of **blood derivatives** [emphasis by the author], in order to make possible a vaccine at low cost; second, we wished to include in the starting material particles of all morphologic types particularly **Dane particles** [i.e. full hepatitis B virions, i.e. live infectious hepatitis B virus; emphasis by the author], since it has been suggested [Moodie J., Stannard L.M., and Kipps A.J., 1974, Gen. Virol. 24:375] **that they may have unique specificities that could be useful in providing optimal protection**. (Emphasis by the author; Prince, in Vyas et al., 1978:509).*

This passage indicates that the starting material did not exclude full viruses (virions); and that there was a definite competitive effort to exceed other vaccines in immunogenicity and thus efficacy of protective potency. Once the raw material was permitted to include full hepatitis B virus particles, all other full virus particles potentially present could have been included as well (such as HIV and HCV). Furthermore, since immunogenicity was the special objective of this vaccine project, there may have been a temptation to include hepatitis B antigen (and virus particles) from chimpanzees: hepatitis B virus or antigen could not be grown in tissue culture, as is done for other vaccines; and

chimpanzees were the only possible source of hepatitis B antigenic material besides human donors for vaccine production.

Note: Since vaccines were commonly derived from material grown in tissue culture of monkey origin, the idea to use chimpanzee material was, relatively speaking, not as horrendous as it may appear.

However, while these and other circumstances suggest the New York Blood Center vaccine as a likely candidate for HIV transmission from chimpanzees to humans, the possibility of other vaccines such as the ones prepared by the National Institutes of Health (NIH) being contaminated can not be excluded.

Both, Factor VIII concentrate and hepatitis B vaccines produced from human sources were high-risk undertakings. Factor VIII depended on the collection of plasma from paid donors who were known to transmit hepatitis in the order of 10 times more frequently than voluntary donors, some of them hepatitis B type, but also of the non-A, non-B type. For cost-effective, large scale production the plasma had to be pooled, and a single contaminated unit of donated plasma could contaminate an entire pool. Raw material for hepatitis B vaccine was collected from carriers of hepatitis B antigen, some of who also would have carried other viruses. Again, for large-scale production plasma had to be pooled, although not as large as for Factor VIII production. Nonetheless, the 200,000 trial doses prepared by Merck Sharp & Dohme in 1974 would have required a considerable number of donations, and possibly some pooling.

In both cases aggressive viral inactivation procedures would have resulted in loss of biological activity (biologically active factor VIII; immunogenicity of the vaccine).

Factor VIII concentrate sold in the late seventies was not virus-inactivated at all. The viral inactivation procedures for all trial hepatitis B vaccines were kept at a minimum (gradient centrifugation (purification) and treatment with formaldehyde; with a pepsin digestion step added by Merck; the New York Blood Center using an entirely different protocol.)

The possibility of any kind of vaccination leading to further propagation of viral contamination via transfusion therapy has never been fully investigated. With few exceptions, investigations on donors have not been carried out. For instance, we know that yellow fever vaccine caused hepatitis in military personnel. We do not know to what extent these epidemics were propagated via blood donations by soldiers and ex-soldiers donating blood or plasma.

MODELS

The vaccine model of the origins of AIDS is both falsifiable and verifiable with direct evidence that has existed and ought to exist now, if it has not been destroyed (specimens collections on vaccine trials; transfusion studies and the clinical trial on surrogate testing in Canada; laboratory records; unpublished data; eye-witnesses, who have never been subjected to full scrutiny with respect to the hepatitis B vaccine development).

The bush meat model, which will be elaborated in comparison with the vaccine model in the next section, is neither plausible nor verifiable, nor falsifiable with direct evidence (there is no evidence to be discovered, whatever may have existed for a brief

moment in time at some obscure place in Central Africa, is gone, the bushmeat has been eaten, the first people infected would have died by now, and experiments of this kind can hardly be expected to be acceptable on ethical grounds). It can be falsified to some extent with contradictory, indirect evidence: the model does not match the epidemiological conditions in Central Africa; it cannot explain the simultaneous outbreak of the AIDS pandemic in at least three continents, nor the delay of the outbreak in Asia, where there are places of epidemiological conditions similar to those cited in Africa, Europe and America: high prevalence of intravenous drug use as well as of commercial sex work. It cannot explain the early appearance of HIV antibodies in US drug addicts in the early seventies. The hepatitis B vaccine model, on the other hand, is compatible with all of these conditions and more.

The vaccine model also provides maps and coordinates into which specific pieces of evidence can be placed with little difficulty, and without contradicting the model or other pieces of evidence. Most importantly, even pieces of evidence that have been produced in the past to refute allegations that hepatitis 'the B vaccine' was responsible for the spread of HIV support the vaccine model of the AIDS pandemic. An example are the vaccine safety tests, which were conducted in 1984 by the US CDC and Merck, Sharp & Dohme, to quell rising concerns regarding AIDS originating from the Merck hepatitis B vaccine. By itself, this evidence gives the impression that AIDS had nothing to do with the vaccine trials. If these claims are placed into the context of the entire model with all of its contingencies, the accounting methods reveal that there were several hepatitis B vaccine trials, the safety of which has never been verified; that these safety tests were not conducted by independent laboratories, but by the very parties and institutions who were

involved in the vaccine development (Merck; US government; SUNY); and that the virus inactivation procedures were enhanced for the batches licensed by the US FDA in 1981, and 'proven to be free of HIV' in 1984. These contingencies of the 'safety demonstrations' and their 'reassuring results' support the vaccine model, they do not refute it. At the very best the results testify that certain vaccine lots which probably were safely assumed to be free of HIV (i.e. they contained no material derived from chimpanzees, or from high risk donors of HBs antigen plasma), and were therefore known with certainty to be free of HIV before they were tested.

The Krever Inquiry (the Commission of Inquiry on the Future of the Blood System in Canada) produced hundreds of thousands of pages of evidence, but starts its AIDS investigation calendar of events in 1981, despite early observations of HIV-infections in the seventies. It also does not address hepatitis B vaccine, despite the fact that they were plasma derivatives. In other words, it chose not to address hepatitis B vaccines and other active and passive immunization products at all.

Note: By extending the critical paths and related investigations into the seventies, and into the US, Africa, and Europe, the evidence may swell into millions of pages. This is obviously out of reach for the purposes of this dissertation. Therefore, the dissertation only offers a *prima facie* case and proposes that the evidence presented here is sufficient to indeed warrant such an investigation.

The two pieces of evidence (organizational and natural environment contingencies), credited to Horowitz and Gao earlier represent crucial contingencies for the vaccine model of AIDS. Without them the case could still have been made, but with

much more difficulty. The chimpanzee/HIV-1 connection provides for conditions under which the HIV-1 virus could have jumped into human populations in three continents at the same time; and the dual involvement of the participants in the NIH vaccine research and in blood safety/licensing issues provides a basis for explaining the bizarre handling of surrogate testing by the same individuals.

The significance of these findings might have been missed by the author had he not: a) been looking for evidence to fill the 'fields of contingencies' in the 'contingency schema of disasters', developed in the *Introduction and Methodology sections*; and b) recognized their significance. The contingency schema has served this investigation very well. It can also be said that the vaccine model emerged in its entirety only by accounting for findings of the natural sciences (e.g. chimps being the natural reservoir of HIV-1); the development use of technologies (e.g. vaccines development and trials); the analysis of social communal and organizational conditions (e.g. the institutional blood/cancer/vaccine networks; as well as by examining the social constructions as to what happened (e.g. the 'bush meat theory').

The schema of 'levels of knowledge construction' (ontological, material, social constructionist, sociological-human ecological) has been helpful also. The ontology of the 'global ecological mess' and its assumptions have served to camouflage and confuse the material facts, and have given rise to popular, and sometimes highly objectionable social constructions of the origins of AIDS: the CIA was out to commit genocide on Africans; Africans either have sex with monkeys or they eat them; or, the origins of AIDS are a 'mystery'.

Social constructions of this sort arise from a selective presentation of facts to the public. The pattern of selection and resulting social constructions can provide clues as to the missing or withheld facts: there is an observable correspondence between the selectively presented facts and the dissemination of certain social constructions. For instance, by promoting the 'safe hepatitis B vaccine data', but not investigating all trial vaccines, one needs to make at least the tentative assumption that the trial vaccines which were not investigated were not safe at all. Similarly, a continued insistence that the AIDS pandemic originated in African populations, together with a lack of investigation of hepatitis trial vaccines, at least as potential source of HIV, point strongly to the possibility that some trial vaccines may have been the source of HIV; and that AIDS did not come 'out of Africa', but that it was brought 'into Africa'.

3.3 THE BUSH MEAT MODEL, THE INJECTIONIST MODEL, AND THE EXPERIMENTAL HEPATITIS B VACCINE MODEL OF THE OUTBREAK OF THE AIDS PANDEMIC

MODELS OF THE ORIGINS OF THE AIDS PANDEMIC

Because chimpanzees have been identified as the natural reservoir of HIV-1 (the retrovirus causing AIDS; Gao et al., 1999), there are only four hypotheses for the origins of the AIDS pandemic to be considered :

- 1) **The contaminated bush meat model.** It assumes that the virus jumped in Africa either from chimpanzee to poachers (scratches, bites), who either caught young chimpanzees for laboratories; or sold the flesh of the parents as bush meat; or through the consumption of such bushmeat by other humans.
- 2) **The injectionist model.** Needles and syringes contaminated in animal facilities for hepatitis research in Africa may have found their way in to the black markets for injectionists.
- 3) **The contaminated hepatitis B vaccine model.** It assumes that the virus 'jumped' from animal to vaccine product and from there to humans.
- 4) **The contaminated oral polio vaccine model (Hooper, 1999).** The assumption is the same as in 3).

THE BUSHMEAT MODEL

At issue all along has been whether AIDS originated in Africa, through specific cultural practices, or in the US and Europe through laboratory and vaccine production

practices. At the present time, the hepatitis vaccine model has no currency at all. Horowitz's book, because of its conspiratorial, genocidal hypothesis has not been helpful in that respect. The bushmeat model is at present the only model seriously (or officially) entertained in academic circles (Weiss and Wrangham, 1999): if it fails to persuade, then the vaccine model is the explanatory alternative, and not welcome after 20 years of costly concealment.

In addition to the physical damage inflicted on Africa (20 million infected, more than a million dead), the continued efforts to locate the origins of AIDS somehow in Africa, and to somehow blame Africans for it, is not something that should go unchallenged. While early American allegations painted Africans as having sex with monkeys, the bush meat model and the redirection of the public to a threatened primate species and the African poachers is better, but not by much. After all, the big demand for baby chimpanzees arose from the various vaccine developers, who needed the chimpanzees to test their theories and the safety and efficacy of their trial vaccines, to use their livers for reagent production, and later to experiment with HCV and HIV as well. Yet, deplorable as that may be, it does not seem appropriate to make this issue bigger than the AIDS catastrophe among African human populations.

The fact that chimpanzees are the natural reservoir of HIV-1 (Gao et al. 1999), and the fact HIV-1 has been found in the United States in laboratory animals which had no laboratory or captivity-related exposure to HIV-1, provide a rational basis for either model. However, the 'ecological turmoil theory' of AIDS, advanced by Harvard University makes the bushmeat hypothesis very difficult to verify or falsify, and works in the interest of those who want to have the bushmeat model believed. The hepatitis B trial

vaccine model, on the other hand, could be readily falsified or verified, but that was never even attempted.

While considerable research efforts have been invested for almost twenty years exclusively in demonstrating the African origin of the pandemic, the specimens which could clarify the role of vaccines have been sitting in storage facilities of research laboratories and government agencies, or they have been destroyed. This circumstance is perhaps the most important indirect evidence that should keep the vaccine hypothesis alive, until either the necessary investigations are carried out, or until the reference material is officially declared lost or destroyed. This study does not claim that transmission of HIV through some kind of natural contact between humans and apes did not happen or that it could not have happened. It suggests that it is a rather long jump from one or two sporadic cases before the seventies to the massive outbreak of AIDS which occurred simultaneously on three continents, with marked differences in associated sexual preferences.

Despite a major focus on the African origin of AIDS, and with the exception of speculation over one or two specimens (too few not to be suspect) there has been no demonstrated cases of direct chimpanzee-to-human transfer of HIV-1 virus, despite the fact that there are now 198 experimentally infected chimpanzees in the US, and

'.....hunters are paid by timber companies to provision logging camps while the kill of freelance hunters are traded as far as the cities. Ape meat can fetch premium prices in middle class restaurants.' (Weiss and Wrangham, 1999)

This bushmeat model suggests that chimpanzees were (and are) caught by poachers, butchered and sold as 'bushmeat'. Poachers and/or their customers were infected in the process, and then spread the virus to the general population, e.g. though

prostitutes along African trade routes, trading posts, riverboat routes, and into the cities. From there it would have been propagated through intravenous drug users and gay networks, and travelers into Europe and the US.

However, the bushmeat model cannot explain the bizarre events and decisions surrounding the non-use of surrogate tests during the early years of the pandemic, while it was understood that such tests could have prevented the majority of transfusion-related transmissions of HIV-1, HBV and HCV.

Apart from the four circumstances already mentioned:

- 1) That there is no demonstrated case of direct transmission of HIV-1 from chimpanzees to humans, in the wild or in laboratories;**
- 2) That this model cannot explain the massive, simultaneous outbreak of the AIDS pandemic on at least three continents;**
- 3) That the alternative model, the trial hepatitis B vaccine model, was never tested; and**
- 4) The bizarre handling (or 'not-handling') of the contamination of the blood supply with HIV and hepatitis non-A,non-B has remained unexplained;**

there are several other difficulties with this model. First, however, the evidence in support of the bushmeat model is introduced and discussed.

OBSERVATIONS IN SUPPORT OF THE BUSHMEAT MODEL.

HIV-2. Strains of HIV-2, a genetic 'relative' of the HIV-1 retrovirus, were shown in 'middle-aged prostitutes' in West Africa (e.g. Senegal). The sooty mangabey (a macaque subspecies) is the natural reservoir of HIV-2. (Novak, 1992). The sooty mangabey is part of the diet of populations in Africa, including Pygmies. However, HIV-

2 infections could not be demonstrated in pygmy populations (Rouzioux et al., 1991). Cases of HIV-2 and SIVmac laboratory infections of animal handlers have been reported in the US (Khabbaz et al. 1994).

The African ‘human-ecological crisis’ (Garrett, 1994; Don Francis, as witness in the Krever Inquiry, as informant to other writers); HIV-1 infections of commercial sex workers, together with social-political turmoils in Africa and observations of HIV-2 infections have served as an ‘extensional framework’ to infer that what happened with HIV-2, ‘must’ have happened with HIV-1 as well. However, one would have some difficulties in explaining the HIV-infections amongst intravenous drug-users in the US in 1971/2.

The bushmeat model requires many ‘ad hoc explanations’: for instance, it requires the simultaneous jumping of the virus from chimpanzees to humans, in diverse geographic locations, within a few years, for different subtypes of HIV-1.

Note: The African ‘ecological turmoil’ and ‘bushmeat hypothesis’ have been promoted by Harvard University. Harvard was involved in the tracking of the virus to primates as possible reservoir for retroviruses such as HIV-1. Don Francis, head of the CDC hepatitis section, was connected to Harvard (his Alma Mater) and its School of Public Health, and with Max Essex, his mentor and animal virus researcher at Harvard, who, in 1985, for the first time, informed the American public that HIV-2, the genetic relative of HIV-1 was harbored by African macaques and transmitted to humans. The Harvard School of Public Health has supported studies which promote the African and global environmental chaos theory, such as that put forth by Laurie Garrett (1994); and earlier, bureaucratic chaos theories such as that promoted by Sandra Panem (Panem, 1988: *The AIDS Bureaucracy. Why society failed to meet the AIDS crisis and how we might improve our response*). (**Note:** Panem was also guided by Jonas Salk, the inventor of the Salk polio vaccines, which became infamous by the SV40 vaccine contamination). Accordingly, Harvard’s claims regarding the origins of AIDS (‘mystery’, or through environmental chaos and the bushmeat trade) cannot

be accepted at face value. Richard Wrangham an anthropologist at Harvard, who, with Robin Weiss wrote the commentary on the bushmeat model (1999), is the latest of Harvard's efforts to locate the outbreak of the AIDS pandemic in the African ecology.

Laurie Garrett:

The 1979 overthrow of Amin would only continue the crisis, putting it in the hands of the President Milton Obote. Famine would strike, particularly in the West Nile region of Northern Uganda. An estimated 300,000 had already fled that area as refugees from Amin's brutality. They had taken up unwelcome residence in eastern Zaire, Uganda's Rakai District, and southern Sudan. As famine conditions worsened, the refugee flow would turn into a tidal wave, and the 1983 census would reveal that 57 percent of the region's former residents were either dead or living elsewhere.

The famine would expand in 1982 into Southern Uganda -particularly the Rakai and Mbarara districts- and ethnic tensions would become violent. Clashes between local residents and the tens of thousands of refugees in the area (who came not only from northern Uganda but also from Rwanda, fleeing political massacres), would drive even the black-market economy into chaos.

Nearly all of Africa's social and political upheavals had multilateral ramifications, and several served as proxy Cold War confrontations between the United States and the Soviet Union. The region's governments and insurgents were armed to the teeth, and even local tribes warfare became increasingly high-tech and costly in human lives as the decade wore on. The civilian toll, both in direct loss of life and in social disruption, homelessness, famine, and refugee migration, was severe (Garrett, 1995:368-9).

While this is a good account, it does not explain how chimpanzee meat from Western Equatorial Africa got into Uganda.

PROBLEMS WITH THE BUSHMEAT MODEL.

HIV-1 infections in the US before 1978, the assumed date of the outbreak of the AIDS Pandemic.

.....A study by the U.S. National Institute of Drug Abuse found that serum drawn from injecting drug users in 1971-72 tested positive for antibodies to HTLV-III (HIV). Some 1129 samples obtained from 238 individuals who were surveyed for other reasons at that time were reexamined using the Abbott ELISA test for HTLV-III (the standard test) about 10% were positive. The possibly infected samples, which came from all over the United States, were retested using a more precise method - the Western Blot - and fourteen were positive, for an infection rate of 1.2 percent..... (Garrett, 1994:363).

Data on HIV-1 in drug users observed in the late eighties showed that HIV did not travel easily from city to city (by 1990 there were still many major cities where HIV did not spread significantly amongst needle-sharers). The bushmeat model would require that some drug users were infected in Africa, and then spread it in the US amongst themselves. Also, there does not appear to be further spread of HIV from these early cases. The patterns of spread of HIV-1, the 1971/2 drug user data, and the bushmeat model do not fit together.

HIV-1 infections in Africa before 1978. In 1985 McCormick of the CDC studied the prevalence of HIV in Yambuku, Zaire (the site of the first Ebola outbreak in 1976). 0.8% of the samples collected tested positive for HIV. Two persons were found alive in 1985. The other three had died from what might have been AIDS. One was a

woman who had worked as prostitute in Kinshasa between 1972 and 1976. The overall prevalence of HIV antibody in 1985 was still under 1% (Garrett, 1994:369-71). Neither the drug-users nor the people of Yambuku started an outbreak of the epidemic. The fact that HIV did not spread was explained by McCormick with the chastity of the villagers. Sera of inhabitants, collected in 1976 during one the first two Ebola outbreaks in Southern Sudan tested positive for HIV also. An inquiry in Yambuku - Zaire revealed that some of them may have died with AIDS-like symptoms; a few were still alive in 1984, immune compromised. Also, a Danish doctor who had worked in Zaire and had died in 1978 with AIDS-like symptoms seems to fit into this category of early AIDS cases.

He [McCormick] discovered that 0.8 percent (5 of 659) of the blood samples collected around Yambuku [in Zaire; the first of two sites of the Ebola outbreak] in 1976 were infected with HIV.....Similarly, just under 1 percent of the serum samples he had collected in Southern Sudan [where the other, simultaneous outbreak of Ebola took place in 1976] in 1979 had antibodies to HIV. .... The overall prevalence of HIV positive individuals in the Yambuku area in 1985 was the same as in 1976 [where some of the originally infected people had died from what might have been AIDS]: just under 1%. (Garrett, 1996: 368-70).

All HIV-1 can be traced to its host species and natural reservoir, where it co-evolved with the host species, the subspecies of chimpanzees *Pan troglodytes troglodytes*, prevalent in Western Zaire and the Congo. The southern part of the Sudan would be closest to the distribution of another subspecies, *Pan troglodytes Schweinfurthi* (whose habitat does not extend to the Sudan), which carries HIV-like retroviruses, which have not been found in humans. It is highly unlikely that poachers would have sold the

meat of western Zairean chimpanzees to Sudanese villagers. The chastity of the villagers seems rather like an ad-hoc explanation to 'solve the puzzle,' and may be confused with the traditions of premarital virginity. The same 'chastity hypothesis' would have to be applied the 1971/2 intravenous drug users, an obviously absurd proposition.

The African AIDS epicenter on the eastern shore of Lake Victoria. In Central Africa, only two countries had accumulated a substantial number of reported cases in 1984: Rwanda (83 cases), and Tanzania (109 cases). These two countries also had the highest rates of new cases in 1990. None of the other African countries (exception South Africa with 15) had any cases reported in 1984. It was not until 1985 that the neighbors of these countries showed signs of AIDS spreading. In comparison, the first cases of AIDS in the US were reported in 1981. If AIDS had been imported from Africa, one could expect a difference in reported cases in the opposite direction.

The African reports have to be accepted with caution, as epidemiological statistics in African countries were not reliable. However, there is some general agreement that the main epicenter of the AIDS epidemic in Africa was Rwanda, Tanzania and Uganda. This epicenter is about 1000 miles east of the habitat of *Pan troglodytes troglodytes*. The following two maps (pp. 139-40) show the relationships between various epidemiological contingencies related to the AIDS epidemic in Central Africa. Both maps have been adapted from maps used by Laurie Garrett (1994).

Fig. 11 points to the habitats of *Pan troglodytes troglodytes* and the epicenter of the African AIDS epidemic. As indicated earlier, *Pan troglodytes Schweinfurthi* does not carry HIV-1, the virus of the AIDS pandemic. The map also shows the relative position of

the Sudan, which had some of the early cases of HIV infections, and its distance to the HIV-1 carrying chimpanzees. The map points to the Cancer Research Center in Entebbe, Uganda, to show that there was an interest in this region as to the endemicity of hepatitis B and liver cancer.

Fig. 12 gives a more comprehensive picture. It shows the distribution of urban AIDS in Africa (from Mann et al. (eds.), 1992; a Harvard publication); the location of major research centers of the IARC (international agency for Cancer Research) and its major centers in Bethesda, Maryland in the US; and in Lyon, France; major drug users and gay networks (none in Africa); and the distribution of the four subspecies of chimpanzees which is the natural reservoir for all three HIV-1 subtypes observed in humans so far. Subtype M is the main subtype of the pandemic; subtype O was observed in Cameroon, Gabon and Equatorial Guinea; only two cases with subtype N were observed in Cameroon. The most important information on these maps is the circumstance that the habitat of *Pan troglodytes troglodytes* does not match the main epicenter of the pandemic at Lake Victoria, and other centers such Cote d'Ivoire. Neither the chimpanzees close to Central African epicenters nor those living in West Africa are hosts for HIV-1. The match between these geographic contingencies and the bushmeat model is very poor indeed.

Schematic map of Equatorial African countries.

Fig. 11: This schematic map of Central Equatorial Africa shows the geographic habitat of *Pan t. troglodytes*, the subspecies which is the reservoir for the AIDS virus (HIV-1); and the geographic habitat of the *Pt. Schweinfurthi*, which carries a different, HIV-like virus which is not involved in the AIDS pandemic. Constructed after J. Mann et al. (eds.), 1992 (annual national case numbers of AIDS); Gao et al., 1999 (*Science*), on the distribution of chimpanzee subspecies as reservoirs for HIV-like viruses; and Higginson, 1974, on the epidemiologic program of the International Agency for Research on Cancer (IARC); East African Virus Research Institute, Entebbe, Uganda, supported by the US National Cancer Institute Bethesda (quoted in Horowitz, 1997:115).

Figure 12: Distribution of MNO types of HIV-1, chimpanzee subspecies, high density of urban HIV-1 seropositivity and research sites of the International Agency for Research on Cancer (IARC)

THE INTITAL AIDS COHORTS.

If one assumes that AIDS started with one or more cases and then was spread into the rest of the population at risk (as could be observed in several African countries, or in Asian countries), one would expect a smooth ascent of the annual number of cases.

Discontinuities in that curve can be expected when there are disturbances in the population due to other causes, as for instance in Africa, when in sub-Saharan countries the spread of AIDS coincided with the drought and famine conditions. Several countries show discontinuities in the number of cases reported, and one can assume that people died from causes other than AIDS before AIDS could become clinically manifest.

While those African discontinuities were observable in the late eighties in the US, Canada, European countries and Haiti, the discontinuity can be seen around 1984/5, still early in the spread of the pandemic. This pattern is suggestive of a cohort of infections being different from the following cohorts. This pattern does not fit the assumption of individuals being infected with HIV through contact with Africans who had been infected via the bushmeat route. Rather it looks like a cohort that was either infected outside of the home-country, or spent some time outside the home country immediately after (simultaneous) infection, and then returned home and spread HIV amongst populations there.

This pattern is particularly noticeable in the Haitian curve, the Belgian curve, and the curve for Guadeloupe, which show a separate peak of cases reported before the main progression of the epidemic. In countries like the US, Canada or Germany, there is no separate peak in the progression of the annual number of cases, but rather a 'shoulder' in the ascent of the curve. The theoretical model for such phenomena is shown in the following graph:

Superimposition of a hypothetical small lead cohort and secondary infected cohorts.

Annual rates of HIV positivity or AIDS.

Fig. 13: Hypothetical curves of vaccine cohorts and secondarily infected individuals. This hypothetical curve may take on different shapes depending on relative size of cohorts, level of interaction, other epidemiological conditions. There may not actually be a 'lead peak' but rather just a slowdown in the ascent of annual rates.

Table 10: shows AIDS cases reported for a number of countries (from Mann et al., 1992.)

	1980	1981	1982	1983	(1979-84) (84)	1985	1986	1987	1988	1989	1990
US					(10,546)	11,315	18,423	27,464	33,297	37,556	36,658
Canada					(259)	357	579	876	1,007	1,133	867
France					(367)	564	1,218	2,188	2,976	3,631	3,857
Germany					(203)	319	586	1,075	1,357	1,633	1,263
Spain					(65)	158	437	974	1,992	2,618	2,811
Italy					(44)	196	452	1,036	1,741	2,413	2,977
Netherlands					(55)	66	137	242	322	385	405
Dom. Rep.					(9)	40	67	294	292	499	284
Haiti					(443)	110	242	477	731	453	630
Belgium					(109)	67	74	121	138	159	184
Guadeloupe					(14)	6	27	41	47	54	6

THE INJECTIONIST/LOOTING MODEL

‘Injectionists’ throughout Sub-Saharan Africa may have utilized discarded, HIV-infected needles and syringes, used in animal experiments: and research and animal facilities may have been looted during the upheaval in Uganda in the late seventies. These practices and occurrences are included here as possible alternative explanations for the origins of AIDS, although there is not a shred of evidence that this is the way it happened.

It is a plausible model: the International Association for the Research on Cancer had a facility in Uganda (near the epicenter of the African AIDS outbreak), and conducted research into hepatitis B-related primary liver cancer. Other facilities existed in Western Equatorial Africa (Senegal, Gabon, Liberia). Like the bushmeat model, however, the injectionist model is not falsifiable nor verifiable as the mechanism responsible for the outbreak of the AIDS pandemic.

If Africans had received HIV-contaminated hepatitis B trial vaccines, this would have resulted in patterns similar to those resulting from injectionism. In contrast, however, such a model of vaccination of Africans would be both plausible and falsifiable/verifiable. With the exception of the studies in Senegal by French teams, there is, like in the U.S., a lack of reports of early phase clinical trials. The only traces are the HIV-1 positive findings in villagers of Yambuku in Zaire, and N’zara in Sudan.

The injectionist model and the African vaccination model could help in explaining certain genetic characteristics of AIDS and its radiation. In the US and Europe, AIDS is characterized by a dominant clade (genetic variant, less than 20% different from other variants) of HIV-1, which is rarely found across Africa. Other clades may be found in more specific locations (for instance, the most lethal clade D, was found in Uganda). This distribution suggests that more than one mechanism may have been involved in the entry of HIV-1 into human populations in Africa.

The 'clade model' has been dubbed the '*Big-Bang*' theory of AIDS. It assumes that all subtypes came from a single strain that had entered into humans and then began to mutate wildly (Myers, 1993). However, recent genetic research (Gao et al., 1999) on simian retroviruses and chimpanzees and their coevolution suggests that multiple sources (several chimpanzees, most of them of the same subspecies – pan troglodytes troglodytes) and multiple instances of the virus 'jumping' from chimpanzees to humans, could underlie this diversity in HIV-1 subtypes.

The bushmeat model has been shown to be an implausible model, because of the geographic distance between the chimpanzee subspecies and the main epicentre of HIV-1 epidemic in Central Africa (Uganda, Tanzania, Rwanda). The distribution of clades puts the bushmeat model into question even further. If the bushmeat model was true, one would have to assume that all initial European and US cases of AIDS became infected in a single set of conditions in one location in Africa, and then spread it throughout Africa, Europe, US and Latin America. One would also have to assume that some viruses mutated and others did not (such as the clade that spread in the U.S.).

If, on the other hand, Europeans, Latin Americans and Americans were infected in more than one location, then the US and European pattern would have looked more like the pattern of radiation from Africa to Asia clades A, B, C (excluding D, because East Indians were driven out of Uganda – the main locations of D – by Idi Amin in the early seventies).

The epicenters in the US (New York, San Francisco, Los Angeles), showing a single clade (B), suggest that US, Europe and Haiti had a common source of HIV-1, i.e. a vaccine that was given to foreign aid workers (such as the Peace Corps), who spread it first in Africa (1977) and then in Europe and the US (1978) upon their return from duty. This U.S. vaccine (foreign aid worker) model, however, cannot explain the HIV-1 diversity in Africa and related radiations. If more than one vaccine derived from different chimpanzees had been used in the U.S., then the clade patterns in Africa, the US and in Asian should have been more or less the same. This is not the case.

This reasoning led the author to the proposition that the origin of AIDS in Africa cannot be explained with a single mechanism (bushmeat or vaccinations in the U.S.), and that more than one mechanism may have been contributing. All of them, however, in one way or another, appear to be related to the utilization of chimpanzees in hepatitis research (hepatitis B, hepatitis non-A,non-B, primarily liver cancer, hepatitis B vaccine trials). Indeed, the distribution of HIV-1 in Africa appears to be grouped around major research centers of the IARC (International Agency for Cancer Research) in Uganda, Cote d'Ivoire and Durban, and less so around Senegal. Amongst possible alternative mechanisms, the African practice of injectionism, and the destruction and looting of research facilities and exposure of looters and the populations to contaminated injection equipment and lab

equipment are plausible possibilities for spreading not just HIV-1, but also other blood-born diseases. However, these mechanisms cannot exclude the possible use of several vaccines, contaminated with different HIV-1 subtypes, in African hepatitis B vaccine trials. The U.S. vaccine model is not invalidated by these additional models, but supplemented by them. The combination of models can explain the 'jumping' of genetically diverse strains of HIV from chimpanzees to humans in the course of just a few years, in different locations, better than any singular model.

The entry of HIV-1 into human populations must be distinguished from subsequent mechanisms of spread and radiation by 'amplifiers': sexual transmission; STD; intravenous drug use; pregnancy; injectionism. Such multiple mechanisms, and the obfuscation of 'origins' by giving research priority to secondary mechanisms of propagation, made the role of hepatitis B vaccine trials in the genesis of the AIDS pandemic (i.e. originating mechanism(s)) 'deniable' – but, as this dissertation seeks to show, not completely so.

To examine the possibility of multiple mechanisms, the paths of two other epidemics were briefly examined: HIV-2 and Ebola. The epidemiology of HIV-2 and its link to Guinea-Bissau seems to be similar to conditions in Uganda for the spread of HIV-1; the latter, at least in the early outbreaks, seems to be related to the earliest HIV-1 epidemics (not sporadic cases) observed in Central Africa, in 1976 (Yambuku and N'zara). Although HIV-2, and the sooty mangabey as its natural reservoir, have been used to promote the 'bushmeat model', the 'needle' seems to be a far more efficient vector for an explosive propagation of such infections than captured and cooked macaques.

The shortage of needles and syringes was severe in small, remote hospitals in Africa. This is well-known from the conditions of the Belgian mission hospitals in Yambuku in the Bumba region of Northern Zaire, the location of the Ebola outbreak in 1976, where only five syringes were issued daily for the treatment of hundreds of patients. These conditions added to the propagation of infections, and were identified as one of the most likely mechanisms of propagation of Ebola in Yambuku/Zaire. Women in Yambuku had come to the mission for Vitamin B complex shots (which made them feel better). The other mechanisms reported were the burial practices and cleansing of the bowels of the deceased without evisceration (see Garrett, 1994: 144). It is also hard to tell what happened to the 'garbage' (i.e. the syringes and needles that were decommissioned every day in the Yambuku hospital and countless similar facilities in Africa). Normally they should have been incinerated, which is not something that very likely to have taken place in the African rain forest.

Note: A Canadian English teacher, working recently in Eritrea, north of Ethiopia, observed a public health nurse giving injections to girls in a local school and clinic. There appeared to have been an unlimited supply of needles, but not of syringes. After a needle had been used, the nurse would simply throw it on the floor (Lynda Bertrand, personal communication, 1999). Both, the class room floor and the clinic floor, were littered with needles.

The older technologies of reusable glass syringes and reusable needles, combined with the use of boilers and autoclaves, or even just boiling, would have provided a reusable technology, at a comparatively very low cost. Needles can be reused several times before their points become blunt.

Note: In the late sixties, the author worked in an Austrian rural hospital which used rising, boiling and autoclaving as sterilization method for reusable syringes and needs. To the best of his recollection, this did not result in any cases of hepatitis. With the advent of disposable injection equipment, older, but very effective sterilization techniques for reusable injection equipment were no longer applicable. Laurie Garrett describes the disposable syringe situation in the Soviet Union in 1988 (only in the order of 1/100 of required disposable syringes and needles were produced; Garrett, 1994: 501). At that time, the Soviet Union needed 3 per capita and year. If reusable glass syringes had been used instead, sterilized every day, that would have been in the order of .03 syringes per capita and year. Glass syringes can be autoclaved (i.e. in steam, under pressure, exceeding 100C), but plastic syringes cannot be sterilized in this fashion. Autoclaving is still the standard procedure for metallic surgical equipment. The introduction of disposable injection equipment, without retaining reusable technologies and related sterilization equipment in hospitals of very poor countries was economically absurd, to say the least. Also, reusable syringes stay in the wards and clinics, not in cartons and crates in warehouses. Thus theft is a lot easier to control. The profits for medical suppliers from disposable injection equipment became immense. While the objective of disposable injection technology was reduction in nosocomial infection, the net-effect was probably negligible in Western industrialized countries, and a massive amplification of infections in developing countries, at a much higher cost to any health-care system. The only group for whom availability of disposable injection equipment would make an enormous difference, and would prevent perhaps tens of thousands of unnecessary deaths annually world-wide, are intravenous drug users – an intervention which is blocked by the ‘war-on-drugs’ ideology which, in the US, has become a socio-economic and cultural system almost identical to witch-hunting culture and its employment and real-estate – related incentives (including forfeiture of property by the accused).

Since the badly managed African economies could not afford a constant supply of disposable injection equipment, disposable injection equipment was reused throughout Africa without proper sterilization. In addition, the ‘injection’ may be associated with some kind of belief in special healing powers (a sort of cargo-cult, a faith in the ‘ordeal’ of the needle), and with a relative lack of faith in pills and other forms of oral medications. With Western industrial surplus production of useful and not so useful drugs and supplements entering into the African black markets, injectionists became a wide-

spread trade. Injectionists used (and still use) the same syringes and needles over and over again. Any commodity which is in high demand that is in short supply tends to generate a black market. Conceivably, needles used in animal experiments in Africa were either not incinerated or were stolen and smuggled out and showed up in black markets for syringes and needles. Garrett (1994: 681) notes:

Corruption and black-marketeering were critical problems for antibiotic distribution and misuse in developing countries. In many parts of the world untrained 'injectionists' earned a living by injecting illegally obtained antibiotics and vitamins into customers, often in the major market places in full view of the police. Needles and medicinal drugs were, therefore, of very high value. Such misuse of the drugs no doubt contributed to the resistance [of pathogens to antibiotics] and to lack of supplies for diarrheal epidemics. The following wire story release from the Associated Press in July 1993 illustrated the problem:

Nairobi, Kenya (AP) – Patients bring their own medicine, food and syringes to some government hospitals because employees often steal and sell what few supplies that are issued.

Inflation is soaring, partly because the government printed billions of new shillings last year to finance the ruling party's campaign and bribe voters.

Much of the social security fund was lost when officials illegally put it into real estate deals and other bad investments. Asked by journalists whether anyone would be held accountable, Treasury Secretary Wilfred Koinange replied "What do you want, heads to roll?"

Note: About 10 years later, anthropologist Richard Leaky has been appointed by the former target of his critiques, Kenyan President Danile arap Moi, to head the Kenyan civil service, the highest non-political job in the Kenyan administration, "to change the culture of corruption and inefficiency in our public service" (*Science*, 1999: 285-286).

In the case of Uganda, the spread of disease may have been the result of the violence and warfare of the late seventies, and the ransacking of the cancer research facility by soldiers and civilians around 1977 (under Idi Amin's regime), which might have put a particularly virulent 'clade of viruses' (clade 'D') into populations in that area. Laurie Garrett (1994: 241).

...Between 1975 and 1980, Uganda, its entire health infrastructure devastated, experienced epidemics of malaria, leprosy, tuberculosis, cholera, visceral leishmaniasis (kala-azar), and virtually every vector-borne ailment known to the continent. A French team found evidence of more exotic diseases as well when they took blood surveys of villages in Western Uganda. Ebola, Marburg, Lassa, West-Nile fever, Crimean-Congo haemorrhagic fever, and Chikungunya were among the viruses found in the region's populace...

...Makerere University, which had been the primary training Centre for East-Africa's doctors, was looted right down to its electrical sockets, and bathroom tiles. By the end of the 1970s the nation of Uganda would be completely out of toilet paper, antibiotics, aspirin, sterilizers, cotton wool, bed linens, soap, clean water, light bulbs, suturing equipment, and surgical gowns. Rumors of strange disease outbreaks were rampant, but there was nobody left to investigate these claims...[emphasis by the author].

For both, the injectionist and the looting model of HIV-1, entry into human populations, a laboratory facility using chimpanzee would have been essential. Such facilities existed. For instance, Alfred Prince, the hepatitis B vaccine developer of the New York Blood Centre, relocated his chimpanzee experiments into Liberia, because chimpanzees were too easily infected with hepatitis B in quarantine and other holding facilities. Specific HIV-1 subtypes, including major subtypes such as N and O could be linked to such research establishments. Also, this model could explain what the bushmeat model cannot; namely how viruses firmly linked to pan troglodytes troglodytes (the HIV-1 virus) showed up almost a thousand miles away from the habitat of their host species. The same applies to HIV-2 and the sooty mangabey. It may not have been feasible to

move bushmeat over such a distance. However, chimpanzees for experimental purposes could have been driven or flown into such a research facility in Uganda or South Africa (Durban). The research facilities in Uganda seems to have been a store for vast variety of viruses, either in vials or in monkeys that were being experimented on. Horowitz shows a map for international cancer research, and the Uganda facility which is noted for the following types of cancer and carcinogens to be investigated: oesophagus, liver, stomach, prostate, herpes type viruses (herpes type I and II, cytomegaly, Epstein-Barr). The same map shows IARC research facilities dedicated exclusively to liver cancer in Durban, South Africa, Cote d'Ivoire and Senegal (Horowitz, 1996:114; from Higginson J and Muir CS. Epidemiologic program of the International Agency for Cancer Research on Cancer (IARC) In: *The Notional Cancer Program and International Cancer Research, National Cancer Institute Monograph*, 1974:40-65).

Edward Hooper and the OPV model of the AIDS pandemic. At the end of 1999, shortly after closing the research for this dissertation, Edward Hooper published his book on the origins of AIDS. Edward Hooper's analysis is almost entirely focused on Sabin-type (attenuated virus) polio vaccines, some of which were developed by Hilary Koprowski in the late fifties at the Whistar Institute in Philadelphia. Hooper's model suggests that Koprowski may have used chimpanzee kidneys for attenuating passages of the polio viruses, and that a particular line of production, the 'CHAT vaccine,' was used in the USA experimentally on children of women imprisoned at the Clinton penitentiary, and on populations in Central Africa. Koprowski used an experimental monkey facility in

Western Zaire (at Lindi, near Stanleyville on the Congo River), which also housed many chimpanzees.

In order to construct a connection between those vaccines and AIDS it is necessary to assume that people who might have been infected by such vaccines would not have transmitted HIV-1 easily (or not at all), and may not even have become clinically ill themselves. Accordingly, it is necessary to assume that AIDS started as a 'low-grade' iatrogenic epidemic, which remained dormant for at least two decades. Hooper's model must further assume that, in the early and mid-seventies, a rapid mutation of the virus occurred, which also resulted in higher pathogenicity of some or all of the new strains (the 'big-bang' or 'starburst' theory of the AIDS pandemic: one or more precursors of HIV-1, type M, diverged into subtypes ('clades'), which are referred to with capital letters of the alphabet (A,B,C etc; Myers et al., 1993)).

While this assumption matches somewhat the characteristics of the spread of AIDS in Africa, there is a problem with this model: clade B was the exclusive agent of gay AIDS in North America, Europe, Japan, and Australia, and of homo- and heterosexual AIDS in Haiti. Yet B is rarely seen in Central Africa. There is another problem with the 'star burst theory': as rapidly as HIV-1 began to mutate, it stopped mutating at the same rate, once it had entered into the various populations (such as in the US, where the epidemic is almost uniformly clade B).

Hooper also reports on HIV-2, and the fact that the habitat of the sooty mangabey (the natural reservoir of HIV-2) lies outside of the epicenter of the HIV-2 epidemic: Guinea-Bissau. The bushmeat model, which was originally developed by Harvard University on the basis of observations on HIV-2 epidemic, and then extrapolated to the

HIV-1 pandemic, is contradicted by Hooper, for HIV-1 as well as for HIV-2. In this dissertation, the author offers the 'injectionist model' as an alternative to vaccine trial models. However, the dissertation also states that a contribution of vaccination programs to the HIV-2 epidemic cannot be excluded. Indeed, the 'middle-aged prostitutes', who were found to be positive for HIV-2 in Senegal by French researcher in the mid-eighties, may well have been a vaccination cohort. Their age would fit the timing of experimental polio vaccinations in Africa in the late fifties: those women may have been infected as babies in Guinea-Bissau in the late fifties or early sixties; they became refugees during the Portuguese colonial war in Guinea-Bissau, and some may have settled as prostitutes in Senegal (the refugee trek between Guinea-Bissau and Senegal has been documented by Hooper), while many of the men may have joined the rebel armies. By the time they tested positive for HIV-2 in the mid-eighties, these women would have been 'middle-aged'. While there is no record of sooty mangabeys actually being used in vaccine production, mangabeys are nonetheless macaques and thus relatives of the rhesus monkeys, whose kidneys were used for polio vaccine production of Salk and Sabin vaccines - until they were found to carry tumor viruses (simian virus 40) and were replaced with the assumed safer green monkeys. Alternatively, green monkeys may have become cross-infected with HIV-2 by macaques in shared monkey facilities.

As was the case with the discussion of the hepatitis B trial vaccine model, there is no direct evidence that chimpanzee material was actually used in polio trial vaccine production: in other words, neither Hooper nor the author have any direct evidence to prove or disprove the polio or the hepatitis B vaccine model. However, Hooper's model hinges almost entirely on early sporadic cases of likely HIV-1 infections, predating the

AIDS pandemic, and the starburst theory. The hepatitis B vaccine model, on the other hand, while it is clearly irrelevant for HIV-2, fits closely the outbreak of the AIDS pandemic and genetic variability observed in the AIDS pandemic. In addition, the hepatitis B trial vaccine model includes the contingencies of surrogate testing of the blood supply in Western industrialized nations: most of the blood bank professionals who recommended against surrogate testing were also directly or indirectly involved in hepatitis B vaccine development. Some, such as the Germans and the Scots, may have been more concerned with the contamination of the blood supply with hepatitis non-A,non-B viruses than with HIV-1.

Unlike the polio vaccine model, the hepatitis B model does not depend on a few sporadic cases (which may well have been due to early experiments with vaccines such as polio). It can be directly related to the characteristics and epidemiological patterns of the actual pandemic. At the closing of the research for this dissertation, the vaccine identified as the most likely one to have started the pandemic was the one prepared by the New York Blood Center by Alfred Prince and his team. However, the possibility that other hepatitis B trial vaccines were involved in Africa in the seventies could not be excluded.

Hooper had difficulties answering the questions: how did HIV-1, type M, subtype B get from Africa to America? And why only subtype B?. This dissertation suggests that AIDS did not come 'out of Africa', that American gay men and Haitian men were infected in the US by the NYBC trial vaccine, including perhaps those who worked in the Peace Corps or other aid organizations; that this would explain early cohorts of AIDS cases in Haiti, Belgium the US, which died out around 1986. Early cases in the US (iv

drug users) and in Africa (N'zara/Sudan, Yambuku/Zaire) may have been due to early hepatitis B vaccination experiments.

A hepatitis B trial vaccine model can assume multiple vaccine preparation, utilizing plasma from chimpanzees from different locations (or perhaps chimpanzees multiply infected in animal facilities). At the time of closing the research the author had only observed that the New York Blood Center had a research facility in Liberia (the habitat of a different chimpanzee subspecies, not linked to the AIDS pandemic). The best reference for the possibility of experiments with chimpanzees came from Horowitz's reproduction of the IARC map – International Agency for the Research on Cancer, which shows the two main research centers, the NIH in the US and a facility in Lyon, in Southern France. It also shows a facility in Uganda, somewhere near Entebbe, and thus close to the epicenter of the AIDS pandemic. However, the author did not feel that he had enough indirect evidence to outright suggest that AIDS may have been introduced in Africa via hepatitis B trial vaccines.

Hooper's book provides evidence of an early connection between New York, hepatitis research, and Zaire. Koprowski's monkey facility, which he used for his polio experiments, was located at Lindi, near Stanleyville (now Kisangani), only 200-300 miles west of the epicenter of the AIDS pandemic on the eastern shore of Lake Victoria. In the late fifties, the late Fritz Deinhardt from the Max von Pettenkofer Institute in Munich inoculated Koprowski's chimpanzees with fecal preparations derived from children of the Willowbrook facility in New York, i.e. Saul Krugman's research material (Saul Krugman was the first to produce a trial vaccine against hepatitis B and used the Willowbrook children for his early experiments). Fritz Deinhardt remained involved in vaccine

development and chimpanzee experiments, and he still presented a paper in 1980 at the hepatitis B vaccine symposium in Paris. His wife, Jean Deinhart, was a colleague of Koprowski at the Whistar Institute in Philadelphia. Thus there had been a definite connection between the New York hepatitis research group and experimental vaccine facilities and vaccine programs involving chimpanzees in Central Africa.

A second clue that multiple hepatitis B trial vaccine preparations may have started the AIDS pandemic in Central Africa is as follows: amongst all the vaccine developers, Alfred Prince was the only researcher who deliberately used whole hepatitis virus and e-antigen in his raw material preparations (something all the other developers avoided for fear of viral inactivation problems) to maximize the immunogenic effect of his vaccine and make it more competitive. Trepo, a hepatitis researcher from Lyon, France (not affiliated with the Institute Pasteur and P. Maupas in Paris, but possibly affiliated with the IARC in Lyon) showed considerable interest in the role of whole hepatitis B virus and e-antigen in vaccine preparations. At the 1978 conference in Los Angeles, where Prince introduced his vaccine protocol, Trepo co-authored a workshop paper with Prince. At the 1980 conference in Paris he presented a paper on the subject, while Prince no longer talked about his vaccine. Instead he talked about NIH/Purcell/Gerin preparations, which had been proposed by Lewellys Barker in 1978 as possible international hepatitis B vaccine standard.

The author believes that during 1980, and perhaps as early as 1979, the New York group had come to realize that something had gone wrong with the NYBC vaccine, but did not inform all of their international colleagues. Increases in strange infections had been observed in New York over a period of 30 months prior to the CDC's first

announcement of AIDS in mid-1980, which places the infection date of those cases at some time after 1975, roughly the same time suspected as the beginning of the AIDS pandemic by African physicians. In 1983, Trepo was one of those blood bankers/vaccine developers who advocated against the use of surrogate testing of the blood supply. One can combine these observations with the observation that the US FDA in the person of Lewellys Barker (former FDA) and Gerety (FDA, well into the eighties) were the first and strongest advocates against surrogate testing. Barker had been involved in hepatitis B research with chimpanzees. Gerety was in charge of blood products (not vaccines) at the FDA, because the vaccine was indeed a plasma product. Gerety, in 1982 at a symposium at Munich, also argued that the commercial Merck hepatitis B vaccine was free of hepatitis C (although he had no direct evidence to give such assurances). Most importantly, Gerety and the FDA had no business whatsoever to recommend against a safety test (surrogate tests). If the industry wanted to introduce tests above required standards, it would have been their decision alone, and the FDA would have had no right to intervene.

The third clue is derived from the way Hooper refers to Alfred Prince – as ‘Fred Prince,’ in a single footnote (namely Prince’s testing of Pan troglodytes verus for HIV-1 and the negative results of this study). This suggests a certain degree of personal familiarity. Prince may effectively have diverted Hooper’s attention away from his hepatitis B vaccine, which Hooper introduces briefly, and then drops with hardly any and incorrect evidence. A similar pattern is apparent in Laurie Garret’s account, which devotes 2 lines to the subject (apparently she was coached by Donald Francis). Horowitz makes hepatitis B vaccines a possible candidate for having started the AIDS pandemic, but

diverts attention away from the Prince vaccine. Instead, he implicates the Merck vaccine, and the Purcell/Gerin/NIH vaccine. Horowitz would have looked at the very same references as the author of this thesis, and it is highly unlikely that he would have missed Prince's presentation of his vaccine in 1978. Indeed it was the 1978 reference on the Los Angeles symposium referred to by Horowitz which put the author on the NYBC/Prince path and away from Horowitz's misleading NIH and Merck vaccine paths; notably, this reference has been permanently removed from the inventories of two major scientific libraries in Ottawa.

After a preliminary review of Hooper's account of the AIDS pandemic, the argument made in this dissertation (AIDS was due to a contaminated hepatitis vaccine, most likely of NYBC origin) still stands, but the following amendments to the thesis should be made, and the following paths are suggested as worthwhile following:

- 1) Polio vaccinations in Guinea-Bissau in the late fifties may have led to the introduction of HIV-2 into human populations in West-Equatorial Africa;

- 2) Prince's vaccine may have started the outbreak of AIDS in the US and Haiti, possibly in Europe;

- 3) The multi-clade outbreak of AIDS in Central Africa could be due to Prince's trial vaccine preparations; or vaccines used by Belgian/French researchers according to Prince's protocol, in the eastern Zaire (possibly including Yambuku and N'zara), Uganda and Rwanda, Burundi and Tanzania;

- 4) Belgian gay men (and gay men in France, cases with mode of infection 'unknown.') and some Haitians (probably male, perhaps working in Zaire in a vaccination program) could have been vaccinated with the NYBC trial vaccine;

- 5) Accordingly, HIV-1 could have been introduced separately in the US (vaccinations of gay men, iv drug users in the Eastern US), in Europe (gay men), in Africa (women of child-bearing age) and in Haiti (heterosexual men, perhaps some women), and hence the homo-heterosexual discrepancy between AIDS in

Africa, Haiti, and the US/Europe. This is supported by the WHO's insistence that the AIDS pandemic started simultaneously in at least three continents;

6) The early 'vaccine cohort phenomenon' observed in Haiti, the US and in Belgium could be due to either absence of these individuals from the country (aid work in Africa), differences in virus load (high in vaccines, low in sexual contact), or changes in the virulence of the virus after the first human passage;

7) Polio vaccines, injectionism and bushmeat may have led to some sporadic cases prior to 1975, but are not very likely the mechanism by which the AIDS pandemic was set off simultaneously in the US and in Africa.

Towards the end of his book Hooper refers to an interview with a British scientist who had been involved in polio vaccine research in the fifties.

At the end we argued whether or not it was important to write about the [polio vaccine] theory [of AIDS]. I said that if this was actually what happened, then surely it was vital to bring the full story out in the open, thereby lessening the risk of similar unintentional catastrophes in the future. He disagreed. "No. If the theory's correct, it would make the US responsible for the AIDS epidemic, and possibly have to go and take care of those people over there with AIDS." He had got up to escort me out, but I was still scribbling his words down in my notebook. "You can keep this inflamed, and you can keep waving it, but I'm not sure that you are going to get anywhere with it," he went on. As we walked toward the door, he added that if I quoted him on any of this [including the possibility that Koprowski may have used chimpanzee-derived kidney cell tissue culture for his polio vaccine preparations] he would simply deny he had said it.

When we shook hands, I pressed him one more time, saying that if the OPV[Oral Polio Vaccine]/AIDS theory had merit, then surely it was vital that the truth came out. "I don't know if truth in itself has merit," he answered. "I think that truth which makes a contribution has merit."

Apparently, in this scientist's mind, helping Africans with AIDS and their families would not be a contribution of the truth that has any merit whatsoever. This thesis makes the same assumptions as to the motivation why surrogate testing was suppressed in 1981 – except in reference to hepatitis B vaccines not polio vaccines: the enormous extent of the liability associated with one or the other vaccine. The final comments of the interviewee match a comment made to the author by a major player in the Canadian AIDS

crisis in the mid-eighties: *'The whole truth shall never be told.'* Hooper and the author made many of the same assumptions, but they differ as to which vaccine actually started the AIDS pandemic. The author has avoided Hooper's kind of commitment to his own theory as the only plausible explanation of the AIDS pandemic. The author merely makes the claim of a *prima facie* case for a full inquiry. An inquiry may well prove him wrong.

Beatrice Hahn on the origins of AIDS. In *Science*, 267:607-614, 28 January 2000, Beatrice Hahn (University of Alabama, Birmingham) published a review of the genetics and epidemiology of AIDS. She gives Hooper's book and the oral polio vaccine model of AIDS short shrift. She does support the bushmeat model of AIDS, without direct evidence and references, but with pictures of killed, butchered and smoked monkeys, including a chimpanzee.

In summary we subscribe to the hypothesis that direct human contact with chimpanzee and sooty mangabey blood resulted in zoonotic transmission of SIVcpz and SIVsm to humans, and that social, economic, and behavioral changes that occurred in the early and mid 20th century provided the circumstances whereby these viruses could expand and reach epidemic proportions. (Hahn, 2000:612)

She believes that HIV-1 radiated (with genetic changes) from a human source:

It is possible to construct a scenario in which the radiation of lineages currently constituting HIV-1 group M occurred before the chimpanzee-to-human transmission event, and that humans subsequently became infected by multiple descendant SIVcpz lineages. However, this seems quite implausible. In particular, it would require that the group M subtypes resulted from independent transmissions of at least 10 different, and genetically equidistant, chimpanzee viruses. In turn, these viruses either would have had to come from different animals, or must represent diverse members of a quasispecies from a single animal. Under the former scenario, equidistant subtypes would not be expected,

given the clear phylogenetic substructure seen within the radiation of SIVcpz (see Fig. 2) and indeed seen among SIVs naturally infecting other species such as sooty mangabeys (6) or vervets. (Fig. 2). Under the latter scenario, no clear virus subtypes would be expected at all, given that recombination among members of the quasispecies (43) would blur the distinction between lineages. In contrast, the starburst radiation at the origin of the group M subtypes (Fig.2) is best explained by a rapid expansion of virus population size, as has been seen with other epidemically spreading pathogens. (44, 45). Thus it is far more parsimonious to assume that the last common ancestor of group M infected a human rather than a chimpanzee, and that the AIDS pandemic began to spread decades before the OPV trials [oral polio vaccines, in reference to Hooper's model] were conducted. (Hahn et al., Science 287:612, 2000).

Hahn's arguments are problematic because:

- 1) They are based on genetic data alone, not on epidemiological data;
- 2) The massive propagation of subtype M/B in America and Europe was not associated with additional 'starbursts', and hence her expansion model does not hold up outside of Africa;
- 3) The effect of large holding, quarantine and experimental facilities for monkeys in Africa on HIV propagation, mutation and recombination is not part of Hahn's terms of reference.
- 4) We do not know what happens genetically at the point of chimpanzee-to human transmission. The discontinuity in transmission ('jumping species') may provide conditions for substantial changes in the viruses genes, which may not intervene in intra-species expansion of the epidemic.

Hahn's arguments are thus presented in an epidemiological vacuum, which is filled with analogies and speculation. For North America, it would be crucial to test any remaining aliquots of the trial hepatitis B vaccines. In order to explain the diversity of HIV- subtypes in Africa would require to test any remaining aliquots of trial vaccine used there as well as the blood specimens of chimpanzees kept in African facilities. As was mentioned earlier, ecological conditions for monkeys living in the wild and living in captivity are not the same.

Hahn's most serious refutation of any vaccine model of HIV-1 is her belief that, based on genetic differences, the original HIV-1 virus transgressed from monkeys to humans as early as 1930, and therefore much earlier than any relevant vaccination program. She supports her claim with the observation that human subtypes M, N and O are similar to SIVcpz of Pan troglodytes troglodytes, but that none of the subtypes and subtypes (clades A-J) were found in chimpanzees themselves. The timing is based on models of 'molecular clocks,' which estimate rates of mutation of particular genomic sequences of the viruses studied. However, there are major unknowns in this reasoning:

- 1) We know what happens genetically in human-to-human transmission, human to chimpanzee transmission, perhaps experimental chimpanzee to chimpanzee transmission, but nothing about what happens in chimpanzee to human transmissions and what happened in holding facilities for chimpanzees, which were not used for HIV- experiments.

- 2) While genetic HIV-1 characterizations can be based on immense number of specimens, there are only few SIVcpz-positive chimpanzee specimens. available, in particular from wild-living chimpanzees.

- 3) Wild-living chimpanzee populations have been decimated over last few decades. Weiss and Wrangham (1999) suggest that before 1990 there were still 200,000 chimpanzees living in the wild, and since then several thousand have been killed every year. We can assume that hundreds of thousands were killed before 1990, and that the populations which carried the 'jumping' virus may no longer exist.

- 4) Specimens from captive chimpanzees are obtained mostly from animals kept in the US, and we have heard very little about animals kept and used in Africa, in particular Pan troglodytes troglodytes.

- 5) Why did the radiation start and then stop; why are there so many subtypes in Africa, but not in America?

The genomic trees presented by Hahn show HIV-1 subtypes interspersed with the SIVcpz of Pan troglodytes troglodytes, and a very similar picture is presented for HIV-2 and common ancestry for HIV-1-M and its clades. To deduce from that, and from present observations of mutational rates, a valid 'molecular clock', without an accounting for the above mentioned epidemiological factors, including the possibility of transmission via vaccines, is not a convincing case for rejecting, out of hand, the possibility that vaccines played a role in various HIV-transmissions. The case to be made for investigating the hepatitis B vaccine program of the seventies and early eighties is the same as the one made by Hooper for oral polio vaccines: since we cannot reconstruct the direct evidence for the bushmeat model, one should at the very least seek the exclusion of alternative models such as vaccine –related transmissions – and only if this inquiry is exhausted should speculation be the mode of explanation of last resort. While Hahn says that there is no evidence to support Hooper's oral polio vaccine model, she provides no evidence which conclusively refutes Hooper's allegations – because what could be done (testing stored vaccine and monkey specimens) has not, and still is not done. Besides, the current model of the molecular clock is presently promoted by one group only, which at the time of Hahn's publication had not been submitted their findings for publication (Korber et al.). Overall, the strongest objections to Hahn's is claims is that one cannot deduce an epidemiological process from genetic data alone; and that the material that could generate model-verifying or falsifying data related to vaccine programs is not being investigated.

Last but not least, part of Hahn's research is funded by the Veterans Administration, and thus by the U.S. military, which played a peculiar role in the

handling of HIV and HCV in the early eighties. One can trust Hahn's data, but one may not necessarily believe in her interpretations.

HIV-2 and Ebola. It is necessary to strike some kind of balance for the examination of additional paths and branches of the main paths: the issues outlined can only be considered to the extent that they are relevant to the question of whether hepatitis B trial vaccines could have played a role in the initiation of the AIDS pandemic or not. The spread of HIV-2 is of interest with respect to the possible role of experimental animal facilities in the availability of contaminated injection equipment and the spread of HIV-1 by injectionists and looters. Ebola is of interest, because its particularly severe manifestation in Yambuku (Northern Zaire, more than 90% fatality of those infected), and fairly severe manifestations in N'zara (Southern Sudan, up to 70% fatality), may be linked to earlier infections with HIV-1; and because there is a question as to how these early infections with HIV-1 may have taken place.

In Yambuku, mostly young women and children were infected, and the possibility of a vaccine trial cannot be excluded (the Belgian nuns at the Yambuku mission hospital did administer vaccines; and women of child-bearing age were one of the main targets of hepatitis B vaccine trials in Africa). Other leads, such as the fact that Litton-Bionetics, a military contractor, had animal facilities in Uganda and is listed in a 1985 letter to the editor of the *NEJM* (Stevens et al., 1985) as one of the organizations stating that the Merck commercial hepatitis B vaccines were free of HIV-1 contamination, may be additional 'critical paths' to follow. The authorship of that letter includes the Canadian

hepatitis researcher, Patricia Taylor, who at the time of the letter was associated with the New York Blood Center (earlier, in 1978, she was employed by the Health Protection Branch of Health and Welfare Canada and representing Canada in viral hepatitis conferences which also discussed hepatitis B trial vaccines); and Robert Gallo of the National Cancer Institute of the NIH.

This section also illustrates the possible complex consequences of the intrusion of Western-capitalist cultural practices into non-Western ecologies. In the post-colonial era, Africa became an arena of the Cold War conflict with often severe consequences for capitalist and communist – controlled populations alike. The changes in social and natural ecologies (in particular social conditions of urbanization and warfare) were profound. At the same time, modern Western medicine, and with it, experimental medicine, descended upon Africa. It led to the much celebrated eradication of small pox. However, a major reduction of other diseases has not been accomplished. Any success came at the expense of introducing or amplifying other kinds of diseases and infections (such as hepatitis C and hepatitis B).

HIV-2

It takes more than a leap of faith to believe that HIV-2 (a relative of HIV-1, the agent of the AIDS pandemic) has a peculiar preference for 'Senegalese, middle-aged prostitutes', and only 4-10% of them, as suggested by French researchers studying HIV-2 in Senegal (Kanki et al. 1986, 1987, 1992; Clavel et al., 1986). Guinea-Bissau, the small former West African Portuguese colony, which is surrounded by Senegal, appears to have been the epicentre for the HIV-2 epidemic in Africa, with levels of HIV-2 similar to those observed for HIV-1 around Lake Victoria. At the same time, there is very little HIV-1 in Guinea-Bissau.

HIV-2 was exported by Portuguese and African soldiers from Guinea-Bissau into Angola and Mozambique during and after the colonial conflict in Guinea-Bissau. This mode of spread of HIV-2 has not been confirmed, like so many other epidemiological features of the HIV-1 and HIV-2 epidemics in Africa. In 1988, a high level of HIV-2 infections was reported in Uganda, perhaps as high as HIV-1 and definitely higher than in Senegal.

From Laurie Garrett (1994:692-3). (**Note:** Bukoba in Tanzania is situated at the shore of Lake Victoria, close to the Ugandan border. The earliest cases of AIDS were reported in this northern corner of Tanzania.)

	Guinea Bissau 1988		Senegal, Dakar 1988		Tanzania, Bukoba 1998	
	% HIV-1 pos	% HIV-2 pos	% HIV-1 pos	% HIV-2 pos	% HIV-1 pos	% HIV-2 pos
General population	0.001	10.2				
Blood donors Bissau	?	25.9				
Hospital staff Bissau	?	40.0				
Malaria patients	?	75.0				
Young adults Bukoba					50.0	0.0
Household survey Bukoba					32.6	0.0
Female prostitutes Dakar, Bukoba			0.0 (1989-91) 1.0	4.0 (1989-91) 10.0	90.0	0.0

Table 11: Comparative HIV-1 and HIV-2 prevalence in Guinea-Bissau, Senegal and Tanzania in 1988 (after Garrett, 1994, 692-3)

The 1988 statistics also show a 19% dual infection with HIV-1 and HIV-2 in hospital patients in Kampala, Uganda (45% infected with HIV-1 only; Garrett states that the testing was done with valid blood tests) and none with HIV-2. In the tables for 1989/91 and 1992/93, no dual infections no HIV-2 infections are shown for Uganda. No dual infections or HIV-2 infections are reported in any of the three observation periods for neighboring Tanzania, Rwanda, Kenya, Burundi (no HIV-2 tests were done for Zaire).

At first sight, this distribution of HIV-2 does not make geographic epidemiological sense, since HIV-2 carrying macaques live in Western Equatorial Africa. But HIV-1 infections in Uganda do not make sense either, for similar reasons, nor do observations for Lassa-fever, which occurs in the regions from Liberia to Cameroon, in particular Sierra Leone. Veterans of the Guinea-Bissau war serving Amin perhaps could explain HIV-2, and perhaps some positive Lassa findings. The possibility that such a

research or animal facility existed in or close to Guinea-Bissau cannot be excluded, and it may not have belonged to a US or European country. During those days the Soviet Union was as much interested in biological weapons as was the US, and in particular in lethal haemorrhagic fevers such as Lassa (which can be as lethal as Ebola or Marburg).

It seems that HIV-2 in Senegalese middle-aged prostitutes was linked somehow to conditions in Guinea-Bissau in the early seventies, which were similar to Uganda in the late seventies. While in Uganda there was a major research faculty for oncogenic viruses and a potential source for used and contaminated syringe needles, a facility of this sort close to Guinea Bissau known to the author was the French facility in Dakar, about 200 km to the north of Guinea-Bissau. 'Injectionism' utilizing used needles from experimental facilities holding HIV-2 infected macaques could have been available, and could have been a factor in the spread of HIV-2 in Guinea-Bissau. Luckily, it seems. HIV-2 does not cause illness as frequently as does HIV-1; it is not as readily propagated through sexual intercourse as HIV-1 – but it is not a harmless infection. Garrett provides the following references to HIV-2 transmission:

The most salient characteristics of HIV-2 are as follows:

1) Three outbreaks in a California holding facility for macaques had lymphomas and opportunistic infections due to suppression of the T-cell immune system: (Henrickson et al., 1983, 'Epidemic of Acquired Immunodeficiency in Rhesus Monkeys.' *Lancet* 1 (1983) 1279-80; in Garrett, 1994:371.

1969 (lasted six years, 42 macaques)

1976

1978

'Simian AIDS' (SAIDS) confirmed by injecting two healthy monkeys with blood from two dying monkeys (London et al., 1983, 'Experimental Transmission of

Simian Acquired Immunodeficiency Syndrome (SAIDS) and Kaposi's-Like Lesions. *Lancet* II (1983): 869-73).

2) Harvard's 1985 discovery of SIVagm of green monkeys non-pathogenic in green monkeys and in humans. (Note: Most of polio vaccines were grown on rhesus kidney cell culture and then switched to green monkey kidney cell culture). What has been killing the macaques was SIVmac, a different strain. Kanki et al., 1985 *Lancet* I : 1330-32). The Americans claimed that it is a harmless virus (but then most of the American polio vaccine production had been carried out with green monkey cell cultures), whereas Montagnier's lab insisted that it was a rather lethal virus. Essex of Harvard thought that HIV-2 was some kind of missing link to the evolution of HIV-1. (Kanki et al., 'New Human T-Lymphocyte Retrovirus (HTLV-IV) related to Simian T-Lymphotropic Virus Type III (STLV-III agm). *Science* 232 (1986): 236-25. Kanki et al.: 'Human T-lymphotropic Virus Type 4 and the Human Immunodeficiency Virus in West Africa', *Science* 236 (1987: 827-31). Eventually M'Boup could confirm that HIV-2 (replacing the older nomenclature) was less virulent than HIV-1, and that it occurred mainly in middle-aged female prostitutes (i.e. in a cohort of prostitutes) in Senegal. Kanki's studies had shown a rate of infection as high as nearly 20% in prostitutes, whereas many segments of the population remained free of infection, and three quarters of the infected remained healthy. (Kanki et al., 'Prevalence and Risk Determinant of Human Immunodeficiency Virus Type 2 (HIV-2) and Human Immunodeficiency Virus Type 1 (HIV-1) in West African Female Prostitutes.' *American Journal of Epidemiology* 136 (1992:895-907). Essex's (SIVmac) virus was later identified as a lab (or monkey) contaminant.

3) These observations were followed by several attempts to find a schema of viral evolution of simian retroviruses. Similar viruses were found in sooty mangabeys, stump-tailed macaques, cynomolgus monkeys, and chimpanzees. Some were so similar to HIV-2 (human) that it was concluded that transmission between species had occurred as late as in the post-World War II period. This culminated in Beatrice Hahn's conclusion that SIVsm (SIV in the sooty mangabey) infected research macaques in captivity and also humans capturing them for consumption. This theory of course does not match the observations of mainly middle-aged prostitutes being infected in Senegal. It also does not fit the observation that Pygmies in Central Africa, who always had mangabey meat in their regular diet, were never infected with HIV-2 (verified for the 70's and 80's). (Rouzioux et al., 1986, 'Absence of Antibody to LAV/HTLVIII and STLVIII (mac) in Pygmies'. *II International Conference on AIDS*, Paris, June 23-5, 1986, in Garrett, 1994: 376; Brun-Vezinet et al., 1986). Nowak, 1992, 'HIV-2 and SIV May Be the Same Virus'. *Journal of NIH Research* 4 (1992) 38-40.

Ever since Hahn's assertions, the bushmeat model of AIDS (HIV-1 and HIV-2)' has remained the dominant model. The distribution of the sooty mangabey matched the distribution of HIV-2 in Western Africa. Garrett seemed to think epidemic levels of HIV-2 prevalence in humans started in 1980, and that

there were only sporadic occurrences before that. However, the Guinea-Bissau picture, and its similarity to Uganda, would place the beginning a few years earlier. The middle-aged prostitute cohort (1992) may well have been HIV-2 infected women and prostitutes fleeing from Guinea-Bissau (before or after 1975, the year of Guinea-Bissau's independence). In the case of Uganda, it seems that prostitutes moved from the east shore of Lake Victoria to the west shore, where an extensive black market exchange had developed along the Uganda-Tanzanian border, and were infected there – with HIV-1 (amongst other things).

4) Two HIV-2 infections of animal keepers at an animal facility of the NIH in 1992 strengthened the bushmeat model propaganda for the origins of HIV-1. One worker developed early symptoms of HIV-2 disease transferred from macaques. (Khabbaz et al., 'Brief Report: Infection of a Laboratory Worker with Simian Immunodeficiency Virus. *NEJM* 330 (1994) 172-77) The mechanism included 'bites, scratches and needle sticks', in the case of handling the macaques or their tissue (which means that 'needle sticks' may have been the critical occurrences, involving transfer of macaque blood into humans). Garrett points out that 'bites and scratches' were common also when Pygmies were hunting mangabeys. Nonetheless, the authors concluded that "*Our findings support both the idea that this lentivirus can cause zoonotic infections and the hypothesis that HIV-2 originated from SIV.*" It does not follow from this that the transmission occurs under non-laboratory conditions.

The evidence suggests that:

Cross-species infection amongst monkeys with HIV-2 is common in holding facilities;

Monkey-to-human transmission in the wild and under laboratory conditions is extremely rare, and 'needle sticks' in the form of injectionism, vaccination or accidentally during blood sampling may be necessary for monkey-to-human transmission;

Some HIV-2 may have been transmitted by macaques and laboratory-infected green monkeys, but related human outbreaks of HIV-2 via this route were not observed or not reported.

There have been no demonstrated cases of HIV-2 infection from polio or other vaccines (as far as we know);

Uganda has remained an anomaly with respect to the distribution of HIV-2 infected persons;

The sale of injectable vitamins, dietary supplements and vaccines by European drug companies created a vast black market and the enterprise of 'injectionists' in Africa. This and the outbreaks of warfare in Central Africa (Idi Amin) and in Guinea-Bissau (colonial war 1965-75) could have led to the use of animal contaminated needles and syringes, because of the extreme shortage of injection equipment. Blood-born viruses are propagated through whatever 'blood path' becomes available to them;

The possible role of yet another (HIV-2 contaminated) vaccine cannot be excluded.

The 'needle' or the 'vaccine' seem to be the most likely vectors for HIV-2 to jump from monkeys to humans. Needles and syringes were used in animal facilities on HIV-2 infected monkeys held in Cote d'Ivoire, Senegal, Liberia, or elsewhere, finding their way into black markets for injectionists. The propagation of infections could have been amplified by war conditions or post-war conditions in Guinea-Bissau. The spread of HIV-2 into Angola and Mozambique can be related to the post-war movement of the Portuguese soldiers. The presence of HIV-2 in Uganda could be related to either the presence of Portuguese and African mercenaries or to the effects of plundering of research facilities. Plundering is the more plausible scenario because of the presence of other infections that do not fit Ugandan epidemiological conditions.

The main problem with understanding HIV-2 was the exclusive focus of biologists and epidemiologists on the genetic relationships amongst simian retroviruses. Nobody really bothered to look at what exactly happened socially in and around Guinea-Bissau during and after the 1965-75 colonial war (Garrett, 1994: 389). Some answers cannot be found in the test-tube, the tissue-culture flask, the gel-phoresis slab or the electron-microscope.

In Cote d'Ivoire, the outbreak of HIV-1 and HIV-2 appeared to have happened roughly at the same time (around 1980), suggesting a common factor in the mechanism for its distribution. In comparison, Nigeria was a late-comer (mid-eighties) in HIV infection, HIV-1 as well as HIV-2 and may have lacked that factor for the starting mechanism of the pandemic there. Injectionism may have been practiced in Cote d'Ivoire, and it definitely contributed to the spread of Lassa fever in Nigeria. A factor present in Cote d'Ivoire (and Liberia) and absent in Nigeria was a research facility for the study of liver cancer.

EBOLA

Note: Garrett provides the following references on Ebola/haemorrhagic fevers: Baron, McCormick et al., 1983. 'Ebola Virus Disease in Southern Sudan: Hospital Dissemination and Intrafamilial Spread.' *Bulletin of the WHO* 61 (1983); 997-1003. Rollins et al., "Lassa Fever Epidemic in Plateau state. Nigeria – 1993, presentation to the annual meeting of the American Society for Tropical Medicine and Hygiene, Atlanta, October 1993. Fisher-Hoch, Tomori and Perez-Ornonoz et al., 1993, 'Transmission of Lethal Viruses Through Routine Parenteral Drug Administration', personal communication to Garrett, 1993.

Ebola belongs to a group of viral infectious diseases referred to as 'hemorrhagic fevers' (the better known of which are yellow fever and Lassa fever). The pathogen is an RNA virus of the group of 'filiform' (thread-like) viruses. The first major outbreaks were observed in Yambuku and vicinity in 1976, at the Ebola River (a Northern sidearm of the Congo River). Some weeks earlier, there was an outbreak in an Azande village (N'zara)

in Southern Sudan. Another major outbreak occurred again in N'zara in 1979. Sporadic outbreaks have occurred in Africa since. These events were preceded by outbreaks in an animal facility of the Behring Werke Hoechst in Marburg, Germany (Marburg Virus) and in Belgrade, Yugoslavia in 1967. These viruses are serologically different but belong to the same group of viruses as Ebola. They also look the same: 'shepherd's staff'.

Note: The disease appears to cause disseminated intravascular coagulation, consumption coagulopathy, bleeding, fluid loss and shock due to the destruction of the capillary endothelium (lining of small blood vessels). Similar syndromes are observed in women after delivery or septicaemia, and the first three cases in Yambuku in 1976 (coincidentally) were actually three women who bled to death after delivery. Symptoms set in 2 weeks after exposure, frequently progress to death in just a few days after their onset. Pain may be excruciating, and brain haemorrhages occur. Therapy is not available and antisera from convalescent patients have not been effective. It appears that, in severe cases, the virus replicates very rapidly, even when the initial inoculum was minute, and without apparent immune response. Humans and monkeys appear to be the most common targets of infection.

While the Marburg, Yambuku/Zaire and Reston/Virginia outbreaks have drawn a lot of public attention, there have been several outbreaks of both in Africa. These outbreaks are of interest because, apart from Marburg, there are no documented outbreaks before 1975 (the earliest being an outbreak of Marburg disease in 1975 in Zimbabwe). 1975 is also the earliest year in which infections with HIV-1 infections can be assumed to have occurred in close to 1% of the non-diseased populations of Yambuku, N'zara, and surroundings (Yambuku, 1976, N'zara, 1976).

The CDC identified the Yambuku and N'zara Ebola strains as different strains of the virus, and thus associated with clearly separate, almost simultaneous outbreaks in the two locations. The two sites are several hundred kilometres apart, and it takes more than

four days with a land rover to go from one place to the other. There were no outbreaks between these two locations, however. Despite assertions of the CDC to the contrary at the time, the two outbreaks must be considered to be independent. The only known common factor was the level of infection with HIV-1 in 1976. According to Garrett, HIV-1 antibodies were determined in a few hundred samples taken from the surviving, healthy populations, and we do not know the HIV-1 status of the infected individuals (although, according to Garrett, the Belgian investigator, Peter Piot (later working with the CDC in the U.S.), took 'thousands of samples' home to Belgium.

Later, in 1985, Belgium was obviously dishonest with its AIDS statistics. It was hiding the gay cases of its populations, and lumped them together with cases with origin of infection 'unknown' (presumably 'arrivals from Africa'). As to Yambuku, Laurie Garrett mentions that women may have received vaccines, but we do not know what kind. While injectionism could have brought HIV-1 to Yambuku, the possible role of a hepatitis B trial vaccine, similar to the ones used in the US in the early seventies, cannot and should not have been excluded. Garrett remains silent about any of the IARC facilities in Uganda, African vaccine trials, and says hardly anything about hepatitis B vaccines.

The following table has been derived from graphs of the WHO *Weekly Epidemiological Record*, 1985, 40:309. Since the report does not provide the raw data, the data in the table were estimated from the bar graphs in the report – with a small error. The differences are large enough to have 'confidence' in the difference between Belgian and other European AIDS data.

Risk groups as % of total number of reported AIDS cases					
	France	Belgium	Nether-lands	United Kingdom	Germany (West)
Risk factor unknown	25%	75%	4%	6%	7%
Homosexual males	71%	15%	92%	89%	79%
Haemophiliacs + Transfusion	3%	3%	4%	4%	7%
I.V drug users	1%	1%	0%	2%	6%
Total cases (N)	(392) 100%	(99) 100%	(66) 100%	(178) 100%	(220) 100%

Table 12: Difference in ratio between homosexual and non-homosexual infections in Belgium, compared with other European countries. A similar data manipulation occurred in France. (Note: If Belgium and The Netherlands are compared, a Chi-square test suggests that the probability of Belgium not misrepresenting their AIDS statistics is $p < 0.0005$)

Given the atrocities committed during King Leopold's II's regime in the late 19th century by the Belgians, during which millions of Africans were killed in the King's ivory and rubber enterprises, it is understandable that the Belgians would have been particularly apprehensive about possible connections between vaccinations and their missions as well as possible connections between vaccinations, foreign aid workers in the region, and AIDS and Ebola.

The two first Ebola outbreaks (Yambuku, N'zara) fit the pattern of a vaccine having spread immune deficiency, rather than the patterns of the other models (bushmeat, injectionists). Although there are no reports of hepatitis B vaccine experiments in Africa (other than the French experiments in Senegal, in the early eighties in Burundi), the presence of several hepatitis B-related cancer research centers strongly suggests that such experiments did take place. But the way in which drugs, vitamins and vaccines were dispensed in rural hospitals would have made it impossible for any African group to recall any connection between a specific needlestick and subsequent AIDS. Bearing in

mind that 'bushmeat' is a highly implausible model, the evidence implicating a possible role of hepatitis B vaccines is as follows:

- Family clustering of Ebola (explained with burial rituals);
- The close temporal proximity of the Yambuku and N'zara outbreaks (more likely due to a vaccination programs than due to an injectionist passing through); Uganda (as possible source of HIV-1 contaminated needles and syringes) was even less accessible from Yambuku than from N'zara. Yambuku and N'zara were connected by a bush road, deteriorated to a 'track' at the time.
- The effect of Ebola on women and children in Yambuku, who would have been the primary target of hepatitis B vaccine programs;
- The two populations being spatially separated by hundreds of kilometers; and their ethnic and linguistic differences; there were no cases observed between Yambuku and N'Zara.
- Their separation by a political border;
- There are no reports on early vaccine trials in Africa, while hepatitis B and its role in primary liver cell carcinoma was one of the prime research targets in the region.

Something seems to be amiss in the epidemiology of Ebola:

- Ebola antibodies are ubiquitous (they were even found in Alaska; CDC findings reported by Garrett, 1994: 601).
- 10-20% of African populations studied (rain forest) have antibodies to Ebola-type viruses;
- Monkeys could have acquired the infection during shipment or holding, not in their natural habitat;
- Marburg of the Reston/Virginia Ebola outbreak falling ill 2-3 weeks after arrival in Reston (Garrett, 1994:598) . The KLM Amsterdam facility handled 25,000 monkeys from all over the world per year; and JFK Airport processed 50,000 animals every year (Garrett, 1994:599). Five animal handlers at JFK airport had antibodies to Ebola, but did not fall sick. Most monkeys experimentally infected with the Reston Ebola strain (which was similar to Ebola/Zaire) did not fall ill;

- Individuals working close to an infected individual had a higher chance of becoming infected than those staying away:
- With the exception of the Marburg outbreak (which is immunologically very different from the Reston, Yambuku, Kikwit and N'Zara strains), the series of outbreaks with Ebola-type viruses started approximately at the same time as the first HIV-positive cases in Africa (around 1975).

The patterns suggests that:

- Ebola type viruses are ubiquitous.
- They are generally non-pathogenic:
- The vector appears to be equally ubiquitous:
- The virus depends on human and primate populations, only humans and monkeys are particularly susceptible for infection:
- A cofactor (such as simian immunodeficiency or human immunodeficiency) may be required to cause manifest disease in humans, primates or other animals.

Thus two aspects of this disease need to be paid attention to: immunological cofactors: and a blood sucking parasite that prefers humans and primates. There may be a better chance to find the vector parasite in Amsterdam or New York than in the Zairian rain forest or in the elephant grass near the cotton factory of N'zara, where apparently the two index cases of the N'zara outbreak in 1976 and 1979 were infected.

THE HEPATITIS B TRIAL VACCINE MODEL

During the seventies and early eighties, clinical trials of hepatitis B vaccines were conducted in the US, Europe and in Africa. The trials in Africa were reported on by French researchers, and very little is known about U.S. activities there. One of the few clues is that the New York Blood Center operated a research laboratory in Liberia. Chimpanzees that were imported into the U.S. tended to become infected with hepatitis B and were then useless for hepatitis B research. Thus there is at least some direct evidence of at least some vaccine-related US presence in Africa. A hepatitis trial vaccine hypothesis assumes that either Africans were infected with HIV by contaminated hepatitis B trial vaccines.

Apart from the epidemiological assumptions, as outlined earlier, the vaccine model must assume that:

1) Laboratory chimpanzees are the natural source of HIV-1. Chimpanzee studies in the US have shown that laboratory chimpanzees are naturally infected with HIV (Gao et al., 1999).

2) There was a rationale for using plasma from hepatitis B infected chimpanzees as starting material for vaccines. Hepatitis B virus could not be grown in tissue culture, hence chimpanzees were the only alternative source for hepatitis B material other than human plasma donors. There was a more specific rationale for the New York Blood Center team, who believed that whole virus is more immunogenic than just surface antigen; and who had an interest in competing at in vaccine efficacy with other developers. Tissue cultures derived from monkey species were (and are still) used for vaccine production, the use of chimpanzee serum for trial vaccine production was therefore not something completely unheard of in the hepatitis B vaccine development. However, some lessons of vaccine contamination with animal viruses had been learned earlier in the development of polio vaccines (such as the contamination of the Salk vaccine with SV40 from Rhesus monkey kidney cell cultures, which were later replaced with tissue cultures derived from green monkeys, perceived as safer). Only very

recently has there been a public announcement that the production of the Sabin vaccine will be restricted to very special cases only and generally be replaced with a new vaccine (presumably a recombinant DNA product of specific parts of the virus).

3) The trial vaccines were inadequately inactivated. There was a controversy regarding the efficacy of inactivation procedures. Merck upgraded its inactivation protocol for its commercial above the protocols of all other trial vaccines.

4) The chimpanzee material was actually used on humans. This is the only assumption for which there is no direct evidence, and hence all the indirect evidence must be used to support or reject this assumption.

The vaccine model is not invalidated by observations of other viruses entering from monkey populations into human populations, or by sporadic cases reported to have taken place before the seventies. Sporadic cases and a massive outbreak are not mutually exclusive. By the same token, the vaccine model does not invalidate observations of sporadic cases of animal-to-human transmissions of HIV, or the non-vaccine-related transmission of other animal viruses to humans. The question is whether the particular spread of HIV on three continents (the 'pandemic') was due to animal-to-human transfer or due to animal-to-vaccine-to human transfer, and how any of these possibilities can be verified or falsified.

THE POSSIBILITY OF THREE SEPARATE OUTBREAKS OF AIDS.

There appear to have been three separate 'outbreaks' of AIDS (or HIV infection):

1971/2: HIV-1 amongst drug users in the US;

1975/6: HIV-1 amongst villagers in rural Zaire and rural Sudan

1978: the HIV-1 pandemic in Africa, US, Europe, Haiti

Next to the retarded Willowbrook children, intravenous drug users and needle-sharers were probably judged low enough on the social ladder to be considered suitable and eligible for vaccine experiments. They were a group clearly known at risk of being infected with hepatitis B. There is no plausible explanation other than a contaminated trial vaccine for the spread of HIV amongst intravenous drug users in the early seventies in the US.

Also, a study conducted by Levy (Levy et al., 1986) showed no HIV infections in Africa prior to 1975. Whether these data can be considered representative is unclear; most likely they were not, and small pockets of sporadic infections or of trial immunization projects could have been missed. Other than the Willowbrook experiments on retarded children (Krugman 1967), none of the phase 1 and phase 2 human experiments with hepatitis B trial vaccines carried out in the US are properly reported.

The early rural infections in Africa with HIV (after 1975) could possibly be linked to the expanded immunization program of the WHO. The bushmeat model definitely does not work for the cases of early HIV infections in the Southern Sudan. Not only are there no HIV-1 carrying chimpanzees, but in the seventies the road between Yambuku (Zaire)

and N'Zara in Sudan was little more than a bush path, which took several days travel with a Land Rover.

Amongst Africans, hepatitis B sero-negative newborns, young children, pregnant women and women of child-bearing age were considered at high risk for hepatitis B infection in Equatorial Africa. Neither the 1975/6 outbreaks (Yambuku, N'zara), nor the 1978 outbreaks include children being infected with HIV early on in the epidemic. That came later, and not in the regions of Yambuku and N'Zara, once women had been infected sexually and passed on the infection perinatally.

Apparently, the AIDS epidemic in Africa did not start with these early cases in Zaire and Sudan or in the U.S. The infectivity of such early vaccine-related infections may have been very low. This is not unusual, because there are cases of transfusion-infected persons, whose spouses were never infected with HIV, despite years of unprotected sex. Conditions of blood storage, vaccine preparation, and Factor VIII production may damage the virus just enough to render it non-infectious through routes other than injection.

The outbreak of the 1978 pandemic. Besides Africans, another group of people that would have been considered 'at risk' of hepatitis B infection in Africa, were foreign aid workers, notably health care workers and relief workers (such as working for the WHO in its initiative of stepping up vaccination in Africa). The group may have included some Haitians, who had previously participated in work projects in Zaire (up to 1975). If we can believe Levy's and other data (Levy et al., 1986; Sher et al., 1987; Tabor et al.,

1990), those Haitians working in Zaire would not have been exposed to and infected with HIV.

The progression of the annual rates of AIDS cases reported in Haiti also does not support this possibility. In the early stages of the pandemic, the peak of manifest AIDS cases in an infected cohort, appeared to have followed six years after the time of infection. Thus AIDS cases should have been observed in considerable numbers in Haiti before 1980. In Haiti, only one case was observed to have tested positive in 1979, and 9 in 1980 (no difference from the US). By 1984, 731 cases had been confirmed. (Garrett, 1994).

Some sexual (homosexual and heterosexual) contact between aid workers and Africans is likely to have occurred (Lynda Bertrand, personal communication). Perceived protection from being infected with hepatitis B as a result of vaccination (which was known early in the seventies to be transmitted by sexual contact) may actually have encouraged aid workers to have sex with Africans. This model fits Laurie Garrett's hint that many of the early cases had been 'traveling abroad' ('abroad' remains undefined). However, the 'traveling abroad model' does not explain why only one clade (B) appeared in the U.S. and in Europe.

Prince's report on the New York Blood Center trial vaccine is the only one which mentions the Peace Corps as a possible target group for vaccine trials. This group may have included some gay men from New York, California, Canada and from European countries, and workers from Haiti (who possibly had worked there before, in particular in the former French and Belgian colonies). Hepatitis vaccinations contaminated with HIV could explain the explosive outbreaks in the US. If the aid worker model is used, then the

lag between the initial cohort and the main spread of the pandemic can be explained: aid workers, upon returning from their tour of duty a few months would have begun to infect Americans.

Alternatively, one might consider that the AIDS epidemic was well in progress in Africa, when the foreign aid workers arrived. There is no indication that this was the case before 1978. Length of stay in Africa, and in the US, the proportion of individuals which were not vaccinated for traveling purposes (large in the US, small in Haiti and Belgium), would explain the different shapes of the ascent in the progression of annually reported AIDS cases in different countries. Apparently, a large portion of workers from Belgium, Haiti and Guadeloupe were vaccinated, while most of the trial participants in New York and San Francisco and Los Angeles were gay men who did not 'travel abroad'.

USA and Canada, New York and San Francisco/Los Angeles. The observation of a discontinuity in the curve of annually reported cases of AIDS is not proof of a vaccine-related lead cohort of AIDS cases, but it surely makes arguments in the direction of alternative epidemiological modes of spread more difficult. Such discontinuities were actually observed in the overall US rates of HIV as well as the rates for gays in New York and San Francisco (the site of the CDC-Merck vaccination project) and in New York (the site of the New York Blood Center - Merck vaccination program). It appears that these discontinuities (slowdowns of the progression of reported cases) did not come entirely as a surprise for CDC scientists. Garrett notes:

In Atlanta, Jim Curran also ended the year counting deaths: 2042 cumulative AIDS cases reported since May 1981, and 1,283 were already dead. He predicted [!?] that the epidemic would continue to expand in 1984 but not at 1983's rapid pace. (Emphasis by the author; Garrett, 1994:332).

Jim Curran was off by one year (it slowed down in 1985). This was a rather surprising prediction to make for a brand-new kind of epidemic, just from the data, as early as 1983 - unless Jim Curran had an explanation and an expectation, namely the possible connection to the vaccine trials. If he observed the beginning of a slowdown in 1983, it might have been caused by the relatively small core group of individuals possibly infected with live virus and their immediate contacts. Indeed, data from New York (the site of the majority of initial cases) showed a slowing down during 1983. (Horowitz, 1996, displaying data of Fumento, 1990).

CDC studies of HIV/blood connections in Los Angeles that revealed the earliest date of a person receiving contaminated blood products was 1978. It was an isolated case, however. This is consistent with the fact that in 1978, only 5% of the participants entering the Merck vaccine trials were HIV-1 positive. Between that date and the peak of the first cohort there is an interval of 6 years, which corresponds to the median of symptom-free intervals for HIV-infected individuals ranging from 2 to 10 years.

Europe (without Belgium). 7 of 14 early AIDS cases in the UK had contact with gays in the US. Other countries are suspect of such a cohort as well, in particular those with relatively high annual rates of AIDS, such as Germany, France, UK, Switzerland and Spain. In 1990, Germany alone had 1633 new cases of AIDS, whereas Ireland, Greece, Norway, Finland taken together had only 217 new cases of AIDS. In addition,

Germany had accumulated 203 cases of AIDS in 1984, whereas Ireland, Greece, Norway and Finland together had reported only 24 cases. Italy, with a population larger than Germany, had only 44 cases reported by 1984, and had 2413 new cases in 1989. However, it is possible that Europe had vaccination cohorts as well, i.e. individuals working in some foreign aid projects.

In Middle and South America only Mexico and Brazil had a substantial accumulation of cases in 1984 and may have participated in vaccine trials.

Belgium, Guadeloupe and Haiti. These countries are of particular interest because they do not merely show a slow-down in the annual rate in 1985, but actually a 'dip' as predicted in the hypothetical curve. Aid workers from these countries may have stayed longer in Africa than others, and thus delayed the spread of HIV in their own countries.

Africa. While the pandemic is related to the 'M' subtype of HIV-1, Gao reports earlier findings that subtype 'O' had been found in isolates from individuals in Cameroon, Equatorial Guinea and Cameroon (Gao, 1999). The first AIDS cases in Cameroon and Gabon were not reported until 1986. The rates then show the 'early-cohort phenomenon' described earlier. However, the total number of AIDS cases reported by 1989 was only 114, i.e. it did not seem to be a very aggressive epidemic in that region, and like the early 'outbreaks' of AIDS may have been due to different trial vaccines. Garrett reports that, by 1990, there was a substantial and sophisticated research

establishment in Gabon, which might have existed earlier; and local monkeys (Pan troglodytes troglodytes) carrying the M-type of HIV-1 may have been used in experimental vaccine production there.

The highest rates for West Equatorial Africa were in Ghana (formerly British) and the Cote d'Ivoire (formerly French), separated by low rates in Nigeria, Cameroon, and the Central African Republic from central Africa.

US infections prior to the Merck vaccine trial in New York and California.

By the time the Merck phase 3 trials began in New York and San Francisco, it is likely that Purcell's group (NIH) and Prince's group (New York Blood Center), but also Merck, had used gay men formerly recruited to collect baseline data on hepatitis in gay men, and who were a preselection of possible candidates for participation in vaccine trials.

Later studies found that anywhere between 1 and 5% of the phase 3 trial participants had been infected with HIV prior to their recruitment into the Merck study. These individuals could not have been those who had participated in some other trial, because their vaccination would have led to a sero-positive status for hepatitis B, which, in turn, would have led to their exclusion from the Merck vaccine trials. Most likely, the individuals who had been infected by individuals participating in the possible New York Blood Center/Prince trials preceding the Merck trials.

The vaccine-infected cohort appears to have shaped the early progression of reported AIDS cases. This is also apparent in the progression of deaths from AIDS in the early stages of the epidemic, peaking in 1984, 6 years after 1978 the year of the NIH

and/or NYBC vaccine trial projects. The early cases of AIDS died soon after diagnosis, whereas in later cases (the second wave), infected through sexual intercourse, there was an increase in the time between diagnosis and death. This early difference may have been the result of the number of infectious units transmitted: vaccination would have transmitted a large amount of virus, three times per individual, directly into the blood stream (each vaccination consisted of three successive doses). The number of infectious units (viruses) transmitted during sexual intercourse could be very much smaller.

Intravenous drug users, relationship between HIV in intravenous drug users and gay populations. An additional initial, vaccine-related cohort may have been intravenous drug users in New York and Baltimore. In San Francisco, by 1988, only 10% of needle-sharers were reported to test positive for HIV; half of the needle-sharers in Baltimore were positive, and almost 100% of needle sharers in New York City. (Lange et al., 1988; reproduced in Horowitz, 1994:241). The model which proposes that drug addicts were infected by gay men who were also drug addicts, is contradicted by these numbers. The San Francisco data indicate that gay and drug-user populations do not have much contact, and that gay drug users remain within the gay networks and normally do not cross over into the mostly heterosexual drug user networks. Accordingly, infection routes into the gay communities and into the intravenous drug user communities were separate occasions, and there seems to be very little travelling from one drug user community to another. This circumstance and the distribution of HIV among gay and drug user communities support the vaccine model, not the bushmeat model. Also, there is

nothing in Central Africa that would attract drug users. On the other hand, gay men may well have participated in foreign aid projects.

Surrogate testing for HIV and hepatitis non-A,nonB.

Vaccine trials on gay men were carried out in New York and California between 1977 and 1989. Most likely, vaccines from at least three sources were tested:

- 1) The Merck trial vaccine (from the pool of 200,000 doses or more produced in 1974;)**
- 2) The New York Blood Center trial vaccines;**
- 3) The NIH-Union Carbide/Purcell-Gerin trial vaccines.**

Only the New York City and California data were ever published. There is no indication that any of the 200,000 doses (in four lots) of the Merck trial vaccine were causing AIDS. However, the US investigation of 'the Merck hepatitis B vaccine' is invalid (it was not carried out by independent laboratories, nor was it carried out on the Merck trial vaccine.

HIV spread at equal rates through vaccinated, non-vaccinated and placebo (sexually active) groups in New York and California. This has been used as a argument to demonstrate that the Merck vaccines were HIV-free. As was mentioned, the Merck study and placebo groups would not have included gay men that had already been vaccinated with one of the other trial vaccines. Gay men participating in the Merck vaccine trials would have been sexually infected by the vaccine cohort. Thus the study that claimed that

the Merck vaccine was safe may well have been telling the truth. However, it did not refer to any of the trial vaccines - the kind of vaccines suspect of having started the AIDS pandemic.

Hepatitis B markers as possible markers for vaccine-related HIV-infections.

In the context of the vaccine hypothesis (but not of the bushmeat hypothesis), anti-HBc, a marker for hepatitis B infection, would also have been a marker for possible vaccination (amongst other possible routes of exposure to immunogenic material). If individuals had been vaccinated against hepatitis B, and later showed anti-HBc antibodies in their blood, then this meant that there was a chance that they had been injected with live (hepatitis B) virus. If the individual also was diagnosed later with AIDS, then there was a chance that the individual had received a vaccine contaminated with HIV.

This situation could have arisen from such an individual presenting as a donor at a blood clinic, had he tested positive for anti-HBc. The test result would have had to be revealed to him and/or his physician. Accordingly, the identification of anti-HBc positive donors, who also were vaccinated, would have opened a line of inquiry leading to the possible disclosure of the involvement of one or more trial vaccines. The bushmeat theory, on the other hand, would not have raised these concern with respect to hepatitis B markers and their use in the screening if blood donors. On the contrary, in the absence of specific tests for AIDS, anti- HBc would have been seen as a welcome chance to reduce the transmission of HIV-1 via the blood transfusion and blood products routes.

AIDS after 1978. There is no indication that there was any new entry of HIV-1, of any subtype, from any chimpanzee subspecies entering into human populations in the

US after 1980. The epidemiology of the origins of AIDS ends here. Given the claim that HIV had jumped on various separate occasions from monkeys to humans during the eighties, and more than once around 1978, the complete absence of such occurrences, and the lack of appearance of new strains do not support the bushmeat theory. If anything, the droughts of the early eighties in Africa and the mass migration provided the kind of ecological turmoil which should have made such infections even more likely than the political events in seventies.

The period during which HIV first entered into human populations was followed by a period of rapid spread of AIDS from primarily infected individuals through sexual contact, transfusion, prenatal infections or intravenous drug use and needle sharing. 'Dirty needles' and the practice of 'injectionists' in Africa might have made an additional contribution to the spread in Africa (as well hepatitis, B, as well as hepatitis C). Contaminated needles may even have played a role in various Ebola outbreaks.

What appears to have followed was an institutional response to a mishap in vaccine development, such as what was briefly introduced as the 'surrogate testing controversy'. These responses were characterized earlier as the 'bizarre manner' in which the contamination of blood supply with HIV and HCV was handled. At least some of this 'bizarre manner' supplies additional, indirect evidence in favor of the vaccine model.

RESISTANCE TO INVESTIGATING THE ORIGINS OF AIDS: 'OSTRICH POLITICS' DIFFICULT TO ACCEPT AT FACE VALUE

Although the major research efforts on the origins of AIDS were focused on an African explanation, the efforts were really slow in coming – too slow in any case to

explore in detail the history of the first cases of AIDS for clues of the infection. These efforts were discontinued simply on the basis of African and homosexual promiscuity, which allegedly made it difficult to track the infections to their origin. On the other hand, British scientists did not seem to have great difficulties to establish that a considerable portion of their early AIDS cases (gay men) had traveled to the US, and American cases had been known to have traveled 'abroad', according to Laurie Garrett. If that much was known, surely, it would have been known where they had traveled and what had occurred on those travels.

The fact the chimpanzees are the natural reservoir of HIV-1 was not 'discovered' until the nineties by Montagnier's team. Given that the HIV family of retroviruses had been recognized as simian viruses, it would have been logical to have every monkey species known examined for the possibility of being the natural reservoir. It may well have been done, but, like other evidence, not been published.

The gay community, the main 'vector' of the spread of AIDS in the US and Europe, has remained very silent with respect to the origins of the AIDS pandemic, despite the fact that they were blamed for it in the United States, and would have been the main group to 'import' AIDS from Africa. It does not make any sense that on one hand the spread of HIV through the gay community in the United States is extensively documented, including Gaetan Ducas's case ('patient Zero'), as presented in Randy Shilts's book (Shilts, 1988); but on the other hand, there is complete silence as to the circumstances under which gays might have acquired AIDS in Africa – if the bushmeat theory is accepted as true. If the vaccine model holds true, it does not make sense that the gay community would not have tried to get to the bottom of this and sought

compensation, at least when the issue was on the table in the mid-eighties. A similar lack of questions concerning the origins of AIDS apparent amongst African political leaders and amongst scientists.

The politics of not wanting to know (Laurie Garrett, 1994:361-2):

Because of the legacy of blame, accusation, and exaggeration concerning AIDS in Africa it was impossible to have an apolitical "pure science" discussion of the origins of the human immunodeficiency virus during the 1980s. Not until the Sorbonne's Mirko Grmek published his book in France in 1989 would discussion begin to free itself from the fetters of prior blame. The official line of the World Health Organization, first enunciated by Assad in 1985, would remain the agency's position in 1994: AIDS emerged simultaneously on at least three continents. ....

Shunning the subject, some scientists would simply say, well, it doesn't matter, really. AIDS is here, the pandemic is spreading all over the planet. Let's deal with the here and now. What's past is past.

Or as Zambian President Kenneth Kaunda put it in 1987: "what is more important than knowing where the disease came from is where it is going." [Emphasis by the author]

But few scientists honestly [emphasis by the author] held such a belief. .... Unfortunately, to protect themselves from potential lawsuits brought by people who acquired HIV as a result of transfusions, or use of plasma products, many European and American hospitals deliberately destroyed old records and blood samples. Under US law they were required to maintain such records and samples only for five years, and by 1986 hospitals and blood banks all over the country began actively shredding their 1982 paper trails and purging computer files. By allowing such wholesale destruction, the US Government condoned elimination of a crucial set of clues in the AIDS controversy.

Laurie Garrett herself appears to be no exception. Garrett mentions that there was some speculation regarding the hepatitis B vaccine trials, then she drops the subject and never picks it up again:

But other scientists were looking at the same data on AIDS patients and reaching very different conclusions. Some felt AIDS was simply a new manifestation of the hepatitis B virus, or of some unknown contaminant of the hepatitis vaccine first experimental trials of which had been on gay Americans. (Garrett, 1994:322).

This does not even amount to two whole lines on the question of possible vaccine contamination. Besides, the first experimental trials were not carried out on gay men, but on retarded children in the Willowbrook facility on Staten Island (the Krugman trials). Pasteur Productions and its affiliated Institute Pasteur (where Montagnier and his team did their work) were also working on a vaccine. French and Belgian teams may have used the Merck vaccine in their own country and in former French colonies. Early in 1982 Don Francis of the CDC reassured Luc Montagnier (of the Louis Pasteur Institute, who responded to concerns by the Pasteur Productions) - that the Merck hepatitis B vaccine was not the cause of the AIDS epidemic (Shilts, 1988:203-4). By 1990, there was finally an investigation of chimpanzees living in the wild.

It would not be until 1990 that a simian virus bearing significant homology with HIV-1 would be found - in chimpanzees. A Pasteur Institute team, led by Simon Wain-Hobson, discovered SIVcpz (simian immuno- deficiency virus type cpz, the genetic type of HIV-1, in two out of eighty-three wild chimpanzees tested in Gabon. When the Paris group did molecular analysis of the SIVcpz virus, they found that it was remarkably similar to several HIV-1 strains, and only distantly related to HIV-2 and all other known SIV's. (Garrett, 1994:377).

It took almost another decade before research had moved to confirm chimpanzees as the only natural reservoir for HIV-1 (Gao et al., 1999) in the U.S., in particular those living in Gabon and vicinity (Pan troglodytes troglodytes).

In summary, African leaders, gay leaders, scientists, and health administrators all acted 'out of character' or differently from what one would expect beyond some initial bafflement over the outbreak of a new disease of global proportions.

Apart from the massive liability issue mentioned earlier, there might have been a real fear that the disclosure of a vaccine connection would not only start a storm of litigation worldwide, but also an outbreak of violence against Africa's white population, such as in the regions of the former Rhodesia or in South Africa and in the major cities. Africa was ripe for total radicalization and Soviet control, and an explanation of African AIDS (in advance of the first cases of AIDS reported there) could have become an igniting spark. In the mid-eighties, the KGB did use the African AIDS epidemic as a propaganda issue against the US, for which the Soviet Union (under Gorbachev's leadership) apologized later.

Gay men became the first scapegoats, Africans were second, both on the basis of actual or assumed sexual practices (which changed to production and consumption of bushmeat later for the Africans). The American and European West has not yet taken its turn to address its own possible role in the pandemic.

Note: Ostrich politics of this sort (or the **pretense** of playing ostrich) are not a new phenomenon in public health. *Roughly 24% of the people of Egypt are estimated to carry hepatitis C virus (HCV) ...In 1918, Frank [Strickland] explained, physicians began popularizing various injectable treatments, called parenteral antischistosomal therapy, or PAT, which typically required 10-12 injections and was usually given with reusable syringes. The campaigns began tapering off in the 1970s when oral schisto drugs became available. By studying schistosomiasis archives at the World Health Organization, PAT records at the Egyptian Ministry of Health, census records, and HCV infection surveys of 10,000 Egyptians, the researchers pieced together the link between the two diseases. Age and demographic data indicate that people who were most exposed to PAT had*

the highest HCV prevalence. "That's the first time the data convincingly show this," [emphasis by the author; the data had been around for decades] *says Robert Purcell, a virologist at the US National Institute of Allergy and Infectious Diseases, whose laboratory has played central roles in the study of every hepatitis-causing virus.* (John Cohen, 1999, *Science*, 285:27). Robert Purcell was the principal investigator of the grant proposal (20 years ago) for hepatitis B vaccine research mentioned earlier, and whose trial vaccines are among those suspect for HIV contamination. Apparently, and for good reasons, the WHO did not want to know the connection.

WHICH MODEL?

The bushmeat model has very little to offer besides analogy to other, similar zoonoses, and a couple of disputed, sporadic cases of HIV-1 infection. As to the epidemiological features of the pandemic in North-America, Europe, Africa and Haiti, it can offer very little matching evidence, and relies almost entirely on ad-hoc speculation and environmental transcendentalism. Most importantly, the model cannot explain the handling of the contamination of the blood supply and the total lack of investigations of a plausible alternative model, namely the vaccine model.

On the other hand, while the vaccine model can explain much of what the bushmeat model cannot explain, it lacks, like the bushmeat model, direct evidence (specimens and laboratory records), not because they were difficult to obtain, but because appropriate investigations were not done at all. Accordingly, in the light of these issues, this study focuses on the vaccine model and asks whether there is at least a *prima facie* case for an investigation on the role of hepatitis B trial vaccines in the outbreak of the

AIDS pandemic. In the absence of direct evidence, the prima facie case in favor of the vaccine model must rest:

- 1) On the exclusion of other models by lack of explanatory power (bushmeat model);**
- 2) On setting aside other models lacking verifiability and falsifiability (injectionist and bushmeat model);**
- 3) On its own explanatory power;**
- 4) On indirect, circumstantial evidence supporting it;**
- 5) On its (at least potential) verifiability/falsifiability with direct evidence.**

It must be stressed, that, at the outset of this study, the author had no particular bias for or against any of the models. It was only when the analysis of the contamination of the blood supply and its handling could not produce satisfactory answers, that the author began to consider the vaccine model to be the most promising model to be considered.

The author remains open-minded to alternative explanations, and as neither the injectionist model nor the bushmeat model can be falsified, they cannot be rejected. No evidence – so far – has emerged that would seriously challenge the validity of the hepatitis B trial vaccine model and the inferences made from it with respect to the 'critical paths' presented in this study.

THE HEPATITIS B VACCINE/HBIG MODEL OF THE SPREAD OF HEPATITIS C

There is far less information on hepatitis C than there is on AIDS. AIDS was a brand new disease, whereas hepatitis C had been around for a long time. Secondly, hepatitis C differs in its infectivity, as HIV and HBV are readily transmitted through sexual contact, and hepatitis B also through close contact (saliva), whereas HCV is not easily transmitted without entry of blood from one individual into another: transfusion, vaccinations, injections. It is not commonly transmitted through sexual contact.

HCV is present in most countries at low levels of prevalence, but it is 'endemic' in Brazil, Equatorial Africa, in northeastern Africa, in China, Mongolia, South-East Asia, and in the Australian portion of New Guinea, but not in the Indonesian portions. Hepatitis C hotspots (more than 10% of the population infected) are: Egypt; Tanzania, Cameroon, Guinea, Bolivia and Mongolia. Between 5-10% of the population is infected in Gabon, Ghana, Zaire, Libya, Vietnam, Papua New Guinea, and Burma. Some of these regions overlap with WHO activities in the fight against schistosomiasis (liver fluke), except for Bolivia and Mongolia, where perhaps other conditions leading to the use of infected injection equipment led to the spread of hepatitis C.

The Vietnam war and the rise of hepatitis C in the US may have a meaningful connection, as well as a British association between hepatitis C and chronic liver disease and prevalence of hepatitis C in South-East Asia. The best example of different, most likely so-called 'public health conditions', is New Guinea, where the former Dutch and now Indonesian western part has a very low prevalence of hepatitis C, whereas it has a high prevalence in the Eastern, Australian administered section. Interestingly, Australia is

one of the countries with the lowest prevalence of hepatitis C. (Note: a similar discrepancy was observed with respect to AIDS; Haiti had a pattern of the epidemic resembling the Belgian pattern; the neighboring Dominican Republic had a pattern more similar to the US, and thus more likely caused by homosexual contacts with US visitors).

An example of public health spreading hepatitis B comes from the US (yellow fever vaccines) and an example from Austria: when the Russian troupes entered Vienna in 1945, rape of scores of Viennese women was part of Stalin's payoff to his conscripted Siberian and Turkish troops (who had lived through horrendous losses and paid the highest blood-toll of the war). Many of these women were infected with syphilis, and showed up for treatment at Viennese public health facilities. The injections were given without proper sterilization of needles and syringes. Two or three months later, many of them were back with jaundice and hepatitis (for which, of course, there was no treatment). It is now believed to have been mostly hepatitis B.

Wherever hepatitis C is spread through public health conditions, hepatitis B and HIV can be spread as well through the very same conditions (transfer of blood). If one accepts the vaccine model of AIDS, all three diseases can be seen as mainly 'public health diseases' and 'iatrogenic diseases', i.e. spread through biomedical practice and larger public health initiatives. The spread of HBV can now be controlled with fairly safe, bio-engineered vaccines. HIV remains a problem because no effective vaccines have yet been developed, and because the main transmission route is sexual contact. HCV, because of its relatively low infectivity, can be reduced by simply reducing the risk from public health interventions. This has actually happened in the US, where the annual cases are estimated by the CDC to have dropped from 230,000 a year in the eighties to 36,000 in

1996 (Cohen, 1999). The most effective intervention has been the screening of blood transfusion for hepatitis C. Needle and syringe programs for intravenous drug users could reduce the problem even further. While sexual and perinatal transmissions are possible, these transmission routes constitute only a minor problem and do not lead to high-grade epidemics.

Given the low-grade infectivity HCV, any substantial increase in its spread must first of all be suspect of a 'public health intervention'. In Toronto, the prevalence of hepatitis non-A,non-B went up substantially in the early eighties: it doubled infectivity of voluntary blood donors went up by 100% between 1984 and 1985. Such a dramatic increase cannot be solely attributed with change in intravenous drug use (as most drug users would not be voluntary blood donors). The increase was the most important finding of the Feinman study of 1984/5 (Feinman, 1988), yet nobody has bothered to explain it.

Increases in hepatitis non-A,non-B in voluntary donors was also observed in Germany (Mueller, 1983) and in Great Britain, where it doubled. In the absence of any other good explanation, the only recent epidemiological change in the early eighties that could have been responsible for the increase was the introduction of hepatitis B vaccines in Canada. At that time (in the early days of the AIDS pandemic), the only hepatitis B vaccines on the global market were the Merck vaccines, either the left-overs of the 200,000 or so trial vaccines doses, or the commercial vaccines, of which in the order of 5,000,000 doses were sold. The author has not found any evidence that would shed a more light on this.

As was in the case of the AIDS pandemic, the circumstantial evidence for making the hepatitis vaccines suspect was the handling of the spread of disease, in particular the

protracted avoidance of surrogate testing Canada. In fact, in Canada the two available tests were never used. The same rationale that was used for explaining the link between avoidance of surrogate testing to detect HIV transmitting donors can be used for explaining the avoidance of surrogate testing for the detecting HCV transmitting (then hepatitis non-A,non-B transmitting) donors. Positive hepatitis B markers would have raised suspicion as to the infectivity of the vaccine. Since these tests were never used in Canada, it is safe to assume that this problem is still active in Canada (and remains concealed).

A special condition exists in Canada, because any hepatitis B vaccine safe or not, contaminated or not would have been a product licensed and sold in violation of the Food and Drugs Act (see Appendix 3). The same condition applies to the sale of HBIG (human hepatitis B immune serum, used for passive immunization). This product was derived from donors with high levels of antibodies to hepatitis B surface antigen (HbsAg). Such donors could have been infected with HIV and HCV, in particular if such material was derived from hemophiliacs, who, because of their treatment used to have high levels of anti-HBs antibody.

It was a common belief that the plasma fractionation process renders immunoglobulin preparations non-infectious, but there has been a widely publicized case in Ireland which shows that thousands of women were infected with HCV with another immunoglobulin preparation, anti-Rhesus antibody, which is given to Rhesus negative women who are pregnant with a presumed Rhesus positive child. This treatment is intended to prevent immunization of the mother against the fetus's Rhesus positive blood

cells, and subsequent serious jaundice of the newborn: antibodies produced by the mother may destroy the baby's red cells.

3. 4 THE CRITICAL PATH OF HEPATITIS B VACCINES AND THE AIDS PANDEMIC

Introductory notes: The critical paths presented in this and the following three sections are reconstructed on the basis of the assumption of the validity of the hepatitis B trial vaccine model for the outbreak of the AIDS pandemic; and of the spread of hepatitis C. The critical path that links the AIDS pandemic to one of more of the hepatitis trial vaccines is presented first, because it is potentially associated with the most severe liabilities arising from the use of contaminated vaccines. It reaches from the early beginnings of hepatitis B vaccine development (around 1970) in Paris (Soulier) and in the United States (Krugman), to the decision by the US in 1986 to use surrogate testing, and the decision by the Canadian Red Cross not to use surrogate testing in the same year. A compressed version of critical path construction is used (as discussed in the section on methodology).

Since reference is made to 'phases of clinical trials', the term 'phase' will not be used in connection with 'critical path construction', but rather in connection with clinical trials of vaccines. All phases of the clinical trials taken together can be viewed as the 'development' phase of the hepatitis B vaccine technology. The commercial Merck, Sharp & Dohme hepatitis B vaccine (licensed in 1981, distributed in 1982-1984) appears to be an 'operational' product. However, because of its possible implications in the spread of hepatitis C, and concerns raised regarding viral inactivation, it is treated as a trial vaccine, under Phase 4 clinical trial conditions ('post-marketing surveillance', 'looking for unusual side-effects'). Thus all hepatitis B vaccines produced from human sources can be considered 'trial vaccines', and both, the outbreak of the AIDS pandemic and the spread of hepatitis C, as technological development problems.

There are additional questions to be asked, for instance, with regard to the origin of the Delta agent, an incomplete virus particle which is pathogenic only in the presence of HBV, and which is associated with the most severe chronic and acute cases of hepatitis B; or hepatitis non-ABC, which appears to be a nosocomial disease not transmitted by blood transfusion. There are still tens of thousands of pages of literature and documentation to be searched for additional evidence, which may support or contradict the vaccine model.

The evidence presented and discussed here was considered sufficient for a *prima facie* case for the role of vaccines in the origin of the AIDS pandemic and the spread of HCV, warranting full investigation and discovery. **It is clearly not sufficient to serve as 'proof.'**

CRITICAL PATH PRESENTATION; CLINICAL TRIALS; VACCINE EFFICACY AND SAFETY;

As indicated in the *Methodology* section, because of the complexity of the issues (four interrelated critical paths, multiple institutions), the full spatio-temporal grid was abandoned in favor of a simplified version as follows:

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C SOCIAL CONSTRUCTION CONTINGENCIES
1959				
	01	See Note for that field		
	02		Progression of AIDS pandemic	AIDS came out of Africa

The data fields contain references to notes and literature. Each field is characterized with a geographic location (e.g. U.S., Canada, etc.) and codes for respective fields of contingencies. Where more than one field of contingency is noted, the significance of respective boundaries is implied. The codes are as follows:

- C** communal
- E** natural environment
- O** organizational
- T** technological
- RTSC** ring of techno-scientific controls

Example: (C,O) (US) means that the reference refers to communal and organizational contingencies in the US. There may be communications problem across the organizational/communal boundary.

Notes: At the end of each critical path segment notes are provided in reference to individual entries in the grid. The notes are linked to the grid by a code.

Example: 59/A/12 stands for year 1959, column A, row 12 for that year.

In the grids, elements which have a note are flagged with grey shading. Elements which refer to the progression of the AIDS pandemic are flagged with a heavy frame. Fields (in column C) with notable social constructions are blackened.

CLINICAL TRIAL PHASES (after Piantadosi, 1997:79-86; annotated)

All new pharmaceuticals and other treatment (and diagnostic) methods have to be 'tried' on humans before they can be accepted as 'efficacious', i.e. having a therapeutic effect. Efficacy is established under controlled experimental conditions in humans. The therapeutic effect or diagnostic value must not be merely 'statistically significant,' but large enough to justify the cost of manufacturing. Substances and devices used in therapeutic interventions also need to be safe. These efficacy and safety trials are the most important phase of medical technology development, before commercial licenses for the marketing and sale of products are granted. They are commonly referred to as 'clinical trials.'

Once a drug or treatment method is marketed, unusual or unexpected damaging side-effects may give rise to 'post-marketing surveillance' which, in some cases, may lead to the withdrawal of the product from the market (e.g. Thalidomide) - but not very often. During this phase, the industry is most resistant to acknowledging side-effects. By then major economic commitments (investments) have been made, and investors expect accrual of returns on their investments. Post-marketing surveillance takes place in a natural, uncontrolled environment (study of 'effectiveness'), not under controlled hospital conditions (study of 'efficacy'). Under such conditions it is difficult to establish how big a therapeutic effect really is, as it depends on patient compliance, what conditions the drug is prescribed for, interactions with other drugs, the changing epidemiology of the condition for which it was developed, and so forth. Effectiveness trials are, therefore, very difficult to conduct, fraught with uncertainties, and tend to give rise to lengthy

disputes. For instance, to this day, we do not know how many people were infected with HIV-1 and HCV by which blood products, how many became ill, how many died from it, how many are still surviving.

Once a drug has been marketed, it would be difficult to repeat placebo-controlled clinical trials, as it would necessitate the withholding of available therapeutic benefit from a control group. Notwithstanding all of these weaknesses, clinical trials are the only known method by which the useless and unsafe can be distinguished from the useful and safe.

Note: A case could be made that, before an unrestricted license is issued, a treatment should be subjected to effectiveness studies, because in 'real life' conditions the therapeutic effect may be lost, and only under such conditions, over long periods of time, would all of the possible side-effects become apparent. However, competitive investment and product market pressures, as well as consumer pressures, make such an approach all but impossible. Furthermore, many new drugs are only marginally more efficacious than existing drugs, and such marginal improvements may become irrelevant under effectiveness conditions. The proliferation of only marginally different drugs make the oversight of extensive trials virtually impossible. What is referred to as '*the tragedy of capitalism*' in this study can be studied in all of its facets in the field of medical technology.

There is an important difference between estimating efficacy and estimating safety (side-effects). In the progression from phase 1 to phase 3 trials, efficacy is established with increasing certainty, and this is justifiable with a need to establish the usefulness of a treatment beyond reasonable doubt. However, the seeking of the same level of certainty is not justifiable for demonstrating safety, in particular when lower levels trials already show significant side-effects.

From a common sense point of view, it would be unethical to expose patients to a serious hazard, when lower level trials already indicate that such a hazard is present.

Unfortunately, clinical epidemiologists have not established hard and fast rules concerning what level of certainty is required before a treatment is considered unsafe. The matter is complicated by the circumstance that safety is never evaluated in its own right, but as a trade-off against benefits. The waters are muddied even further, when cost/profit benefits, and contingent benefits, such as employment, or economic development, enter into the calculus.

Note: This safety-related loophole in the 'scientific rigor' was used to proceed with the '*Canadian clinical trial on surrogate testing*.' (This issue is presented and discussed in detail in the section on the critical path for surrogate testing).

This rather large 'soft spot' in the rigor of clinical trials exists despite all the paraphernalia of the 'scientific method' and statistics. It is not just important on technical grounds, but for the entire system of drug regulation and product licensing. We need to be very clear about the fact that we cannot use scientific method in the final evaluation of damaging side-effects of drugs at the same level of certainty as their benefits, without crossing the line into the unethical, or even the criminal (in the sense of the Nuremberg Code). Scientific method, therefore, necessarily fails us in the evaluation of damaging side-effects for these two reasons:

- 1) The balancing of therapeutic effects (efficacy) with damaging side-effects (safety);
- 2) The ethical (and criminal) barriers to conducting prospective controlled trials on retrospectively recognized or expected damaging side-effects.

There is no basis for a scientific decision system to determine what are acceptable or unacceptable side-effects, i.e. there is no decision system for 'required safety' or 'acceptable side-effects' which can yield conclusions without political judgement. Therefore, the decision as to what is deemed safe enough and what not, should not be made by scientists or scientific managers, but must be left to a political process. The distribution of benefits (within limited, and sometimes scarce resources) can arguably be decisions made by representative bodies of a society or community as a whole and their systems of administration. The decisions about whether side-effects are acceptable are not theirs to make, but they must be made by those who are exposed to such risks. Notwithstanding the millions of pages already written about bioethics, bioethics can be reduced to these few issues, which appear simple enough, but are difficult to resolve.

There is no valid justification for keeping any information on side-effects hidden from the public eye, on any grounds, be it 'proprietary secrecy', or incomplete or inadequate information. On the same grounds, none of this information must be withheld, in any part, from patients using a treatment method or participating in a clinical trial, at any level. The current position of the Canadian Blood Agency that information on adverse reaction to products should be withheld until '*all the ducks are lined up*', or Sabin's position that one should not scare the public unnecessarily' (Horowitz, 1996:487) have no foundation in the public interest whatsoever. They tend to open the floodgates for seriously misleading public information, and they should be challenged vigorously. In particular, the conflict between proprietary secrecy and the patients' right to know has not been resolved, or even be clarified, in codes of ethics for medical experimentation on humans.

The following is a brief summary of the different phases used in clinical treatment evaluation (after laboratory and animal experiments):

Phase 1 (DF, dose finding) drug studies. TM (treatment mechanism for vaccines): This is the first kind of study in which drugs are administered to humans, to establish safe dosage and schedule of administration, also to investigate side-effects and toxicity. The number of patients is small. In drug trials, patients with a specific condition under investigation are selected. Since the risks and benefits are usually unknown, patients with an advanced disease, but relatively normal functions of liver, heart and kidneys are selected to study the pharmacokinetic functions (how the drug is absorbed, distributed, metabolized and eliminated). In vaccine trials this would translate into individuals which have not been infected but are under high risk of infection. Side-effects may be studied in this phase.

Note: There is a danger in this construction of what are suitable trial subjects, in that *patients with advanced disease, but liver heart and kidneys still working*, may be exposed to damaging side-effects, '*because they are going to die anyway*'. In other words, some of the individuals most vulnerable to abusive research are selected for research that is potentially the most abusive. The step from potentially abusive research to actually abusive research is a very small one. In the author's own observations, patients may not be informed, but 'quasi-informed' and manipulated into participation.

Phase 2 (SE safety and efficacy) trials; analyzing immunogenicity for vaccines: These trials use a fixed dosage or treatment modality to determine whether the treatment should be used in large-scale comparative studies. This also includes a third variable of interest, i.e. feasibility of large-scale trials. Side-effects are determined, but in absence of known, defined criteria. Sample sizes are relatively small (tens to hundreds). For hepatitis vaccines, that would have been, for instance, intravenous drug users, gays, Africans at high risk of hepatitis B infection, in particular newborns and women of child bearing age.

Phase 3 trial (CTE, comparative treatment efficacy trial): Such a trial has to show large scale benefit in comparison with a control group or an alternative treatment. This phase is referred to as 'pivotal', i.e. crucial for the drug to be marketed and to be licensed. These trials weigh treatment effects and side-effects against standard therapy. (In the case of the hepatitis vaccine, there was no standard therapy.) They are large-scale, and often multi-center, i.e. involving multiple institutions. Combined modalities may be tested (combinations with other treatments). HB vaccine trials which would have been conducted on a large scale in the US (New and California) were phase 3 trials.

Phase 4 (ES, expanded safety): Post-marketing surveillance is looking for unusual side-effects. When large populations are tested, there is a possibility of encountering rare, but serious side-effects (which can only be discovered by such trials). Phase III designs may be useful in post-marketing trials, and may lead (occasionally) to the removal of a drug from the market. Observations on the effects and side-effects of the commercial Merck vaccine would have been such a phase. There is some indication that after 1980, Merck ran comparative trials (trial vaccine and commercial vaccines, for instance. in Greece). **Note:** Besides side-effects, treatment effectiveness and failure could be tested in such trials. However, Piantadosi does not indicate that trials are ever conducted for that purpose.

Phases in the clinical trial of the hepatitis B vaccines. The distinction between the various phases in the development of hepatitis B vaccines is somewhat murky, as such trials on humans were announced on several occasions, but rarely reported on. The following table approximates such phase distinctions:

Phase 1:	Krugman (US) and Soulier (Paris) experiments (around 1970)
Phase 2:	All others discussed in this study, for which there exist few if any reports on results (1970-1978)
Phase 3:	Merck trial vaccines used in the US trials (New York and California, 1978/9); French trial vaccines used in Africa (1978 – 1984(?))
Phase 4:	Merck commercial vaccine, licensed in 1981

HEPATITIS B VACCINE: VIRAL INACTIVATION PROTOCOLS

Before the era of bioengineered (recombinant DNA) vaccines, vaccines had to be produced from cultures of live virus, followed by an ‘inactivation’ of such viruses. This process is aimed at preventing the virus present in the vaccine from replicating in the vaccinee, without destroying immunogenicity of the material (i.e. the property of inducing

immunity in the vaccinated individual). While most vaccine developers used formaldehyde for viral inactivation of hepatitis B vaccines, there were differences in the protocol details, which might have been critical for the ultimate safety of those vaccines. Of all the vaccines used, the Merck vaccine appears to be the least likely contaminated with HIV-1. However, the Merck vaccines had a credibility problem as to vaccine safety because of variations in the reported inactivation protocols.

This is of particular importance with respect to hepatitis C: when the vaccines were produced, hepatitis non-A,non-B was well recognized, but no specific agent had been identified or isolated. Therefore, there was no direct way of determining whether the vaccine was contaminated with live or inactive virus causing hepatitis non-A,non-B; and whether the inactivation process had completely inactivated the hepatitis non-A, non-B agent (in part, later identified as hepatitis C virus, HCV). HIV-1, hepatitis B virus, hepatitis non-A,non-B viruses were not the only agents that might have been present in insufficiently inactivated contaminating viral residuals. The New York vaccine study suggests that CMV and EBV, common amongst potential donors (i.e. hepatitis B surface antigen positive gay donors) may not have been fully inactivated.

The question of adequacy of inactivation has special significance, once the assumption is made that one or more vaccines contained material from chimpanzees infected with hepatitis B. Inadequacies in the inactivation protocols are an essential condition for the transmission of HIV-1 from chimpanzees to humans via hepatitis B vaccines.

The following virus inactivation protocols were in use:

Table 13: Overview of inactivation protocols for hepatitis B vaccines

VACCINE	PURIFICATION INACTIVATION
The Soulier/Paris) trial vaccine: Soulier et al. 1970 <i>Am J Dis Child</i> 123: 429-36	<u>Inactivation:</u> Heating 60°C for 10 hours. Apparently this inactivation was not complete.
The Krugman trial vaccine: Krugman et al. 1970, <i>J Infect Dis</i> 122:432-436 Krugman et al. 1971, <i>JAMA</i> 217:41-45 Krugman et al. 1973, <i>NEJM</i> 288:755-760 Krugman et al. 1979, <i>NEJM</i> 300:101-106	<u>Inactivation:</u> 'Boiling of serum' <u>Inactivation of inoculum:</u> 0.1ml of serum (MS-2 Willowbrook strain, patient 'HAM', (hepatitis B) heated at 98°C for 1 minute
The Prince/New York Blood Center trial vaccine (NYBC B-Vax) : Prince et al. May 12, 1978, In Vyas et al. (eds.) Second Symposium on Viral Hepatitis, UC:507-523	<u>Purification:</u> Polyethylene glycol precipitation; adsorption with hydroxyl apatite; flotation through a Cesium chloride gradient. <u>Inactivation:</u> Tween 80 (detergent), formaldehyde 1/2000, 3 days at 37°C
The Reesink/Dutch Red Cross trial vaccine Reesink et al. 1976. p. 119. Purcell and Gerin, in Vyas et al. eds., 1978	<u>Purification:</u> adsorption to colloidal silicate, fractionation with polyethyleneglycol, followed by differential centrifugation. <u>Inactivation:</u> 101°C for 90sec. 65°C for 10 hours.
The Maupas/French trial vaccine: Maupas, Gouday, Coursaget et al. 1976 <i>Lancet</i> i: 1367-1370 Maupas, Gouday, Coursaget et al., 1978, <i>Intervirology</i> 10:196-208	<u>Purification:</u> adsorption of HbsAg to colloidal silicate; extraction by sodium deoxycholate in borax buffer; two successive treatments with polyethylene glycol 6000; gel filtration to eliminate proteins; zonal ultracentrifugation in cesium chloride linear gradient. <u>Inactivation:</u> Formaldehyde 1/2500 for 48 hrs at and 1 week at 4°C. Purcell and Gerin in Vyas 1978, report that Maupas used formaldehyde at 1/1000, at 37°C for 48 hours, and at 4°C for one week.

VACCINE	PURIFICATION - INACTIVATION
The Purcell/Gerin/NIH/FDA/Union Carbide ('UC') trial vaccine (with Purcell (NIH); Gerin (Un.Carb.), Barker (FDA), Gerety (FDA), Holland (NIH), Maynard (CDC): Gerin, Holland, Purcell, 1971; <i>J Virol.</i> 7:569 Purcell & Gerin: <i>Am. J. Med. Sci.</i> 1975, 270:395-399	Purification: Isopyknic banding and rate zonal centrifugation; Inactivation: Formaldehyde 1/2000 at 37°C for 96 hours. At that level, some live but attenuated virus may have been present, i.e. one animal had an anti-HBc response indicative of some live viral material. (Purcell and Gerin, in Vyas et al. eds., 1978:495)
The Merck/Hilleman trial vaccine (200,000 doses): Hilleman, Buynak et al. 1975 <i>Am. J. Med. Sci.</i> 270: 401-404. Hilleman, Bertland, Buynak et al. 1978, in Vyas et al. eds., <i>Second Symposium on Viral Hepatitis</i>, UC: 525-537. 11 lots, Lot 559 most extensively tested, pool of four human donors) Szmunness, 1979, <i>J. Med. Vir.</i> 4:327-40 Szmunness, 1980, <i>NEJM</i>, 303:833-841. Buynak et al. 1976. <i>Proc. Soc. Exp. Biol. Med.</i> 151:694 Vaccine (-s? Merck?) described by the CDC (referred to as 'US-manufactured') (MMWR (CDC), June 18, 1982, 31:317-22; 327-8). Since this report includes references to the CDC multi-center study on gay men, including San Francisco (Francis et al., 1982, <i>Ann. Int. Med.</i>) and the Szmunness trial on gay men in New York (1980), the report implicitly refers to the Merck trial vaccine. However, the commercial Merck vaccine had been licensed in 1981. A reference to 12,000 recipients of the vaccine suggests that this includes participants in the CDC multi-center trials, the New York trial and the commercial vaccine - without specifying any one them in the vaccine characterization.	<u>Inactivation:</u> 'formaldehyde' <u>Inactivation:</u> 'formaldehyde' 559 727 723 751...? (not always clear what is 'study' and what is 'lot') <u>Inactivation:</u> 'formaldehyde' <u>Purification:</u> by ammonium sulfate concentration, isopyknic banding on sodium bromide, sucrose gradient-rate zonal separation, enzymatic digestion with pepsin. <u>Inactivation:</u> with formaldehyde at concentration of 1/4000 for 72 hours at 36°C to kill residual live virus. <u>Purification:</u> 'A combination of biophysical (ultracentrifugational) and biochemical procedures (not specified). <u>Inactivation:</u> 8-M urea, pepsin at pH 2, 1:4000 formaldehyde

The Merck commercial vaccine (licensed), appr. 5,000,000 doses: Hilleman, December 1984 (Ann. Int. Med. 101:852-858)	'More' than three different inactivation steps that assure [not prove!] destruction of residual viruses that might be present in human blood. (Hence claim of no HIV-1 infectivity)

Notes:

1) The distinction of 'purification' and 'inactivation' is not a sharp one, since some steps can be characterized by both (e.g. Cesium Chloride gradient centrifugation, or digestion with pepsin).

2) Inactivation is extremely poorly reported by Merck Sharp & Dohme up to the trial report by Szmuness in 1980. Hilleman uses the term 'formaldehyde' in his 1978 presentation (Vyas et al. eds., 1978), no time, no concentration.

3) The record shows a wide variation in purification and inactivation protocols, and with Merck, a gradual increase in inactivation steps. Some of the variations (instead of improving a standard protocol) may have been motivated by intentions to have the vaccines patented.

4) By 1978, there were four vaccines still competing:

**Merck Sharp & Dohme
Reesink (Belgium)
Maupas (France)
Prince (New York Blood Center)**

Purcell and Gerin (NIH and Union Carbide) made an attempt to have the FDA accept their preparation as vaccine standard. Most likely, because of the involvement of the FDA through Barker and Gerety, the commercial exploitation of that experimental vaccine had become impossible. In any case, the original expertise of Krugman and others, had been transferred to Merck Sharp & Dohme.

Leonard Horowitz, in his 1996 account, tries to focus attention on the Purcell/Gerin and Merck vaccines. It seems, however, that these are the least suspect vaccines, whereas the Belgian, French and New Blood Center vaccines can at least be linked in some fashion to vaccine operations in Africa. It is not possible to tell whether Horowitz deliberately tried to mislead his readership, or whether he was set up by his informants (Martin, Strecker) to mislead. However, his informants may have been misled themselves.

CRITICAL PATH 1970-1974; MILESTONE 1970

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1970		Milestone	Start of international competition in hepatitis B vaccine development	
	01	(T) (US) Phase I trials. Krugman's first experiments with heat-inactivated, hepatitis B and A positive serum on the Willowbrook children. (<i>J. Infect. Dis.</i> 122:432-6)	(T,O,RTSC) (world-wide) HbsAg testing implemented world-wide on a large scale in blood banking and clinical practice. Rise of STD's in North America since the mid sixties. Accumulation of Vietnam veterans.	(O,C) (US) See path of surrogate testing, re: the Willowbrook children. ('They will get hepatitis anyway').
	02	(T) (US) The beginning of vaccine developments by Prince at the New York Blood Center. (Prince et al., in Vyas et al. (eds.), <i>Viral Hepatitis</i> , 1978) No report before or after 1978.		
	03	(T) (France) Soulier, Paris: heat inactivated vaccine, beginning of French vaccine development Soulier et al. 1970 <i>Am J Dis Child</i> 123: 429-36.		
	04	(E,O,T) (Africa) Vogel, Anthony, Mody, Barker. Hepatitis associated antigen in Ugandan patients with hepato-cellular carcinoma (<i>Lancet</i> ii, 1970, 621-4). Connection of Barker with hepatitis, Central Africa and cancer prevention programs in Africa (IARC, International Agency for Cancer Research).	(O,T) (Global). The IARC had a major cancer research laboratory in Africa, including research on hepato-cellular cancer (hepatitis B virus-related). The main centers were in Lyon, France and at the NIH in the US (Barker, Purcell). (Horowitz, 1996)	
1971				
	01	(T) (US) Phase I trials. Further studies by Krugman with hepatitis B on the Willowbrook children. (<i>JAMA</i> , 217:41-5)		
	02	(T) (US) Gerin, Holland and Purcell produce purified hepatitis B antigen from one of the Willowbrook children (<i>J. Virol.</i> 7:569; 1971) (In Vyas et al. eds. 1978)		

TIME	ROW	A. CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
	04		(T,C) (US) Testing of 1971/2 samples from drug addicts in the US ('all over the US') 5% infected with HIV. (Garrett, 1994)	(T, C) (US) Purcell suggests that this vaccine could not be tested, because of the introduction of the chimpanzee model and "changing social concepts concerning the use of human volunteers." Testing postponed till 1974. (Purcell in Vyas et al., eds., 1978)
1972				
	01		(O,RTSC) (US): In 1972 transfer of the regulatory responsibilities for biologics from the NIH to the FDA. (Panem, 1988:50-63)	
	02	(T, E) (US, Africa) <u>Prince</u> et al. publish research in the <u>chimpanzee model</u> of hepatitis B. (<i>Medical Primatology</i> , 1972, part III, p. 97-109).		
1973				
	01	(T) (US) Krugman, additional observations (Phase I trials) (<i>NEJM</i> , 288:755-60)		
	02	(T, E) (Belgium, Africa) <u>Desmyter</u> (Belgium) describes <u>chimpanzee model</u> of hepatitis B. (Desmyter et al., <i>Vox Sang.</i> , Suppl 24, 17-26)		
	03	(T, E) (US, Africa) <u>Barker</u> et al. describe <u>chimpanzee model</u> of hepatitis B. (<i>J. Inf. Dis.</i> 127, 648-662)		
	04	(E) (Africa) Szmuness, Prince et al. describe epidemiology of hepatitis B in Africa. (Survey in Senegal). (<i>Am. J. Epidem.</i> 98, 104-110)		

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1974				
	01		(T,C) (O) (US) Beginning of TTV studies on surrogate testing for transfusion-related hepatitis non-A, non-B, commissioned by the NIH Hepatitis non-A,non-B recognized as major problem of transfusion-related hepatitis after the implementation of Hbs-Ag testing. Merger of NIMH, NIDA, and NIAAA into ADAMHA (Alcohol,Drug Abuse, and Mental Health Administration)	
	02	(T,O) (US) Announcement by Merck that a trial vaccine for hepatitis B is available (200,000 doses).		

71/A/01

In the early seventies there were already five hepatitis B trial vaccines in existence:

- 1) The **Krugman** vaccines
- 2) The Merck trial vaccines (**Hilleman**)
- 3) The Paris (**Soulier**) vaccines
- 4) The New York Blood Center trial vaccines (**Prince**)
- 5) The **Purcell/Gerin-NIH/Union Carbide** vaccines

The NIH (Purcell et al.) may have been developing their vaccine as well. Prince does indicate in his 1978 paper that he started in 1970. The infection of drug addicts in the US could have been the result of trials with any of these vaccines. We do know that Krugman faced increasing, world-wide opposition to the experiments on the Willowbrook children. The author recollects repeated discussions on this subject with his former colleagues in Europe, at the time. However, as objectionable as the Krugman trials may have been, at least there is a record. There is no public record on the early experiments by Merck, Sharp & Dohme, NIH/Union Carbide/Purcell/Gerin and by the New York Blood Center. The 200,000 doses by Merck announced in 1974 were Phase 3 trial doses (for pre-licensing and pre-marketing trial).

70/A/04

The connection of L. Barker with the IARC and the research facility in Uganda in the early seventies is one of the few 'needles in the haystack' which establish a connection between hepatitis B research, hepatitis B vaccine development, and the African epicenter of the AIDS pandemic. While this does not 'prove' anything, it is an important critical subpath which would have to be explored in a formal investigation.

72/B/01

The US FDA, Bureau of Biologics: The US Food and Drugs Act of 1906 was originally administered by the Department of Agriculture (mostly for pesticides and herbicides). New Deal legislation led to a new act, which became law in 1938 and remains the governing statute. "*The licensing, research, and regulation of foods drugs, biologicals, cosmetics, and medical devices remain functions of the FDA.*" (Panem, 1988:51). However, the oversight of toxins, serum, and vaccines remained with the NIH as a vestige of the Hygienic Laboratory's nineteenth century charter. Only in 1972 did the Congress transfer regulatory control over these biological products to the FDA. Accordingly, the regulation of hepatitis B vaccine would have become a responsibility of the FDA in 1972. Because it was a blood product, it would have been the responsibility of the Bureau of Biologics, *Blood Products Division* (Barker and Gerety), the agency that also regulated the safety of blood, blood products and plasma derivatives, such Factor VIII concentrate for hemophiliacs.

Canada: the Health Protection Branch, Bureau of Biologics (Part of the Drugs Directorate). The Bureau was created in 1974, when several divisions in the Laboratory Center for Disease Control (LCDC) were consolidated. Dr. John Furesz was director from 1974-1992 (1992 was the year of the start of the parliamentary inquiry into the contamination of the Canadian Blood supply). The LCDC was non-regulatory, and performed epidemiological functions similar to the CDC. Dr. Alistair Clayton was Director General from January 1979-July 1987. During that period he was also Chairman of the NACAIDS (National Action Committee on AIDS, a committee advising the Minister, Monique Begin, Jake Epp, Perrin Beatty).

US: Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). In 1974, NIMH (National Institutes of Mental Health); NIDA (National Institute of Drug Abuse) and NIAAA (National Institute on Alcohol Abuse and Alcoholism) were merged into ADAMHA. (Panem, 1988:61). The changes in the US had two consequences:

- 1) A close link between the blood regulators at the FDA (Food and Drugs administration, Bureau of biologics, Blood Products division: Barker, Gerety); with blood experts at the NHLBI (National Heart, Lung and Blood Institute, NIH: Alter, Holland); the vaccine developers at the NIAID (National Institutes for Allergy and Infectious Diseases, NIH: Purcell, Gerin); and through Gerin with the Molecular Anatomy (MAN) Laboratories of Union Carbide. Since the NHLBI also funded the hepatitis and surrogate-testing-related activities at the New York Blood Center, the New York Blood Center vaccine development was part of this 'loop'. Merck Sharp & Dohme had its own research facilities and was joined by

Krugman as a consultant. Merck was connected to the CDC (Centers for Disease Control, Foege, Young), and through the trials in New York with the NIH/FDA complex. Thus, at the time of the outbreak of AIDS, hepatitis B vaccines, blood products, development, production, and regulation, surrogate testing for AIDS and for hepatitis non-A,non-B were all controlled by a small group of institutionally connected individuals from the FDA, the CDC, the US military, the NIH, Merck and the New York Blood Center.

2) The consolidation of the NIMH and related institutes under central administration may have made previously possible experiments with retarded children and with drug addicts more difficult. Thus experimentation would have turned to animal experiments (chimpanzees) and to other risk populations: gays, hemodialysis units, Africans, foreign aid workers in Africa.

In Canada the control network was differently constituted and consisted of the following individuals:

Red Cross: Dr. Perrault, Dr. Davey, Dr. Derrick(†), Dr. Naylor(†)
McMaster University/Red Cross: Prof. Bienenstock, Huguette Labelle
Health Protection Branch: Dr. Morrison, Dr. Liston
Bureau of Biologics: Dr. Furesz, Dr. Boucher, Dr. Pope
LCDC: Dr. Alistair Clayton
CBC (federally funded office of the Executive Director): Dr. Lerclerc-Chevalier
Connaught Laboratories, Toronto

It is important to bear in mind that most of the individuals involved in the U.S. and in Canada were relatively low level scientists and bureaucrats, who could not have acted without senior bureaucratic direction, and the senior bureaucrats, given the seriousness of the problem, could not have acted without political understandings with respective governmental Houses and administrations.

CRITICAL PATH 1974-78; MILESTONES 1974, 1978

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C SOCIAL CONSTRUCTION CONTINGENCIES
1974				
		Milestone First major conference on hepatitis B trial vaccines. Meeting of main vaccine developers		
	01	(T) (Global) Viral Hepatitis Symposium in Milano, Italy. (Regamey et al., eds., 1975).		(T, C) (Global) In the discussion of experimental vaccines, Krugman suggests some preliminary trials on humans first, then announces the strategy on human uses of hepatitis B vaccines. (Regamey et al., eds., 1975)
	02	(T) (Global) Discussion on active immunization against hepatitis B. Discussants: Hilleman (Merck); Vyas (US, Union Carbide); Prince (New York Blood Center); Desmyter (Belgium). (Regamey et al., eds., 1975).		
	03	(E) (Africa) Presentation of Hepatitis B epidemiology research by Desmyter (Belgium) in Mali. (Regamey et al., eds., 1975).		
	04	(E, T) (US, Belgium). Desmyter and Prince discuss hepatitis B infection of chimpanzees in American and European holding facilities; more than 70% have anti-HBs antibody, rendering them useless for hepatitis B and hepatitis B vaccination experiments. (Regamey et al., eds., 1975).		
	05	(T) (US) Purcell and Gerin (NIH, Union Carbide) begin to use chimpanzees for hepatitis B vaccine testing (Purcell and Gerin, in Vyas et al. (eds.) 1978).		
1975				
	01	(T, C) (France) Beginning of hepatitis B immunization studies by Maupas et al. (Intervirology, 1978, 10:196-208) in France, Loire Valley, Tours, Orléans) on hemodialysis patients and staff. Patients less responsive than staff. (Progr. Med. Virol. 27: 185-201. France has entered into the international competition in vaccine development.	(T,O) (France) Production of the vaccine was carried out by the Institute Pasteur (Institute Pasteur Productions).	

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1975	02	(E, C) (Africa) Study by Prince and Szmunes: case control study of the association between primary liver cancer and hepatitis B infection in Senegal. (Int. J. Cancer 16:376-383.)	(E,T,C) (Africa) Possible opportunity for spread of HIV in Africa (South. Sudan, Yambuku) by hepatitis B vaccines; low infectivity.	
1976				
	01		(E,T,C) (Africa) Outbreak of Ebola in Yambuku-Zaire and Southern Sudan; HIV positive specimens discovered amongst villagers at that time and later (Garrett, 1994).	
1977				
	01	(T,C) (US) Szmunes's baseline data collection for vaccine trials; published in Vyas et al. eds., 1978. 10,000 gay men were investigated for hepatitis B status. Pool of 2500 hepatitis B negative individuals; 1083 individuals were entered into the New York trial portion.	(T,C) (U.S.) Preliminary data on surrogate testing (ALT) produced by the NYBC, presented by Aach.	(T,C) (US) The actual trial refers to men, not gay men.
	02	(T,O) The Purcell (NIH) grant proposal for vaccine development asks for money for the same time period; (Horowitz, 1996)	(E,C) (Africa) Start of spread of HIV-1 positivity in sub-Saharan Africa (Mann et al., eds. 1992)	
		Milestone Start of Merck vaccine trials in New York		
1978				
	01	(T) (Global) Symposium on viral hepatitis in San Francisco. (Vyas et al, eds., 1978)		
	02	(T,C) (France) Report of hepatitis B immunization studies by Maupas et al. (Intervirology 10:196-208) in France Loire Valley, Tours, Orleans); study on hemodialysis patients and staff. Not possible to tell from the report whether infections in non-responsive individuals were due to vaccine or to environmental conditions.		(T,C) (France) 'First cancer vaccine' (Maupas) Vaccine is 'efficacious', doesn't say 'safe' (safe in 5 chimpanzees, but in humans?). (Maupas et al., <i>Progr. Med. Virol.</i> 27:185-201)
	03	(T,C) (France, Senegal) Beginning of Maupas's studies in Senegal (1978, Maupas et al. <i>Progr. Med. Virol.</i> 27:185-201).	Start of spread of HIV-1 positivity in North America, Western Europe. (Mann et al., eds. 1992:880)	

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1978	04	(T, C) (US) Report by Prince on New York Blood Center vaccine; mentioning of Peace Corps in paper. (In Vyas et al. (eds.) 1978)	(T,C) (US) 5% of Merck trial participants already HIV-1 infected in 1978. First case of infection of a hemophiliac.	
	05	(T,C) (US) First individuals vaccinated with Merck vaccine in New York.		
	06	(T,C,RTSC) (US, Global) Barker, Gerety (et al.) indicate that the NIH/Union Carbide trial vaccine is considered to be used as a vaccine standard by the FDA. (In Vyas et al., 1978)		
1979				
	01	(T, RTSC) (US) Krugman et al. 1979, <i>NEJM</i> 300:101-106. Indicates that inactivation of trial vaccine in earlier studies (Krugman et al. 1970, <i>J Infect Dis</i> 122: 432-436 Krugman et al. 1971, <i>JAMA</i> 217:41-45. Krugman et al. 1973, <i>NEJM</i> 288:755-760) has not been complete (subclinical infection in 3 of 29 recipients; transient HBsAg and HBeAg; later anti-HBc and anti-HBs). Vaccine-like 'live-attenuated vaccine'.	(T, C) (Canada) Distribution of Factor VIII concentrate in Canada, replacement of cryoprecipitate (Some factor concentrate already infected)	
	02	(T, C) (US) Publication of baseline data for vaccine trial (Szmunnness et al., <i>Journ. Med. Vir.</i> 4:327-40 Reference is made to the Merck vaccine, Lot: No 751. Only formaldehyde is mentioned as inactivation procedure Note 2.	(O) (US) Lewellys Barker moves from the FDA (B.o.B Blood Products Div.) to the American Red Cross (Vice-president, Health Services)	(T, C) (US) This publication refers to homosexual men (appr. 3000). In the trial report, the discourse on October 1980 is changed (more than 2500) 'men.' 500 voluntary participants are 'missing.'
	03	(T,C) (US) Last participants inoculated in the New York vaccine trials.	(C) (Haiti) Start of spread of HIV-1 positivity in Haiti ('Caribbean') (Mann et al., eds. 1992:880)	
	04		Szmunnness is hired by Lewellys Barker of the American Red Cross as epidemiological consultant at 10-times the going rates for consultants	
1980				
	01	Publication of New York portion of Merck Phase 3 vaccine trial.		

Notes:

78/B/04 CDC studies of HIV/blood connections in Los Angeles, however, revealed that the earliest date of HIV-infection of a person receiving blood clotting products was 1978. (Garrett, 1994). Thus the beginning of the HIV positivity of the pandemic can be placed into 1978; the first peak in North-America was 1984. Accordingly, the author works with the assumption of an average interval of 6 years between infection and diagnosis of AIDS, at least for the first infected cohort. Similar assumptions can be made for the first cohorts in Tanzania/Rwanda, Haiti and Belgium. It is suggested that this cohort may have been infected by injection, not by sexual contact.

79/A/02 Szmunness writes: *"one lot (no 751) of the Merck vaccine has been extensively studied in human volunteers and found to be safe, highly immunogenic, and to have good stability during long-term storage. ....This vaccine was also free of possible residual infectivity or contamination with other hepatitis causing agents."* (Szmunness et al. 1979).

The following questions can be raised concerning these statements:

- 1) There is no record of the extensive testing of human volunteers with that vaccine lot (or any other vaccine lot).
- 2) This vaccine is described as being inactivated by formaldehyde only. In the vaccine report the inactivation includes pepsin, but is mentioned as purification, not inactivation.
- 3) It was impossible at that time for Szmunness to conclusively demonstrate freedom from other hepatitis causing agents, since the agent for hepatitis Non-A,non-B was unknown.
- 4) While the pool of potential participants was refereed to as 'homosexual men' (late in 1979), in the vaccine trial report it is changed to 'men' (October 1980). The thinking at the time (1980) may have already included the infection of 'Haitian men'.

Szmunness continues:

As early as 1971 Krugman demonstrated that a vaccine against hepatitis B can be prepared by boiling dilute sera from chronic asymptomatic HBV carriers and that such a vaccine is safe, immunogenic and protective [Krugman et al. 1971]. Subsequently, two more sophisticated vaccines were developed in this country: the NLAIID vaccine [Purcell and Gerin, 1978] and the Merck vaccine [Hilleman et al., 1978]. Both consist of highly purified and formalin inactivated

hepatitis B surface antigen (HbsAg) particles, administered in aqueous or alum adjuvant formulation.

Because the NIAID vaccine is not intended for mass-production, field trials on efficacy are being limited to the vaccine manufactured by Merck.

This implies the following:

- 1) Phase 2 trials had been carried out for Merck and the NIH (Purcell). Purcell was not proceeding to the decisive phase 3 trial.
- 2) The fact that Purcell was not proceeding to the Phase 3 trials does not preclude that phase 2 trials were carried out (which would have been consistent with the Purcell grant proposal of 1977/8).
- 3) Purcell would have had access to the New York pool of 2500-3000 hepatitis B negative males as early as 1977.
- 4) The New York Blood Center trial vaccine is no longer mentioned at all, although it had been presented by Prince a year earlier. This vaccine was intended for commercial purposes, and that should at least raise the suspicion that the phase 2 trial had been carried out. There hundreds of volunteers which were not needed for the New York trials. Rather it seems that the pool was 'split'.
- 5) If people were infected as early as 1977, first signs of AIDS-like symptoms might have arisen in 1979 (minimal symptom-free period of AIDS was 2 years). By the end of 1979, the first trial results would have become available. It is later reported that in the order of 5% of the volunteers who entered the Merck phase vaccine trials (November 1978-October 1979) were already infected with HIV-1. The first observations on individuals entering into the Merck trial in 1978 could have been made by the end of 1979).
- 6) One must at least ask the question, why the NIH and the New York Blood Center vaccine were withdrawn from any commercial purpose; and what the result of the phase 2 trials on those vaccine were.

75/B/02 76/B/01 77/A/03 78/A/04 79/A/03 The starting dates of the spread of HIV-1 infections, in the context of contaminated vaccines can be modeled as follows:

- 1) 1977 vaccination and infection of US and European gay men working in foreign aid programs in Africa;
- 2) First spread in Central Africa (1977/78);

- 3) 1978 Spread of AIDS in Europe and North-America by workers returning from Africa (after a 6 month tour or so).
- 4) 1978 Vaccination of Haitian men working in Africa, additional infections in Africa possibly in French speaking countries; and/or infection by first wave of already infected Africans.
- 5) 1979 Haitian men returning, beginning spread in Haiti, beginning infections amongst women.
- 6) All other infections through sexual contact (e.g. Australia, Japan, New Zealand, South America – Rio de Janeiro)

77/A/02   **The Purcell grant proposal.** This grant proposal is more important for the institutional connections of US vaccine development and blood product safety, than for the outbreak of AIDS. As mentioned in an earlier note, the Purcell trial vaccines were developed in a biological laboratory of Union Carbide (Gerin). Attempts were underway to use only HbsAg subparticles for immunization (possible coupled to other vaccines, such Measles or Pertussis), instead of the whole HBsAg particle. At the 1978 viral hepatitis symposium in San Francisco, Lewellys Barker, then already working for the FDA, proposed that the Union Carbide vaccine ('UC' vaccine) be used as a standard for Vaccine production. Work on the subparticle vaccine was also presented by a group working with Girish Vyas, (editor of the Proceedings of the San Francisco conference).

CRITICAL PATH AND MILESTONES 1980-81

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1980	01		First observations of AIDS like symptoms in gay men by Gottlieb	
	02		Surrogate testing studies (ALT, anti-HBc) by Aach et al. completed, but not published.	
Summer 1980	03		Likely recognition of vaccine-AIDS problem in vaccine cohorts	
Oct. 9, 1980	04	Publication by Szmunn, Stevens et al. and Kellner on clinical trial of Merck trial vaccine (NEJM 303:833-41) Note: I		

Notes:

80/A/04

Summary of hepatitis B events. Hepatitis B events in the Szmunn

study include hepatitis B, mild hepatitis B, antigenemia without signs of hepatitis, and anti-HBc only. The peak of hepatitis B cases (HbsAg positive plus substantial elevation of ALT) could be due to residual hepatitis B virus, or it could be due to concurrent hepatitis non-A, non-B. The peak of infection (however small) does not fit the pre-vaccination or post-vaccination infections with hepatitis B shown for the placebo group.

Fig.14: Hepatitis B markers in Hepatitis B vaccine trials.

	Vaccine group	Placebo Group
Hepatitis A	15	12
CMV (cytomegaly virus), <u>without</u> concurrent hepatitis B	7	1
CMV (cytomegaly virus), <u>with</u> concurrent hepatitis B	1	5
EB (Epstein Barr)	2	0
Hepatitis non-A,non-B	10	5
Total	35	23

Table 14: Markers of infectious disease in hepatitis B vaccine recipients.

Since all types of infections are higher in the vaccine group, and since this was a double-blinded, randomized trial, the only difference between the two groups is the vaccine. Szmunnness tries to downplay the difference by indicating that the 'attack rates' were not different ($p>0.05$) for hepatitis A (which is an enteral infection and therefore independent of vaccination); and for hepatitis non-A,non-B, which is at the very least suspect, given that not all hepatitis non-A,non-B was hepatitis C. The difference could have been caused by vaccine related hepatitis C transmission.

Szmunnness interprets the higher incidence in a rather strange way:

The fact that slightly more [in reality substantially more] vaccine recipients than placebo recipients had non-A,non-B and cytomegalo-virus hepatitis is in accordance with our expectations: in placebo recipients, episodes of low or moderate elevations in ALT were probably masked by frequent HBV events. This explanation is supported by the detection of six additional cytomegaly-virus sero-conversions among HBV cases, five in placebo recipients, and one in a vaccine recipient.

The case for hepatitis non-A,non-B is incomplete, because only participants with an elevated ALT were tested for additional markers. Brief or briefly recurrent ALT elevations, or infections without detected ALT elevations could have been missed. Szmunnness reports that the Merck trial vaccine is efficacious, but nowhere in this paper does he state that it is safe, although that would have been the most critical aspect for licensing of the vaccine. This is an important change from his 1979 baseline data paper, where he claims that the Merck, Sharp & Dohme vaccine had been found to be 'safe'.

The implication is that Szmunnness himself could not declare the vaccine to be safe. This is the first instance in a long chain of 'plays with truth and falsity'. If he felt that the vaccine

safe, or not safe, it was his obligation to say so, not simply to remain quiet about. In a phase 3 clinical trial report this is a serious omission, because, beyond efficacy, safety is the main issue which calls for licensing or withholding of a license. There is some indication that the vaccine may have transmitted live CMV, hepatitis non-A,non-B, perhaps EBV, and even HBV. Given that this was the most investigated vaccine lot, and given that no comparable data exist on any other vaccine lot or vaccine, experimental or commercial, none of the trial vaccines can be assumed to have been safe: all vaccines may have contained one or more live viral agents. This may have included HIV infections, and definitively non-A,non-B hepatitis infections.

. The HIV-1 contamination study conducted by Merck and the CDC on the Merck commercial vaccine, which did not show HIV-1 contamination, is meaningless, as it does not include phase 3 clinical trial data and results on safety. (Merck may just have known that there was no chimpanzee material in their commercial vaccine).

. Similarly, Gerety's (FDA) 1982 (Munich) report on the safety of the commercial vaccine is meaningless, as they do not include a phase 3 clinical trial. Changes in the inactivation protocol and a delay between licensing and distribution of the commercial vaccine are consistent with the conclusions one would reach from Szmunn's data.

In conclusion, just like factor VIII concentrate, the hepatitis B vaccines of human origin should have never been licensed: the only substantial phase 3 clinical trial, which also addressed safety of human plasma-derived hepatitis B vaccines, the New York study, **does not show beyond reasonable doubt that the Merck, Sharp & Dohme trial vaccine (Lot 751) was safe.** The Szmunn data alone represent sufficient prima facie evidence to call for an inquiry into the role of commercial and experimental hepatitis B vaccine for human origin in the spread of HIV-1 and HCV.

CRITICAL PATH 1981-86; MILESTONES 1981, 1985

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C SOCIAL CONSTRUCTION CONTINGENCIES
1981				
Feb. 6, 1981	01		(O) (France) Death of Philippe Maupas in a car accident near his home in Tours, France, 2 months after an International symposium on viral hepatitis in Paris (Dec. 8.-9., 1980). At that time AIDS had emerged.	(E) (Africa) 1981 AIDS came out of Africa (Garrett, 1994:290-1). Peter Piot, Belgian, working for the CDC in Africa: 1978, Greek fisherman from Lake Tanganyika died of AIDS in Antwerp. 3 Zairens died before 1980 in Belgium, incl. one female.
	02	(T, RSTC, O) (US) Suppression of ALT as surrogate test by the FDA and the US military.	(C) (US) First official report of AIDS in the US by the CDC (June 1981)	(C) (Caribbean) 1981: AIDS came from the Caribbean: Black Dominican women had died from AIDS 1979 at the Mount Sinai Hospital in NY. This case did not fit into risk factors(gay/male/drugs/prostitution).(Garrett,1994:296).
	03			(C) (US) 1981: AIDS came from drug users: Three of the first eleven cases of AIDS studied in N.Y. were heroin addicts (the others were not.) (Garrett,1994:297).
1982				
	01		(O) (US) Death of Wolf Szmunes ('terminal illness').	
	02		Publication of Don Francis's data on the Merck hepatitis B vaccine trials of homosexual men (notably in California (Francis DP et al., Ann. Intern. Med. 97:362-6).	(C) (US) 1982: AIDS is a gay disease: 1982 Gaetan Ducas ("Patient Zero", CDC); gays started it. Highest number of cases in San Francisco's Castro district, the 'hub' of the gay community. (Garrett, 1994:300)
	03			(E) (Africa) 1982: Liebovitch (France) AIDS is a viral disease of African origin. 'burns out immune system.'(Garrett,1994:320)
August 1982	04			(O) (US) CDC changes 'GRID' to 'AIDS')

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1983				
	01			(E) (Africa) 1983: AIDS came from Africa; Gallo/NIH: 'HTLV is endemic in the Caribbean and seems to be relatively common in Africa, and of course AIDS has some link with the Caribbean island of Haiti and with Kaposi's sarcoma found traditionally in Africa,' Gallo told the JAMA in August 1983. (Garrett, 1994:321)
	02		(T) (France) Barre-Sinoussi isolates AIDS causing virus (LAV) in Montagnier's laboratory at the Institute Pasteur.	(E) (Africa) 1983: Bedekas, Teas and Hebert, US: AIDS related to African swine fever virus. A 1978 outbreak in Cuba and Haiti was linked to an effort of the CIA to destabilize Castro's government. (Garrett, 1994: 323)
	03			(C) (US) 1983 AIDS is a gay disease. US: AIDS is syphilis, or syphilis is cofactor. (Garrett, 1984:323)
	04			(O) (US, Africa) 1983: New England Journal of Medicine rejects paper on AIDS cases on Zaire; because peer reviewers did not believe that AIDS in Africa was heterosexually transmitted.
	05			(O) (England) 1983 UK: AIDS is not a problem. John Maddox, editor of <i>Nature</i> (Garrett, 1994)
1984				
Jan. 1984	01		Report of 18 US cases of transfusion associated AIDS (<i>NEJM</i> ; Krever 1997:728) Report of AIDS in spouse of hemophiliac (Ann. Int. Med. Krever, 1997:728)	

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1984 Jan. 1984	02		(T,O,RTSC) (US) Cutter, Armour and Alpha (plasma fractionators) are granted license for heat-treated Factor VIII. (RTSC, C) (US) Report of 18 US cases of transfusion-associated AIDS (<i>NEJM</i>; Krever 1997:728)	
March 9-11	03	(T, O) (US) Annual scientific Symposium of the American Red Cross, Washington. 'Infection, Immunity & Blood Transfusion. Eds.: Lewellys Barker, Senior Vice-president Development, American Red Cross. Planning Committee: Barker, Cole, Dodd, Francis, Keating, Scheibel.	(RTSC) (Canada) Feinman's (Toronto) post-transfusion-hepatitis study in progress. (RTSC, O) (US) Cutter and five blood banks in San Francisco implement anti-HBc as surrogate test (for HIV).	
April 1984	04		(T) (US) 'Isolation' of HIV-1 (HTLV -III) and beginning of production of test kits. 1984, Gallo: AIDS is caused by HTLV-III (but he stole the virus (LAV) from Montagnier; or Gallo's cultures became 'contaminated' with Montagnier's virus). (Garrett, 1994:331) First tests on Africans (Zaire). Testing of Canadian Hemophiliacs.	(C) (US) 1984, Reverend Billy Graham: "AIDS is the judgment of God" (Garrett, 1994:330) (C) (US) 1984, Reverend Jerry Falwell: "AIDS is God's punishment". (Garrett, 1994:330) (C) (US) 1984, Senator Jeremiah Denton: "Let the faggots die." (Garrett, 1994:330)
May 1984	05		(T) (US) Gallo's publication in <i>Science</i> on HTLV-III as virus causing AIDS (Krever, 1997:728)	(O, RTSC) (Canada) First (ineffective) pamphlet on AIDS issued to Canadian blood donors.

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1984 Oct. 5, 1984	06	(O,T,C) (Canada) WHO report on baseline studies for hepatitis B vaccination in Victoria, BC, General Hospital. In Quebec, in a residence and rehabilitation center for the mentally handicapped it was <u>decided</u> that hepatitis B vaccine to be given to all current and new residents, and offered to employees. (WHO wkly. <i>Epidem. Rec.</i> 1984 40:310-11; based on <i>Canada Diseases Weekly Report</i> 15&17).	(RTSC, O) (US) US FDA position remains against surrogate testing of blood donors.	(O,T,C) (Canada) Hepatitis B vaccine to be <u>given</u> to all patients, and <u>offered</u> to employees (suspect of human rights violation)
Nov. 23, 1984	07	(T) (Asia) Report of the Western Pacific Region, Second Task Force on Viral Hepatitis B. (Aug. 27-30, 1984, in Sendai, Japan). Report states that US, Dutch and French vaccines have been studied in the region. <u>They are being produced in China, Japan, and Singapore.</u> Chinese hamster ovary cells can be used as tissue culture. Also, <u>bioengineered (yeast base) vaccines are being considered.</u> (WHO Wkly. <i>Epidem. Rec.</i> 47:363)	(RTSC, T) (Canada) Consensus conference in Canada, which decides to use up old stocks of HIV-contaminated Factor VIII.	(RTSC, T) (Asia) Issues of vaccine safety are not discussed in the Asian conference.
TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1984 Oct 18, 1984	08	(RTSC, T) (US) Jacobson et al. (<i>NEJM</i> , 311:1030-2). Paper on lack of effect of hepatitis	(O) (US) Studies carried out at Massachusetts General Hospital and the Department of Medicine,	(RTSC, C, O) (US) The issue of contaminated hepatitis B vaccine has affected (deterred people

		B vaccine on T-cell phenotypes (i.e. T4/T8 lymphocyte ratio, which is reduced in AIDS, because of reduced number of T (t4) helper cells. (actually, immunization seems to stimulate T4 cell numbers temporarily)	Harvard Medical School. Beginnings of Harvard's involvement in 'dys-information'.	from) the use of the vaccine. This is the vaccine developers' argument, that reports on adverse reactions to vaccines affects those individuals who are in need of immunization. It only deals with the commercial vaccine not with trial vaccines. Most importantly, it propagates the assumption that, if a hepatitis vaccine was contaminated with HIV, then it would be because a donor in the plasma pool might have been infected with HIV. Also, hepatitis non-A, non-B is not addressed.
	09	(RTSC) (US) Poiesz et al. (MMWR 1984:33, 685-7) Claim that hepatitis B vaccine is not contaminated.		
Dec. 1984	10	(RTSC) (US) Hilleman's (Merck) paper on new vaccine technologies (recombinant DNA) using yeast cells. Discusses hepatitis B vaccines; <u>experimental hepatitis included attenuation passage in marmosets</u> ; vaccine was tested in humans in 1984. Extent of use of commercial vaccines: 350,000 persons in the US (including health care personnel); 1,000,000 world-wide.	(RTSC) (US) Stevens (New York Blood Center) publishes data on anti-HBc as surrogate test (TTVS).	(RTSC) (US) Merck propagates the notion that its commercial vaccine was safe (i.e. did not propagate HIV-1), but offers no evidence to that effect.
1985				
Feb. 7, 1985	01	(RTSC) (US) Stevens, Taylor Rubinstein et al. (NYBC). US hepatitis B vaccine is not contaminated with HIV-1. (NEJM, 312:375-6)		(T) (US) Casual use of the term 'hepatitis B vaccine produced in the US'
TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
Feb. 7, 1985	02	(RSTC) (US) Dienstag et al. (co-workers of Jacobson) assert that the 'hepatitis B vaccine' is		(T) (US) Casual use of the term 'hepatitis B vaccine'

		safe.		
Feb. 7, 1985	03	(RSTC) (Greece) Papaevangelou et al. (<i>NEJM</i> , 312:376-7). Greece. Merck vaccines are safe (trial <u>and</u> commercial vaccines), do not transmit HIV-1.		(T) (US) Reference to specific commercial and trial lot numbers.
Beginning of 1985	04	END OF USES OF HEPATITIS B VACCINES FROM HUMAN SOURCES	(RSTC) (Canada) Feinman study on post-transfusion hepatitis in Toronto in progress; shows that post-transfusion hepatitis non-A, non-B is rapidly increasing in Toronto; program of issuing contaminated, non-heat-treated factor VIII concentrate to Canadian hemophiliacs.	END OF DEBATE ON CONTAMINATION OF HEPATITIS B VACCINES FROM HUMAN SOURCES

83/C/05

1983 UK: AIDS is not a problem. John Maddox, editor of *Nature*:

Amid the confusion, physicist John Maddox, editor of England's most distinguished scientific journal, Nature, penned an April editorial entitled "No Need to Panic About AIDS". "There is now a serious danger that alarm about the disease physicians call acquired immune deficiency syndrome (unhelpful, AIDS for short) will get out of hand," he wrote, "for the characteristics of this previously unrecognized and perhaps non-existent [emphasis added] condition are so alarming that the temptation to portray it as a disease invited by a decadent civilization – a kind of latter day version of Sodom and Gomorrah – is almost irresistible." Maddox denounced the pathetic promiscuity of homosexuals, calling it "the most obvious threat to public health". Dismissing AIDS as a disease that occurred among fewer than one thousand people, 70% of whom were homosexuals, Maddox berated alarmists adding that "mercifully, the disease – whatever its causation – is neither especially infectious ...nor certain in its effects." (Garrett, 1994:324).

This section of the critical path suggest that hepatitis B trial vaccines and the Merck commercial vaccine had been used all over the world, with assertions of safety, while the main study indicated that at least one lot of the Merck trial vaccine was not safe. At the same time, the vaccine developers in the vaccine producer countries suppressed surrogate testing of blood donors. By 1985, according to the Purcell paper,

and according to Hilleman of Merck, Sharp & Dohme, production non-engineered vaccines had come to an end. The Merck, Sharp & Dohme vaccine remained the only vaccine ever licensed (and as shown, should not have been licensed). The WHO played a central role in assuring the world that those vaccines were safe. The main inhibiting factor limiting a wider use of the vaccine mentioned by the WHO is that it was too expensive.

Proposals from a WHO programme for viral hepatitis were drafted last year by a consultative group. The report of the group was endorsed by the Executive Board, and a Technical Advisory Group on the WHO Viral Hepatitis Programme was established. The Technical Advisory Group, which comprises experts in clinical medicine, virology and epidemiology from each of the WHO Regions, met in Geneva from 2 to 6 July 1984 to review the programme and to advise the WHO on priority in services and research (The report of the meeting will be available upon request from the Virus Diseases Unit, World Health Organization, 1211 Geneva 27, Switzerland).

The group noted that safe [!] and effective vaccines [Emphasis by the author] against hepatitis B are already available and that vaccines against hepatitis A are under development. Vaccination of high-risk groups is at present practiced in many industrialized countries. The available vaccines are, however, expensive.

...[The Group] noted specifically, the need to increase production of hepatitis B vaccines on a regional basis, to reduce their cost to a level which developing countries could afford, and to support research into alternative methods of vaccine production. (WHO Weekly Epidemiology Record, 38:291)

Thus the group was recommending the production of vaccines from human sources in countries where there was already high incidence of non-A,non-B hepatitis, later recognized as hepatitis C. Fortunately, no licensed vaccines have apparently come from this recommendation.

All of the foregoing was shown to indicate that the hepatitis B vaccines of human origin had serious problems of viral inactivation, and that those vaccines had been used in many places all over the world, including Canada; that the vaccines was pronounced safe although the clinical trial evidence pointed in the other direction. Most of these observations are significant for the possible role of hepatitis B vaccines in the spread of hepatitis C. However, if such a serious inactivation problem existed (which could well have extended into hamster derived cells and vaccine production therein), then the presence of HIV-contaminated chimpanzee plasma could also have led to HIV contamination and transmission via such vaccines. While there is no positive proof that chimpanzee-derived raw material was used in the production of one or more trial vaccines, there is at least enough evidence to show that, if it had been used, it also could have been infective.

The AIDS/hepatitis B vaccine path of technical decision came to an end, along with the following events:

- 1) The likely vaccinated cohorts of people with AIDS had died, most of them probably by 1985;
- 2) By the end of 1984, production of hepatitis B vaccines from human or animal sources had come to an end;
- 3) In 1985 HIV-testing of blood donors was implemented in most countries;
- 4) In 1986 the US decided to use anti-HBc and ALT as surrogate tests.

However, the path shifted over to social constructions of the origins of AIDS, i.e. on the boundary between communal fields of contingencies and technology development research and communal contingencies. This path continues to this day. 1986 and the US decision can be viewed as the 'milestone' for this path (see path on surrogate testing).

The Gallo-Montagnier fracas. Gallo and Montagnier were both retroviral researchers. Shilts reports that by 1982, Gallo knew that AIDS was caused by a retrovirus, that he was frustrated, because the virus killed his cell cultures; and that he stopped the research because he did not like gays and their sexual practices. When in 1983 Barre-Sinoussi at Montagnier's lab isolated the AIDS-causing virus (and called it LAV-lymphadenopathy virus), Gallo still did not follow this track. Instead he pursued the HTLV-I track with Max Essex at Harvard. When in 1984 he 'discovered' HTLV-III, it was the Barre-Sinoussi isolate, and it was promptly accepted by the media that Gallo had 'stolen' the virus.

With this story one would have to accept that

- a) Gallo was not interested in a Nobel prize opportunity, because he was Italian and Catholic;
- b) He would commit scientific fraud, obviously and blatantly so;
- c) That he did not know until 1984 to keep the cell cultures alive.

The first assumption is the least credible one. The discontinuation of AIDS research at National Cancer Institute, NIH at the end of 1982 is rather consistent with the suppression of surrogate testing a year earlier by the National Heart, Lung and Blood Institute, NIH. But by 1984, serious questions could have been asked as to what was going on at the NIH, and some 'proof' that he really had not discovered the cause of AIDS earlier was needed. The best method was to 'steal the virus' from lymphatic tissue material from Montagnier's laboratory and gave a different name: HTLV-III. To this day this is the accepted story (except Horowitz, 1996). The fact that the NIH suddenly had enough virus cultured to supply six commercial manufacturers to develop HIV-tests undermines these claims.

Notes on 'dysinformation':

The 'Roswell industry': In 1947, some aero-space experiment near test sites in New Mexico had gone wrong, and something crashed near Roswell. After the initial stories, an alien landing story was propagated. This story became a fixed belief, once it was enhanced with a government cover-up. While the government wanted to cover up something, it surely was not aliens. Ever since there has been industry catering to those who believe in alien landings, and to those who believe in the government cover-up of those landings.

Robert Gallo: Gallo's behavior suggests that he was proceeding with AIDS research in secret, and hence the story of him being the son of 'Catholic Italian' parents, not liking gays and not being able to keep cell cultures alive. This story became more believable, once reports came out that he 'stole' Montagnier's (LAV) virus isolate and presented it as his own discovery (HTLV-III). After that nobody (except Horowitz) doubted that he had not been able to isolate the virus earlier.

The Krever report, the issue of non-heat-treated Factor VIII when heat-treated Factor VIII was already sitting on the shelf. It seems incredible that for several years managers, administrators, scientists and bureaucrats would withhold measures that could have made blood transfusion therapy safer during the AIDS crisis, just because they were preoccupied with costs or were 'greedy': **After the contaminated, heat-treated Factor VIII had been issued in Canada in 1985, 'there could not be any doubt' that this indeed was the case.**

These examples suggest that, if something very serious has gone wrong that needs to be covered up, a tactic may be used which promotes something that is obviously unethical even to the simple-minded, and can easily be spread in public awareness. The 'dysinforming parties' are willing to be attacked on the 'lesser evil', while public attention is diverted from the more serious problems.

Another strategy of dysinformation is trivializing adverse side-effects. The Merck hepatitis A vaccine trials Phase 1 (probably 1984) (Hilleman, 1984) included an attenuation passage in Marmosets and is described as follows:

The vaccine induces antibody in nearly all persons after a single parenteral injection without important adverse effect other than transient elevation in serum enzyme levels in some recipients.

This sort of casual, virtually meaningless, reporting was typical of phase 1 and 2 trials of hepatitis vaccine in the US (with the exception of the Krugman trials on the Willowbrook children). *'Transient elevation in serum enzyme levels in some recipients'* (which ones?) is similar to the casual reports on hepatitis non-A,non-B in vaccinated trial participants in the Merck/New York trial on gay men. Timing and phasing of the human trials indicate that these hepatitis A trial vaccines were not linked to the spread of HIV-1 or HCV before 1986. They are mentioned here mainly to show:

- 1) That despite a growing knowledge about Simian viruses, Simian passage was continued;
- 2) How poorly reported early human vaccine trial results still were in 1984 (the animal experiments had been published in 1983: Provost et al., 1983; Hilleman et al., 1983).

CRITICAL PATH 1986-

In 1984, the propaganda machine of the religious Right in the US had focused on gays in the US and in Europe. In 1985, with the advent of HIV testing, the attention shifted to Africa, with attempts to construct a mechanism by which AIDS would have started there and then radiated into the US and into Europe. Ever since, however, the mechanism by which AIDS was spread into US and European gay populations, and into heterosexual populations into Haiti, has remained unexplained. The strategies of **'relocating the origins of AIDS' from the US into Africa** were accompanied by a **'pandemic of theories of AIDS'**. The sole focus on Africa amongst 'reputable' theorists (such as Harvard University) put into question the motivations of at least some of the 'theorists.' In the same vein, the large number of early cases in France, Belgium and Switzerland with the origin of infection 'unknown', (in particular in Belgium) (75% unknown, 15% gay) is highly suspect, to say the least. This section of the critical path overlaps somewhat with the previous section and begins in 1985. The **'gay disease'** and the beginnings of the **'out-of-Africa'** theory have been addressed in the preceding section sections of the critical hepatitis B vaccine path. For the most part this section of the path does not deal with vaccines at all, but with AIDS and its social construction. If we assume, however, that much of this 'constructing' was strategic to divert attention away from vaccines, then this section is very much part of the 'critical path' of the hepatitis B trial vaccines.

TIME	R O W	A. CRITICAL PATH	B. MATERIAL CONTINGENCIES	C. 'SOCIAL CONSTRUCTION' CONTINGENCIES
1985				
	01		(T) (US, Europe) HIV testing implemented in North America, Europe	
	02			(E) (Global) 1985: New Zealand: AIDS like scrapie, Kuru and Creutzfeld-Jacob disease. (Garrett, 1994:323)
	03			(E,C) (Africa) 1985: Central Africa: Juliana's disease, slim disease, witches, whores, girls' disease, boys' disease, Vinidogodogo (a very little thing): 'injectionists' using dirty needles; reuse of needles in hospitals; AIDS is a heterosexual disease. (Garrett, 1994)
	04			(E,T) (Africa) 1985: National Cancer Institute: 25-80% of Ugandans infected in 1972/3. Later found to be a laboratory problem, and false: ('sticky sera', caused by malaria, leishmania etc.). (Garrett, 1994:352)

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1985	05		1985, Essex, Harvard: Simian HTLV-III in vervets and macaques. Therefore, AIDS started out as African monkey disease, and only recently through means unknown entered into human populations (Garrett, 1994:353)	(E,C) (Africa) 1985. US. Africans have sex with monkeys. American journalists question a delegation of Zairian doctors: (Garrett, 1994:353).
	06			(E) 1985: AIDS is spread by mosquitoes (but in the early days children rarely had AIDS.) (Garrett, 1994:357).
	07		The official line in the WHO first announced by Assad in 1985, would remain the Agency's position in 1994: AIDS emerged simultaneously on at least three continents. (Garrett, 1994: 361-2).	(E) (Africa, US, Europe) 1985, US, Anti-African hate campaign, and vice-versa against American and European 'Safari science'.
	08			(O) (US) 1985 Purpose is not to pinpoint the source or to cast blame (Darrow, sociologist at the CDC). (Garret, 1994:364, quoting Darrow).
	09			(C) (US) 1985 'First infections cannot be traced. [By 1985 most of the 'first cases' would have had died]
	10			(C) (Africa) 1985: National Cancer Institute: 25-80% of Ugandans infected in 1972/3. Later found to be a laboratory problem, and false. ('sticky sera', caused by malaria, leishmania etc.). (Garrett, 1994:352)
1986			Publication of NIH data on the use of anti-anti-HBc as surrogate test (Koziol et al. Ann Intern Med 104:488-95)	
	01		US implements surrogate testing (ALT, anti-HBc) of donated blood and plasma.	
1987				
1988				

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1989				
	01			(C) (US) The 1988-1990 public opinion poll: (Stephen Thomas and Sandra Crouse-Quinn): African Americans: suburban Washington, Atlanta Detroit, Kansas City and Tuscaloosa - members of church congregations: 65% agree or not sure that AIDS was produced to commit genocide on Africans. Many believe it was produced in a germ-warfare laboratory. (Garrett, 1994)
1990				
1991				
1992			(E,C,O) (US, Africa) The monkey meat-model: AIDS-like syndromes were observed in laboratory macaques, in the US, which were later identified as HIV-2. HIV-2 was found virus in healthy, middle-aged, Senegalese prostitutes. In 1992, two lab workers at the NIH were infected with by HIV-2 (bites, needle-sticks and scratches). The same strain is found in the sooty mangabey which are the natural reservoir of HIV-2. Habitat of mangabeys matches the spread of HIV-2 in West Central Africa). Pygmies have them as part of their diet, but showed no signs of infection with HIV-2. Garrett, 1994:372). Studies in Liberia suggested do occur. (Garrett, 1994:374-6)	
			(E) (Africa) 1990 Pasteur Institute found HIV in two out of 83 wild Gabon chimps (Garrett, 1994:377)	(E) (Global) Laurie Garrett: the ecological mess argument. In the Harvard publication: AIDS in the World (1992, Mann et a. eds.)

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1994				
				(E) (Global) Laurie Garrett: More ecological mess argument <i>The Coming Plague</i> , 1994)
				(E) (Global) 1994: Laurie Garrett: <i>Though it had been the focus of attention of some of the greatest minds in contemporary biomedical medicine on at least four continents, nobody by 1994 had yet pinpointed a time, place or key event responsible for the emergence of HIV-1.</i> (Garrett, 1994:289)
1995				
1996				
				(T, O) (US) Horowitz: Fort Deterick and the engineering of viruses to destroy African populations.
1997				
1998				
1999				
			(E) (Africa) Gao et al. Wild chimpanzees in West Central Africa are the natural reservoir for HIV-1.	(E) (Africa) More bushmeat theory.

Notes

85/C/05 1985, US, Africans have sex with monkeys. American journalists question a delegation of Zairian doctors:

"We have all heard what Max Essex said here about AIDS originating as an African monkey disease. Tell me doctor, is it true that Africans have sex with monkeys?" Response: "Madam, I don't know what you are talking about. We don't do these things. But I believe in Europe they make movies where women have sex with dogs. And I've also heard that in the US there are all these dogs as pets at home, and that they sometimes, well, you know what I mean....." (Garrett, 1994:353).

85/C/07 1985, US, Anti-African hate campaign, and vice-versa against American and European 'Safari science'.

Because of the legacy of blame, accusation, and exaggeration, concerning AIDS in Africa it was impossible to have an apolitical, "pure science" discussion of the origins of the human immunodeficiency virus during the 1980's. ...there would remain in the 1990's a decided timidity in AIDS academic and policy circles about broaching the subject of the origins of the AIDS pandemic. The official line in the World Health Organization, first announced by Assad in 1985, would remain the Agency's position in 1994: AIDS emerged simultaneously on at least three continents. (Garrett, 1994:361-2. Emphasis by the author).

Shunning the subject, some scientists would simply say: "Well, it does not really matter, really [where AIDS came from]. AIDS is here, the pandemic is spreading all over the planet. Let's deal with the here and the now. What's past is past." Or as Zambian President Kenneth Kaunda put it in 1987: "What is more important than knowing where the disease came from is where it is going." (Garrett, 1994:362).

Unfortunately, to protect themselves from potential lawsuits brought by people who acquired AIDS as a result of transfusions or use of plasma products, many European and American hospitals deliberately destroyed old records and blood samples. [Confirmed by a former colleague of the author in Europe. When a new chief of a hemophilia treatment center was appointed in the early eighties, he first of all destroyed all the records and stored blood samples. The author's colleague, who had been investigating AIDS in hemophilia had her career terminated]. Under US law they were required to maintain such records and samples only for 5 years, and in 1986 hospitals and blood banks began actively shredding their pre-1982 paper trails and purging computer files. By allowing such wholesale destruction, the US government condoned elimination of a crucial set of clues in the AIDS mystery. [Emphasis by the author].

85/C/08 1985 Purpose is not to pinpoint the source or to cast blame (Darrow, sociologist at the CDC). However:

We found that the earliest cases included gay men involved in international travel. It is impossible to conclude that any of these men are responsible for introducing the virus to the United States. In fact, the virus may have evolved or arrived in some other way. Our purpose is not to pinpoint the source or to cast blame, but to show that social conditions in the mid-1970s provided a unique opportunity for the introduction and transmission of an insidious and highly fatal viral disease. (Garret, 1994:364, quoting Darrow of the CDC).

Since international travel seemed to be a key contingency for the spread of the epidemic, is hard to believe that the interviewers of those gay men did not ask the

questions what these gay men were doing there – and other circumstances. Actually, Bill Darrow's comment points away from Africa and in the direction of vaccines. Apparently Bill Darrow did not feel comfortable at all with the 'OUT OF AFRICA' theory.

85/C/09

1985 'First infections cannot be traced.

Given the numbers of sexual partners many gay men had prior to becoming infected with HIV, it was considered nearly impossible to trace the epidemic back in time through that population. Researchers could never know who gave the virus to whom and when. [By 1985 most of the 'first cases' would have had died]

This comment stands in stark contrast with the earlier observations and comments made by Bill Darrow. (Bill Darrow was the sociologist of the CDC who confirmed the sexual transmission of the AIDS agent.)

ADDITIONAL NOTES

Sporadic cases

The case of the Danish surgeon Margrethe Rask, working in rural Zaire. She died in 1977 of acute immune deficiency. (She could have been part of vaccine experiments around 1975, which also caused AIDS in some rural regions in Zaire and the Southern Sudan). (Garrett, 1994:365).

The case of a Norwegian sailor who died of AIDS like symptoms in 1966. Over the next ten years his wife and one of his three children, born in 1967, died as well). (Garrett, 1994:365).

Note: These cases do not fit the vaccine theory. The others either fit (like Dr. Rask's case, or they encountered verification problems after the release of the initial report). This case contradicts the vaccine model. However, by itself, it does not disprove it. Infectious diseases often show both: 'epidemics', i.e. mass-infections; and 'sporadic cases,' i.e. isolated cases of infection. There are probably many different ways in which sailors could have been infected by chimpanzees. Even very recently, dozens of chimpanzees were used in Spain for entertainment and advertising purposes, some of which have been rescued with the help of Jane Goodall, and moved to chimpanzee rehabilitation centers. So far, however, no new cases of HIV-1 infections have been reported as a result of these activities. None of the early cases can be shown to be linked to the massive outbreak of the

pandemic in 1978, or even the 'lesser' outbreaks in 1971/2 in the US; and in 1975/6 in Zaire and the Sudan.

The case of the sailor that died of AIDS in New York City in 1959. No blood or tissue specimens could be tested (Garrett, 1994:364).

The case of the Manchester sailor who died of AIDS-like symptoms in 1959. (Garrett, 1994:365). This case was invalidated (Horowitz, 1996).

The Greek fisherman (Lake Victoria) who had died of AIDS in 1978 tested positive for HIV. He fits into the group infected around 1975. (Garrett, 1994:364).

St. Louis, 15 year old boy (Robert R.) died of AIDS in 1968. *No specimens.* Garrett, 1994:364). Later invalidated.

The Leopoldville specimen. Max Essex's group at Harvard, together with scientific teams from Emory University, Duke University, and the University of Washington tested 1213 samples collected between 1959 and 1982 in Zaire, Congo and South Africa and Mozambique; one 1959 sample repeatedly tested positive for antibodies to HIV. The test was never independently confirmed (Garrett, 1994:371).

The vaccine dispute:

Laurie Garrett does not discuss the issue of hepatitis vaccines in the body of information on various vaccine theories, but much earlier and only very briefly (two lines).

Polio vaccines (Lederele, distributed in 1977. Determined to be AIDS free. (Garrett, 1994:381) **Polio vaccines were used in 1977 by homosexuals to treat herpes.** (Garrett, 1994:381). It was also used on Polish school children in New York. No HIV-transmissions related to these vaccinations could be found.

Small pox vaccination activated AIDS: discredited (Garrett, 1994:381)

Small pox virus plus bovine leukemia virus recombining: discredited. (Garrett, 1994:381)

Dr. John Seale: HIV was produced at Fort Deterick (biological weapons development (bovine leukemia virus plus Visna (sheep) plus horse and goat lentiviruses, plus HTLV-1). Led to a KGB campaign against the US. However the reverse also took place. (Garrett, 1994:382)

Dr. Robert Strecker: '*Strecker memorandum*,' HIV is an engineered combination of viruses (Garrett, 1994:382).

Other theories

Harvard and Gallo, NCI: Haitian guest workers in Zaire brought the virus to the US. (They worked there from 1960-1975) (Garrett, 1994:365). The time between the last cohort of workers and the first cases is too long: the first one in 1979), the first cohort peaked in 1984 – it should have peaked in 1981 (median of 6 years interval between infection and AIDS symptoms. (Garrett, 1994:365). **Late seventies in Africa:** Levy: No HIV in Central Africa before 1975. Garrett, 1994:367)

Clades and ‘Big bang’: (genetic differences of less than 20%) Most lethal clade (D) found only in Tanzania, Rwanda and Uganda (‘epicenter’ of African epidemic). AIDS mutates at rate of 1% per year. Europe and US had mostly type B. (Garrett, 1994:377-8).

North-Korea blamed South Korea for producing the virus (Garrett, 1994:383)

Sir Fred Hyle and Chandra Wickramasinghe, British astronomers announce that AIDS came from outer space.

UC Berkley: Peter Duesberg: HIV has nothing to do with AIDS. Self-destructive gay life-style. 1981: Gay disease. GRID – Gay-related immunodeficiency disease (CDC, 1981): ‘GRID is the result of microbial overload of gay men’ (i.e. too many infections)’ (Sonnabend, in Garrett, 1994:292). Something similar was later suggested for changes in the immune system in hemophiliacs; and Duesberg elaborated this non-viral theory. Amylnitrite (poppers) are responsible (they do result in a mild immunedepression; Garrett: 1994:296). It is still believed by some, including an HIV-positive mother who insisted on breast-feeding (recollection from CNN broadcast). The ‘popper model’ was disproved by Bill Darrow, the CDC sociologist (he also proved sexual transmission; Garrett, 1994:304).

Dr. Anthony Pinching, St. Mary’s Hospital Medical School in London: HIV had been dormant in some remote African village in humans, through people movement it was spread into the cities (perhaps in reference to the prostitute from Yambuku working in Kinshasa).

1982: Haitian Virus (1982, National Cancer Institute): Outbreak of AIDS amongst Haitians in Port-au-Prince, New York, Miami and Montreal. ‘Haitian virus’ brought back by gays vacationing in Haiti (Garrett, 1984:307).

3.5 THE CRITICAL PATH OF HEPATITIS B VACCINES/ HBIG AND THE SPREAD OF HCV IN CANADA.

The path of the relationship between hepatitis B vaccines and HCV infections follows the initial path of the relationship between HIV-1 infections and hepatitis B vaccines. However, the indirect evidence for hepatitis B vaccines having spread hepatitis C is not as clear as it is for AIDS. The available indirect evidence points to the New York Blood Center vaccine as the most likely culprit in the origins of AIDS. In the case of hepatitis C, several vaccines may have been contaminated with HCV; and besides the vaccines, hepatitis B immunoserum may also have been contaminated with HCV (or even with HIV-1). HBIG, hepatitis B immunoglobulin, was used for passive immunization, for instance, in babies of hepatitis B positive mothers. Other gammaglobulin products such as those used for Rhesus prophylaxis may also have been contaminated.

The spread of HCV is difficult to investigate, because, unlike HIV-1, it had been spread in human populations for a long time. In the US and Europe, intravenous drug use and needle sharing had been a major mode of propagation. In Third World countries, unsterile injection practices had been a major mechanism of propagation. Furthermore, the AIDS pandemic, and the attention it generated, eclipsed the attention given to HCV (then known as hepatitis non-A, non-B). Hepatitis B vaccines briefly entered the AIDS debate, but not into hepatitis C debate.

The path for hepatitis B vaccines and spread of hepatitis C remains sketchy at best, and is, therefore, not developed as fully as the path for the vaccines in relationship to AIDS. The following is a collection of observations and notes concerning this link. It must be remembered, that this not about establishing proof that the vaccine had caused AIDS or hepatitis, but to establish whether there is a *prima facie* case to investigate the possibility that HCV was spread by trial or commercial hepatitis B vaccines.

The position of hepatitis C in the field of hepatitis infections and their causes.

Hepatitis is considered a '*disease of antiquity*' (Kellner 1985; Krever 1997:613), and is mentioned by Hippocrates. Hepatitis A has a predominantly fecal-oral route of infection and leads to epidemics from time to time. Hepatitis B is sexually transmitted as well as 'blood-routes,' saliva and any other bodily fluids. Ludwig van Beethoven, for instance, died from the sequelae of hepatitis (cirrhosis of the liver), which he allegedly contracted though intercourse, a circumstance which led him to remain a bachelor for life. It is a major problem today amongst sexually active young people (teenagers) and sexually active homosexuals. The first 'blood-route' ever known was related to vaccinations: an outbreak in 1883 in Bremen, Germany, where factory workers were vaccinated against small pox; 30,000 cases as a consequences of yellow fever vaccinations in the US

military in 1941; other outbreaks occurred as a results of measles and mumps vaccinations. (Krever, 1997:612-3). In addition, during WWII, pooled human serum was used as blood volume expander and led to additional outbreaks of hepatitis. **Hepatitis has been a hazard for medical personnel and patients** (such as, for instance, in hemodialysis units). A prominent victim of disease was **Dr. Henry Norman Bethune** (1890-1939), a Canadian thoracic surgeon who first worked with the Communist forces in the Spanish Civil war, where he organized the first mobile blood-transfusion service, and later in China. In China he is viewed as a hero, because of a memorial essay written by Mao Zedong. He became infected from a small cut during a surgical procedure. The author's teacher, Prof. F. Wewalka, also died from hepatitis B, after a small scratch with liver biopsy needle. The author became infected with hepatitis B as a result of his laboratory work with hepatitis B-contaminated material.

In developing countries and amongst intravenous drug users hepatitis B was spread though the use of unsterile syringes and needles. However, other practices, such as tattooing, or circumcision, may play a role as well, and because of its transmissibility via saliva, shared dinnerware may became the conduit of infection. Once a significant portion of a population is infected, the main transmission occurs from mother to child, before, during or after delivery. Transfusion of blood and blood products became a major route of transmission during World War II: any other route of transmission may be extended further by donors of blood an plasma, and also by organ donors. Transfusion-related hepatitis has been the main side-effect of blood transfusions as soon as they had been integrated into clinical practice. Because of the connection to the use of human serum in vaccines, and to the use of serum in early transfusion practice, the term 'serum-hepatitis' was coined. ('*Homologous serum hepatitis*', editorial in *The Lancet* , Nov. 8, 1947:691). The terms hepatitis A (for 'infectious hepatitis', mostly affecting children through oral transmission) and hepatitis B (for 'homologous serum hepatitis') were proposed by O.F. McCallum at an International Congress of Physicians in 1947.

Hepatitis non-A,non-B, hepatitis C. Hepatitis A, B, and other types of hepatitis could not be specifically differentiated from hepatitis B until the discovery of hepatitis B surface antigen (HbsAg) by **Baruch Blumberg** in 1965 (for which he received the Nobel Prize) and its application to donor screening by **Alfred Prince** (1968). Once hepatitis A was identified and specific tests developed (**Feinstone**, 1975), the remainder was referred to as 'hepatitis non-A,non-B'. As of 1989, since the development of a specific test systems for hepatitis C (**Choo et al.**, 1989), all remaining hepatitis is referred to as hepatitis non-A,B,C. Additional agents discovered are given a capital letter (following 'D', see note below). Hepatitis C is mainly spread through injection or similar routes of infection, i.e. today mainly through intravenous drug-use. **Hepatitis D, 'Delta agent'** (HDV) is an incomplete virus which is pathogenic only as a co-infection or super-infection of hepatitis B virus infections. As **co-infecting agent**, it often leads to **fulminant hepatitis** (with lethal outcome). As **super-infecting agent** in hepatitis B virus carriers it tends to promote **chronic hepatitis**. Evidence of its presence has been found in immuneserumglobulin samples of 1944 in the US. It is mainly spread amongst intravenous drug users and their sexual contacts. Its association with outbreaks of

fulminant hepatitis amongst intravenous drug users has been demonstrated in an outbreak in Worcester Massachusetts in 1984 (WHO *Weekly Epidemiological Record*, 1984, 51/52:393-4; based on US CDC *MMWR (Morbidity and Mortality Weekly Report)* 1984, 33, No. 35). A similar occurrence has been observed by Don Francis of the CDC in 1980 in New Bern, North Carolina (Garrett, 1994: 280).

Primary liver cancer. Both hepatitis B and C can lead to chronic liver disease, some of which may develop into hepatocellular carcinoma (primary liver cancer). This cancer affects mostly males, and is common in Asia and Africa. Together with Epstein-Barr virus (EBV, a virus of the herpes group of viruses) which causes Burkitt's lymphoma in African children and nasopharyngeal cancer in Asia, hepatitis B virus was one of first identified human oncogenic (cancer-causing) viruses. Hepatitis is a world-wide problem. On a global scale, hundreds of millions of people are carriers of hepatitis viruses, and in the order of 1 or 2 billion may have markers of hepatitis infections. Hepatitis is a significant cause of death, through acute liver failure, chronic liver failure or hepatocellular cancer. **Hepatitis A** is mainly associated with poor hygienic conditions. **Hepatitis B** is a venereal disease, but also associated with poor medical and public health practice (unsterile syringes, needles, vaccines, blood products); and cultural practice (tattooing, piercing, scarring, circumcision, acupuncture, 'injectionism'. Intravenous drug use.) **He-patitis C** is a iatrogenic/nosocomial disease, i.e. propagated through medical procedures involving breakage of skin and unsterile syringes, needles and products such a blood products; and secondly through intravenous drug use (also via unsterile syringes and needles).

Hepatitis B and AIDS are similar in their epidemiology; whereas hepatitis C is rarely propagated sexually, and practically never through casual, non-sexual contact (unlike hepatitis B). Thus the spread of hepatitis B and C (and after its initiating introduction, HIV-1) were **amplified**, to different degrees in different locations, as **iatrogenic/nosocomial diseases of modern civilization**, which then could be propagated further through cultural practices and general social conditions. The origins for hepatitis B and C are unknown, the origins of HIV-1 and HIV-2 infections are a matter of analysis and discussion in this dissertation. Once propagated, **mother-to-child transmissions** become highly prevalent, in particular for HBV and HIV-1. The very same capabilities and processes which enable Western civilization to invent more and more means of fighting infectious diseases, also create conditions under which old diseases can be propagated and new disease can enter into human populations (see Garrett, 1994). So far, this seems to be a losing battle, a circumstance of which politicians of the capitalist market economy are either ignorant or in denial. HIV-1, HBV and HCV are just three examples of this phenomenon. No cure has been found for any of the three infections, and preventive immunization is effective only for hepatitis B, not for HIV-1 and hepatitis C.

The following graph is an overview of the global problem of hepatitis B, C and hepatocellular cancer. Because of the different epidemiology, the distributions differ. The distribution of hepatocellular cancer is a composite of distributions of hepatitis B and C. The distribution of HIV-1 in Africa follows the pattern of hepatocellular cancer, and a

sexual (hepatitis B-type) propagation pattern. The maps have been developed from material in Mann et al. (eds.), 1992; Cohen (1999) in *Science* 28; and Maupas et al. (1978).

Fig. 15.: Sketches of global distributions of HIV-1 infection, hepatitis B, hepatitis C, primary cancer of the liver and schistosomiasis. HIV-1 follows the distribution of hepatitis B, and a possible vaccination program. Hepatitis C follows the pattern of schistosomiasis and its intervention program. Cancer of the liver distributes along both, the pattern of hepatitis B and C. The map provided by Mann et al. (1992, Fig. 2.28, page 80) on HIV-1 in Africa is derived from data of the Center for International Research, U.S. Bureau of the Census.

In the following table the main forms of hepatitis (A,B,C) are characterized.

Characteristic	HEPATITIS A	HEPATITIS B	HEPATITIS C
VIRUS	RNA-virus (enterovirus of the Picorna group).	DNA-virus (hepa-dna viruses, similar to viruses affecting woodchucks, ground squirrels and Peking duck).	RNA-virus (Flavi viruses, similar to bovine diarrhea, hog cholera, yellow fever)
CARRIER STATE	NO	YES	YES
GLOBAL PREVALENCE OF CARRIERS (reservoir)	Reservoir ?	250,000,000 (HIV-1 appr. 40 mill.)	170,000,000
MODE OF TRANSMISSION	Feco-oral Blood-to-blood (unusual)	Sexual (very common) oral; blood-to-blood: transfusion; unsterile needles, syringes, tattooing, acupuncture, etc. folk-medicine, public health campaigns, mother-to-child	Sexual (rare, if at all; Alter, NIH). Blood to blood, mostly unsterile needles etc., and blood transfusion. Folk-medicine; Public health campaigns; 6% of babies born by pos. mothers
INCUBATION PERIOD	2-6 weeks mode: 4 weeks	4-26 weeks mode: 12 weeks	3-8 weeks mode: 6 weeks?
COURSE OF DISEASE Fulminant Acute hepatitis Transient, subclinical hepatitis Recovery Chronic hepatitis Cirrhosis H.C. Carcinoma	Rare Most Close to 100%	<1% 35% 65% >95% <5% 1% ?	Rare Most 20% 80% 10-15% 1-5%
DIAGNOSTIC SEROLOGY	Anti-HAV	HBsAg HBcAg HBeAg Anti-HBs Anti-HBc Anti-HBe DNA polymerase	Anti-HCV

Table 15: Hepatitis A,B,C. The most critical features of epidemiology and natural history of the three main types of human hepatitis are compared.

THE QUESTION WHETHER HEPATITIS NON-A, NON-B SHOULD HAVE BEEN CONSIDERED A SERIOUS DISEASE IN 1981.

	Acute, fulminant	Acute, surviving fulminant	Acute viral hepatitis	Developing chronic aggressive hepatitis
Hepatitis A (adult)	6	?		
Hepatitis B	41	14 (34%)		
Hepatitis non-A, non-B (not transfusion-related)	?	?		
Rakela and Redeker (1978)			70	0 (0%)
Post-transfusion hep. non-A, -B				
Koretz, 1976			29	(est. 31%)
Knodell, 1977			44	9 (20.4%)
Rakela and Redeker (1978)			17	4 (23%)
Hep. A, plus Hep. NANB	26	3 (12%)		

Table 16: Knowledge of serious consequences of hepatitis non-A, non-B before 1981. Redeker (1978, in Vyas et al., 425-429) fulminant hepatitis in 1% of cases of acute hepatitis; 75-80% of fulminant cases die.

In 1978:

- 3 years before the US and Canadian decision not to use surrogate testing;
- the year of the beginning of the Merck trials of its experimental vaccine;
- the year that the Canadian Red Cross began to ship plasma to Cutter in the United States to produce Factor VIII concentrate;

the following was understood:

- 1) In comparison with hepatitis B, fulminant and lethal outcome may be three times more frequent for hepatitis Non-A, non-B;
- 2) In comparison with hepatitis B, transfusion-related hepatitis non-A, non-B may be a five-times more likely to result in chronic hepatitis (including portal hypertension, an effect of chronic inflammatory and scarring processes on the hepatic circulation system);
- 3) At least two viruses may be involved in hepatitis non-A, non-B, one more related to transfusion, and the other being propagated through some other route. Only the transfusion-related cases had serious chronic outcomes, and one might have assumed that a portion of the transfusion-related cases was due to infections through non-transfusion routes of transmission. (Similar observations were made by Stevens et al, 1984, and confirmed by Blajchman et al., 1995)

The early findings on hepatitis non-A,non-B were serious enough to have warranted moratoria on the wide-spread use of hepatitis B trial vaccines and Factor VIII concentrate, and to call for a more cautious use of all of the blood products. However, at that time, both, the vaccine industry and the plasma fractionation industry, forged ahead with their product marketing strategies, without any attempt by the FDA (or the Health Protection Branch of Health and Welfare Canada) to intervene.

These early studies on the seriousness of hepatitis non-A,non-B are not addressed in the Krever report. Harvey Alter's, in his 1985 paper presented at the 1984 American Red Cross symposium on blood-transmissible diseases, mentions only the 1977 Knodell study, built on the early results by Koretz and Rakela.

Redeker (University of Southern California, Liver unit) 1978: *It appears that post-transfusion hepatitis non-A,non-B is a problem with serious long-term consequences.*

Alter, National Heart, Lung and Blood Institute, NIH) 1985: *an "astounding" number of acute NANB-PTH cases progress to chronic hepatitis (quotation marks by the author).*

Krever 1997 (p. 635-6): *According to both Dr. James Mosley, a U.S. hepatitis expert and co-investigator of the TTV study, and Dr. Thomas Zuck, a blood banker and former senior official of the U.S. Food and Drug Administration, both of whom testified at the hearings, the main reason that the U.S. blood-banking industry did not introduce ALT testing in the early 80's was that it did not recognize that non-A,non-B hepatitis could produce serious clinical disease in large numbers of persons. Dr. Zuck said that the reason ALT testing was not instituted was not because the data from the TTV study were wrong; "It [was] because we really didn't believe it was a serious disease." This was a commonly held view in the early 1980s. Dr. Harvey Alter, the principal investigator in the NIH study wrote in 1980, for example, that "[a]lthough recognition of non-A, non-B hepatitis has been a relatively recent event, a characteristics, though not pathognomonic [indicative of disease], clinical pattern is beginning to emerge." An editorial in the 11 July issue of the The Lancet said:*

Although regular users of blood products do get chronic liver diseases which is probably due to non-A,non-B agents, there is not much information about the long-term consequences of subclinical hepatitis after a single transfusion episode. In the U.K. there is no report about long-term follow-up of transaminitis patients. (Note: 'Transaminitis' is a pejorative term describing some kind of presumed harmless disturbance of the liver; it has no place in scientific argument.)

Despite the controversy about ALT testing, some blood centers decided to implement the tests routinely. The New York Blood Center, a participant in the TTV study, began routine ALT testing of all donation in 1982. An explanation for that decision, given by Dr. Johanna Pindyck, the Director of the Greater New York Blood Program, appeared in the Journal of the American Medical Association:

.....particularly if one considers that many of those who contract NANB hepatitis will go on to have chronic liver disease.

At the same 1978 San Francisco, meeting, where Redeker presented his non-A,non-B hepatitis data, there was also a preliminary presentation of the TTV study by Aach et al. on surrogate testing (results from observations between July 1974 and December 1976). The early estimates of disease and epidemiological parameters of hepatitis non-A,non-B pattern of these observations never substantially modified by subsequent studies, including the Canadian Study conducted almost 20 years later.

Attack rates:

- Overall: 12.6%
- George Washington University: 5.4%
- UCLA: 18.5%
- Hepatitis occurred in 3.4% of recipients who received donor units with normal ALT values in contrast to 38.9% among those given a donor unit(s) with elevated ALT.

The knowledge concerning the incidence and seriousness of hepatitis non-A,non-B in 1978 can be summarized as:

- On average, 10% of all transfused patients are infected with hepatitis non-A,non-B;
- A portion of that may not be transfusion-related;
- The transfusion-related hepatitis cases have a least a 25% or much higher chance of developing chronic liver disease (with including proven changes in portal blood pressure);
- In the US, that would have meant in the order of 100,000 cases of transfusion-related chronic liver disease every year;
- A substantial portion could be prevented with using ALT as surrogate test for hepatitis non-A,non-B.

Bill Mosley was not only co-author of the TTV study but also co-author of the Rakela and Redeker study. Therefore his testimony seriously misled the Krever Inquiry. Thomas Zuck, formerly of the FDA, misled the inquiry by pretending that the thrust for not using surrogate testing came from blood bankers, when in fact it came from the FDA, the NIH and the military. The problem was well known in quantity and seriousness of consequences, and at a meeting in early 1981 blood bankers in Atlanta were actually getting ready for surrogate testing. Mosley's and Zuck's presentations also contradict the rationales of the ad hoc group on ALT testing (Alter, Barker, Gerety, Bove etc.), which were formulated as 'scientific and economic uncertainty'. Mosley and Zuck were giving ad-hoc justifications to the Krever inquiry, not explanations.

The possible role of hepatitis B vaccines in the spread of HCV.

The Merck Sharp & Dohme hepatitis B trial vaccines are possible candidates for the spread of HCV. There were at least 200,000 doses of a trial vaccine, such as those used in the New York trials; there were several million doses of a commercial vaccine, the only vaccine ever licensed. In 1982, the main safety concern regarding the Merck commercial vaccine in professional circles was hepatitis non-A,non-B transmission, not HIV-1 transmission. At a meeting on viral hepatitis in 1982 in Munich, Merck (and the FDA through Gerety) tried to prove safety of the commercial vaccine by showing that the inactivation procedure used in the manufacturing of the Merck commercial vaccine inactivated a number of known viruses, and concluded that it, therefore, also inactivated unknown viruses responsible for hepatitis non-A,non-B. This was an unacceptable, if not unethical logic, in particular since the Szmuness report (1980) contained data suggesting the possibility of hepatitis B vaccine-related hepatitis non-A,non-B transmission. The Merck trial vaccines are also suspect because of:

- 1) A generally very poor disclosure of Merck's manufacturing specifications (source material, purification, inactivation). The first detailed disclosure which the author could find was in 1982 at the symposium in Munich, where apparently serious questions on hepatitis non-A,non-B were raised;
- 2) A gradual escalation of the Merck inactivation protocol: from formaldehyde, to formaldehyde + pepsin, to formaldehyde + pepsin + urea.

The Merck commercial vaccine was the only licensed vaccine ever commercially distributed in North America and outside. While the commercial vaccine (or perhaps most lots) may have been safe, the Merck trial vaccine may not have been safe. Merck would have been left with most of its 200,000 trial doses after the clinical trials in the US (the NYBC trial, the Merck/CDC trials). The trial vaccine did not have the same inactivation protocol as the commercial vaccine (lacking the urea step). Thus it seems that one or more lots of this particular trial vaccine source could have had a significant impact with respect to the spread of HCV, at least in some countries (such as perhaps Canada, the United Kingdom and Germany).

No assumption is made here that any of these vaccines were contaminated with HIV (despite the questionable conduct of the vaccine test mentioned in the AIDS/vaccine path). Since there is no trace of a formal trial on the commercial vaccine known to the author other than the report from Greece, any investigation concerning the Merck vaccine used outside of the US would fall under the category of 'post marketing surveillance'. (Phase 4 clinical trials). A formal phase 3 trial of the commercial vaccine (with the altered inactivation protocol) was never conducted.

The path of the hepatitis B vaccines in relation to HCV is intertwined with the debate on surrogate testing for hepatitis non-A, non-B. It should be noted that anti-HBc testing was not even discussed in 1981 by the Americans, but suppressed immediately after Stevens's abstract (New York Blood Center), presented at a meeting of the American Association of Blood Banks (AABB) that year. In 1983, at the meeting of the blood bankers reported by Randy Shilts, and acknowledged by Don Francis during his testimony in the Krever Inquiry, the main resistance was to anti-HBc, notably by Aaron Kellner, President of the New York Blood Center. He had implemented ALT testing of donated blood in the New York Blood Center the year before. In the international forum on ALT testing, anti-HBc was not even discussed. Since the forum was composed of vaccine developers, who were also blood bankers, it seems that their concern was not just one of vaccine-related AIDS, but of vaccine-related hepatitis as well.

This overall picture led the author to the speculation that, as of 1980, anti-HBc testing was suppressed, because of its possible relationship the non-Merck trials of hepatitis B vaccines in New York (such as the New York Blood Center/Prince vaccine). By 1981, there also had been suspicion that the Merck trial vaccine (200,000 or more doses) was transmitting hepatitis non-A, non B. This matches the delay between licensing of the vaccine and 'availability for distribution' of the commercial vaccine, which resulted in an upgraded viral inactivation protocol of the commercial Merck vaccine (5 million doses). The final clue came from the fact that the two urban centers in Canada (Vancouver and Montreal) had reported in the WHO Weekly Epidemiology Record that a Merck vaccine would be used for patients and/or hospital personnel. Subsequently, these two centers, which were initially planned to be used as trial site for the clinical trial on surrogate testing in Canada, were dropped from the trial and replaced with Hamilton and Winnipeg.

The peculiar handling of surrogate testing in Canada..

The following features were unique to Canada:

- 1) Between 1983 and 1985, post-transfusion hepatitis doubled; no attempt was ever made to explain it;
- 2) In 1986, after the US had decided to use surrogate testing of donated blood for hepatitis non-A, non-B, Canada decided not use surrogate testing – and never used it on a routine basis.

- 3) Effective donor selection procedures were not implemented until 1988; therefore not only was donor blood not tested, but potentially infectious donors kept contaminating the Canadian blood supply.

In the US, before the AIDS crisis, the non-use of ALT for surrogate testing was primarily driven by the rising incidence of elevated ALT in commercial donor populations, which in the US were, for some time, a source of blood donations as well as of plasma donors for plasmapheresis. By the mid-seventies commercial blood donations were discontinued. However, the incidence of transfusion-related hepatitis continued to rise. The commercial plasma sector continued to depend on commercial donors, and incurred higher and higher rates of donors with elevated liver enzymes. HbsAg testing did not reduce this problem.

The 1981 recommendations, and earlier decisions not to use ALT testing, was made by vaccine developers not to use surrogate testing, are the strongest indirect evidence that these recommendations were most likely linked to concerns with hepatitis B trial vaccines. While the early suppression of anti-HBc testing points to an HIV-1 contaminated vaccine, the later emphasis on the suppression of ALT testing, point to a vaccine which was not HIV-1 contaminated but HCV-contaminated. There is some indication that HCV was more resistant to some forms of inactivation (in particular dry heat inactivation) and perhaps more resistant than hepatitis B virus inactivation as well. It is conceivable that the Merck vaccines, which apparently were HIV-1-free, may have contained some HCV-positive material – and hence the resistance to ALT testing.

The argument is confused because the same conditions which would have been hiding vaccine-related infections, allowed the plasma industry to continue using plasma from donors of high risk of being infected with HIV, HVC and HBV. This is notable in with respect to Connaught Laboratories, which increasingly depended on the plasma acquired from plasma brokers (Cryosan). Plasma brokers imported plasma from various places on the globe – mostly from people of low SES, and hence a high likelihood of being carriers of viruses. Connaught's role as supplier to the Canadian Red Cross may have resulted in various delays (including the delayed implementation of HIV testing) in Canada, and in the delay of using heat-treated material, and to sell its inferior dry-heat treated material in Canada. As long as factor VIII concentrate manufactured from plasma which had not been surrogate tested was sold in Canada, blood donations remained untested with surrogate tests, possibly because there could not be two different standards for the two classes of products.

One could then argue that the 1986 decision by the Red Cross not to use surrogate testing was designed to keep Connaught in business, which continued to depend on material which was not surrogate tested. This is the impression one gets from the Krever Report. However, by 1988 Connaught left the business and this argument is irrelevant from then on: these 'motivations' would have disappeared and there was really no reason not to use

surrogate testing, unless the vaccine issue reached beyond 1988. There are few clues that the Canadian situation was linked to the Merck vaccine as follows:

- 1) **ALT as a marker for possible vaccine-related hepatitis infections.** ALT was not a good marker for possible vaccine-linked HIV-1 infections. It is therefore not surprising the New York Blood Center implemented it in 1982. However, ALT could have been a marker for hepatitis non-A,non-B infections, not just in North America, but also in Western Europe (and hence the consensus on the non-use of ALT testing in France, Britain, Holland, Canada and the US).
- 2) **Possible inadequate viral inactivation of the Merck commercial vaccine.** Concerns were raised by a German group at the University of Goettingen, on the occasion of a hepatitis symposium in Munich in 1982. Gerety of the US FDA, who also had been one of the first US scientists to argue against the use ALT as surrogate test, promoted the safety of the commercial Merck vaccine. The Goettingen group criticized the lowering of the formaldehyde concentration in the production of the commercial Merck vaccine, in comparison with the concentration used for the preparation of the trial vaccines. (Merck had added a urea step, but reduced the formaldehyde concentration).
- 3) **Unique safety problems for every vaccine lot.** The problem of new and different inactivation problem was associated with every new lot of hepatitis vaccines. (In comparison, vaccines produced in tissue cultures use the same culture tissue over and over gain).
- 4) **A single virus may start liver disease.** In his testimony at the Krever Inquiry, Don Francis of the US CDC pointed out that a single intact virus (virion) that has entered into a liver cell is enough to start the disease processes by replication. (Therefore, viral inactivation protocols that claim reduction of virions, but not elimination, cannot assure safety of the vaccine).
- 5) **Possible resistance of HCV to viral inactivation.** HCV is more resistant to inactivation than HBV and HIV-1. Krever reports that it was known that hepatitis C virus could resist inactivation processes for Factor VIII concentrate sterilization which HIV could not.
- 6) **No published phase 3 trials for the Commercial Merck vaccine.** Merck changed its viral inactivation protocol for lincensing in 1981 or 1982, but did not conduct (published) phase 3 trials of the kind conducted previously with its trial vaccines used in New York and California.
- 7) **Non-examination of Merck trial vaccines.** Only the commercial Merck vaccines were examined for presence of HIV-1, not the trial vaccines.

8) Commercial and trial Merck vaccines were sold outside of the US. At least one report from Greece provides evidence that both the commercial as well as the trial vaccines of Merck were sold outside the US. It may thus be possible that the trial vaccine was also sold in Canada.

8) Delay between licensing of the Merck commercial vaccine and availability of the vaccine for distribution. There was a one-year delay between licensing (1981) and the availability of the commercial Merck vaccine in 1982. Possibly, inactivation specifications were changed during this period. The author could not ascertain at what level of inactivation the Merck vaccine was licensed by the US FDA.

9) Some indication that Merck trial vaccines used in New York may have contained live hepatitis B virus. In the Oct. 1980 Szmuness report on the Merck vaccine trials on gay men in New York, there is some indication that the vaccine may not have been completely inactivated (from aldehyde and pepsin), and that some live hepatitis B virus was left in some of the material. While the Merck trial vaccine may have been free of HIV-1 (i.e. it did not contain material from chimpanzees), it may well have been contaminated with HCV.

10) None of the vaccines (commercial and trial) were ever examined for the presence of hepatitis C virus.

11) Unexplained increases of hepatitis non-A, non-B in Canada, Germany and Great Britain, but not in the US. In the early eighties there was an increase in hepatitis Non-A, non-B in Britain. A doubling of post-transfusion hepatitis non-A, non-B was observed in Toronto in 1984/5. Canadian statistics do not show a heightened activity of intravenous drug-use (the most common transmission route for HCV in Western industrialized countries) during those years. It must be conceded, however, that there are no statistics on ear-piercing and tattooing as possible transmission routes.

12) Discrepancy between the Feinman study on post transfusion hepatitis in Toronto and observations by the Krever Inquiry. There is a discrepancy between what Feinman claimed in his study (Feinman 1988; only a few donor samples were tested) and what Krever reports (the majority of donor samples were available for anti-HBc testing). Samples collected late in 1985 may have been of concern with respect to HIV infections due to the delay in the Canadian implementation of the test, no such conditions existed before that. ALT could not be reliably determined on stored samples. However, anti-HBc tests could be carried out even years later. It is suggested that Feinman or some other lab may have tested them.

13) The 1,000,000 samples of Toronto blood donors. Hundreds of thousands more samples were collected in the Toronto Blood Center after the Feinman

study, which most likely were used for various testing purposes (HIV-1, non-A, nonB post-transfusion hepatitis). None of these samples were ever tested for hepatitis C or for anti-HBc, or the results were not published. Only few tens of thousands were eventually tested for HIV-1, under persisting pressure from HIV-infected persons (HIV-T group).

14) No rigorous donor selection in Canada until 1988. There is no obvious reason why the Canadian Red Cross Society did not use the same donor selection criteria as the US as of 1985, the year of implementation of HIV-testing in Canada. While the non-use of surrogate testing could be explained with the interests of Connaught Laboratories in Toronto and its dependence on imported commercial plasma, the donor selection process in use suggests that there may have been cause and interest to leave the donors unselected – for investigation of their blood. This appears to be consistent with the continued collection of blood donor samples in Toronto after 1985, the ‘official’ end of the Feinman study of post-transfusion hepatitis.

15) Montreal and Vancouver were initially included in the Canadian clinical trial on surrogate testing and then excluded. The two cities had a high incidence of non-A,non-B post-transfusion hepatitis, and a study would have been of interest there. They were replaced with two centers with lower incidence (Winnipeg and Hamilton). British Columbia and Quebec were the two provinces reporting to the WHO that they would introduce hepatitis B vaccine for certain hospital personnel.

16) Surrogate testing was never used in Canada.

17) Refusal by the Canadian federal government to compensate persons who were HCV transfusion-infected before 1986. This refusal is maintained despite the fact that the conditions and circumstances, as well as the state of scientific knowledge were exactly the same in 1981 as they were in 1986. It raises suspicions that the federal government is avoiding an opening of the compensation process might open up the vaccine-related infection-trails.

18) Nowhere in the medical-scientific literature on the epidemiology of hepatitis C are vaccine-related questions asked. Vaccination does not exist anywhere as a possible source of hepatitis C infections in the literature.

Note: During the early seventies, the author followed blood donors who had been identified as hepatitis B virus carriers in his out-patient liver clinic. One of the standard questions concerned whether the donor had received any vaccinations. Vaccines as a possible source of hepatitis infections were under active consideration then, at least in Austria, but never again. The categories of *‘injection’* and *‘travel to countries with high prevalence of HIV’* may serve investigators as a ‘surrogate questions’

for inquiries into possible vaccine-related origins if HCV infections. Africa has a high prevalence for HIV, but also for hepatitis C and hepatitis B.

19) **'Unknown causes of HCV infections.'** Despite intensive questioning, sometimes bordering on patient harassment (according to HCV-infected persons who had gone through this procedure), there remains a sizable group of HCV-positive individuals for which the source of infection with HCV is 'unknown'. Vaccines are not on the list of possible sources presented to the infected person. One is reminded of the Belgian early AIDS epidemiology reports, which show virtually no male homosexual AIDS cases (which was by far the largest AIDS group elsewhere in Europe), and 'unknown factors' as the largest group.

20) **Lack of reference to hepatitis B vaccines by the Krever report, although they were blood derivatives.** The Krever Inquiry did not deal with hepatitis B vaccines, although they were clearly regulated blood products (blood derivatives) and had been licensed by the US and the Canadian Bureaus of Biologics, blood products divisions.

Each of these arguments, individually, is weak. Taken together, they do form a pattern of practices, decisions, unanswered questions and unresolved issues, and a lack of forthrightness displayed by all parties involved. The possibility of a link between the sudden rise of hepatitis non-A, non-B in Britain, and the sudden rise of non-A, Non-B post-transfusion hepatitis in Toronto in 1984/5 needs to be seriously considered. The observation that no similar rise of hepatitis non-A, non-B was observed in the US during the early eighties points to the possibility the different vaccine lots with different levels of infectivity may have been used. And that the less safe trial vaccines were perhaps distributed in Canada and Britain. While the conduct of the plasma industry (notably Connaught Laboratories) can be interpreted as one of taking advantage of the AIDS-vaccine link and the corresponding suppression of surrogate testing, the distribution and possible investigation of Merck vaccines in Canada can be interpreted as taking advantage of a compromised Canadian plasma industry (Connaught Laboratories), well into the eighties. Without data, records and a formal investigation and with investigating serum samples, if they still exist, this 'web' cannot be untangled. However, the facts that

- Merck hepatitis B vaccines were licensed for distribution in contravention of the Canadian Food and Drugs Act, and are thus associated with possible liabilities of the Canadian federal government;

- Canadian authorities permanently resisted the use of surrogate testing;

- Canadian voluntary blood donors were not screened rigorously until 1988;

suggest that not only were contaminated vaccines distributed in Canada, but that Canada may also have been a (publicly undeclared) testing ground for these vaccines (phase 4, post-marketing trials, search for 'unusual side-effects'), and hence the *prima facie* case for an investigation on the role of hepatitis B vaccines in the spread of hepatitis C in Canada in the early eighties.

3.6 THE CRITICAL PATH OF FACTOR VIII CONCENTRATE AND OTHER BLOOD PRODUCTS

Three categories of blood products are of interest for the propagation of HIV-1 and HCV infections:

- 1) **'Blood derivatives:' Antihemophilic Factors** (Factor VIII for the treatment of hemophilia A, Factor IX for the treatment of hemophilia B).
- 2) **'Blood derivatives:' Gammaglobulin preparations**, in particular HBIG, the serum for passive immunization against hepatitis B; **'Rh-Gammaglobulin'** for treatment of Rhesus factor negative mothers pregnant with possible Rhesus factor positive children, to prevent hemolytic disease of the newborn. **Immunoglobulin**, i.e. the fraction of plasma, which contains all antibodies to infectious agents.
- 3) **'Blood components:' Fresh preparations** from blood donations produced in blood centers such as red cell concentrates, fresh frozen plasma, cryoprecipitate, platelet concentrate.

The distinction of '**blood derivatives**' (products made of plasma by plasma fractionation on an industrial scale) and '**blood components**' is a **regulatory distinction**, not a logical/functional distinction: only '**blood derivatives**' manufactured by industrial enterprises were regulated in Canada (i.e. required a license) as part of '**Schedule D**' in the Food and Drugs Act. Logical arguments against this interpretation have led nowhere. In 1989, '**blood components**' were included in '**Schedule D**.' The argument that plasma from blood donors ('**recovered plasma**') was not only a '**blood component**,' but also raw-material for '**blood derivative**' production and thus subject to regulation, also remained inconsequential for responsible regulators. As mentioned earlier, hepatitis B vaccines (but also HBIG, a gammaglobulin product for used for passive immunization against hepatitis B) are unquestionably '**derivatives**' (i.e. require a manufacturing process, and use a pool of donor plasma), and they were derived from donors with history of a disease transmissible by blood (unless immunized with hepatitis B vaccine or HBIG) and thus should not have been licensed without special provisions and amendments to the regulations (See Appendix 3).

Each blood product represents a specific technology. To simplify the documentation, they are combined in a single critical path (with the exception of the hepatitis B vaccines, of course). In addition, the main emphasis will be on Factor VIII preparations, '**blood transfusions**' in general, and immunoglobulins. It is organized according to the use of two factor VIII preparations in Canada: cryoprecipitate and Factor VIII concentrate. Cryoprecipitate was introduced by Judy Pool and her co-workers in 1965 in the US (and later in Canada). Factor VIII concentrate had begun to enter the market in the mid-sixties, at the same as time cryoprecipitate. Canada implemented cryoprecipitate, and then went

on to a lengthy negotiating process to convert hemophilia treatment with cryoprecipitate to Factor VIII concentrate. In 1978, as per contracts between Cutter/Bayer and the Canadian Red Cross Society, Factor VIII concentrate made from plasma recovered from voluntary blood donations went into production and was distributed in Canada in 1979. Because of production losses (see Appendix 2), the balance of Factor VIII requirements had to be made up from Factor VIII concentrate derived from commercial plasma donors. By coincidence, 1978 was the same year in which the Merck hepatitis B vaccine trials took place in the United States.

Because of the low recovery of factor VIII (less than 20% for Factor VIII concentrate vs. 50% by cryoprecipitation), only half of the Canadian demand for Factor VIII could be supplied from Canadian volunteer plasma, even without safety precautions to prevent transmission of hepatitis. During the eighties, part of the production of Factor VIII from volunteer blood and from commercial plasma was carried out by Connaught Laboratories. In 1985, when heat-treated Factor VIII was introduced in Canada, Armour Pharmaceuticals became a major co-supplier of Factor VIII. Finally, by 1988, after Connaught withdrew from the plasma business and the contract with Armour expired, Cutter (Miles Canada, Bayer) became the main supplier of Factor VIII again.

Thus Canada shifted to Factor VIII concentrate the very year the outbreak of AIDS had already started on at least three continents, followed by a rise in hepatitis non-A, non-B in some places like Germany, Canada, and the United Kingdom. **The shift in hemophilia treatment in 1978/79 occurred with the full understanding that hepatitis non-A, non-B would infect virtually every hemophiliac treated.** By 1982, there was no doubt that the AIDS-causing agent was in the blood supply (AIDS reported in three hemophiliacs), while serious suspicions would have existed much earlier than that. However, the production and sale of both, human plasma-derived Factor VIII concentrate and of hepatitis B vaccines, stayed on track.

This leaves the **impression** that the non-use of surrogate-testing (anti-HBc being quietly suppressed in 1980, ALT being formally suppressed in 1981) was solely to ensure that the plasma fractionation industry could continue the sale of their products, while preparing for a switch in production to heat-treated products, and later to bio-engineered products; and that therefore the supply of blood and red cells also remained untested. Cost-preoccupied bureaucrats were cooperating in this strategy, or so it appears. This impression has been heightened by the *Krever Report* and media attention to specific portions to that report, and a focus of the ongoing RCMP investigation on this kind of issues:

- 1) **The non-use of effective donor selection in Canada criteria until 1988;**
- 2) **Several months of delay in the introduction of HIV-testing in Canada (November 1985);**

- 3) The distribution of non-heat-treated Factor VIII, (albeit fairly small amounts), while heat-treated Factor VIII was sitting on the shelves in Canadian blood centers (1985);**
- 4) The use of plasma from prison inmates and high risk areas (San Francisco, the 'Arkansas prison collections') by Connaught Laboratories (early 80s);**
- 5) The distribution of inadequately heat-inactivated Factor VIII concentrate (Armour; mid-eighties);**
- 6) The Canadian decision not to use surrogate testing in 1981; and again in 1986;**

If one looks carefully, however, in each instance the liability from unsafe product appears to be rather huge in comparison with the cost saved. Whether planned or not, however, these events have provided an effective smokescreen for potentially more serious issues and questions:

- 1) Why was a hazardous product (factor VIII concentrate) licensed and introduced in 1978?**
- 2) Was the origin of AIDS and of the spread of HCV related to hepatitis B vaccines?**
- 3) How was it possible that products manufactured from sources prohibited for use by the Food and Drugs Act (hepatitis B vaccine, and possibly anti-HBs (HBIG, for passive immune prophylaxis) were licensed and distributed in Canada?**

In addition, there are four issues which cannot be adequately explained with the interests of the plasma fractionation industry alone:

- 1) The virtually undisputed suppression of anti-HBc testing in 1980;**
- 2) A 2-year delay between the discovery of the AIDS agent and the implementation of HIV testing in the US;**
- 2) A 3-year delay between the licensing of heat-treated Factor VIII (Jan. 1984) and the implementation of surrogate testing in the US (end of 1986);**
- 4) The absolute and permanent non-use of surrogate testing in Canada.**

The four aspects indicate that the primary concern were not the fractionation industry and their survival, but something else: the need to camouflage and avoid an investigation on

hepatitis B trial vaccines and related transmissions of HIV-1 and HCV (and possibly others, such as HTLV-1, and HIV-2). Thus it appears that the **plasma fractionation industry could 'piggy-back' its 'survival strategies'** onto the dominant, vaccine-related public health strategies. This makes the analysis of the public policies regarding contamination of the blood supply in the context of the plasma fractionation strategies virtually a 'side-show': the plasma fractionation industry 'followed' (the hepatitis B vaccine developers), it did not 'lead'. If one would make the assumption of the blood fractionation technology to be the 'lead-path', one may arrive at the wrong conclusions, if any. So far, the various governmental and industrial public relations machinery, including the Krever Inquiry, the RCMP investigation, Harvard University and the media reports, intentionally or inadvertently, have accomplished precisely that.

'FORESIGHT' AND 'HINDSIGHT' WITH RESPECT TO FACTOR VIII CONCENTRATE MANUFACTURED FROM PLASMA OF PAID DONORS.

Over and over again, witnesses questioned during the Krever Inquiry stated that in the early eighties, everything was uncertain; that one should not look at the decisions made then with the knowledge available today ('20/20 hindsight'). However, foresight at the time, and even as early as the seventies was not lacking focus, as for instance the comparison between the risk associated with commercial and voluntary donors shows:

	Ratio of prevalence between paid and unpaid donors	Year	Source
'FORESIGHT'			
Hepatitis B	3:1	1975	M. Goldfield in T.J. Greenwalt and G.A. Jamieson. <i>Transmissible Disease and Blood Transfusion</i> 1975: 1412-51
Hepatitis non-A,non-B	2.5:1	1977	<i>Gastroenterology</i> 72: 111-2
Hepatitis "carrier" rate	11.9:1	1975	Prince et al. in Greenwalt and Jamieson: 129-40.
'HINDSIGHT'			
Hepatitis C (US)	280:1	1991	<i>J. Clin. Microbiology</i> 29: 551-6
Hepatitis C (several countries)	8:1 to 55:1		Abbott slide data
HIV (US)	7.4:1	1990	<i>JAMA</i> 236:2194-97
HIV (Mexico)	70:1	1989	<i>Bull. WHO</i> 23: 108-14
HTLV-1	10:1	1990	<i>Transfusion</i> 30 (1990): 780-2

Table 17: Relative risks of blood from voluntary and paid blood donors, known before and after HCV (HIV) testing became available. From Mann et al., (eds.) 1192: 428.

**THE WASTEFULNESS OF FACTOR VIII CONCENTRATE VIS-A-VIS
CRYOPRECIPITATE (See Appendix 2)**

CRITICAL PATH 1964-

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1964				
	01	(T) (Britain) Kekwick and Walton's paper on dried factor VIII concentrate. (<i>Brit. Journ. Haemat.</i> 10:299) Very little Factor-VIII activity loss at 4°C (refrigerator). Precise dosing.	(T) (Global) Hemophiliacs had been treated with fresh frozen plasma, which was difficult to administer and led to protein overload. Also Factor-VIII has a half-life in plasma of only 4 months. (Pool and Robinson, 1959)	(T) (Global) Both, cryoprecipitate and factor VIII concentrate were hailed as life-saving for hemophiliacs, while concentrate had the claimed benefit of offering the hemophiliacs a 'normal life'.
1965	02			
		(T) (Global) Judy Pool's and Shannon's paper on the production of cryoprecipitate. Imprecise dosing. The method was implemented in Canada during the late sixties.	(T) (Global) Judy Pool's cryoprecipitate had the advantage, that relatively little factor VIII activity was lost in production, that it did not require elaborate manufacturing, and most of a national supply could be supported with plasma from voluntary blood donations alone. Beginning of wide-spread use of HbsAg testing of blood and plasma donors.	(cont. from above) Most of Factor VIII concentrate was produced from paid plasma donors who, by then were known to carry a higher risk of being carriers of hepatitis. In addition, plasma for concentrate needed to be pooled from large numbers of donations. This risk was played down by the manufacturers ('plasma fractionators').

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1970				
	01	(T) (Global) Pool's paper shows that cryoprecipitate can be stored at -20°C without activity loss. (T) (Global) In the late sixties and early seventies plasma fractionators began to sell Factor VIII concentrate.	(T,O) (Canada) Report of the Canadian Hematology Society (Krever, 1997).	
	02	(T,O, RTSC) (Global) WHO raises concerns re: commercial fractionators buying plasma from paid donors. In 1975 the WHO promoted the use of national services to ensure supply of voluntary donations (Krever, 1997).		
1971				
	01	(T,O) (Canada) Ad hoc committee of the Canadian Hematology Society to study Canadian blood and blood product needs. (Krever, 1997)		
1972				
			(RTSC,O) (US) Transfer of regulatory function for biologics (including blood and blood products from the NIH to the FDA. (Panem, 1988)	
		(T,O) (Canada) Report of the ad hoc committee. Recommendation to build fractionation plant, to produce a full range of products incl. factor VIII concentr. (Krever, 1997)		
1974				
	01	(T,O) (Canada) Beginning of campaign for Red Cross fractionation plant, by Dr. Perrault, National Dir. of the Can. Red Cross Blood Transfusion Service (CRCBTS).	(RTSC, O) (Canada) Establishment of Bureau of Biologics in Canada. (Krever, 1997)	
	02		(RTSC) (US) Beginning of recognition of the seriousness of hepatitis non-A,non-B in the US. Start of the TTV studies.	

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1975				
	01			(RTSC) (Canada) Pro-paganda: <i>despite the recognition that factor VIII concentrate would transmit hepatitis with near certainty: even this risk was considered acceptable when weighed against the 'enormous' benefits of using concentrates</i> (Krever, 1997:619); emphasis and quotes by the author
1978				
		Milestone Switch from cryoprecipitate to Factor VIII concentrate production in Canada.		
	01	(T) (Canada,US) Beginning of plasma collection to be sent to American based fractionators for Factor VIII production.	(T, RTSC) (US) Beginning Merck hepatitis B vaccine trials in New York and San Francisco	Full propaganda for Factor VIII concentrates as life-saving, permitting normal life and standardized dosage.
1979				
	01	(T) (Canada) Full introduction of Factor VIII conc. in Canada.		
Apr 27 1979	02	(T,O) (Canada, US) Fractionation contract with Cutter from custom fractionation of Red Cross supplied fresh frozen plasma, and supply of additional Factor VIII concentrate (produced from commercial plasma) to make up the shortfall.		
1980				
June 26, 1980	01		(T, E, RTSC) (US) Suspected date of discovery that 'something had gone wrong' with vaccinations and that there may be a threat to the blood supply.	
Oct. 9, 1980.	02		(T, RTSC) (US) Report by Szmunn of clinical trial of hepatitis B vaccines in New York. First observations of AIDS-like symptoms in the US.	

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
	03	(T, RTSC, E) (US) June, 1980 Suspected date of discovery that 'something had gone wrong with vaccinations and that there may be a threat to the blood supply	(T, RTSC) (US) Oct. 9, 1980. Report by Szmuness on trial in NY. First observations of AIDS symptoms in US.	
1981				
		Milestone Decisions not to use surrogate testing; decision to keep distributing Factor VIII concentrate		
July 13, 1981	01	(RTSC, O) (Canada) Meeting of Red Cross officials with bureau of biologics officials: Factor VIII concentrates not be destroyed when derived from a person subsequently found positive for hepatitis B. Hepatitis B contaminated product can be distributed when product is in short supply. The policy was affirmed in July 1985 and 1987. (Krever, 1997:619).		
1984				
	02	(RTSC) (Canada) Consensus conference to continue issuing unheat-treated Factor VIII concentrate in Canada. (Krever, 1997)		
1985				
	01	(T) (Canada) Stocks of Factor VIII concentrate are used up.		
1986				
		Milestone Decisions not to use surrogate testing in Canada		
	01	(RTSC) (US) Decision in the US to use surrogate testing		
	02	(RTSC) (Canada) Decision in Canada (Canadian Red Cross Society) not to use surrogate testing but to do a clinical trial		
		Report by Boucher and Furesz (Bureau of Biologics, Canada; 1987) on the safety of plasma products. The study shows presence of HIV-1 antibodies in HBIG, IVIG (intravenous immune globulin) and IG (immune globulin). 5 out of 6 lots of HBIG tested positive; also 3 of 6 lots of IG; and 1 of 10 lots of IVIG. The authors recommended consideration of sterilization methods to prevent transmission of hepatitis non-A,non-B. They also mention that wet-heat treatment is necessary to kill virus associated with hepatitis non-A,non-B.		

Note: The changes in direction of the Canadian plasma fractionation industry happened at the same time as the National Director of the Canadian Blood Transfusion Service had a heart attack, and at the same time as the US vaccine developers might have discovered the first traces of AIDS amongst vaccinated individuals. In the following years Connaught Laboratories become one the major suppliers of Factor VIII concentrate, and the provinces took over the management of the blood program, whereas the federal government and Cutter pulled back.

The moratorium on the Cutter/Red Cross joint venture and the transfer of fractionation to Connaught may have been a **Trojan horse** for both the provinces and for Connaught laboratories: they took on a technology that would by then have been doomed to be outdated (and eventually replaced with bioengineered products), and it was already well understood that Factor VIII concentrate was contaminated with non-A, non-B hepatitis virus, and AIDS was well on the rise in the US.

Connaught Laboratories did not start producing Factor VIII concentrate until 1982, so there would have been a perfect opportunity for Canada to switch back to cryoprecipitate.

3.7 THE CRITICAL PATH OF SURROGATE TESTING OF BLOOD DONORS FOR HEPATITIS NON-A, NON-B

The 'critical path' for surrogate testing starts in 1959 (Bang et al.), the first year of the use of a 'surrogate test' ('ALT'; then used in the form of 'SGOT,' and later, the more liver-specific 'SGPT'). This was followed by the identification of the virus related to **hepatitis B** (Blumberg, 1965; Prince, 1968); and of the virus related to **hepatitis A** (Feinstone, 1973). After specific tests had been developed for these two viruses, surrogate tests (most importantly ALT and anti-HBc) were examined for their usefulness to detect carriers of virus(es) associated with **hepatitis non-A, non-B** (Prince, 1974). The usefulness of the surrogate tests became evident during the **multi-center 'TTVs'** (Transfusion-Transmitted Viruses study), sponsored by the NIH (US, National Institutes of Health), the result of which were published progressively in 1975, 1978, 1981, 1984 (ALT), and 1981 (abstract of association paper), 1984 (**anti-HBc**). Similar data collected, on a much smaller sample of donors and recipients, became known as the single-center '**NIH study**', the results of which were published in 1981 (ALT) and 1986 (**anti-HBc**). In combination, the two surrogate tests would have prevented not just transfusion-related transmission of hepatitis non-A, non-B (and thus most cases of transfusion-related **hepatitis C**), but also the vast majority of cases of transfusion-related transmissions of HIV-1 (the agent causing **AIDS**).

There are two major milestones along this critical path: 1981, the US and Canadian decision not to use surrogate testing; and the 1986 decision by the US to use surrogate testing and the Canadian decision not to use it and to conduct a phase 3-type clinical trial of surrogate testing instead. These decisions resulted in hundreds of thousands of patients being infected with transfusion-related hepatitis (worldwide); and thousands infected with HIV-1. These outcomes and related liabilities were predictable.

As of 1981, there was no valid reason not to use surrogate testing for the screening of donated blood and plasma. The only liabilities conceivably greater than those resulting from the non-use of surrogate testing would have been consequences from the use of contaminated vaccines. This study seeks to find a critical path which can identify a potential link between the decisions on surrogate testing and the vaccine model of the origins of HIV-1 and the spread of hepatitis C. Such a path was indeed identified. The evidence is suggestive of two separate occurrences, which were 'managed' as one problem during the early eighties (as of 1980):

A vaccine which was responsible for the introduction of HIV-1 into human populations (the NYBC vaccines being the most likely candidate);

A vaccine (or immunoglobulin) may have introduced additional HCV into human populations, in particular in Canada and Europe (the Merck, Sharp & Dohme trial vaccine being the most likely candidate).

The path is also suggestive of the use of a HVC-contaminated hepatitis B vaccine which was more extensively used in Canada than in the US; and that, alternatively, the effects of HCV-contaminated hepatitis B vaccines and/or immunoglobulins were studied in Canada, and hence the Canadian decision not to use the surrogate tests. The Canadian clinical trial on surrogate testing (1988-91) is shown to have been, at the very least, unethical; and like much of unethical research, bogus science.

The rhetoric on why surrogate tests were not used in the early eighties changed from 'we did not think it was a serious disease' to being 'surprised how serious it is,' to being surprised again that 'only' 5% or so of HCV-infected individuals end up with serious liver disease. **But 5% is still five-times more serious** than the chronic sequelae of hepatitis B, for which huge investments have been made to eradicate it. Hepatitis B always was considered a serious disease, and even 1% of 100,000,000 is still 1,000,000.

Donor selection and screening of donor samples to reduce PTH. As soon as it was recognized that blood transfusion was associated with this kind of risk, strategies were designed to reduce that risk. Up to the discovery of blood transaminases (also known as aminotransferases) as indicators of presence and severity of ongoing processes which destroy liver cells, only a donor history was available to exclude those who might transmit hepatitis: donors with a history of jaundice were excluded. Even in the absence of laboratory tests, commercial donors were recognized as posing a much higher risk of transmitting hepatitis than volunteer donors. (e.g. Kunin, 1959). Allen et al. in Chicago (1959) noticed an increase in the incidence of post transfusion hepatitis from 0% to approximately 1% of transfused patients in 1957 between 1946 and 1957, as the percentage of paid donors increased from 0 to 60%. The same year a study by Bang et al. (1959), who used a liver enzyme tests to diagnose hepatitis, found the rate of infection of donors to be around 3%.

Thus, by the early sixties, two things were certain: hepatitis was a significant complication of blood transfusion; and commercial donors posed higher risk than voluntary blood donors. By the early eighties non-A,nonB hepatitis rates had gone up to 10%, and in the order of half of the commercial donors were transmitting hepatitis. In 1968 (Prince) hepatitis B testing was introduced into donor screening, and in the mid-seventies (Almeida et al.) and antibody, hepatitis B core antibody, was first recognized as to its significance for hepatitis B, and following that its significance as surrogate test for hepatitis non-A,non-B. Finally, by 1981, both surrogate testing systems would have been very effective in screening out blood donors infected with HIV-1.

The ALT surrogate test. Any kind of liver damage will lead to a rise of the level this enzyme in the blood stream, not just hepatitis. However, the presence of an elevated value routinely leads to further investigations of liver function and pathology. On the other hand, any kind of acute or chronic liver infection may be associated with an elevated ALT level. Thus a positive ALT test would catch some but not all people carrying a hepatitis virus; and individuals with a negative test may be carrying a hepatitis virus (even in

conjunction with advanced cirrhosis of liver, i.e. a hardening of the liver due to reorganization and fibrous tissue). The potential loss of donors by commercial blood banks was a strong disincentive to use the tests, notwithstanding the damage (including death) from hepatitis virus contaminated blood. For the ten years following Bang's observations, hardly any research was carried out in this area in North America. In Goettingen, Germany, Creutzfeld and co-workers demonstrated the benefit of ALT testing in the late sixties. Some blood banks used ALT testing. The author is aware of at least one blood bank that sent ALT positive donations to plasma fractionators. It must be borne in mind also that during those years plasma fractionators were supplying the hospitals with specific protein fractions derived from human plasma, and depended entirely on commercial donors of plasma. A study conducted by Grady in Boston in 1964 did not show much new, except it pointed to a mortality rate of 12% from acute hepatitis following blood transfusion. (These enzymes serve as catalysts for the transfer of nitrogen (amino-groups) for excretion or for incorporation into other compounds). Over the years the terminology for these liver enzymes changed somewhat, and is briefly reviewed here:

ALT	Alanine aminotransferase	Catalyses reaction L-alanin + 2-ketoglu-tarate = pyruvate + L-glutamate	Specific for liver damage	New terminology
SGPT	Serum glutamate pyruvate transaminase			Old terminology for ALT

When damage to liver cells occurs (cell death, the enzymes are leaked into the blood stream), their concentration in serum can be measured. The more cells are destroyed, the higher the level. The highest levels are obtained during acute hepatitis, while smaller elevations are observed in chronic hepatitis. In the case of fibrosing (hardening) processes taking place in the liver as a result of hepatitis C infection, the enzymes may remain normal. In acute liver failure, the liver virtually collapses and is accompanied by a sudden drop in enzyme levels in blood.

The anti-HBc surrogate test. The presence of hepatitis B virus can be detected by positive tests for two antigens:

1) **The hepatitis B surface antigen (HBsAg).** It is a virus envelope protein, and is often present in blood in abundance, even in the absence of full viruses. It was the starting materials for the development of hepatitis B vaccines. The antigen is produced in the later phases of the incubation period, and it is then cleared during the acute phase and during convalescence. If it persists the hepatitis may become chronic. Hepatitis B virus, which is transmitted early in life, such as during the perinatal period, leads to a chronic carrier status, i.e. presence antigen without apparent illness.

2) The hepatitis B core antigen (HBcAg). It is a protein that is present in the inner portions of the virus. It is more difficult to detect.

Both antigens give rise to the formation of antibodies. The anti-HBc antibody rises early in an infection and then persist for many years. It does not provide immunity. The anti-HBs antibody rises during convalescence and provides immunity (and hence the attempts to immunize with the corresponding HbsAg). Accordingly, anti-HBc is a universal indicator of a past infection with hepatitis B virus. Anti-HBs is an indicator of a past infection, if it is accompanied by anti-HBc. If it is found alone, it may be the outcome of active or passive immunization.

Since anti-HBc is associated with life-styles and conditions that were also exposing individuals to hepatitis C infections and HIV infections, it would have been a life-style indicator like ALT. ALT and anti-HBc detect different populations of infected individuals. Together, therefore, they could have effectively reduced transfusion-related HIV and HCV infections (plus any residual HBV infections, as the HBV test had not been perfected yet around 1980).

High rate of transmission of hepatitis virus by commercial donors. The high rate of hepatitis virus carriers amongst commercial donors was a consequence of their recruitment from economically disadvantaged classes, including intravenous drug users, some of them veterans from the Korean and Vietnam wars. Increases in modes of hepatitis infections from practices such as piercing, tattooing, injecting, and sexual contact, notably homosexual contact, added to the high hepatitis carrier rates in commercial blood donors. As of 1965, just about all STDs were on the rise in North - America, including hepatitis B. A leveling off occurred in the late seventies, most likely because of the **herpes virus type Type II (herpes genitalis)** scare; and in the early eighties, most likely because of the **AIDS** scare.

CRITICAL PATH 1959-1981

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1959				
	01	(T, RTSC) (US): Bang's study of use of SGOT (similar to ALT) in detecting carrier of hepatitis virus in donor populations. (<i>JAMA</i> , 171:2303-6)	(C) US: Post-WWII and post- Korean War period	

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1965				
	01		(C) (US): Vietnam War, Hippie movement, rise of drug culture, sexual liberation, STD.	
	02	(C) (US) Australia : Blumberg's discovery of Australia antigen (later known as HbsAg). <i>JAMA</i> 191:101-6		
1967				
		(O) (US) Krugman's experiments on the Willowbrook for retarded children to distinguish hepatitis A from B. <i>JAMA</i> 200:95-103.	(O, C) (US) A considerable number of the children in the Willowbrook facility were infected with hepatitis during their stay. Trial participation became a condition of having children admitted to the facility. Project financed by the US military and the Office of the Surgeon General.	(O) (US) 'All children in the Willowbrook facility get infected with hepatitis anyway.'
1968				
	01	(O,RSTC) (US) Prince's paper on the HbsAg as marker for hepatitis B transmission via blood transfusion (<i>Proc. Nat. Acad. Sci.</i> 60:814-21).		
1970				
	01	(O,C,RSTC) (US) Walsh, Purcell et al. 60% transfused with commercial blood develop hepatitis, none with voluntary donations. (<i>JAMA</i> 211: 261-5). Confirmed by Alter et al. (<i>Ann. Int. Med.</i> , 1972; 77:691-9).	(T, O) (Global) Development of fractionation products exclusively from commercial donors was well underway. Virtually all hemophiliacs treated with concentrate were bound to be infected with hepatitis	(O) (Global) 'Hemophiliacs get infected with hepatitis anyway'

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1970				
1971				
	01	(T, RSTC) (Canada) Introduction of hepatitis HBsAg testing in Canada. (Krever, 1997:621) (T, C, RSTC) England: Almeida's et al. discovery of hepatitis B core antigen and antibody. (<i>The Lancet</i> Dec.4, 1971:1225-7)	(C,RSTC) (Canada) Canada discontinues to collect blood from prison inmates (Krever, 1997: 618)	
1973			Post-Vietnam period	
	01	(T, O, RSTC) (US) Hoofnagle, Barker and Gerety of the FDA produce reagents from anti-HBc detection. Recognized as present in all chronic carriers of HBsAg and in incubation period of hepatitis B. (<i>The Lancet</i> , Aug 3, 1974:241-6)	(T, E) (US) Chimpanzees were already in demand for vaccine development; In this case a chimpanzee had to be killed for the production of reagents for anti-HBc testing (from infected chimpanzee liver).	

TIME	ROW	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1973				
	03	(T) (US): Feinstone et al. Discovery of hepatitis A virus. (Science, 182:1026-8)		
1974				
	04	(T, TSRC) (US): Prince's paper on 'hepatitis non-A, non-B', proposed as hepatitis C. (The Lancet, Aug 3, 1974:241-6). From hereon, hepatitis non-A, non-B existed as a distinct entity.	(C, O) (US) End of Nixon era; followed by Gerald Ford (1974-77); then Jimmy Carter (1977-81). During the Ford administration, movement of industry against regulation, in favor of voluntary quality assurance; continued during Carter era, culminating during Reagan-Bush era (1981-89; 1989-93) (T, RSTC) US: Beginning of TTV studies on post-transfusion hepatitis(C) Gay movement accelerating, also spread of STDs.	(C,O) (US) Beginning movement against 'big government'.
	05	(T, RSTC) (US) Beginning of TTV studies in the US (Krever, 1997:629)		
1975				
	01	(T, RSTC) (US) Auslander's first preliminary report on TTVS results Abstract (<i>Gastroenterology</i> 69:A4/804). ALT testing is effective	(T, C) (US, France) French begin systematic development of hepatitis B vaccines; competition; Shifting interest in hepatitis B from testing to vaccination.	
	02	(E) (US) Feinstone's report on hepatitis NANB (<i>NEJM</i> , 292:767-70)		
	03	(RSTC) (US) Alter's study on transfusion-associated hepatitis (<i>The Lancet</i> , July 12, 1975: (64-5)		

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1976				
	01	See Note 76/77/A/01		
1977				
	01	See Note 76/77/A/01		
1978				
	01	(RSCT) (US) FDA rules that blood bags must be labeled to show whether the donation came from a voluntary or paid donor. (Krever 1997:617)	(T,C) (US) Implementation of non-virus-inactivated, Factor VIII concentrate produced from commercial donors in Canada, replacing cryoprecipitate – despite warnings from 1975/8 studies on non-A, non-B hepatitis. Presentation of papers from the US and Europe on vaccines, including the only paper by Prince (New York Blood Center)	(C) (Global) 'Hemophiliacs get hepatitis anyway'; Factor VIII 'saves lives'; Factor VIII concentrate permits hemophiliacs lead a 'normal life'.
	02	(T, TSRC) (US) Gitnick's paper on ALT use in preventing acute and chronic hepatitis. (Vyas et al. (eds. 1978, Viral Hepatitis:431-8)		
	03	(T, TSRC) (US) Hoofnagle's paper on HbsAg tests not excluding all carriers of hepatitis B. (NEJM 298:1379-83).		
	04	(T, TSRC) (US) Katchaki's letter to the editor, confirming Hoofnagle's findings. (NEJM 298:1421-2)		
1979				
	01	79/80/A/01		
1980				
	01	79/80/A/01		

[76/77/A/01](#)

Despite rather important findings concerning hepatitis non-A, non-B there was very little research activity in this field. Despite high incidence of post-transfusion hepatitis, the TTV studies sponsored by the NIH on surrogate testing were

progressing at a snail's pace (a hundred cases or less a year). The most likely reason for this was that the main actors in the field (NIH: Purcell, Alter, Holland; New York Blood Center: Prince, Szmunn; FDA: Barker Gerety; VA (?) Bancroft, Zimmerman) were involved mainly in vaccine development. See also the Purcell grant proposal in the 'critical path' for AIDS/vaccine. The TTV study, funded mainly by the NIH, was really the 'only funded game in town' with respect to surrogate testing.

79/80/A/01

The years 1979 and 1980 are 'silent' with respect to surrogate testing. There is a publication gap between June 1978 and April 1981 (almost three years). Data collection for the TTV surrogate testing study ended in November 1979. Thus there is a gap of 15 months between closing of the data collection and the publication of the data. Judging from the publication, and given the generous funding and staffing the New York Blood Center's chief epidemiologist Wolf Szmunn had at his disposal, work-up of the data and writing of the paper should not have taken more than three or four months (the paper is not very complicated; the more complicated data on the vaccine trials has been published a year earlier). **The publication of the data was delayed for a whole year.** The data on anti-HBc testing were also delayed and then only shown as a meeting paper, after the publication of the *NEJM* article on ALT testing, but not published. The following happened during that period:

- 1) The New York Blood Center had completed its recruitment of vaccine trial participants in 1979;
- 2) Barker had moved from the FDA Bureau of Biologics, Blood Products Division to the American Red Cross as Vice-president Health Services. At the end of 1979 he hired Szmunn the principal investigator of the Merck vaccine trial in New York as a consultant at ten times the going rate of consulting fees;
- 3) Early in 1980 the Merck vaccine trial data were published by Szmunn, no data on the trials of the New York Blood Center hepatitis B vaccine and the NIH hepatitis B vaccine were ever published; nor were the data of the San Francisco portion of the Merck trial. Szmunn is very fuzzy with respect to failures and side effects of the vaccines.
- 4) Merck was getting ready to have its commercial vaccine licensed;
- 5) In mid-1980, the Canadian federal government suddenly (after having been committed for years) changed course and no longer supported Cutter in establishing a fractionation plant in Canada. Instead, the Canadian Blood Committee was established, and three fractionation plants (Toronto Connaught Laboratories, Winnipeg Rhesus Institute, and Armand Frappier in Montreal) were suggested as alternative fractionators. Before 1980, Connaught Laboratories had been the only serious contender and remained the only significant Canadian supplier during the eighties. It never made any sense at all to have three

fractionation plants in Canada, as none of them could operate cost-effectively with the volume of plasma available in Canada. This constituted a move which was in crass contradiction to claims of 'cost-consciousness' of provincial funders of the Canadian Red Cross blood program (such as claimed as reason for not using surrogate testing ever in Canada); and cannot be taken seriously at face value;

6) Canadian data in 1979 had been presented in Alberta showing that the factor VIII concentrate had led to substantial transmissions of hepatitis in hemophiliacs. The medical director of the Calgary center, who recommended the alternative, safer, product, cryoprecipitate, was removed from his job in Calgary, given a lesser job in Toronto, and eventually resigned in 1985;

7) The NIH quickly conducted a surrogate testing study (but in contrast to the TTVS did not publish the dates). The NIH sample (283 patients enrolled) was so small that it really did not add anything to the TTV study (1513 patients enrolled), and there is really no reason to call it a 'major study.' Rather it seems that this study created the conditions (and an excuse) for the NIH vaccine development group (Purcell, Alter, Holland) to take a lead in the surrogate testing debate (which they promptly did). Also, they served as 'advisors' on the TTV study.

All of these occurrences, in combination with the delay and suppression of surrogate testing data indicated to the author, that something, and most likely the vaccine trials (but not the Merck trials, initially) had raised serious concerns directed at the emerging AIDS crisis. The circumstance that half the individuals signing the recommendation against surrogate testing were from the US military suggest that this concern may have reached into the US armed forces. If AIDS was caused by one or more of the viral vaccines used in New York and San Francisco, then the first signs would have appeared in towards the end of 1979 (two years into the trials). They would have been observed by the vaccine and surrogate testing investigators (who were more or less the same people), long before general practitioners saw the first AIDS patients.

The author believes that, based on these circumstances, the bad news was broken to key individuals in the summer of 1980, and from then on strategies were developed as to how to handle the impending crises: outbreak of a new epidemic and contamination of the blood supply. This strategy included the handling of the data on surrogate testing collected in the two major studies (the TTV (New York Blood Center, Aach et al. and the Alter study (NIH; see below), and the NIH taking lead role in the suppression of surrogate testing. 1981 then became the year an orchestrated campaign by parties involved in hepatitis B vaccine development to avoid surrogate testing. Apparently, the Canadian government was somehow induced to participate in this campaign.

TIME	ROW	A. CRITICAL PATH	B. MATERIAL CONTINGENCIES	C. 'SOCIAL CONSTRUCTION' CONTINGENCIES
1981				
		Milestone	Decision not to use surrogate testing	
January 8, 1981	01	(T,RTSC) (US) First meeting of the ad hoc committee on ALT testing. There was considerable support for its implementation. (Krever, 1997)		
Apr. 23, 1981	02	(T,RTSC) (US) Publication of the final result of the report of the Transfusion-Transmitted Viruses (TTV) Study Group (Aach and Szmuness et al.) NEJM 304:989-94). This study showed effectiveness of ALT testing in the prevention of transfusion-related hepatitis non-A, non-B. (Note 1). Frequency of post transfusion hepatitis 10%; 40% of PTH could have been prevented if units with level of ALT 45 Units or greater had been discarded, at a loss of [only] 3% of donations. Use of ALT testing is recommended (but anti-HBc data were not reported on).		
1981	03	(RTSC) (Canada) Several efforts by various individuals in the Canadian Red Cross to establish a registry for donors implicated in post transfusion hepatitis. This was not accomplished. Also reporting of post transfusion hepatitis to provincial authorities was minimal during the eighties. (Krever 1997:625-7) A national registry for transfusion-related non-A,non-B hepatitis was never developed.		
April 24, 1981	04	(O, RTSC) (Canada, US) Meeting of Scientific Advisory Committee of the Canadian Red Cross Society. Derrick reports that use of ALT testing is under consideration in the US and may be imminent. (Krever, 1997).	(C) (US) Number of cases with AIDS-like symptoms increasing in the US.	

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C 'SOCIAL CONSTRUCTION' CONTINGENCIES
1981				
June 22, 1981	05	(O, RTSC) (US) Memo: Barker (ARC, former FDA), Gerety (FDA) and Zimmerman to AABB, ARC and CCBC re: not to use surrogate testing, on the grounds that effectiveness is not proven, data are insufficient for conclusion (see difference to January meeting) (Krever, 1997).		(O, RTSC) (US) Beginning of the US-led propaganda that there is no scientific proof of the effectiveness of surrogate testing, that it would be financially irresponsible to use the tests without proving their effectiveness.
July 11, 1981	06			(T) (England) Lancet Editorial: Hepatitis non-A, non-B as a result of product use labeled as 'transaminitis'. Long-term consequences not known.
July 13, 1981	07	(O, RTSC) (Canada, US) Canadian Bureau of Biologics (Boucher, Pope), Canadian Red Cross (Perrault, Derrick). Discussion of ALT testing. (Note 4); Perrault: no intent to implement surrogate testing, further study of the evidence and implications	(C) (US) June 1981: First case of AIDS published by CDC (MMWR)	(C) (US) AIDS considered to be a 'gay disease': GRID (gay-related immunodeficiency; CDC).
Aug. 7, 1981	08	(T, RTSC) (US) Publication of ALT study on ALT testing by the National Institutes of Health (NIH). Alter et al., JAMA, 246: 63-4. Confirms the results of TTV study. 29% % of post transfusion hepatitis could have been prevented. At a loss of 1.6% of donors. <u>Recommends prospective clinical trial before implementation.</u>		
Sept. -Oct. 1981	09	(T, RTSC) (US) Association paper abstract by Stevens (part of TTV study group) on the effectiveness on anti-HBc testing as surrogate test for hepatitis non-A, non-B.		

TIME	R O W	A CRITICAL PATH	B MATERIAL CONTINGENCIES	C SOCIAL CONSTRUCTION CONTINGENCIES
1981				
Nov.13, 1981	10	(O, RTSC) (Canada) Meeting of Scientific Advisory Committee of the Canadian Red Cross Society.	(C) (France) Aug. 1981 Report of AIDS in a homosexual man in France. (C) (UK Netherlands) Sept. – Dec. 1981: Reports of AIDS in homosexual men in UK and Netherlands.	
1982				
	01	(RTSC) (US) New York Blood Center implements ALT testing.		
1983				
	01	(RTSC) (US) AABB committee advises against the use of surrogate testing (Krever 1997:635)		
March 1983	02	(RTSC) (US) US FDA majority of opinions against surrogate testing. (Krever, 1997:635)		Hepatitis non-A,non,B not a serious disease. (Krever 19997:635)

Note 1: Preliminary results of that study had been published in 1975 (Auslander et al., 1975, *Gastroenterology*, 69 (A-4/804) and in 1978 (Aach et al., in Vyas, *Viral Hepatitis*, 1978, 383-96).

Note 2: Derrick mentioned the results of the TTV study just published in the New England Journal of Medicine that showed a benefit of ALT testing.

Note 3: This is the essence of the memo and a summary of the meeting of the ad hoc group published in *Transfusion* 1982, 22(4-5).

Note 4: Derrick's trip report, meeting with the American Red Cross (ARC), filed with Krever Inquiry, indicates that legal liability, not safety is motivating American blood bankers. "It was once again observed that as long as a test is not part of the standard operating procedures, the ARC cannot be held legally responsible for any illness resulting from transfusion of blood with elevated ALT levels. The ARC realizes that the cost of implementing the test may be less than the cost of the disease' [because of a chronicity problem].

Note 5: Dr. Alistair Clayton, Chairman of the National Action Committee on AIDS, thought that four or five extra case of hepatitis did not justify the expense of surrogate testing (despite the TTV and NIH studies on ALT, both of which had been published

by then). Dr. Martin Davey, assistant national director of the Red Cross Blood transfusion Service agreed, and said that without Canadian data nothing should be done about it. The issue was put to a Red Cross Working Group which never did anything about it.

The data of the TTV study had shown that surrogate testing would be effective in reducing post transfusion hepatitis (non-A, non-B). A significant number of AIDS cases was increasing in the US, and first reports of cases with AIDS-like symptoms were coming from Europe. It was known that AIDS-like symptoms affected mostly gay individuals. At the same time it was known that up to half of commercial donors would transmit hepatitis, that a large portion of gay donors had been infected with hepatitis B, and that the hepatitis B test was not excluding all hepatitis B donors from donating. Accordingly, surrogate testing should have been an effective means of reducing transmission of HBV (hepatitis B virus), HCV (hepatitis C virus) and HIV (human immunodeficiency virus). The demonstrated effectiveness of surrogate testing for reducing transfusion-related non-A, non-B hepatitis would have been enough to warrant the tests. The avoidance of HIV and HBV transmissions could have been a 'fringe benefit'.

In 1981, while the AIDS pandemic was on the rise and affected primarily gay men, the main target of US trials of hepatitis B vaccines. The three leading scientists arguing against surrogate testing had been involved in the development and/or licensing of hepatitis B trial vaccines. One of them (Barker) was, in 1981, also the lead voice at the American Red Cross on these matters and thus the key reference for the Canadian Red Cross (as per reports by Derrick). Accordingly, there is, at the very least, a strong possibility that the entire campaign against surrogate testing was not driven by blood concerns, but by concerns regarding the past use of hepatitis B trial vaccines. The American Red Cross position that, if a test is not part of standard operating procedures then its non-use would not incur any liability, suggests that, from a legal point of view, this campaign against surrogate testing was considered 'doable' (and by implication, the role of hepatitis B vaccines 'deniable'). Most significantly, the data on the use of anti-HBc as surrogate tests, after a presentation at a meeting in the US in 1981, was suppressed and did not resurface until December 1984. Anti-HBc would have been a marker for a possible failed vaccination with a hepatitis B trial vaccine, or for the use of a vaccine that contained incompletely inactivated hepatitis B virus. While the test was by no means proof of an infectious vaccine, such a vaccine would have been one of the possible sources of infection with HCV, HBV or HIV.

The NIH data on the use of surrogate testing with anti-HBc were not published until 1986 (Koziol et al. *Ann Intern Med* 104:488-95). This was also the time when Canada decided not to use surrogate testing.

THE ISSUE OF THE NEED FOR A CLINICAL TRIAL

In 1981 Harvey Alter of the NIH advocated for a prospective, randomized, controlled clinical trial of ALT surrogate testing of donated blood. It is suggested here that this was an unprecedented manipulation of the good intent of clinical trials, i.e. a 'redirection' of the observer to overlook the actual purpose for not using the test.

1) The purpose of phase 3 clinical trials is not to measure the exact size of a side-effect, nor the definite proof of efficacy of preventive measures. Purposes of clinical trials were introduced earlier. Such trials are aimed at measuring the 'effect of a treatment', the beneficial effect of a therapeutic intervention. Surrogate testing to detect contamination was not a 'treatment of the patient', but a product quality control measure to reduce the consequences of a known contamination. Side-effects are not the subject of controlled clinical trials, in particular phase 3 trials. Under conditions of uncertainty some kind of trial may be justified, but not when already reasonable cause exists that a particular measure can substantially reduce a known risk. Unfortunately, however, the discipline of clinical epidemiology does not provide any norm and standards, how side-effects of therapeutic products are to be investigated, and there is no norm on the books which could have prevented Harvey Alter's propositions. However, the unethical nature of such trials is self-evident: they would be trials on damages, not on benefits.

2) The misleading nature of Harvey Alter's propositions is self-evident from the fact that similar safety measures, such as heat-treatment of Factor VIII, donor selection by history, hepatitis B testing, Hepatitis C testing and HIV testing were never subjected to controlled clinical trials in Canada or anywhere else before their implementations. The claim that these were specific measures and tests is irrelevant, if a controlled clinical (phase 3) trial is the gold standard, as it was claimed to be in the case of surrogate testing.

3) The claim that the TTV and NIH studies on ALT-testing could not show whether removal of surrogate positive units could actually reduce the incidence of non-A, non-B hepatitis is absurd. Instead of having two treatment groups, one receiving blood from a pool with positive units removed, the other receiving blood from a pool with positive unit not removed, one can just take the results from the two studies and compare the incidence of hepatitis with the positive units removed, with the incidence when positive units are not removed – on paper.

4) The focus of the two studies, as it should have been, was to determine the relative risk of surrogate positive and negative units. All the studies ever conducted found this difference to be significant. By using pools with positive units removed and not removed, because of the 'dilution effected' of negative units the significance is bound to drop. In particular when the incidence of post-transfusion hepatitis is low. While the statistics derived from this manipulation would be biased in the direction of not using the

tests, positive units do not get any safer in comparison with negative units by this deceptive strategy.

5) The two studies gave a clear indication of the relative risk of positive and negative units, which was substantial. To give such units to any one would have been outright unethical, and therefore no trial took ever place in the US. By the same token, there were only minimal trials (no less unethical) in Canada and in France.

6) The only key difference between a controlled trial and the kind of trial performed in the TTV studies is that the TTV studies were not randomized. Short of that, the possible effect of biasing factors could have been evaluated. Chances are the two groups were not all that different, and if they were, it could have been so stated. However, no such comparison was ever carried out to substantiate the claim of need for a controlled trial.

7) The most unethical aspect, however, was the fact that in order to make the trial possible, the entire population had to remain untested. In other words, the continued exposure of an expected number of individuals to infection with hepatitis was a condition of the clinical trials. Therefore, it seems that the government of Canada compensated victims infected after 1986, the year of the decision not to use the tests but to conduct a clinical trial.

8) **However, exactly the same conditions existed in 1981**, at least for ALT testing, and one would have to question the ethics of withholding the data on anti-HBc testing between 1981 and December of 1984 from publication. The Canadian government so far has failed to explain what they perceive the two groups to be different. The US and European countries, which did not use surrogate testing, still have not provided satisfactory answers on this issue.

9) There is testimony to the effect that Americans were well aware that an actual conduct of clinical trial, involving the transfusion of known surrogate positive units would have been unethical. Harvey Alter testified to this effect. Therefore no clinical trial was conducted, even though given the high incidence of transfusion related hepatitis at the time, the trial should have been completed at fairly low cost in matter of months. (the TTV trials were just conducted very slowly, over several years).

Accordingly, both the 1981 the US and Canadian decisions not to use surrogate testing, and the 1986 Canadian decision not to use surrogate testing were unethical, bound to result in substantial liabilities. By appearance, they are nonsensical. They make better sense once considered in connection with the critical paths for hepatitis B vaccines. Apart from the issue at hand, the clinical trial, as designed, has established a kind of unethical research as a new standard – and the scientific community, including the editors of *Lancet*, where the Canadian study was published, did not object.

THE CANADIAN CLINICAL TRIAL ON SURROGATE TESTING.

Report on the Canadian Trial on PTA and Surrogate Testing. (M.A. Blajchman, S.B. Bull, S.V. Feinman, for the Canadian Post-Transfusion Hepatitis Prevention Study Group, 1995: 'Post-transfusion hepatitis: impact of non-A, non-B hepatitis surrogate tests.' *Lancet*, vol. 345, January 7, 1995: 21-5.)

Note: Quotes in this section are from the above publication, and in italics.

The clinical trial appears to have had a corrupted purpose: not to prove efficacy of surrogate testing in reducing post-transfusion hepatitis, but to use the planning, approval and funding processes as tactics to delay and avoid surrogate testing in Canada. This was its purpose in 1981 in the US and Canada, and continued to be its purpose in Canada in 1986. The result was an unnecessary, incomplete, biased, and unethical piece of scientific work, and the decision to take this route **kept an entire population at risk of being infected with hepatitis C as a condition for the trial to be possible.** This latter aspect transcends the ethical problems (such as the 'informed consent'), and raises the question whether something more serious than 'unethical research' has taken place.

The corrupted purpose had the following ramifications:

- 1) False, misleading, and deceptive arguments** why such a trial was necessary;
- 2) Conflict of interest of those arguing against the use of surrogate testing;** non-representatives of blood banking of those making the recommendations; delays of 7 years, following the arguments for a trial, and the beginning such a trial; and an interval of **14 years (!)** between the call for a trial and the publication of the results of the only trial of its kind in North America;
- 3) Incomplete information used to obtain an 'informed consent' from participating patients;**
- 4) An incomplete trial, with multiple signs of investigator bias, i.e. trying to show lack of efficacy of surrogate testing rather than efficacy or, as it should be, being neutral as towards the outcome.** (The study was funded by the Canadian federal government, the Red Cross and Cutter, and such a bias should not be surprising.)

5) The same flawed arguments which were used for the design of the study and for the recruitment of study participants were used after 1992: that surrogate testing is of no value. Yet the U.S. continued to use one surrogate test (anti-HBc) even after 1996.

1. FALSE, OR MISLEADING ARGUMENTS IN FAVOR OF A TRIAL

The epidemiology of HIV, HBV and non-A,non-B hepatitis alone would have made the use of surrogate testing mandatory. To recapitulate, surrogate testing (ALT, anti-HBc) had the capacity to detect blood and plasma donors with acute or chronic infections of the liver, without having the capacity to identify the specific agents. Their extremely high prevalence in prison populations, intravenous drug users, gay men and commercial blood donors made these tests markers of risky lifestyles and conditions, even in the absence of admission of such a lifestyle by a donor presenting at blood or plasma collection facility. HCV, HIV-1, and HBV infections were all linked to one or more of these lifestyles, and the majority of transfusion-related transmission could have been prevented by these tests.

Accordingly, the specifics of the epidemiology of these infectious diseases alone, even without any trial of efficacy of testing, would have been enough to make the use of such tests for the screening of blood and plasma donors mandatory. This was the case immediately after the use of ALT testing by Bang in 1959, and in the source of learning about the significance of anti-HBc and the epidemiology of hepatitis B in the mid-seventies. However, by 1981, when Canada and the US decided not use surrogate testing, there was no longer any reasonable doubt as to the epidemiology of all three infections: HIV, HBC and non-A,non-B hepatitis.

Thus, by the time the studies of the NIH and the TTV study group were published in 1981, their findings would have been little more than confirmation of a foregone conclusion, based on epidemiology alone. One could argue, however, that such studies could have contributed to the knowledge of the size of the effect of surrogate testing. Since it took seven years between the beginning of such studies (1974) and the publication of the results (1981), there was obviously no great urgency to find out.

The TTV studies and the NIH study on surrogate testing were sufficient to confirm a substantial reduction of post transfusion hepatitis by their use. The first problem was that the results of anti-HBc testing were suppressed until late in 1984 (TTVS) and 1986 (NIH). The ALT portion of those trials was sufficient to estimate the effect of ALT testing. Two arguments were used to justify additional prospective, controlled, clinical trials:

1) That the earlier studies were not controlled, randomized and double blinded.

It was argued that any number of factors (sex, age, clinical conditions etc.) could have biased the results. The seriousness of the problem could have been identified by testing whether patients receiving surrogate positive and negative units belonged to the same population with respect to a series of factors. **In fact, it was never demonstrated that such a problem existed.**

Neither the original arguments of the ad hoc advisory group on surrogate testing nor the Canadian study mentioned the need for standardizing the 'input,' **i.e. the selection units for the pools from which blood from which surrogate positive blood was to be removed or not removed.** As presented, the pools could have been manipulated to contain fewer or more surrogate positive units, or fewer or more units causing hepatitis non-A, non-B of the HCV or the non-ABC variety. This circumstance considerably weakens the value of the elaborate control and randomization's of recipient populations.

2) That the earlier studies were not designed to demonstrate efficacy and size of effects by comparing two groups, one receiving blood from pool included surrogate positive units and a pool that had surrogate positive units removed.

The TTVs and the NIH study compared surrogate positive and surrogate negative units and their relative risk associated with them. This was a perfectly legitimate design and answered the essential questions. To design a study comparing two pools of units, one with surrogate positive units removed, and one with surrogate positive units not removed, could only have one (predictable effect): **it would reduce the significance of the relative risk: instead of comparing 'good units with 'bad units', the trial design aimed at comparing 'good units' with bad units mixed in with a majority of 'good units'.** Even if there was insistence on this kind of information, there was no need to compare two groups, because the original studies could be used in two ways:

a) comparing the effects of surrogate positive units with the effects of surrogate negative units

b) Comparing the relative outcome of all units used (including surrogate positive units) with the relative outcome of surrogate negative units (excluding surrogate positive units). While this would not meet the gold standard of a trial of clinical effectiveness, it was surely sufficient to determine the significance of the effect and its magnitude.

As was discussed in the section on clinical trials, such trials are carried out to measure the therapeutic effectiveness, not to measure the effectiveness of a safety procedure.

These three conditions made a clinical trial, as of 1981, unethical, and with that, any argument in favor of such trials instead of using the tests would have been unethical (false, misleading, deceptive) as well. These three conditions existed in addition to the epidemiological evidence on hepatitis and HIV, which was overwhelmingly in favor of surrogate testing.

According to the Krever Report, the Americans were clearly aware of these circumstances and therefore did not conduct a clinical trial. Krever does not go on to point out that the combination of not doing a trial and not using the tests was an even worse ethical infraction, the reasons and motivations of which demand an answer.

All of these conditions prevailed in Canada as well (and it is safe to assume that this included an awareness of all the ethical implications). They prevailed in Canada in 1986, as they prevailed in 1981, notwithstanding all public assertions by the Minister of Health Alan Rock that this is not so. Thus the decision of the Canadian Red Cross Society in 1986 not to use surrogate testing but to conduct a clinical trial was an unethical one.

2. CONFLICTS OF INTEREST; DELAYS AND AVOIDANCE OF A CLINICAL TRIAL

The unacceptability of doing nothing (no trial, no testing) was pointed out by some members of the international forum on ALT-testing in 1983. However as was shown, the panels recommending against surrogate testing were not representative of blood banking but for the most part had vested interests in hepatitis B vaccine development.

The fact that the recommendations against surrogate testing came in part from the US FDA weighs particularly severely. A regulating agency has no business whatsoever to advocate against a safety measure for products under its jurisdiction. This was an absolute perversion of its mandate.

Under such conditions, the fact that the Canadian government did nothing, but kept a 'watching brief' on the US regarding these matters, puts the Canadian Health Protection Branch into the same boat with the US FDA.

The 5 years delay in the US between the recommendations against surrogate testing and the introduction of surrogate testing in 1986, during which time no trial was conducted; and the several year delay between the Canadian decision to conduct a trial and the conduct of the trial; are too long to offer any degree of credibility of the arguments, negotiations, debates, approval processes, etc. as being sincere and in the best interests of

the public. These delays happened during one of the worst health crisis ever, and can only be interpreted as a strategic non-use of surrogate testing, not as policy of making sure that testing is worth the money it costs to do.

3. INCOMPLETE INFORMATION TO OBTAIN INFORMED CONSENT FROM PARTICIPATING PATIENTS.

None of the above was explained to the patients. The most deceptive part of 'information' given to the patients concerned the relative risk. Patients had the relative risk of the 'pools' explained. **They were not informed of the relative risk of surrogate negative and positive units, which was several times higher for positive units than for negative units.** Had the patients been given this information, most likely the investigators would not have been able to find any participants.

4. AN INCOMPLETE TRIAL WITH MULTIPLE SIGNS OF INVESTIGATOR BIAS.

Biases:

- 1) The size of the sample was estimated on the basis of an expectation that surrogate testing would reduce post-transfusion hepatitis by 40%. This was a low estimate if compared with US predictions, but still a rather horrendous assumption to make for a trial of this sort;
- 2) Only by 1988 did the Canadian Red Cross use rigorous selection procedures at its blood clinics. The study was delayed long enough that the expected rate of post-transfusion hepatitis had dropped from 10% in 1985 to 2% by these measures.
- 3) Although the trial was designed for a trial of sample of more than 4000 patients, only 799 were enrolled in the study as designed and approved for funding. After that, HCV-testing was implemented and HCV positive units were removed before pools of surrogate negative and positive units blood to be transfused were established. In other words, these were really two separate studies, and given that the second, larger sample had a known bias, whereas the first smaller sample did not have that bias, the results should not have been pooled. However the results were pooled and yielded a finding that indicated that surrogate testing would not have significantly reduced non-A,non-B post transfusion hepatitis. *Withholding of blood containing NANB surrogate positive units reduced the overall post transfusion rate by 40% ($p=0.065$) and the hepatitis C rate by 70% ($p=0.05$).* The significant result for hepatitis C testing is irrelevant, because this was not what the study intended to establish and was funded for.

4) The results of the small sample were far more significant ($P < 0.001$, two-tailed) than for the total sample ($p = 0.065$, one-tailed), but were not mentioned as such in the abstract summary. (In other words, the most significant results were hidden behind less significant results).

5) One-tailed tests were used only for the total sample, not for subsets, although the direction of expected differences were known from previous studies.

6) The criteria for the diagnosis of post-transfusion hepatitis were more stringent than in earlier trials, and thus influenced the results in favor of non-significance.

7) The study was carried out in Toronto, Winnipeg and Hamilton, but not as originally designed in Vancouver and Montreal. Since post-transfusion hepatitis was a major occurrence in large cities, the change introduced additional bias.

Since all seven biases are in the same direction, i.e. diminishing the significance of relative risks for surrogate tested and not tested blood, the study report is at the very least dishonest.

In addition, the study hides the following:

- **The correlation between hepatitis C positive donors and their ALT and anti-HBc status in the large portion of the study** (the study does not even say what the overall incidence of hepatitis causing units was);

- Although the study was published three years after closing of the participant recruitment, we know nothing of the long-term effects of post-transfusion hepatitis associated with any of the markers; nor do we know anything about those patients who received marker-negative units but might have developed symptoms later.

- We know nothing about the status of marker positive blood donors, although this would have been all-important for the epidemiology of post-transfusion hepatitis. However, this has been the hallmark of all such studies, including the NIH and ITV studies.

5. THE CONTINUED DECEPTION OF THE CANADIAN PUBLIC AFTER 1992.

After the introduction of HCV screening, the overall post-transfusion hepatitis rates were 8.6 and 6.8 per 1000 respectively. Our study indicates that screening of blood donors with the NANB surrogate markers was of value in reducing HCV infection before HCV screening began, but subsequently the value cannot be clearly established.

The small effect is produced by the same research design that was used to hide the effect of surrogate testing and that was used to deceive patients when they were signing the informed consent. Table 17 provides a recalculation of the Chi-Square values based on the data provided in the study. Table 4 of the study report shows that relative risk for non-A.non-B hepatitis and for hepatitis C was still more than twice as high for surrogate test positive units than for negative units – still an unacceptable difference. The p-values for the relative risks could have been given for in Table 4 of the study report, but they were omitted.

Table 18: Comparison of surrogate test studies. **On the left side**, risks of surrogate positive and negative transfusions are compared. **On the right side**, risks of pools of blood units with surrogate-positive units are compared with pools of blood with surrogate-positive blood removed are compared. **Column G** shows that all studies, beyond reasonable doubt showed that surrogate test positive blood (ALT, anti-HBc or both) were more risky than surrogate test negative blood (p-values for Chi-Square tests on surrogate tests positive and negative blood. **Column P** give the p-values for pools of units with surrogate positive blood removed and not removed. As expected, the p-values are much higher (far less significant), and inconsistent. With the exception of the Canadian study (which actually had positive units removed in half of the cases studied), the comparison was made between surrogate negative units and surrogate negative units plus surrogate-positive units. While this is not the same as a true prospective trial, the results nonetheless provide a reasonable estimate for the effect of surrogate testing on pools of blood units.

Explanation of headings (ST stands for 'surrogate test'):

Col. A: No. of patients receiving ST positive blood and developing post-transfusion hepatitis

Col. B: No. of patients receiving ST negative blood and developing post-transfusion hepatitis

Col. C: No. of patients receiving ST positive blood and not developing post-transfusion hepatitis

Col. D: No. of patients receiving ST negative blood and not developing post-transfusion hepatitis

Col. E: Percent of all patients transfused developing post-transfusion hepatitis

Col. F: Chi-Square for above values

Col. G: p-value

Col. H: Relative risk of developing post-transfusion hepatitis from ALT positive and negative blood
(relative risk = $A(B+D)/B(A+C)$)

Col. I: Estimated cases of post-transfusion hepatitis prevented annually in Canada (the estimate is based on an estimate of 300,000 patients transfused per year, and on the (hypothetical) assumption that all patients receive blood from the class of donors specified in Column R)

Col. J: Estimated cases of post-transfusion hepatitis prevented (based on data and assumptions above)

Col. K: No. of patients receiving blood from pool with ST positive not removed and developing post-transfusion hepatitis

Col. L: No. of patients receiving blood from pool with ST positive units removed and developing post-transfusion hepatitis

Col. M: No. of patients receiving blood from pool with ST positive not removed and not developing post-transfusion hepatitis

Col. N: No. of patients receiving blood from pool with ST positive units removed and not developing post-transfusion hepatitis

Col. O,P,Q: see Cols. F,G,H

Col R: Specific portion of surrogate testing study and types of donors used for donating whole blood, type of surrogate test used.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X
1	Hepatitis from surrogate pos/neg units											Hepatitis from pools with surr.-pos units removed/not rem.pools												
	ST+ Hep+	ST- Hep+	ST+H ep- Hep-	ST- Hep+	% PTH Chi-S	% PTH Chi-S	p-value	Rela tive risk	Est. # cases of NA-NB- PTH pre- vented p.a. (Ca- nada)	% PTH prevent ed	ST+ remov ed Hep+	ST+ remov ed Hep+	ST+ remov ed Hep+	ST+ remov ed Hep+	ST-Hep not remov ed	Chi p- value	Rela tive risk							
2																								
3	1959 NILS BANG ET AL.																							
4	30	9	738	594	2.8	7.1206	<0.01	8.5	6565	53.6	39	9	1332	594	3.227	<0.1	1.9	1975	TTV1	all donors	ALT			
5	PRE-1981 RESULTS																							
6	15	13	9	66	27.2	19.716	<0.0005	8.5	43689	53.6	28	13	75	66	2.949	<0.1	1.9	1975	TTV1	all donors	ALT			
7	11	3	4	15	42.4	10.756	<0.0005	13.8	100000	78.5	14	3	19	15	3.477	<0.1	3.6	1975	TTV1	commercial donors	ALT			
8	4	10	5	51	20.0	3.857	<0.05	4.1	17143	28.6	14	10	56	51	0.283	<0.75	1.3	1975	TTV1	voluntary donors	ALT			
9	14	12	22	341	6.7	65.97	<0.0005	18	10797	53.8%	26	12	363	341	4.108	<0.05	2	1978	TTV2	voluntary donors	ALT			
10	1981-RESULTS																							
11	60	100	96	1193	11.0	133.81	<0.0005	7.5	12422	37.5%	160	100	1289	1193	8.712	<0.005	1.5	1981	TTV3	all donors	ALT			
12	25	41	53	977	6.0	100.54	<0.0005	11.2	6843	37.9%	66	41	1030	977	4.369	<0.05	1.6	1981	TTV3	Community agencies, vol. don.	ALT			
13	24	41	29	255	18.6	29.302	<0.0005	5.1	20630	36.9%	65	41	284	255	2.657	<0.25	1.4	1981	TTV3	County-hosp. - don. low SES	ALT			
14	12	9	7	30	36.2	8.859	<0.005	5.7	62069	57.1%	21	9	37	30	1.882	<0.25	1.9	1981	TTV3	Commercial donors	ALT			
15	15	21	37	210	12.7	14.92	<0.0005	3.1	15901	41.6%	36	21	247	210	1.7	<0.25	1.5	1981	NIH study	ALT				
16	66	86	181	965	11.7	66.477	<0.0005	4.1	15254	43.4	152	86	1146	965	7.937	<0.005	1.5	1981	TTV3	all donors	anti-HBc			
17	1984-RESULTS																							
18	57	49	220	825	9.2	56.384	<0.0005	4.4	14857	53.7	106	49	1045	825	9.123	<0.005	1.7	1984	TTV4	all don. anti-HBc+ALT	(at least one +)			
19	39	67	74	971	9.2	95.953	<0.0005	7.6	10165	36.8	106	67	1045	971	5.69	<0.025	1.5	1984	TTV4	volunteer donors	ALT			
20	37	69	161	884	9.2	20.5	<0.0005	2.9	9644	34.9	106	69	1045	884	2.651	<0.25	1.3	1984	TTV4	volunteer donors	anti-HBc			
21	29	17	20	81	31.3	24.8	<0.0005	6.9	59184	63.00%	46	17	101	81	5.986	<0.025	2.2	Diff. between	TTV3 and TTV4	anti-HBc				
22																								
23																								
24																								
25	1988-91 CANADIAN STUDY ON SURROGATE TESTING																							
26	PRE-HCV TESTING																							
27	4	6	66	723	1.3	12.363	<0.0005	7.3	1502	40.00%	10	6	789	723	0.676	<0.50	1.5							
28	3	7	43	746	1.3	10.969	<0.005	7.4	1126	30.00%	10	7	789	746	0.371	<0.60	1.4							
29	3	7	25	764	1.3	21.023	<0.0005	14	1126	30.00%	10	7	789	764	0.433	<0.60	1.4							
30	DURING HCV-TESTING																							
31	4	25	249	3515	0.8	2.3817	<0.25	2.3	316	16.00%	29	25	3764	3515	0.085	<0.80	1.1							
32	2	25	160	3607	0.7	0.6549	<0.5	1.8	158	8.00%	27	25	3767	3607	0.015	<0.95	1.0							
33	2	25	108	3659	0.7	1.9631	<0.2	2.7	158	8.00%	27	25	3767	3659	0.03	<0.90	1.1							

3.8 SYNOPSIS

The four parallel paths of four technologies, the two epidemics, an array of 'social constructions' of the epidemics and practices by public health institutions, several vaccine developments, and scientific studies present a very complex picture. Yet, **there are only a few milestone decisions** along the paths which made all the difference. They are summarized in the following graph:

Fig.16: Critical paths and major milestones of the hepatitis B vaccine-related contamination of the Canadian blood supply.

For the most critical of the six milestone decisions, the use material of monkey-origin in vaccine trials, there is no direct evidence. The indirect evidence and other milestone decisions suggest that it did take place.

1) **In 1970 (?) to use chimpanzee plasma for hepatitis B trial-vaccine production** (not documented; indirect evidence in the form of HIV infected intravenous drug users).

2) **In 1978, to start implementation of production of Factor VIII concentrate for Canada** (documented). Concentrate was known to transmit non-A,non-B hepatitis and should have never been licensed without additional safety measures (such as heat-treatment).

3) **Around 1982: To use one or more hepatitis B vaccines in Canada** (documented). The date of these decisions was not available, however, without such decisions, no vaccine could have been used in Canada. There is evidence that vaccines were used in Canada, so a decision did take place.

The other four milestone decisions were responses to the consequences of the former three decisions:

4) In 1981, the US and Canadian decisions not use to surrogate testing (documented), once AIDS had been formally recognized as an emerging epidemic. The indirect evidence strongly suggests that AIDS had been a liability concern of vaccine developers and surrogate testing would have meant a jeopardy for them; therefore they recommended not to use them.

5) In 1986, the US decision to introduce surrogate testing (documented). Surrogate testing was no longer considered a jeopardy (most likely all vaccine-infected individuals had died).

6) In 1986, the Canadian decision not to use surrogate testing (documented). The evidence and the outright absurd decision suggest that Canada's liability problem reached beyond the outbreak of AIDS. Since vaccine-related HIV would no longer have been a concern, the available evidence, and more so, the evidence that was never produced from available materials (like the 1,000,000 specimens of the Toronto blood center) make HCV-contaminated hepatitis B vaccines the most likely candidate for a significant liability concern. **The fact that at least one hepatitis B vaccine was licensed in violation of the Food and Drugs Act constitutes a liability for the federal government in its own right, regardless of the safety of the vaccines.**

All other decisions, consequences, debates, confusion, misinformation, spread of the epidemic, non-regulated transfusions etc. was a consequence of these first three

decisions, and later for the decisions to avoid liability. **The prima facie case for the two non-documented decisions rests on the documented decisions, data relating to occurrences before 1978, and indirect evidence arising as result of these decisions.**

As stressed repeatedly, this study cannot reach beyond the prima facie case, and only a full inquiry into the submerged decisions (to use vaccines with chimpanzee-derived material, to use Merck vaccines in Canada) can settle the issues, including disclosure of epidemiological findings and test results not made public. Otherwise, the origins of AIDS, the spread of hepatitis C and the bizarre handling of the contamination of blood supply will remain unexplained occurrences, either accepted as 'mysteries', or simply as not making any sense at all. **If, on the other hand, the evidence has been destroyed (which is a real possibility), then the benefit of the doubt should go to the vaccine model of the outbreak of the AIDS pandemic and the spread of hepatitis C.**

Fig. 17 presents an overview of all the critical paths, and occurrences described in the foregoing sections.

Fig. 17: Synopsis of all major contingencies of the contamination of the Canadian blood supply with HIV-1 and HCV.

**Fig. 17: SYNOPSIS OF HEPATITIS B
VACCINE - RELATED
AIDS AND HEPATITIS C
(NON-A, NON-B)**

4. DISCUSSION: THE NEED FOR A SOCIO- LOGY OF TECHNOLOGICAL DEVELOP- MENT AND THE GENESIS OF DISASTERS

4.1 'Dysinformation' ('dys' = bad, defective): The political economy of truth and falsity, disclosure and secrecy; the political economy of ideology

4.2 The case of the contamination of the blood supply: unique or a paradigm of strategy? A comparison with the Challenger incident

4.3 The need for a sociology of technological development; the need for a sociology of disaster genesis

Overview: The case of the Canadian clinical trial on surrogate testing of donated blood for hepatitis non-A, non-B; its possible roots in the hepatitis B vaccine trials; and 'dysinformation' which conceals what had happened; are used to argue for a 'sociology of technological development.' It is suggested that the traditional sociology of production and consumption only addresses the consequences of technological development, not the processes of technological development themselves. Foucault's analysis of knowledge power, practices, discursive practices, and control of truth and knowledge, is focused on steady-state production conditions and respective norms, codes, and disciplines. Technological development and its implications for the conditions of production and consumption have been unfolding, at an accelerated rate, under conditions of the post-colonial and post-Cold War, global, market economy. Heightened competition, economic strategies and practices are becoming 'war-like', i.e. employing winning strategies which used to be reserved for military and security operations. Secrecy, intelligence, dissemination of misleading information, propaganda, are employed as matter of normal practice.

These conditions pose major barriers for carrying out a 'sociology of technological development': sociology may be outright excluded from deliberations, as exemplified by the exclusion of sociologists from the Royal Commission on Reproductive Technology. The example of the hepatitis B vaccines shows how intensive and competitive technology development may take place, protected from public scrutiny; the kinds of risks that are being taken in the battle for market position; and the concealment of serious mishaps. The example of modern transplant technology shows how public consultations may be carried out strategically, not to let the public truly participate, but to reduce or eliminate public resistance to technological development ventures.

The role of capitalism in technological development is discussed as a derivative of the 'tragedy of the commons': the 'tragedy of capitalism', which not only leads to the exhaustion of shared limited resources (the global 'commons'), but also to the exhaustion the capacity for adaptation of biological-ecological processes, including the ecology of the human biological being. None of the solutions considered to remedy the 'tragedy of the capitalism' are particularly encouraging (government regulations, voluntary industrial standards). The consequences of the tragedy may be understood, but not the underlying processes. The methodology developed for this case study is suggested to assist in the elucidation of these processes, as a step towards understanding and dealing with the 'tragedy of capitalism'.

4.1 'DYSINFORMATION' ('DYS' = BAD, DEFECTIVE): THE POLITICAL ECONOMY OF TRUTH AND FALSITY, DISCLOSURE AND SECRECY

Michel Foucault argues that regimes of power are also regimes of knowledge and thus of 'truth'; hence all knowledge is contingent on power relations. (Foucault, 1980:131-2). Foucault identifies five traits of our contemporary 'political economy of truth':

- 1) *Truth is centered on scientific discourse and institutions which produce it;*
- 2) *Truth is in demand for economic production and political power;*
- 3) *Truth is circulated and circulating through the apparatuses of education and information;*
- 4) *Truth is controlled by a few institutions (universities, army, mass media; the author would add publishers and the courts);*
- 5) *Truth is the issue of ideological struggles.*

The study of the origins of the AIDS pandemic and of the spread of hepatitis C in voluntary and commercial blood donor populations suggests that these concepts need to be extended. Regimes of power (and resistance, as the 'other side' in a political struggle) do not control knowledge and truth as a monolithic, static 'ideology of truth', but contingently, adaptively and strategically:

- a) The 'best possible truth' (for themselves);
- b) What of the best possible truth is to be revealed or hidden;
- c) What of the best possible truth is to be 'dissembled' and communicated to be 'perceived as truth', even if it is false.

Examples:

1) Truth/falsity is centered on scientific discourse and institutions which produce it:

a) Best possible truth: For instance, both ALT anti-HBc data on blood donors were available since 1978 to the TTVS group (transfusion-related virus study group within the Council of Community Blood Centers in the U.S. (CCBC)), and the NIH (National Institutes of Health), which studied post-transfusion hepatitis in the US in the late seventies. 'Efficacy' (effect under experimental conditions) was the operative concept used as arguments against testing, whereas 'effectiveness' (effect under uncontrolled, every-day-life conditions) would have been the appropriate concept and provided the compelling evidence in favor of testing.

b) Disclosure and secrecy: Only the ALT efficacy data were published in 1981. Anti-HBc data were presented but not published.

c) Dissembling: The power of these tests was trivialized and misleading arguments against their efficacy were constructed.

2) Truth/falsity is in demand for economic production and political power:

a) Best possible truth: The surrogate test data were needed by the blood industry and the vaccine industry to make decisions as to the continuation of factor VIII and hepatitis B vaccine production, and to estimate the relative liability of selling or discontinuing contaminated products. Since US vaccines were also tested and sold overseas, including the USSR, side-effects of those vaccines carried a political liability as well. The KGB used the notion of contaminated vaccines for political propaganda in Africa.

b) Disclosure and secrecy: It appears that at some point in 1979/80, a decision was reached to withhold information on vaccine safety and risk entirely, to delay the information concerning blood products, but eventually to release it. This ensured continued production and development of new, safer products, and a federal administration protected from litigation and accusation of having failed to protect the safety of the American public. The contamination of the blood supply blood was the 'lesser evil' to be disclosed. The 'larger evil' (contaminated vaccines) remained hidden behind the 'lesser evil.'

c) Dissembling: False information concerning the safety of blood products was released (a risk of 1/1,000,000), and consequently contaminated products could be sold.

3) Truth/falsity is circulated and circulating through the apparatuses of education and information:

a) Best possible truth: The notion that AIDS is a retroviral disease was circulating first through NIH (National Institutes of Health in the U.S.), the FDA (Food and Drug Administration in the U.S.), and the CDC (Centers for Disease Control in the U.S.), the probably the U.S. military and the Institute Pasteur. Bits and pieces of that information were released to the media, but very slowly. The flow of this information was somewhat accelerated by the competition between the NIH and the Institute Pasteur in Paris.

b) Disclosure and secrecy: Early observations by Gallo's NIH labs on reverse transcriptase and the AIDS agent being a retrovirus were withheld. In Canada, the knowledge of the fact that not all hemophiliacs were infected in 1984, and that there was still a susceptible, yet treated, hemophilia subpopulation, were withheld. The circulated assumption was that all hemophiliacs had been infected.

c) Dissembling: The partially false claim that '**the**' hepatitis B vaccine was safe was circulated through scientific publications of the CDC, the WHO and scientific journals (there were several vaccines, and only one had been tested for the presence of HIV).

4) Truth/falsity is controlled by a few institutions (universities, army, mass media, publishers and the courts):

a) Best possible truth: Data on the evaluation of at least three vaccines were held by the New York Blood Center. Only one evaluation was published. Half of the U.S. committee that recommended against surrogate testing were members of the U.S. Veterans Administration. In Canada, Krever and his Commission (and with the co-operation of victim lawyers) held monopoly status on the evidence (some of it given in secrecy) on the contamination of the Canadian blood supply. Canadian media report nothing that is outside the scope of the *Krever Report*.

b) Disclosure and secrecy: Courts in the course of civil litigations have the power to seal the records and to oblige plaintiffs to secrecy as a condition of settlement.

c) Dissembling: Bove, as a faculty member at Yale and as a representative of the American Association of Blood Banks was the key spokesperson on the false claim that the risk of receiving AIDS from a blood transfusion was 1/1,000,000.

5) Truth/falsity is the issue of ideological struggles. Here the author departs somewhat from Foucault. The issue of ideological struggles, most commonly, is economic struggle, justified with ideological claims. Thus the control of truth and falsity as described and exemplified above, is a method or tactic ('means') used in those economic struggles. In public discourses, each side seeks to undermine the other's ideology with selective disclosures of truth, justifications or, if necessary, with falsities - with economic strategies in mind but not disclosed. From this may arise the impression of a primary ideological struggle. In fact, individuals who struggle for ideology's sake alone tend to be considered a nuisance by their more pragmatic affiliates.

a) Best possible truth: Each party needs the best possible truth to successfully select what is most consistent with the ideological justification and, at the same time, ensure a maximum material advantage. This is most evident in struggles of victims of transfusion-related infections, in which material compensation is sought by victims and avoided by liable parties, while both argue ideologically, not materially, and both use selected truths.

b) Disclosure and secrecy: In this struggle, each side seeks to hide the truth that is most disadvantageous and promotes the truths which are most advantageous for material gain (or avoidance of loss).

c) Dissembling: Methods of dysinformation are used when the truth alone is not enough. For instance, the accused may destroy evidence (shredding of records). Plaintiffs in a medical suit or class action, as a collective, may claim equal severity of damage, whereas in reality there is a range of damages ranging from death to merely a positive test result.

In non-sociological terms, one might refer to these three categories of uses of truth and falsity as 'intelligence', 'education/public information', and 'propaganda'. It is therefore not enough to discover, as Foucault suggests, *the ensemble of rules according to which the true and the false are separated, and specific effects of power attached to the true* (Foucault, 1980, *ibid.*). It is also necessary to discover the motivations and specific effects of power attached to falsity. Falsity is not merely the absence of truth, and it is as real in its consequences as the truth. Foucault's five traits of the political economy of

truth apply equally to the political economy of falsity. Scientific institutions are no exception.

The three categories of uses of truth are not independent of one-another, as intelligence is necessary to determine what to construct as 'dysinformation' (propaganda), what to withhold (secrets, intelligence), and what to release (education, public information). Such methods of control of information and communications have been practiced in human history (and still are practiced) under conditions of conflicts. Most conflicts were not decided by brute force, but by advantage in the control of information and communications. Key to the successful execution of this kind of strategic information process is **secrecy**: once secrecy is broken, strategies used by regimes of power tend to fall apart and fail. An example is the 'ENIGMA' coding system of Nazi Germany: the capture of the machine and the breaking of the code may have decided the outcome of the war more than any other contingency.

Assurance of secrecy by regimes of power can be achieved though a multiplicity of methods, through threats, levels of 'classification', spies and informants, selection of 'trusted persons' and 'gate-keepers', sanctions, bribes and other methods of persuasion or coercion, non-keeping of records, shredding and other forms of destruction of documents and evidence. Stories of individuals who feel morally obliged to breach the secrecy ('whistle-blowers'), are not known to have happy endings (for an overview and case studies see Glazer and Glazer, 1989). This is particularly true when the 'whistle-blowing' is done independently of any social movement and organizational support. On the other hand, if whistle blowers join or even start a social movement, they find themselves,

inevitably, under the very same conditions of 'truth' they left behind, albeit with different goals and contents. Whistleblowing, by-and-large is a 'loose-loose' proposition.

Note: Knowing this, the author chose not to be formally tied into the agenda of any of the victim organizations or organizations of social critics.

Whistleblowers appear to violate a 'natural order' (if we can except power relations per se as a natural order), and become a nuisance for regimes of power or resistance.

Note: The mythological figure representing whistleblowers is **Cassandra**, Priam's daughter, who prophesized the truth, but was rendered powerless by Apollo, who made sure that her prophecies were not believed, and that the wooden horse was moved inside of Troy. Cassandras are commonly 'constructed' as annoying, irritating, mad, frustrated, confused, paranoid, irrational, irrelevant, exaggerating, suffering from inflated self-importance, disgruntled, apocalyptic, prophets of doom, treacherous, and most importantly, not to be believed, not to be trusted, and therefore not to be listened to. Under extremely oppressive regimes of power they tend to end up dead, imprisoned, or in a madhouse. Apollo was also the God of prophecy, and thus the myth points out that prophecy is not a phenomenon of important insights to be shared, but a strategic instrument of supreme power and social control. Only prophets who have their prophecies legitimized by such powers, or simply voice the will and intentions of those powers, are listened to and taken seriously. Journalists tend to rely on 'credible sources,' i.e. sources that belong to organizations which are, more or less, compliant with the regime of power.

Secrecy, even without whistleblowing, is never entirely successful. There are always small unintended leaks and scraps of evidence of the truth to be found which, in combination with conspicuously missing information and propaganda can be used to construct what kind of truth it is that is being hidden. Once a 'hit' has been made, all other propaganda statements can be critically examined, with a possible 'hidden truth' in mind.

However, 'counter-intelligence' can actually utilize this kind of intelligence for its own ends. Dissemination of 'dysinformation', that looks like inadvertently lost or leaked secret information, but that is really false and misleading or simply distracting, ('decoys'), can countervail intelligence. The 'revelation' of the 'secret' that the CIA and the US military, in collaboration with the NIH, was engineering a virus (HIV), to be used in Africa for genocidal purposes, is such decoy, and even though quite crude, it was successful. In the early nineties, half of American Black population appears to have believed it – notwithstanding that it does not stand up even to the most basic scrutiny. The alleged involvement of polio vaccines in the origins of the AIDS pandemic was an effective distraction, as it drew attention away from hepatitis vaccines and was easily contradicted. Decoys not only mislead, they also make fools of those who accept them as true and disseminate them as truth. They effectively render would-be Cassandras, who take such decoys at face-value, 'terminally irrelevant.'

More subtle was the use of the discovery by Max Essex of Harvard that macaques were the natural reservoir for HIV-2 virus, and that they were part of the diet of West-African populations. By implication, the 'bushmeat model' of AIDS (HIV-1), without any proof (because it cannot be proven), has remained the dominant model of the outbreak of the AIDS pandemic to this day.

The largest decoy to divert attention away from the vaccine issue was actually the contamination of the blood supply. This decoy was costly, because of the number of people infected and their compensation claims. Still, it was minor in comparison with the terror of AIDS spreading through vaccines first, and then through sexual contact and other forms of transmission. This decoy was exploited to the fullest by the Krever Commission,

which succeeded in focusing all angry reactions on the issues of the contamination of the blood supply. Note: A rather sophisticated ‘decoy’, the temperature/incident charts, kept for the orbiter launches, is discussed in the next chapter.

Knowingly or inadvertently, scientists working in this environment of communications are drawn into the web of strategic information gathering, construction and dissemination. This does not necessarily mean that information is being fabricated, in the sense of scientific fraud, but truthful data can be selected, arranged and reported in such a manner that receivers of that information are bound to arrive at wrong inferences. Expectation, blind faith in science, or distaste of science, ignorance, prejudice, fantasy, rumor, political hatred, gossip, transformation and distortion of information in the chain of communications, misinterpretation, also postmodern tendencies of believing in the ‘relativity and contingency of knowledge’, add ‘noise’ to dyscommunication. Today’s ‘information flood’, the soundbite mode of communication, ever shorter attention spans of audiences, Hollywood, and simple progress of time, with people forgetting and witnesses dying, all of these contingencies help to make the truth eventually unrecognizable and undiscoverable.

Sometimes truths can be hidden under large blanket concepts such as ‘ecological change,’ ‘mystery’, ‘inept or ideologically blinded government’, ‘uncertainty,’ ‘ruthless bureaucrats.’ Once the subject matter is labeled as mysterious, ‘unexplained’, it enters into the realm of the myth. These modern myths, however remote from the central characteristic of ancient myths (i.e. containing ‘kernels of truth’), can become firm beliefs just as the ancient ones.

Given the reality of this weave of truths, half truths, fabrications and things kept secret, inadvertently or deliberately-strategically, the author is left with a large dose of skepticism regarding the findings of this study and the evidence on which they are based. Since the most important direct evidence has been concealed or destroyed, just about all the evidence presented and assembled in this study, scientific or otherwise, must be viewed with a great deal of caution.

This is not good for the future of science. The precedent of the hepatitis B vaccines puts into question all current scientific claims, except for those who have a blind faith in science and blind trust in its leaders. For skeptics, this '*cancer on science*', to use a variation on John Dean's Watergate testimony, will continue to grow. It may perhaps be the most compelling reason to actually have an inquiry on the hepatitis vaccines, assuming that the *prima facie* case will find any acceptance at all. Under current conditions of science communications, public science 'education' is little more than science propaganda and 'illusionism' (deceptive redirection).

Despite all the skepticism which should duly accompany this study, there is, however, one aspect of the two epidemics which cannot be hidden, distorted or misinterpreted: governments and businesses (the blood and plasma industry) were willing to incur horrendous liabilities from the sustained non-use of surrogate testing, far beyond the time when heat-treated factor VIII became available. This cannot be reduced to a recalcitrant, homophobic Reagan administration, greedy corporations, fumbling bureaucrats, or uncertainty and confusion amongst scientists. If scientists were truly that dumb, we might be better served by closing down all research labs and putting an end to science. The only plausible explanation of the absurd responses of governments and

scientists to the epidemics and the non-use of surrogate testing is that the alternative (using surrogate testing) was considered and decided to be worse. Other than blood, only hepatitis vaccines were related to the issue of using surrogate tests. If one considers the full implications of the vaccine model of AIDS and the spread of hepatitis C, it appears that disclosure of a vaccine contamination might have started a political, economic and legal firestorm, not just in the US, but world-wide. The principal US actors (Purcell, Holland, Kellner, Szmuness, and others) in the vaccine game had visited the USSR in 1975 to talk about the vaccine. In 1980, the likely year of the discovery of the consequences of some fateful decisions of 1978, neither the US nor NATO would have been ready for an admission, and even less so if the involvement of Africa was anticipated. They may still not be ready, even today. In the meantime, the use of baboons for animal-to-human transplants have barely been put on hold in the US, and have been all but endorsed by the US FDA. Pigs are being used also (such as fetal pig brain cells for the treatment of Huntington's disease). Yet, we may know less about pig viruses than about monkey viruses.

THE POLITICAL ECONOMY OF IDEOLOGY IN INDUSTRIAL DEVELOPMENT: THE 'HIGHER GOOD' AND THE 'LESSER HUMANS'

'To do evil a human being must first of all believe that what he is doing is good.....

Ideology - that is what gives evil doing its long-sought justification and gives the evildoer the necessary steadfastness and determination. That is the social theory which helps to make his acts seem good instead of bad in his own and others' eyes, so that he won't hear reproaches and curses but will receive

praise and honors. (Alexander Solzhenitsyn, quoted in Horowitz, 1996; Note: the quasi-rational synonym for 'ideology' is 'perspective').

The ideology governing the development of the hepatitis B vaccines did not consist merely in the construction of a higher good (fighting hepatitis B, or eradicating it); but also in justifying how trial subjects were selected, i.e. those '*who would get hepatitis B anyway*' – euphemistically referred to as 'high-risk group', such as the children in the Willowbrook facility. Other such groups eventually included intravenous drug users, sexually active homosexuals, and Africans. The Willowbrook children, the gay men in New York and San Francisco, intravenous drug users and needle-sharers, inhabitants of equatorial Africa, were all marginalized groups and populations, with no or little power, held in low esteem, even viewed with contempt or outright hatred.

A common excuse used by the doctors who performed experiments on inmates of German concentration camps was that the experimental subjects '*were criminals anyway*'. Certainly, there was a difference between Auschwitz and Willowbrook: no consent was required of the inmates of the concentration camps. The trial participants at the Willowbrook facility were 'volunteers' (that is, by proxy through their parents). It remains questionable to this day, however, how 'voluntary' such participation really is, when there is a strong incentive, either through payment (to individuals who desperately need money), or through promising to meet desperate expectations of effective treatment or prevention. While the coercive dimension of the concentration camps has gone, there remains a strong manipulative element in experimental medicine. The study subjects of the hepatitis B vaccine trials could not possibly have been aware how little the hepatitis B vaccine developers really knew of the risks inherent in the source of the vaccine (hepatitis

B, C infected donors and, possibly, in some instances, infected primates); the limited applicability of the vaccine; and the fierce competition for market position that had arisen in the late seventies.

According to Purcell, the chief hepatitis B vaccine investigator at the US NIH, the Willowbrook experiments were '*consistent with the social mores at the time*', which '*changed*' in the early seventies (and also led to the closure of the Willowbrook facility for retarded children in 1976). (Purcell, 1985). This means that the 'mores at the time' were such that the Nuremberg Tribunals might as well never have happened, and that they had no relevance for medical science in the United States between World War II and the early seventies, despite the US's prominent role in the Tribunals. The Nuremberg Tribunals had delivered some kind of standard of what is 'good and evil science', and the use of the Willowbrook children, without doubt, ranks amongst those medical experiments which the Tribunals would have condemned. The fact that the participation was a condition of admission presented to the parents of the Willowbrook children, and the fact that it was not true that '*all children would get infected with hepatitis B anyway*', speak to the moral construction of these experiments.

This is not the end of the similarities. Many of the medical experiments conducted in the concentration camps were done on behalf of the emerging pharmaceutical industry (Bayer/IG Farben) and the German military, i.e. on behalf of the fighting men in the field ('the higher good'). The vaccination experiments benefited the American pharmaceutical industry (Merck, Sharp & Dohme). The military, which sought to reduce hepatitis amongst its personnel (the 'higher good'), actually funded a great deal of hepatitis research, including Krugman's experiments on the Willowbrook children.

THE POLITICAL ECONOMY OF IDEOLOGY IN INDUSTRIAL MARKETING: THE 'INDIVIDUAL GOOD' AND THE 'HIGHER GOOD'

Successful marketing and sales of a product, once developed and licensed, depend on the perceived benefit for the individual using it, not merely on the 'higher good'. The marketing of Factor VIII concentrate promised 'normal life' to hemophiliacs. It did not emphasize that the improvement over the product in use at the time, cryoprecipitate, was marginal, and that the risk of contracting hepatitis was close to 100%. Hepatitis was presented as something of 'minor importance', something that *'hemophiliacs had become used to anyway'*. The 'normal life' argument easily overpowered all other arguments, in terms of benefits for the individual hemophiliac, as well as for the public and the social environment of the hemophiliacs (it served the 'higher good,' and the 'individual good' equally well). Such marketing campaigns 'make or break' the launch of a product launch (snake oil or not), and therefore the 'bad' is not much heard of, while the 'good' receives all the attention.

The marketing of the hepatitis B vaccine took a different turn. While it had been understood all along that the vaccine would not help eradicate the world-wide-problem of hepatitis B, because not enough of it could be produced, the application was restricted as follows:

There has been, however, a general agreement on the population most suitable for vaccination. Thus, the relatively expensive hepatitis B vaccines would be administered preferentially to 'high-risk' populations within 'low-risk countries'. This would be expected to have the most impact on the type B hepatitis with a minimum of outlay of resources. In developing and other countries in which hepatitis B viruses are highly endemic, universal vaccination, especially of young infants and young children, would be contemplated, although such an approach is totally impossible at present because of the high cost of and limited availability of presently licensed vaccines. (Purcell, 1985:24)

Nonetheless, trials on children had been carried out in the late seventies, and in the early eighties, in developing countries. There was no intention, apparently, to let the populations, whose children (and mothers) had been used experimentally, to have the benefit of the outcome of these experiments. The ultimate beneficiaries were healthcare workers (high-risk) group in developed countries. The ideology of 'cost-effectiveness' provided the necessary legitimization ('justification').

THE POLITICAL ECONOMY OF IDEOLOGY IN INDUSTRIAL MISHAPS: THE 'MISHAP' AND THE 'HIGHER GOOD'

Once mishaps occur (e.g. the contamination of the Salk polio vaccine, the contamination of factor VIII concentrate with HIV and HCV), all possible efforts are made to keep it from the public eye and from the eyes of the users. At that point, economic interests and liability concerns become dominant, and the originally announced 'higher good' and the 'individual good' do not surface until occasions of defense arguments during litigation or investigational processes. The most significant example in this respect is Sabin's comment on the suppression of the contamination of polio vaccines. The 'higher good' articulated under those circumstances is that an even greater harm would be prevented: the discontinuation of a vaccine, either by deliberate decisions of the suppliers, or by decision of the public, would create vulnerable populations again. and therefore the use of vaccines must be continued. However, moratoria on the use of such vaccines, until the problems are solved, may not be considered. In the case of factor VIII concentrate, a temporary switch to cryoprecipitate could have been implemented

within weeks, but it would have meant the loss of large quantities of finished products, raw materials and material in process, i.e. severe losses in company assets.

Under these conditions, the 'primary good,' i.e. the growth and viability of a company (and sometimes an entire industry) becomes dominant. Today, this ideology has become equivalent to earlier ideologies, such as the 'good of the nation', the 'good of the Church', or the 'good of the Party'. Times may not be quite ready to proclaim this 'good' publicly. However, as capitalism and vested interests in the viability of enterprises become more and more diffused into larger and larger segments of the population; and as everyday life becomes more and more dependent on the supply of industrial goods and services, the day of proclamation of the ideology of the unquestionable 'good of the corporation' may not be too far away. It can then replace older ideologies such as the 'cost of progress', 'collateral damage', 'necessary sacrifice', even 'heroism'. The imperative of 'efficiency' and 'cost-effectiveness', the 'evil' of wasting money, are parts of this ideology already in place. The ideology of the 'good for the business' has companions for the damaged public: the ideology that 'nothing is hundred percent safe,' 'normal accidents,' 'inevitable mistakes.' While these claims may be true, in their ideological application they take on a different meaning: companies should not be blamed for anything; consumers should be grateful for the benefits; consumer advocates are irrational and litigational lawyers are 'unreasonable' or just outright greedy.

Thus the 'construction of the good' is relentless, if it serves a legitimated economic objective, and the change in these constructions along the 'development cycle of a product' or service is hardly noticed: from the greater societal good, getting the program or product development going; to the individual good, for the launching of a

product and for securing a market position; and to the 'good of the company', avoiding consequences of failure and collapse.

The most visible failures (such as industrial disasters) get the attention in analysis and sociological analysis, but not the earlier conditions which lead to the failure, the genesis of such disasters: the ideologies governing development and marketing. The example of the hepatitis B vaccines and of factor VIII concentrate demonstrate the necessity for inquiring into these early phases in industrial ventures. The decisions with the greatest consequence for our lives are made during technological development, not during technology operation. Today the processes of technological development are almost impenetrable, easily defended by competitive necessities, proprietary privileges and 'intellectual property rights'.

SCIENTISTS, FAILURES, AND THE IDEOLOGY OF THE 'HIGHER GOOD'.

Science for science's sake is utopian, i.e. non-realizable and if realized, destructive. Without motivation anchored in the social, it would be impossible to select the phenomena to be studied, to get the means to study them, and to have the findings accepted. Doing science is a social process as any other human endeavor. Scientists in different social contexts, be it government, business, military, and universities, are all interested in maintaining public legitimization, to sustain flows of funding of their ventures. Realistically, the scientists cannot segregate themselves from such contexts. Therefore, scientists do select and conduct their endeavors, as well as their social relations and interactions, in such a way that they support an institution's continued

viability, on which the scientist's own academic viability depends. Such an orientation is rewarded if it is sustained, and punished if it is violated.

Scientists as well as practicing professionals also learn, soon after they have completed their education, that doing science and professional work are risky undertakings, i.e. things can and will go wrong, by intent or accident. Institutions offer some protection from the consequences of mishaps and failure. Scientists and professionals thus find themselves in a situation of institutional dependency, economically and in terms of protection from liability, not only within their specific institutions, but also within the networks of institutions of which they are members. Taking a stand against someone else's mistake or wrongdoing carries the risk, if not certainty, of losing one's livelihood not just within an institution, but across very large institutional networks. On the other hand, opportunity and rewards arising from cooperation and maintaining 'institutional solidarity' can be high, both economically and in social status.

Given these social contingencies for scientific work, one can expect that scientists will avail themselves of the various constructions of the good and, in their own minds, legitimize the actions of their institutions, their colleagues and their own actions. In other words, scientists can be trusted, when all is well, but they are no more trustworthy than any other individual in any other occupation, when things go wrong.

Given these circumstances it does not come as a surprise to find scientists engaged in contributing to 'dysinformation' on negative consequences of their own or their colleagues' work, i.e. information which is partially true, or which plays with 'possible explanations', suppresses critical information, uncritically accepts hearsay

within scientific circles and from colleagues, and does not critically appraise the claims of others. Rarely is there a need for outright lies, but there is enough scope of distorting and camouflaging the truth and giving wrong impressions, by telling only part of the truth, by playing devil's advocate in the face of compelling truth, to exaggerate uncertainty, to claim personal misinterpretations of such uncertainties and partial knowledge and so forth.

One of the best examples is the Canadian study on AIDS patients which gives certain impressions with a 'cooked' sample (WHO Weekly Epidemiology Record, 1985, 60:314-315), but evades allegations of scientific fraud by referring to a '*selected* (i.e. biased) *group*' in the title. The study refers to a 'selected group' and then does not state the selection criteria. This is an omission, not a commission. It can be claimed, with the full benefit of doubt, to have been an oversight. Everything becomes 'possible' in a day's debate.

One of the easiest ways to tell the truth without informing, or to 'dysinform,' is to '*let the facts speak for themselves*'. Facts are meaningful only from the functional or ideological thinking from which they are born in the first place, and without explicating these contexts, they can be interpreted in an infinite number of ways. To this day, the scientific community has failed to present tested or testable models of the outbreak of the AIDS pandemic, and of the propagation of hepatitis C in voluntary and commercial blood donor populations. Under different circumstances, model building (putting facts into a functional context) of an important outcome like the AIDS pandemic would be one of the scientists' foremost preoccupations. The silence suggests that they prefer to leave the facts lying around, unassembled.

Ideologies of the 'higher good' are easily linked to the physician's dual responsibilities to the individual and the community, including the consequences of discontinuation of vaccinations and the 'shattering of trust in medicine', which, allegedly, might drive people to resort to the exclusive use of unproven methods of 'alternative medicine'. Of course, such 'higher goods' are pure fiction. Even when people learned about the contamination of the blood supply, they did not stop using blood products.

Short of outright sociopathic behavior (which has only one 'good', i.e. the self), even the most objectionable social actions are constructed as 'good', or at least the 'constructed good' is claimed to outweigh the known bad. However, the economic incentives (either as opportunity of gain, or the fear of loss, and all attending consequences for the self), intervene in the 'good/bad' calculus. Nested in enterprising projects may lie an individual scientist's own commercial ambition, the prospect of obtaining 'intellectual property rights', and revenues from patent rights. According to Purcell, even Nobel laureate Baruch Blumberg, the discoverer of the hepatitis B surface antigen, filed for vaccine patent rights – but then chose not to exploit them.

Wolf Szmunes of the New York Blood Center did not (publicly) object to the non-use of surrogate testing (he may even have been the one who recommended not to use anti-HBc as a surrogate test for hepatitis non-A,non-B; his data were withheld until after his death in 1982). He gives a rather confusing account of the side-effects of the Merck vaccine used in the New York 'milestone study' and the Merck hepatitis B vaccine, in particular with respect to anti-HBc positive test results after vaccination, a sign of viral infection according to his earlier studies. Most significantly, his vaccination study addresses anti-HBc, but not ALT (which might have pointed to non-A,non-B

hepatitis infections in the vaccine cohort). His TTV study addresses ALT and hides anti-HBc (which might have pointed to vaccine-related non-A,non-B infections amongst non-A,non-B infections).

In late 1979 he became a consultant to Lewellys Barker the former FDA official, who had joined the American Red Cross, and the person who first argued against the use of ALT in June of 1981, most likely counseled by Wolf Szmunn. In his consulting capacity Szmunn was paid ten times the going rates, negotiated by Kellner. (Kellner, 1985:8):

Lew, after thinking about it for a brief period, agreed completely without haggling, because he knew, and I knew, that even at that price it was a great, great bargain.

THE BANALITY OF 'GOOD AND EVIL'

"The banality of evil". Underneath apocalyptic stories is not 'horrendous evil' but what Hannah Arendt (1964) referred to as 'the banality of evil'. The development of

the hepatitis B vaccine started out with actions resembling those which the German concentration camp doctors were accused of: medical experimentation with captive, powerless individuals, in this case carried out by a pediatrician, Saul Krugman, and the 'inmates' were not Jewish concentration camp inmates, but the inmates of the Willowbrook facility for retarded children. Krugman's experiments are now one of the most frequently quoted examples of 'unethical research' (in the Nuremberg Tribunals there were classified as criminal). In many concentration camp experiments there were two parties of primary interest, the pharmaceutical industry (IG Farben, of which Bayer is a post-war 'descendent'); and the military. There is an almost complete void of information on early phases of the hepatitis B vaccine development in the US, including those carried out by Merck, Sharp & Dohme (Hilleman) and by the NIH/FDA /Union Carbide team (Purcell et al.). After Krugman's experiments, we have no records of those early clinical trials.

Then, it appears, something went very wrong, and there was anticipation of horrendous economic and political damage. After the 'good' had been established (such as: 'save the WHO vaccination program', save the European and American vaccine industries, save the blood products industry, save the NIH, save the FDA, and probably, save the US and other governmental administrations), actors in the unfolding events 'did the job they were hired to do': doctors, scientists, lawyers, judges, public relations experts, administrators, insurance underwriters, production managers and executives, transfusion specialists, vaccine specialists, government regulators, politicians. It was all 'in a day's work' of 'handling a situation' for everybody, while hundreds of thousands of people were unnecessarily infected. It was all presented as 'reasonable', 'cautious,'

‘circumspect,’ anxious not to waste public funds, ensuring that the public would not panic, and preparing quietly for a litigation fallout which was bound to happen at some point (including the first ‘litigation workshops held in California in 1987). The few who did not want ‘to go with the flow’, and those who were anticipated as being not willing to go with the flow, once they had figured out what had happened, were handled more aggressively, i.e. with firings and destruction of credibility, for instance, Dr. Gail Rock, former medical director of the Ottawa Blood Center, who lost her job on grounds of the flimsiest allegations imaginable. Those who had participated in the hepatitis B vaccine trials were given the task to spearhead the dysinformation and were rewarded with continued careers in their respective fields. The only vaccine development team missing in the line-up for ‘dysinformation management’ was really Prince’s team at the New York Blood Center.

The establishment of higher good took these events beyond what Hannah Arendt describes regarding Eichman’s interpretations of his actions (he simply followed orders and established a logistics system for purposes he did not feel were his to question). And it took it beyond what Zygmunt Bauman (1989) describes as the ‘juggernaut of modernity’. efficient management, being the force underneath the holocaust, where average people did their job efficiently (i.e. cost-effectively), as would be expected of them in the Western industrial systems of capitalism. The managers of the HIV and HCV crisis also claimed allegiance to efficiency, but they were also operating on the basis of ‘values, transcending mere efficiency’.

The ‘obeying orders’ defense has been challenged successfully at the Nuremberg trials. The ‘higher good’ defense may be even more objectionable, as it attempts to

dissociate individual action into a realm beyond individual responsibility, i.e. ideology or religion. Ideology and religion are beyond rational challenge. Furthermore, the 'greater good defense' makes possible the use of 'relative risks', of the loss/benefit calculus, and the control of risk information. 'Higher order goods' promising 'future benefits' can be constructed 'ad hoc' for any expected damage, without having to prove the benefits. For instance, the suggestion that not telling the American public about the transmission of SV40 via polio vaccines was based on pure speculation that the public would have avoided vaccinations, if it had been informed.

Note: On a practical level, the 'higher good' defense (not the 'obeying orders defense') has been used on several occasions by the lawyers of the Red Cross during the hearing of the Krever Inquiry to defend the treatment of hemophiliacs with contaminated product: "higher good = saving lives of hemophiliacs and making it possible for them to live a normal life." The 'higher good = cost-effectiveness defense' was used by the US during the early eighties. The US and Canada also used the 'higher good = non-discrimination' to justify non-exclusion of donors with high-risk lifestyles. In all three cases the 'higher good' was constructed on an ad hoc basis, without any attempt to verify its validity and truthfulness.

SPECULATIVE NOISE AND VARIOUS HUMAN-ECOLOGICAL 'MESSES'

Only two models of the origins of AIDS were ever taken seriously, the hepatitis B vaccine model and the bushmeat model. The debate on the hepatitis B vaccine was silenced quickly, the bushmeat model is still being promoted by Harvard University, and others, such as Beatrice Hahn. Other vaccine models, such as the Horowitz's speculation on HIV being an engineered virus used for the contamination of vaccines and 'population control' in Africa were never taken seriously, however, they added to the noise.

"The ecological mess did it." The bushmeat model, which cannot be proven or disproven served 'mystery theorists' well: it supports the idea that the HIV-1 virus has been 'lurking' somewhere in the 'ecology', and jumped from one species to another species, once the ecology was sufficiently upset. As to the spread of hepatitis C, something like a mystery was suggested by Don Francis of the CDC, when he was cross-examined by Alan Powell, the former President of the Hepatitis C Society of Canada.

In response to the next question, "when did hepatitis C emerge and where from?", he said that most of these viruses have always existed, but that an ecological change in humans picks them up out of whatever ecology they are circulating in, either human or non-human. They then enter the human population. " (Powell, 1996:45).

"The human-ecological mess did it". *Clearly, taking blood from one human and giving it to another is a very intimate thing, and a very bizarre and unnatural thing to happen, and therefore it is a new thing within an ecology. (Dr. Donald Francis,*

Inquiry transcript, page 22008). Don Francis was in charge of the hepatitis section at the CDC in Atlanta Georgia. While he insisted orally (and reportedly; "*I rest my laurels on it*") that blood bankers should use surrogate tests to prevent HIV transmission by blood, he never put his position in writing. In a bureaucratic environment, what is not in writing does not exist. There is no record of that meeting. Pounding the table, as Don Francis claims to have done, does not count. Individuals like Don Francis are perhaps the most subtle, yet most effective, 'dysinformers', as they give the impression that they are eager to bring the truth to the public, but then do not do it, in a complete, specific, and comprehensible way. This can be said about the Krever Inquiry, which brought to light some (apparently 'agreed upon') truths, and left out others.

"The bureaucratic mess did it." *The system that governs transfusion medicine in Canada [is] chaotic. And I persist in that view.* (Dr. Victor Feinman, Inquiry transcript, page 23145). Feinman conducted the post-transfusion hepatitis study in Toronto in 1984/5, and was untruthful about the access to donors specimens implicated in cases of post transfusion hepatitis. He was one of the principal investigators of the clinical trial on surrogate testing in Canada.

"The scientific uncertainty did it." *I'm very proud of my decision not to proceed without scientific data.* (Dr. John Furesz, head of the Bureau of Biologics, Canada, re: inactivation of hepatitis B and non-A,non-B by heat treatment. October 27, 1995). Dr. Furesz would was key person who would have made licensing of the hepatitis B vaccines in Canada possible.

The three individuals have in common that they had access to scientific data and evidence which would have clarified what happened, but which are still withheld from the public.

Their explanations, of course, are so general that they cover just about any ecological mechanism one can think of. Powell never asked Don Francis which kind of change he was referring to. The two most drastic ecological changes in this century have been the major wars and the world-wide use of vaccination. War, early vaccinations and garrisons in foreign countries may well have generated the first wave of hepatitis C (starting in Korea, as suggested by Seef of the US Veteran's administration to Allen Powell in a telephone conversation; however, Korea is not a place with high hepatitis C prevalence; hepatitis is rarely transmitted sexually; and Seef's reference again points to the possibility of a vaccine-related spread amongst American service men and women stationed in Korea).

The second wave may have been the spread through blood and plasma donations and intravenous drug-use, in part by veterans. The third wave, in particular in Canada and perhaps in the United Kingdom and elsewhere, appears to have been linked to a hepatitis B active and/or passive immunizations. From the vaccine perspective, Don Francis's explanation is clear. Vaccination is major human ingress into the natural ecology. Without the vaccine model, there is only the vague notion of 'ecological messes' created by human interventions in the environment: the model promoted by Laurie Garrett. Garrett quotes Albert Camus (*The Plague*, 1948):

Everybody knows that pestilences have a way of recurring in the world; yet somehow we find it hard to believe in ones that crash down on our heads from a blue sky. (Garrett, 1994:281)

It is time not to believe in those crashing down on our heads from a blue sky, and to ask more and more questions. In his *Foreword* to Leonard Horowitz's book (1996) John Martin wrote:

.....What makes vaccines so troublesome is that their production and administration allows viral contamination to breach two natural barriers:

First is the skin. Direct inoculation of vaccine breaches this natural barrier and has been shown to produce increased infections in animals and humans. Such was the case when SV40 was injected intramuscularly in contaminated Salk polio vaccine. ...Additionally risky, when it comes to breaking the skin barrier, is the chance of transmitting viruses from one person to another through the use of unsterilized needles.

Second is the unique and natural viral surface characteristic that reduces the chances that viruses might jump species. The mixing of vaccine viruses with others found in the cells and tissues used to develop the vaccine can potentially lead to the development of new recombinant mutants that are more adaptive and have a wider host range than either of the original viruses. This can especially happen when a live viral vaccine produced in cells from one species is then given to another species.

Also of concern is the transmission of new genetic information along with the vaccine virus. For instance, early adenoviral vaccines, produced in rhesus monkey kidney cells, developed to protect people against respiratory infections, incorporate part of the SV40 virus that remained as a vaccine contaminant even after the production of the vaccine viruses was switched to human cells. Numerous other vaccines, especially those used in early field trials in Africa, should be analyzed for those genetic components which characterize today's monkey and human pathogens.

Unfortunately this new awareness of potential problems with live viral vaccines has had little impact on the viral vaccine approval process. Seemingly, US government agencies, principally the FDA, have been reluctant to impose additional testing requirements on vaccines once they are approved for use. In effect, government officials are given a single opportunity to decide on a new vaccine's safety. Even then, government regulators themselves may be denied certain critical information belonging to the vaccine industry. Specifically, FDA regulations are written so as not to compel industry to reveal testing information not directly pertaining to the lots submitted for clinical use. The FDA is reluctant to admit its lack of knowledge about vaccines to the medical/scientific community.

Yet, practicing physicians are expected to unquestionably endorse the safety of vaccines under all circumstances and to all individuals.

Aside from these bureaucratic barriers to viral vaccine safety assurance, there are additional major concerns. Since vaccine development information is considered proprietary - protected by non-disclosure policies – government officials and researchers must shield potential safety issues from public scrutiny. This censorship is rationalized by the all too persuasive argument that vaccines must not be criticized lest the public become non-compliant in taking them. Finally the silence is buttressed by a small number of people capable of critically evaluating vaccine manufacturing and safety testing procedures. In essence, health care professionals and the general public know little about the possible dangers of live viral vaccines.

As an illustration, the issue of possible simian cytomegaly virus (SCMV) contamination of live polio vaccines has been suppressed since 1972. On the eve of Nixon's war on cancer, a joint Lederle Corporation/FDA Bureau of Biologics study showed that eleven test monkeys, imported for polio vaccine production, tested positively for SCMV. The reluctance of the FDA to act on this matter was revealed in a corporate memo delivered the following year. Even in 1995, following a report to FDA officials concerning a patient infected with SCMV-derived virus, no new in-house testing of polio vaccines for SCMV has occurred. Moreover, this author's specific requests for vaccine material to undertake specific testing, were denied on the basis of protecting 'proprietary interests'.

This basic flaw in the regulatory process must be addressed – the FDA must be responsive to the medial-scientific community's need for accurate information regarding the potential hazards of products released for use in society. In the event that public health and safety concerns arise, industry should wave its right to maintain proprietary intelligence. This would enable the FDA to disclose more information concerning the FDA regulated products to the medical scientific community. Such a proposal should be included in all pending and future FDA reforms.....

Martin's discussion of vaccines illustrates that vaccine production were very risky ventures, risky for the immunized populations, that is. Martin's models of the HIV-pandemic (promoted and expounded by Horowitz) included notions that AIDS arose accidentally or naturally from experimentation with viral vaccines; or intentionally through retroviral and other viral biological weapons development by the National Cancer Institute, the US military and the CIA. If the chimpanzee hypotheses (chimpanzees being the natural reservoir of HIV-1) is true, then those models can be put to rest. If the

chimpanzee hypothesis is false or (in the worst case) yet another piece of dysinformation to promote the bushmeat model, then Martin's and Horowitz's propositions (and those of others) cannot be put to rest. The claim that chimpanzees are the natural reservoir for HIV-1 still awaits confirmation by field investigations of wild-living chimpanzees and the epidemiology of HIV-infections in such populations. The blood products connection of the hepatitis vaccine was not exposed by Horowitz, despite the fact that it is self-evident from the Purcell grant proposal, which carries four names of blood product specialists at the FDA and the NIH. Horowitz missed (or omitted) three important points in his arguments:

- 1) The hepatitis B vaccines were not regulated by the vaccine division of the FDA but by the Blood and Blood products division;
- 2) The FDA, although a regulator, was directly involved in product development (phase 2 trials), rather than being the 'evaluator';
- 3) The FDA (Barker and Gerety) blocked the information flows concerning its own activities by arguing against surrogate testing, and then actively promoting the distribution of unsafe blood products to cover their vaccine-related activities and consequences thereof.

W. John Martin. MD, PhD, is (or was, at the time of writing of the Horowitz's book) professor of pathology at the University of Southern California, also Director of the Center for Complex Infectious Diseases in Rosemead, California. Between 1976 and 1980 (i.e. during the critical years of experimentation with hepatitis B vaccines). Martin served as director of the Viral Oncology Branch of the FDA's Bureau of Biologics (now Center for Biologics, Evaluation and Research), the US governments' principal agency in charge of human vaccines. He thus was a colleague of two of the FDA scientists who

took the lead in the suppression of surrogate testing: Barker and Gerety. Martin's 'departure' from the FDA in 1980, may not have been entirely coincidental, and no less than L. Barker's transfer from the FDA Blood and Blood Products Division of the FDA in 1989 to the American Red Cross as Vicepresident, Health Services, and his hiring of Wolf Szmunn, chief epidemiologist of the New York Blood Center, at the end of 1979, at 10 times the going consultancy rates. Also, the budget cuts to the FDA while the AIDS crisis erupted are difficult to accept as coincidental. Around the same time, the entire staff of the National Office of the American Red Cross was fired, and had to reapply for positions. Similar events occurred between 1985 and 1990 in the Canadian Red Cross, when it was preparing for further suppression of surrogate testing, laws suits and inquiries. 11 MDs were removed from their positions, and the National Office of the Canadian Red Cross Society was relocated to Ottawa (a move which most employees did not make). This kind of action is referred to as eliminating 'institutional memory', i.e. removing individuals who know or are suspected of knowing *'how it all hangs together'*, and who are considered a risk to the maintenance of silence. Once removed, their removal in itself leads to discrediting allegations of being 'disgruntled former employees' (which are readily accepted by the media).

FROM CONCEALING THE TRUTH TO DISSEMBLING THE TRUTH TO OUTRIGHT LYING.

Since the bad consequences of hepatitis B vaccine decisions were more or less noticeable (more for AIDS, less for hepatitis C), withholding the truth was not enough,

but measures were taken, to ensure that the path of propagation of HC and HIV could not be readily identified (such as the suppression of surrogate testing). However, it was not enough to hide information, to facilitate the sale of hazardous or potentially hazardous product (blood and blood products and hepatitis B vaccines, respectively); and to prevent questions in the direction of a vaccine-related dissemination of the diseases. It became necessary to disseminate 'dysinformation' on AIDS. With AIDS taking on front-and-center stage, the hepatitis issue could just be 'handled' with silence. The key dysinformation strategies used between 1981 (the year of the decision not to use surrogate testing and 1989 (the year of implementation of hepatitis C testing) were as follows:

1) Surrogate testing is not proven scientifically and requires a prospective controlled clinical trial (which was a false and misleading argument, because some of the data were withheld, and the totality data proved beyond 'reasonable doubt' that surrogate testing was effective in the prevention of hepatitis Non-A,non-B and HIV transmission by blood products).

2) In the early eighties scientists did not have the 20/20 vision of hindsight they had in the nineties. All the information that could have been produced and published, but was not shown, even where it existed, suggests that key scientists had a 20/20 vision then.

3) The chances of getting AIDS from blood transfusion is 1/1,000,000 (Bove of Yale, and American association of Blood Banks). This was a false statement, because it was already understood that AIDS had a long incubation time, and the '1/1,000,000' was based on cases diagnosed as transfusion-related AIDS, not on the basis of an estimate of already infected blood donors. By the time this announcement was made, American health officials would have known, on the basis of epidemiological data that the reported AIDS cases were only the tip of the iceberg.

4) The Merck vaccine was safe. The testing arrangements involved the developers and producers only, not independent laboratories, render this claim invalid. Also, only the commercial, licensed Merck product was tested, but none of the trial vaccines, including the Merck trial vaccine.

5) Factor VIII concentrate saves the lives of hemophiliacs and lets them live a normal life. This was wildly exaggerated (even Laurie Garrett believed it), since the much safer cryoprecipitate could have accomplished almost the same level of life expectancy and quality of life, at a much lower cost, albeit at a somewhat greater inconvenience for the most severe hemophiliacs.

6) AIDS is a gay disease (which was false); **AIDS came out of Africa** (probably false); **it was result of human interventions in the natural ecology** (not false, but so non-specific to render it meaningless). Messy ecological conditions however, did promote the spread of AIDS.

7) AIDS entered into human populations where chimpanzee flesh was used for human consumption. There is no such evidence.

In addition to these most important false and misleading statements, there was a plethora of other misinformation, misrepresentations, outright lies, single cases used as evidence for the origin of AIDS, avoidance of research in surrogate testing for a decade, and last but not least, a multi-million dollar inquiry into Canadian blood system that 'overlooked' the most important blood product: the hepatitis B vaccines. It was headed by a commissioner who had ignored information as co-leader of an earlier inquiry by the Royal Society of Canada into AIDS which overlooked compensation of individuals infected with HIV by blood transfusion and their spouses at risk of being infected as well.

PESHES

In her analysis of the Gospels, Barbara Thiering (1994) describes a method by which ancient Hebrew scribes would write historical records, originally to present history as a fulfillment of prophecy; later, by using this method, to tell the truth under dangerous political conditions, as the historical events were unfolding. As history was written as a

fulfillment of the prophecies, the true meaning of the texts were comprehended only by those who knew the scriptures and prophecies, as well and the historical, political goings-on to which the texts referred: to those who had '*ears to hear*' and '*eyes to see*', i.e. 'insiders' of political leadership groups. The Gospels are written in the format of fulfillment of prophecies, in codes which refer to practices and beliefs of the Essene sect, which maintained a succession of leaders from King David. The Gospels were decipherable only to those people who were on the inside of the Jewish sect (Essene) of and other political leadership at the time. Many events, which are now labeled as 'mysteries' and 'miracles,' are accepted as such by those who want to believe in them. They are rejected as fantastic story-telling by others. There were no 'insiders' alive from the time to which the Gospels refer, at the time of their writing. The writers may no longer have known the exact meanings of all the terms kept alive in oral tradition. With the aid of the Dead Sea Scrolls, Thiering tried to decipher the historical content of the Gospels and to uncover the political/historical contingencies to which they refer.

With respect to hepatitis vaccine program, the AIDS story is being built to fit the bushmeat model of AIDS; and hepatitis C is barely discussed, (it is a major public health problem in the US, attended to by the Surgeon General, as member of the US military, representing the very body that had originally a major interest in that vaccine development). Some of the original insider witnesses have died (Szmunn, Krugman, Kellner), others, like Lewellys Barker have 'disappeared'; others hold firmly cemented positions like Robert Purcell at the NIH. Once the 'vaccine cohort' of scientists has died, they will not have left behind a record of what actually happened, and any theory, model or myth can make it to the ranks of 'official accounts of what happened'.

There are very few individuals who transmitted 'nuggets of truth', but embedded them in *peshers*, such as Don Francis and Sandra Panem embedded factual claims in 'ecological or bureaucratic mess prophecies' (bureaucratic, ecological apocalypse?). Writers like Randy Shilts, Laurie Garrett and Sandra Panem, and ultimately Horace Krever, picked up those prophecies (although Krever might have known more than his report reveals). Martin and Horowitz embedded their nuggets of truth in a conspiracy theory involving the WHO, the CIA, Kissinger and the National Institutes of Health, to exercise population control by engineering deadly viruses (the 'evil empire apocalypse'?). These accounts then do not really serve the revelation of the 'truth', but rather to conceal it even further, to hide the facts, transmitted to a few who may still be able to identify them; buried as needles in far more haystacks than there are needles.

The significance of this dysinformation and 'peshering of the truth' does not lie in the fact that it was done, but in the circumstance that it was done to 'handle' what is possibly the worst human-made disaster in biomedicine, and so far, successfully so. The search for the needles in the haystack in this study have yielded nothing more than a *prima facie* case for an inquiry, not what really happened. As will be discussed, the chances of such an inquiry ever taking place are very small. The handling of the HIV/HCV crisis has produced a model for 'handling' even most disastrous mishaps in technological development, without any significant repercussions and penalties for those who are 'handling' it; and without the slightest chance for the public to ensure that similar accidents and their handling cannot happen again, or at least are severely curtailed. Not surprisingly, in 1986, there are some similarities between the handling of the Challenger incident and the handling of the vaccine-propagated epidemics.

The cost of these 'successful strategies' were not only dead and damaged people, but also the long-lasting stigmatization of gays ('Patient Zero') and Africans ("*Is it true that Africans have sex with monkeys?*") with respect to their sexual practices. A question yet to be answered is why the leaderships of the groups, the members of which had their health and their reputations damaged, did not press for an in-depth investigation of the origins of the two diseases. They seem to be willing to go to bat on many other, less critical, issues.

THE GROUP AT HARVARD UNIVERSITY

But other scientists were looking at the same data on AIDS patients and reaching very different conclusions. Some felt that AIDS was simply a new manifestation of the hepatitis B virus, or of some unknown contaminant of the hepatitis vaccine, first experimental trials of which had been on gay Americans. (Garrett 1994:322)

This passage is found many pages prior to the discussion of AIDS and various vaccine models. Here it becomes clear that Garrett, a journalist, relied entirely and quite uncritically on interviews of experts for the writing of her account and did not really study the primary sources. On the other hand, she must be considered a serious author on public health, as in Harvard's report on AIDS of 1992, where she wrote the chapter on emerging diseases. Given the vast number of old and emerging viruses she confronted in her accounts, one would have to give Garrett some latitude for not consulting all primary references. It would have been impossible. The source was undoubtedly Don Francis of the CDC, who was a known hepatitis B specialist and graduate of Harvard University,

and who had worked for years with Max Essex, who, in turn had alerted the American public to HIV-2 in 1985 and started the debate how simian immunodeficiency viruses might enter into human populations. Perhaps one can recognize Don Francis's '*peshering*' in this comment on the reference to hepatitis B vaccines: In contrast to her other accounts on vaccine-related infections, Garrett does not state that the hepatitis B vaccine model was refuted.

Research in this field at Harvard has managed to keep the focus on Africa, and away from the major simultaneous outbreaks in New York, San Francisco and Los Angeles, and that this pattern of the epidemic can only be explained with the simultaneous infections of many individuals in selected places, not through a gradual spread through gay and drug user networks. While Harvard seemed to be pleased that the transmission of HIV-2 from laboratory macaques to humans via scratches, bites and needle-sticks had been discovered, the possibility that the same might happen with chimpanzees, which were used in very large numbers for vaccine tests, never even entered into the debate there, until Montagnier's identification of Gabon chimpanzees as likely natural reservoir for HIV-1. Even if the vaccine model is set aside, one needs to account for the substantial populations of captive chimpanzees in laboratories in Africa, the US and in Europe. At the very least, monkey hunters, who capture the chimpanzees, and monkey handlers in the various animal facilities (including zoos and circuses) should have been a logical area to be examined for possible transmission of all sort of viruses. If such work has been done, we have not heard of the results, and definitely not from Harvard, which has such a keen interest in simian viruses.

When Gao et al. published their latest findings on HIV-1 in chimpanzees in *Science* (1999, 397:436), Robin A. Weiss of the Windeyer Institute, University College London, and Richard W. Wrangham of the Department of Anthropology, Harvard University (*Science*, 397:385-6) hurried to comment in a review article in the same issue on the bushmeat trade, and the dual income of monkey hunters, who sell young chimpanzees and their parents and older relatives as bushmeat – overlooking the fact that the AIDS pandemic started at the border of the habitat of a subspecies which does not carry HIV-1.

The picture of the chained chimpanzee also helps to divert attention away from the AIDS problem to the threat of extinction of wild-living chimpanzees. It seems that the Harvard machinery of redirecting attention away from vaccine into the African forests is relentless.

Note: The shrinkage of chimpanzee populations is an important issue, and it appears that it was due to a large extent, to the voracious appetite of Western scientists for baby chimpanzees. At the end of this road one can say that all this carnage, incarceration and mass infection of chimpanzees has been for naught. Again, this carnage was driven by the competitive race for market positions in hepatitis vaccines, not by a scientific need to know. Humans may have paid a price for this primate slaughter – this time.

PETER DUESBERG (after Marsa, 1997)

Together with Vogt, Peter Duesberg had discovered cancer-causing genes in 1970, and also has a hand in retrovirology. In 1984, when Secretary Margret Heckler announced Gallo's 'discovery' of the AIDS virus and the imminent availability of a test, Duesberg began a campaign against Gallo and the HIV-etiology of AIDS. At least on the surface, he

seemed to challenge the ‘establishment’ of viral oncology. He wanted the public to believe:

o That retroviruses cannot cause tumors (HTLV I and II) and, at the same time, cause cell and host destruction (HTLV III alias LAV alias HIV-1, causing T4 lymphocyte destruction). In other words, retroviruses are not ‘that stupid’. However, by then it was also well understood that hepatitis B virus can do exactly that: lead to an acute destruction of the liver (‘fulminant hepatitis’, in the course of which the liver may shrink to the size of fist); and cause liver cancer (primary hepatocellular carcinoma);

o That HIV was just a ‘bystander’. He claimed that AIDS patients were just exposed to a large variety of viruses, which were depressing the immunesystem, whereas AIDS was just a ‘bystander’. He suggested that researchers were seriously misled when they focused on HIV. However, by then it had become clear that patients with a large number of different infections, but who did not have HIV, would not get AIDS (i.e. die from one or more of these exacerbated infections); whereas those who did die were also carriers of HIV;

o That HIV violates non-discrimination between sexes common in infectious diseases (at the time mostly gay men were infected in the US and in Europe); but in 1986 it was also already known that women could be infected as well (Africa, Haiti and some cases in the US);

o That HIV violates Farr’s law (i.e. epidemics produce a bell-shaped curve in the progression of annually reported cases, because people begin to develop immunity). But if the immune-system itself is attacked, Farr’s law cannot possibly apply: it also does not apply to STD pathogens, parasites, hepatitis viruses and so forth;

Duesberg’s attacks continued until 1988, when, in a panel discussion, he finally painted himself into a corner by suggesting that AIDS is not an infectious disease and people need not have protected sex. (Duesberg was a laboratory scientist, not a field epidemiologists, and his wits and understanding did not reach far enough in this direction). After that he kept attacking the establishment, and their resistance to unorthodox ideas. In fact, the establishment did set up a kind of arbitration panel

(Haseltine and Myron Essex, Harvard) as to who would get AIDS research money and who would not, while Harvard got the most money of all applicants (32 million dollars a year by 1989). Essex and Haseltine accumulated stock in vaccine development in the millions.

On the face of it, Duesberg was playing 'devil's advocate'. However, if one looks at his arguments close enough, they are all bogus arguments, and no serious epidemiologist and infectious disease specialist would have made them in this fashion. Duesberg was a genetic cancer specialist, not an infectious diseases specialist. Indeed, at the very same time as Gallo went public with his HIV tests, Duesberg began to propagate the model of the 'misguided, greedy, blinkered, establishment scientist.' This model was fully applied by Linda Marsa in her 1997 book to the case of Robert Gallo.

If one assumes the vaccine model of AIDS and the 'dysinformation campaign' to be valid, then his arguments can be seen to play well into the emerging 'postmodern' questioning of the validity of biomedical scientific claims, and into public aversions against 'greedy scientists'. Duesberg then gives the impression, like Gallo, of a strategically coached scientist, involved in the suppression and distortion of the knowledge on AIDS and its origins, who pushed not only the origins of AIDS in the realm of the mysterious, but the very nature and identity of the responsible pathogen itself.

Unfortunately, Duesberg's intervention, to this day, is not without consequences. An unknown number of HIV-infected mothers will continue to believe that HIV has nothing to do with AIDS, and that therefore it is alright to become pregnant, not to be treated, to breastfeed the baby, and not to have the baby treated. People who believe in

Duesberg and hate the likes of Gallo and the 'biomedical model of disease' believe that the body must 'heal itself', while they are in denial of the millions of those whose body could not heal itself and simply expired.

Accordingly, Duesberg's case and his indirect characterization of Gallo (who used to be a friend of his) is of interest with respect to the 'dysinformation value' its represents; and how the management of dysinformation targets groups and strata with specific antipathies, dislikes and beliefs, thereby closing down critical appraisal of even the most outrageous of claims.

4.2 THE CASE OF THE CONTAMINATION OF THE BLOOD SUPPLY: UNIQUE OR A PARADIGM OF STRATEGY? A COMPARISON WITH THE CHALLENGER INCIDENT.

THE CHALLENGER INCIDENT

Note: This section was developed on the basis of **Richard Feynman's** account of his experiences during the Presidential Inquiry, recorded and narrated by Ralph Leighton (*What do You Care What Other People Think. Further Adventures of a Curious Character.* 1988, Bantam, New Age); and **Diane Vaughan's** 1996 account of the Challenger launch decision.

The space shuttle (orbiter) design replaced the earlier, disposable rocket design of the government/military-managed space program; (Apollo program - flights to the moon). Also, the new space program was given a commercial purpose (commercial pay loads, such as commercial communications satellites) and came under civilian management and direction (NASA - National Aeronautics and Space Administration.)

The key to the new program was the abandonment of the staged disposable rocket design, which could only recover the command capsule. The new design consists of a permanent space shuttle craft (model 'orbiter', e.g. 'Challenger'), a large liquid-fuel tank (hydrogen and oxygen) and two reusable solid-fuel booster rockets. The liquid-fuel tank fuels the main engines of the craft at its tail-end. The solid-fuel booster rockets burn for a few minutes and are then separated and fall into the sea. The main liquid fuel tank separates a few minutes later and breaks up (or is blown up?) before it falls into the sea.

The booster rockets are recovered and parts reused. During the launch, the crew is located in the command module at the front end of the craft, in front of the cargo bay.

Assembly and launch of the spacecraft is carried out at the Kennedy Space Center in Florida. The solid-fuel booster rockets were manufactured by the Morton Thiokol factory in Utah. The segments of the booster rockets were shipped by train. The final assembly of the rocket is done at the Space Center. The joint at the tip of the rocket and the engine-nozzle-to-case joints at the tail-end of the rocket are permanent 'factory joints', i.e. they were assembled and sealed at the factory in Utah. The joints in the midsection of the rocket (the temporary 'field joints') are assembled and sealed at the Space Center in Florida.

Thus manufacturing contract, design, manufacture and assembly of the sections and in particular the joints of a reusable rocket introduced complexities into a relatively simple casing concept, and thus into the overall design of the shuttle, which normally would not have occurred (such in the Apollo program). The permanent factory seals never presented a problem. To equip the entire rocket with such permanent seals, it would have meant that the rocket needed to be built at the Space Center, not in a remote location. The critical elements of the seal between the segment are presented in the following diagram (adapted and simplified from Richard Feynman's account).

In summary: The solid fuel booster rockets were designed for partial recovery and cost saving. This introduced the need for joints between rocket segments, and the joints were, by their very nature, potential loci of instability. The joints and their assembly were designed to compensate for this instability. There was no temperature specification for the launch.

Fig.18. summarizes the critical design elements, the path of the escaping gases and the conditions along the path which made the escape possible. The diagrams were simplified and developed and from various graphic material provided in the Feynman book. The 'gas escape diagram was developed by the author according to Richard Feynman's account. **Joints:** Chromate putty was used a filler for the field joints of the solid booster rocket. Only flight-certified filler material should have been used; chromate putty was apparently not certified material. Joints were pressure-tested at 200 psi. Due to engine vibration the ends of the sections rotate somewhat.. **O-rings:** O-rings were supplied by the Parker Seal Company (64). They were a quarter of an inch thick , 12 feet in diameter and 37 feet in circumference. The O-rings are statically compressed (i.e. before launch) by 20/1000 (1/50) of an inch. If the rings were not resilient for a second or two during the launch that, serious problems could have resulted. During the night before the launch, the temperature was 22 degrees F, and 8 degrees F in some places. The coldest launch had been 53 degrees F. The shuttle took off at 28 degrees F. The Rocket section bulged between the seal-rings during launch due to pressure inside the rocket. This could have lifted the rings off the tang of the joint. To compensate for the bulging, the O-rings were expected to expand and close the gap. **Rocket sections:** After a launch the segments are recovered from the ocean, and then they are no longer perfectly round due to the impact. They are hung from a crane sideways for a few days. The irregularities in the roundness incurred from the impact are re-rounded (elimination of 'nipples') with a rounding machine (a rod, with hydraulic press on one end and nut on the other, used to compress the segment). Three diameters were measured to establish roundness. The three diameters were measured after every rounding attempt. According to specifications, there should not have been a leak leading to an explosion (if everything performed as expected). **However, these specifications included the use of a joint filler material which was not standard (chromate putty).**

Fig. 18: Simplified diagrams of cross-sections of the booster rocket field joints. (Simplified from various diagrams provided by Richard Feynman, 1988)

Summary of the processes leading to the explosion of the craft:

- 1) The zinc chromate putty, which sealed the gap between the inner insulation of the rocket sections, formed bubbles during firing of the engines. A possible cause of the bubbles were 200 psi 'leak checks' performed as 'safety check' (pressurizing the space between the two O-rings through the 'leak-test ports'.) The bubbles let hot gases escape which could reach the O-rings, burn and erode them. The bubbles got larger when hot gases blew through them. The escape of gas was called 'blow-by' by the engineers. Blackening and burning of the O-rings was called 'erosion' by the engineers. Sometimes O-rings were reduced to less than half the original diameter by erosion.
- 2) Under the pressure from within the rocket, the rocket segments bulged between the segmental joints and created a greater gap between clevis and tang at the position of the O-rings (also referred to as 'joint-rotation' which reduced the effectiveness of the O-rings).
- 3) Vibration of the rocket led to a rotating motion between tang and clevis (a problem which Thiokol addressed by 'shimming' the outer gap between tang and clevis (i.e. the gap where there were no O-rings).
- 4) The rocket segment cylinders to be reused and their clevis/tang ends were somewhat deformed by the impact on the ocean surface and thus not perfectly round: there may have been gaps between tang and clevis (referred to as 'nipples' by the factory workers), despite 'rounding procedures'. The Thiokol assembly crew confirmed that three measurements of segment diameters were not enough to ensure perfect roundness of the rocket segments and thus exact fit of tang and clevis.
- 5) In cold temperature, the O-rings, once compressed, would not snap back rapidly to their normal round shape needed for effective sealing (This factor led Richard Feynman to do his now famous public demonstration at the Presidential Inquiry).
- 6) The booster rocket exploded after hot fuel gases escaped from one of the field joints and were ignited. The escape of the gases became possible by the peculiar properties and conditions of the field joints described above. Cold temperature was the most important contingency for this particular incident. The explosion was the result of a leak close to the rocket engine: the gas stream escaping from the seal reached the hot propulsion gases of the engine and was ignited.
- 7) Wind-shear may have added to the forces working on the field joints.

Design and development problems. It appears that the seals on the solid-fuel booster rockets had been a serious problem all along, which was mainly due to the overall design of the shuttle launch systems. The critical path for the orbiter incident thus starts with the decision to change the American space program towards a 'cost-effective' commercial undertaking (although it remained under governmental administration), specifically the cost-savings accrued from the recovery of the booster rockets after every launch. It was known at Thiokol almost from the beginning that the joints were not working right. Parker Seal, the supplier of the O-rings and manufacturer of the rubber used for them, had indicated to Thiokol during the construction of the rockets that the rubber rings were not supposed to be used in the way they were. Therefore, Parker Seal could not give any advice on O-ring problems.

Risk. The 'weakness in the design' manifest under constant or variable contingencies can be expressed as 'risk of failure', in the case of the orbiter as 'mission failure' (i.e. loss of craft crew and cargo). All unmanned rockets had in Ullian's experience a 4% chance of failing (Ullian was the range safety officer at KFC). Allowing for better engineering of manned flights he estimated the risk at 1/100. NASA's rocket engineers estimated the probability of engine failure (that without leak problem in the booster rockets) at 1/200 - 1/300. Their management estimated the risk at 1/100 000 plus a factor epsilon. But they could not (or would not) tell Feynman how they arrived at it. It would have been equivalent to 300 years of daily missions, without failure. NASA's estimate was contrived from component failure estimates (which in reality could not have been estimated, e.g. failure of a pump in the 1/1,000,000 risk). The NASA figure was

therefore a lie. Mr. Ullian decided to set destruct charges anyway based on his compromise of a 1/1000 failure rate. (**Note:** It is not clear from Feynman's account whether the destruct charges were set off in the course of the Challenger incident.) Thiokol engineers advised NASA that the Challenger flight should not take place. At that meeting, Mr. Mulloy of NASA declared the evidence as 'incomplete' and asked Mr. Lund of Thiokol *'to take off his engineering hat and to put on his management hat'*. After that Thiokol reversed its position and Mr. Lund overruled his engineers. The Thiokol engineers arrived at a split decision regarding the flight (2 against, one for and one position unknown).

Operational problems, warning signs. There were 6 O-ring incidents in 4 flights below 65 degrees F, and 3 incidents in 21 flights above 65 degrees.

Contingencies at the time of the launch. By themselves, each one of the problems might not have led to a devastating malfunctioning of the seals. In combination, more serious outcomes became possible. Cold temperature and the stiffening effect on the O-rings appear to have been the *'straw that broke the camel's back'* on the day of the launch. (For example, tide, oceanic earthquake and wind each may create low-level problems in coastal waters; the rare but possible combination of all three may create catastrophic flooding conditions).

Puffs of smoke showed up during the Challenger launch before and after ignition. 4-5 puffs of smoke were coming out of the seal after ignition. About 1 cubic inch of matter escaped. Smoke was carbon and *'mucky stuff'* (Feynman) which was pushed out

because of the pressure in the rocket after ignition. Puffs stopped and showed up again a minute later.

In summary: The design weaknesses and the technical contingencies and failures were known from the start of the orbiter program. None of the problems were successfully corrected. While blow-bys and O-ring erosion had occurred before, escape of smoke and gas happened for the first time during the Challenger incident. The only condition that was different that day was the very cold temperature. Even cool weather was known to increase blow-bys and O-ring erosions. The design flaws became apparent during operation of the orbiter. However, there was no acute consequence, except when the temperature became extremely cold ('environmental contingency'). The technological weaknesses in the operation of the design were the same throughout the program up to and including the Challenger incident.

THE ISSUE OF THE CONTRACT AWARD TO THE MORTON THIOKOL COMPANY

Diane Vaughan responded to the allegation of a Mormon sponsored bidding advantage for Morton Thiokol by showing documentation which contained the management evaluation of the bidding companies. According to this evaluation, Morton Thiokol apparently had not been given any preferential treatment or unfair advantage.

However, Diane Vaughn either did not ask or was not shown the other parts of the response to the 'request for proposal' (RFP) prepared by NASA, or even what NASA's design and operational specifications had been in the first place. There is some legitimacy to keep the responses to the RFP secret (proprietary secrecy). There is no reason at all to keep NASA's specifications secret. Yet NASA did not reveal the design details.

Without this information, the showing of the management competition is meaningless. Management performance says nothing about adequacy of specifications and adequacy of a proposal meeting the specifications. Since Diane Vaughan probably knew little about contracting and competitive bidding, it may have been fairly easy for NASA to 'redirect' her attention. There is a 'prima facie case' that the origins of the Challenger incident can be found in the specification and bidding documents.

THE ISSUE OF THE TEMPERATURE CHARTS

Apart from the incident itself, what remains in public memory is Feynman's demonstration of the behavior of the O-rings in cold temperature during a public event in the course of the Presidential Inquiry (once compressed in ice-water, they would not spring back into their original shape and dimensions and seal the joints, and therefore hot gases could escape, which were propagated through the faulty sealing putty). The chart that shows all launches, the temperature at launch and the incidents ('blow-bys' burning of O-rings) is published in Feynman's book. Diane Vaughn shows both charts, the one with all the launches; and the one with the launches that had an incident .

The two diagrams on the following pages are recreated from Diane Vaughan, *The Challenger Launch Decision* (1996).

The 'popular interpretation' of the charts: Everybody focused on the chart that shows the correlation between temperature and incidents for all flights, associated with the question, how could the engineers have ignored such obvious data? The other chart was believed to have mislead them, while they should have known better. **Obviously this interpretation puts the blame on the Thiokol engineers and launch management.**

Fig. 19: 'Incident' charts of the orbiter program A: Flights with damage to O-rings; no correlation between temperature and number of incidents (damage to O-rings independent of temperature). B: Flights without damages to O-rings and flights with damages to O-rings: negative correlation between temperature and damages to O rings. (damage to O-rings dependent on temperature). Trend lines sketched into the graph (not calculated).

The alternative interpretation of the charts: The engineers were not primarily concerned about the relationship between temperature and number of incidents. The chart that truly worried them, probably from the very beginning of the contract, would have been the one that shows no correlation between temperature and incidents, because:

- 1) It meant that the seals failed repeatedly, independently of temperature;
- 2) That the two seals considered to be 'redundant' were not really 'redundant':
- 3) The contract should not have been awarded, or the orbiter should have been temporarily decommissioned as soon as this became apparent: it is safe to assume that such a lack of seal redundancy would have been in violation of the design specifications.
- 4) Therefore the launch decision was not so much a question whether the launch should take place or not, but whether the orbiter should be decommissioned and design changes be implemented. If Thiokol had decided not to launch because of the cold temperature, this would have put this issue on the table. The day of the launch was also the day of Reagan's State-of-the-Union Address; and NASA had some great public relations expectation from putting a civilian, a female teacher, into space. The leader of the Thiokol team chose not to take that chance with his company, NASA and the public, and a watching world. His gamble took a bad turn.

A cancellation of the flight for the reasons given would have put the blame on the overall NASA design, the people who awarded the contract (i.e. senior management at NASA and Thiokol, the U.S. Administration and the U.S. Congress).

The maneuvering around the 'explanations': According to Feynman, Neil Armstrong may have been the astronaut (or acting on behalf of the astronauts) who tipped off General Kutyna on the O-ring and cold temperature problem. Kutyna then cued

Feynman, while he strongly agreed with Chairman Rogers that it will not be possible to find out what really happened – before the inquiry had started! Another person possibly interested in bringing the O-ring information to Feynman and to use him as the ‘discoverer’ of the O-ring problem: Bill Graham, who as newly appointed Director of NASA did not want to be blamed for the omissions of his predecessor.

It appears that the thinking in NASA and U.S. Government circles was that, if Feynman, as world-famous physicist and Nobel Laureate, would make his discovery of O-ring behavior under cold temperature conditions in public, then that would be the ‘explanation’.

The decision by Mr. Mulloy to override the Thiokol team was a middle-management decision. Mr. Mulloy made a decision ‘he could live with’, it was not a moral or technical decision. He might have known that canceling the launch would have gotten him into trouble with senior NASA management with certainty; he might have known that the cold temperature spelt trouble, but there was a chance that nothing would happen. Hence his decision to go ahead with the launch. To refer the decision upstairs also might have gotten him into some kind of trouble, because the decision base at that level would have had to be on the basis of the lack of redundancy, not the temperature – surely a decision senior management did not want to make.

INTERPRETATION AND COMPARISON

After the completion of the Apollo program, NASA was in search of a *raison d’être* and embarked on commercially oriented technology. The intent was to combine the features of a temporary space station with the ability to send payloads (mostly satellites)

into orbit. Isolated payload technologies were pursued by other countries, e.g. in Europe, and the space station was an isolated project carried out by Russian teams. The dual purpose design required safety features that would not have been necessary for pure payload transportation technology. The result was a hybrid design, referred to as the 'orbiter'. The problem of the orbiter was that its weight required considerable propulsion power, and hence the design of the main fuel tank and the booster rocket. For economic feasibility reasons, the booster rockets were to be recovered for reuse. The design process was one of 'top-down design', not bottom up, in expectation of speeding up the development process. As Feynman pointed out, this process was in conflict with testing procedures, which in a bottom up design could have been done component by component, and partial assembly by partial assembly. Top-down designing was far more difficult to adjust, as at every step more than one component had to be adjusted, every time just one change was required.

It has been pointed out that the contract was awarded to the Morton Thiokol Company in Utah, through preference given to the bid via Mormon connections. In her account of the Challenger incident Diane Vaughan rejects the notion on the basis that NASA had shown her the competitive bid and the evaluation of the bids by NASA. However, she was only shown the portion that defers to the management capability portion, not to the technical design. Of course it was the technical design that ultimately failed, not the management capability.

We know nothing about the performance and problems encountered during the design steps. We only have seen the reports on joint and O-ring problems from the

operational phase of the orbiter. We did learn something out the ‘**risk-dysinformation**’ used to secure congressional funding of the orbiter program.

Diane Vaughan, who investigated the launch decision for nearly a decade, came to the conclusion that what had happened was a gradual adjustment of the organizational culture at NASA to deviance (the ‘normalization of deviance’): i.e. the progressive slippage from adhering to normal safety protocols to an inability to react to more serious contingencies.

Both authors had some preconceived ideas what the problem with the shuttle might have been. Feynman placed his emphasis on risk management, i.e. what was described in the *Introduction* as the ‘techno-scientific ring of control’: the interlocking of machine and human controls in the launch process. By adjusting to the instances of lacks of failure (and lack of total mission failure) instead of to the known failures, the actual non-occurrence of failure became experienced reality of the engineers and management.

Diane Vaughan was already looking for ‘deviance’ and thought that she had found it in the form of organizational deviance, as a gradual process setting in without the social actors being fully aware of it. Neither was looking at the specification documents (probably under proprietary secrecy) and compared them with other design proposals: what happened during the launches and with fatal outcome during the critical launch was already a predetermined outcome inherent in the design for the booster rockets.

Double-binds. Once technology is committed to production, (as was the case in the Challenger disaster, and as was the case in the hepatitis B vaccine, and factor VIII concentrate, and several new drugs), the financial investments and market expectations

are such that it is virtually a turn-around and moratorium becomes almost impossible: in particular when cost of admitting to failure is greater than the liability cost of damages from failure.

Diane Vaughan may have missed the mark, by interpreting the launch decision as 'normalization of deviance and gradual process'. There was nothing 'gradual' about this, as the design was flawed from the start, irrespective of temperature, and the engineers' behavior was rather one of trying to cope with a well-known, fixed 'double-bind' that had existed ever since the orbiter had been commissioned: a decision in favor of the launch was bad in one way; and a decision against the launch was bad in another way. A similar double-bind existed when the AIDS epidemic started: remaining quiet and against surrogate testing was bad in one way; declaring the disaster and beginning effective safety measures was bad in another way.

Deniability. Both discussions have in common 'deniability'. To this day the real problems with the orbiter program have remained submerged; and to this day the outbreak of the AIDS pandemic has remained a 'mystery'. In both cases, scientists (or engineers) cooperated in the denial of the 'larger evil'.

The 'higher good.' The 'higher good' came into play in the form of protecting the technological leadership image of America, staying ahead of the competition (which was real), the reputation and economic integrity of Morton Thiokol, Utah and Utah business networks, the future of the Morton Thiokol-dependent community. As in the case of the hepatitis B vaccines such 'ulterior goods' are never really verified, and as it

turned out, despite a temporary moratorium on the shuttle program, it is still operating successfully, and as far as we know, economically viably. The very same outcome could have been achieved with a moratorium upon recognition of the danger signals. In the case of the vaccines, a moratorium should have been placed immediately on factor VIII and on the vaccine.

'Production pressure.' Both Feynman and Vaughan have described 'production pressures' having been involved in the Challenger launch decision. Production pressures are real, but manageable: business tends to find a steady state between delivery commitments and production resources. The orbiter problem was not a 'production problem', and delay of the launch by a day would not have made much of difference for production schedules. The problem was one of technology development, as it was the case for the vaccine, with European vaccine developers trying to establish a market position in the largely WHO controlled vaccination market. The Americans won, but at what cost. The emphasis on 'production pressure' redirects public attention away from technological development into operational conditions.

Deregulation. The two cases point to the central problem of capitalism: the 'tragedy of the commons': without regulation and imposed enforced restraints within a community, the resources will be exploited to the point of their exhaustion, because of everybody's conviction that if he or she does not get a piece of the resource, the others will. Capitalism is virtually predicated on this tragedy: in a competitive marketplace, nobody will delay entering into a market for the sake of safety or ecological concerns,

because competitors may not worry about such matters and conquer the market first. The 'tragedy' led to the horrendous social conditions of capitalism in the 19th century, and had to be corrected with imposed constraints by governments formulated as 'social democracies' (Drucker, 1989). The risk avoided was extensive social unrest, revolution and anarchy. The threat of Communism being a thing of the past, tendencies of slipping back into those conditions are accelerating, a phenomenon which has been ideologized by Right Wing interests, as 'citizens making their own decisions', rather than leaving it to the state, 'buyer beware', 'nothing is without risk', and 'let's get rid of big government'.

Several serious mishaps, such as the Five Mile Island, or the Bhopal disaster, make complete deregulation virtually impossible. Instead, capitalist states have developed 'partnerships' between government and business, through which business can directly influence (e.g. by funding) the regulatory process. It is deregulation by surrender of boundary between the regulator and the regulated. The replacement of the regulator/regulated relationship with 'partnership' combined with 'higher good' and 'risk acceptance' ideologies, and with skillful dysinformation management when required, has created a new modus operandi for capitalism. It can still dominate and exploit without being seen as dominating and exploiting. Yet still, if problems get seriously out of hand, then it is the government that is seen as defaulting on its duties by being 'controlled by big business', not big business being in control.

Mergers of companies make the commission of serious damages more feasible (i.e. risk free): failure and serious losses in one sector can be compensated with gains in another, by simply compensating large settlements with only very marginal increases in

price distributed over a wide range of goods sold. The company is virtually rendered 'immortal'.

The most serious problem associated with capitalism shown in this study does not relate to the sale of finished and licensed products in operation, but to the development phase, the design decisions, experiments and trials and (like the phases described in the vaccine trials). Corporate capitalism is not taking any real risks any longer, and all the risks rest with the employees and the consumers. The only risk large corporations are taking are very temporary and mostly related to management decisions of investment, mergerism, and speculative take-over.

Comparison of the Challenger incident and the contamination of the blood supply. The similarities between the two cases are sufficient to suggest that technology development, for competitive reasons, is a process which occurs outside of public control, with a minimum of ethical guidelines how to conduct such development (e.g. code of ethics of the Tricouncil of Canada). The 'capitalist tragedy' is thus enlarged by lack of public accountability of the most crucial phases in technology development and the application of science. The overall secrecy problems can be summarized as follows:

- 1) Secrecy of design and trials (proprietary information);
- 2) Managed secrecy in cases of mishap (management of dysinformation);
- 3) Sealing of court records and obligation to confidentiality;
- 4) Secrecy in the case of larger interests (the 'larger good').

- 5) Secrecy of cabinet documents dealing with design and development decisions and with the management of mishaps.
- 6) 'Understanding' of informed individuals of either the 'higher good', or the consequences of 'not going with the flow.'
- 7) Destruction of credibility of key individuals who are not likely to go with the flow and whose opinions are condemned and not sought, ignored or ridiculed ('so-called disgruntled employees').
- 8) Punishment of actual whistle blowers (economic and social destruction)
- 9) Secrecy under conditions of protracted litigation.
- 10) Truncated inquiries and hearings.

An overview of similarities between the cases is shown in the following table:

Table 19: Similarities between the contingencies of the Challenger incident and the contamination of hepatitis B vaccines.

Issue	Challenger	Hepatitis B vaccine
Design	Design ambiguity: payload craft and temporary space station	Design ambiguity: vaccine and blood product
Competition	Competing technologies of space station and payload rockets, outside of NASA.	Several companies competing in market: plus emerging recombinant DNA technology outside the traditional 'blood business'
Contract	Technical specifications data not available	No competitive bidding
Relevant expertise of contractors	Thiokol was a seal company; not a company specializing in rocket engines and spacecraft	Most of the developers of the hepatitis B vaccine were blood product specialists or virologists, not vaccine specialists. Even Purcell of the Laboratory for Infectious Diseases was an expert in laboratory testing, not in vaccine development. Merck had relevant expertise (Hilleman et al.)
Vulnerability of technology	Vulnerable to unforeseen (but foreseeable) extreme weather conditions	Vulnerable to unforeseen (but foreseeable) viral contamination
Development data	Not accessible	Not accessible
Development control	Government (NASA)	Government (NIH, FDA)
Licensing	Government	Government
Business network	Utah	Utah (during crisis)
Pre-development data on risk	Available (1/100 mission failure)	Available (transmission of hepatitis C through Factor VIII products; transmission of SV40 through Salk polio vaccine)
Response to	O-ring burns related to temperature;	Hepatitis B and C infections through factor

Issue	Challenger	Hepatitis B vaccine
danger signals	ignored	VIII and Merck trial vaccine; step up inactivation in vaccine, do nothing for Factor VIII. Ignore.
Response to serious danger situation	Gamble; launch approved	Gamble: vaccine licensed; Factor VIII sold
Response to consequences	Response to visible effects (technical problems, lower management problems; development and higher management problems not addressed)	Response to visible effects (heat treatment, public relations, for Factor VIII)
Inquiry	Limited to technical problems and lower management problems; inquiry into period of consequences only. (truncated inquiry)	Limited to technical problems and lower management problems; inquiry into conditions at the time of launch only (truncated inquiry)
Long-term response	Develop new technology, adjust old technology	Develop new technology in meantime keep old adjusted technology going

FOUCAULT AND STRATEGY

The case of the contaminated hepatitis B vaccine has some similarities with the case of the Salk polio vaccine: serious mishaps occurred (such as the outbreak of poliomyelitis after the use of a Cutter vaccine lot); other serious problems were identified (the discovery of monkey viruses contaminating the tissue cultures); the evidence was suppressed; those who informed the public of such risks were rather severely punished; there was a long delay in the withdrawal of the Salk polio vaccines from the market (presumably to sell off inventories); the secrecy was kept 'for the good of the public' (Sabin quoted in Shorter).

We are accustomed to discussing industrial phenomena as phenomena of production, even in Third World development, where impact of production technologies

are studied, not the development of those technologies themselves. It was suggested here that the most important and far-reaching characteristics of human technology are not 'production decisions and conditions' (modes, means of production), but **developmental decisions** preceding production. These decisions concern new technologies while current production is going on. A production and operational control mentality is engrained not only in Marxism, but also the 'iron cage of bureaucracy' view of Max Weber, and the steady-state functionalism of Durkheim and Parsons. This limited perspective finds support from postmodern viewpoints of society 'always already being there' (Hunt and Wickham, 1994); the 'contingency view' into a time-slice (or point in time'), which sees everything being contingent on everything else past, but in very short distance from the present, and with disregard of the futures that have already been strategically decided.

Foucault, who saw power manifested as social practice and 'regimes of truth,' engulfing individuals as some kind of natural order of things, questioned the origins of such practices. In one response to questions he addresses the strategic, fluid (and thus adaptive) nature of such orders.

*It seems to me that this whole intimidation with the boggy of reform is linked to the lack of strategic analysis appropriate to political struggle, to struggles in the field of political power. The role for theory today seems to me to be just this: not to formulate the global systematic theory which holds everything in place, but to analyze the specificity of mechanisms of power, to locate the connections and extensions, to build little by little a strategic knowledge (savoir). If the 'traditional parties' have re-established their hegemony over the 'Left,' and over the diverse forms of struggle which had not originally been under their control, one reason among many for this was that **only a profoundly inadequate logic was available to these struggles for the analysis of their unfolding and their effects.** [The knowledge for analysis today may be more 'profoundly inadequate' than ever. Foucault invites responses to this: emphasis by the author] *What I have said here is not 'what I think', but often rather what I wonder whether one couldn't think.* (Foucault, 1980:144-5)*

In response:

1) Regimes of power cannot sustain themselves without valid assumptions as to a 'global systematic theory, which holds everything in place'. In other words, regimes of power must be able to assume that humans will behave in at least somewhat predictable ways, and not only that, they must be able to assume that that this behavior can be shaped to serve specific purposes. Therefore, any analysis of power cannot do without a search for such a systematic theory, and knowledge, which regimes of power have and use, explicitly, or intuitively. This knowledge concerns how people experience the world at the moment, at the present, and how they have experienced it in the past.

2) The logic of the struggling Left was profoundly inadequate because this is what it focused on: tactical, not strategic knowledge. But one kind of knowledge without the other necessarily remains 'one hand clapping', and so any critical analysis of power needs both: the systemic savoir and the strategic savoir, and the learning processes which enhance both by including more and more possible 'thought-of' contingencies in the savoir. The viability of the capitalist enterprise depends not so much on knowledge as to 'what happened', but on knowledge of what 'has worked or has not worked', whereas the Left has traditionally focussed on 'what has happened'. In the struggle between 'what has worked' on one side, and 'what has happened' on the other side, the former has the strategic advantage (as the 'Cold War' has amply demonstrated).

Hence the solemnity with which this 'Leninist' thesis was erected into a 'theory' - which is barely on a level with the preliminary training given to a sub-lieutenant in the reserves. And it's in the name of this thesis that every local action is terrorized with the following dilemma: either you attack on a local level, but you must be sure it is at the weakest link, the one whose breakage will demolish the whole structure; or else, since the whole structure fails to collapse, the link wasn't the weakest one, the adversary needed only to reorganize his front, and reform has reabsorbed your attack. (Foucault, ibid.)

But this dichotomy between Leninist systematic theory and local action remains principled and thus 'counter-strategic', as strategy does not pose either/or questions for its means (only for its goals and ends). The weakest links are rarely situated at the local level, where regimes of power normally have already consolidated the practices that sustain their goals. The 'weakest links' may be offered as a token, or **decoy**, to be

attacked, with wrongs that are so 'glaring' that they are bound to find the attention of the Left, creating a smokescreen for the true weaknesses.

The weakest links must be sought in the strategic processes of change, where plans are drawn to disassemble existing practices and to replace them with new ones. Of course, regimes of power, understand this weakness of theirs, and hence the massive fortifications of secrecy behind which these processes take place. It should therefore not come as a surprise that the potential 'attackers' were disinvited from the Royal Commission on Reproductive Technology, and that the participants (trusted individuals only) in the design of the new Blood System in Canada in 1998 were obliged to secrecy.

REACTIVE TIME AND STRATEGIC TIME

Time is experienced differently by strategic enterprise managers on hand, and consumer and workers on the other. However, this may change as more individuals are getting personally involved in their investments and seek information for their investment decisions. It is still common, however, that workers and consumers interpret their life-world in terms of current practice and past experiences. They are therefore **reacting** to life conditions, they are not part of that which generates them. A problem of the politics of the Left has been to follow this pattern, by empathetic alliance with the experiences of its constituents, without being part of the processes of generating the future.

Enterprises work with a different experience and management of time. What is a standard operation practice today, was decided several years earlier. What is going to be

done in the near, and often mid-term future, has probably been decided just recently. The change processes that really matter and are still vulnerable are those that plan the future beyond the immediate and the mid-term. For instance, the Merck trial vaccines were sitting on the shelves for several years before they were issued. Thus the decision to use them had been made in the early seventies. By the time the trial were conducted it was already clear the vaccine from human sources could not possibly supply the world demand for hepatitis B vaccines. However, a large scale production went ahead (the commercial licensed vaccines) while development for a bio-engineered vaccine also was initiated. In the case of the Challenger disaster, the decisions on the orbiter design and production were made in the early seventies, and those decisions are still effective today in the operation of the craft. However, while the operation of the orbiter went on, many different types of space craft, for specialized purposes were progressing, and it is safe to assume that the decisions on what kind of craft will be used in the future have already been made.

Public communications on such developments are rarely more than propagandistic strategies, to drum up public support for ventures for which tax dollars are required, to get investors interested, and to desensitize the public to possible side-effects (environmental, social, psychological, etc.), by creating demand or desire for such changes. These communications cannot be taken seriously as reliable information on technological development.

THE 'TRAGEDY OF CAPITALISM'

The social time of the capitalist enterprise does not arise from interests in domination and/or exploitation (or just simple greed), but rather from the logic of competitive enterprising, as a variant of the '**tragedy of the commons**'. Perhaps it should be referred to as the '**tragedy of capitalism**'. The 'tragedy of the commons' predicts that any resource within the boundaries of communal resources will be exploited to the point of exhaustion, because no member of the community will make the assumption that the other members will use voluntary restraint.

No effective solution other than regulation has come forth, which is successfully undermined by actual and prospective users of various 'commons', despite obvious disasters (fisheries, old forest, pollution etc.). The original idea by G. Hardin (1968) has been discussed by Hardin (1974); Johnston (1992; in favor of regulation); Laver (1984; three solutions: privatization of communal resources; collective agreements among users; and regulation by an external body); Ostrom, E. (1990; favoring collective agreements). In the case of the hepatitis B vaccine, as in the Challenger disaster, competition was the driving force behind that 'tragedy'. The 'commons' at stake in these instances were 'markets'. In contrast to a mere exploitation of a resource, time is essential in the staking out of interests. The 'goldrush' is a good paradigm to illustrate this phenomenon: while it was a given that a goldfield would be fully exploited, it did matter a great deal how soon one would get there. Better even, if one individual had discovered a goldfield, he might not have wasted this knowledge by sharing it with anybody else, as long as possible. Thus both secrecy and speed are essential conditions of competitive capitalist enterprising.

For instance: It was mentioned that the vaccine and blood industries have gone through periods of spreading various zoonoses in human populations. It seems absurd today to find serious debates going on the use of baboons as organ and tissue donors. After all, baboons are carriers of viruses, just like chimpanzees, vervets, macaques and so forth. Why, in the nineties would such a proposition have been endorsed by the FDA, with a smiling commissioner at its helm (with a Cheshire Cat smile, that is)? Protests from American virologists have put a temporary halt on such uses of baboons, but the commissioner still suggested that *'more public debate'* is needed.

At the same time, neurosurgeons are using cells from fetal pig brains as implants into the brains of patients with Huntington's chorea. Yet there is no positive proof that pig tissue is any safer, and Dr. Schumacher, one of the surgeons using this method, when interviewed by the Learning Channel, broadcast on June 26, 1999, indicated that there is no guarantee of safety, but that viral infection would be very unlikely. He can be expected to know fully well that if a procedure is carried out often enough, 'unlikely' means that the 'unlikely' will happen 'eventually'. At the same time, recipients of human transplants are sent on the road with desperate calls for organ donors (of which there will never be enough).

All of this seems to make no sense at all. It does make sense, when one considers that the safest of all sources of such tissues is human fetal brains, which may carry some human viruses, but probably no monkey or pig viruses. It is as safe as the foreskin used for culturing sheets of skin tissue to cover second degree burns – which was also shown in the same documentary. But given the current mood concerning abortion, the use of fetal tissue would be contested. We can safely assume that experimentation with human fetal tissue is well on its way (and prepared for patents), and that the logistics for a production level supply of fetuses from all ages (including those mature fetuses harvested from 'intra-birth abortion') are being discussed and planned.

The organ donor propaganda serves to instill enough anxiety for those who anticipate that one day they may find themselves on a waiting list; the baboon controversy serves to create anxiety as to real dangers of the spread of animal viruses; the pig fares a bit better, but not much; in the meantime successes of that kind of technology can be demonstrated ("if only we could make sure it is safe"). Of course the FDA would like a baboon debate linked with some successes of organ transplant, so that in that collision of emotions, the opposition to the harvesting of fetuses can be silenced: after all, it worked and it would be safe; the alternative, animal tissue, works and it is not safe. On the darker side of this enterprise is a market for aborted fetuses: why should the industry get the 'raw-material for nothing?'

This kind of manipulation of public responses according to the capitalist enterprising calendar is, on a moral level, reminiscent of the parents of the Willowbrook children who were given a choice: to have the children accepted and used in vaccine trials; or to be shown the door. While the public is given the impression that it is making choices, it really is not: the objective is to move

public sentiment in the direction of support of a business strategy through a combination of sensitization and desensitization processes, which cleverly exploit past failures in bioengineering with serious consequences, a process in which the knowledge advantage is clearly on the side of business interests.

This kind of strategy and time management is far more sophisticated than what was used in vaccine and factor VIII development. One could argue that this kind of control pattern is unique to biological technologies (and it has resurfaced with the mad-cow disease). In other words, one might suggest that these technologies may be particularly vulnerable to mishaps; and more generally, that the social processes engaged in the development of a new technology and in the wake of a major mishap are contingent on the specific characteristics of that technology. The assumption of the 'tragedy of capitalism' suggests that it is not at all specific for a particular technology, but simply a consequence of its internally consistent logics of capitalism. The case of the Challenger incident was briefly reviewed as a technology which is very different from vaccines. Just another case, of course, is not enough to generalize on capitalism. The similarities between the cases should be sufficient to have the 'developmental conditions of capitalism' reviewed as essential contingencies for an inquiry into the hepatitis B vaccines. Normally, in an inquiry into socio-technical disasters, these conditions are not questioned at all.

4.3 THE NEED FOR A SOCIOLOGY OF TECHNOLOGICAL DEVELOPMENT; THE NEED FOR A SOCIOLOGY OF DISASTER GENESIS

RECAPITULATION OF MAPPING/ACCOUNTING SYSTEMS FOR THE ANALYSIS OF OUTCOMES OF SOCIO-TECHNICAL ENDEAVORS

It was suggested in the *Introduction* and in the previous chapters, that sociology (but also disaster sociology) is falling short on two counts when exploring (negative or positive) outcomes of human endeavors ('human ecology'):

- 1) The inclusion of non-sociological fields of contingencies in the analysis of outcomes;
- 2) The inclusion of past and future-related contingencies.

The accounting methods used by the author are briefly reviewed:

MAPPING: THE CAPTURE AND SELECTION OF FACTS AND OBSERVATIONS AND THEIR ORGANIZATION ACCORDING TO SPATIO-TEMPORAL COORDINATES; ACCOUNTING FOR MISSING FACTS.

Fields of contingencies (spatial accounting):

- Communal environment
- Organizational environment
- Technology
- Natural environment
- 'Ring of techno-scientific controls'
- Decisions and actions
- Contingencies of social construction: ideations as contingencies being real in their consequences.

Critical path: spatio-temporal accounting of decisions, practices and all relevant contingencies; the critical path of an outcome is a mapping of the trajectory of critical decision and practices of developers and operators of a technology, in relation to the various fields of contingencies; more than one critical path (more than one technology, organization etc.) may be involved.

- Milestones
- Phases

Fractal segments (the 'macro-micro' continuum)

KNOWLEDGE CONSTRUCTION, MODELING, THEORIZING

Levels of knowledge construction

Material construction: all material conditions in the various fields of technology, including organizational configurations, functions and relationships; specific actions and written opinions of social actors; essentially what can be found in the 'fields of contingencies', including social relations of power and control;

Social construction: Interpretation of material reality, 'sense-making' of material and social phenomena; communications by regimes of power, truth and falsity, disclosure and secrecy, 'decoys,' 'social construction of 'disasters.'

Sociological explanation: (human ecological explanation) Critical analysis of outcomes; analysis of material knowledge and social constructions of material and social realities; and interactions between the two constructions;

Embedded in ontologies. Sociological analysis in this dissertation uses human-ecological assumptions (ontology).

APPLICATION OF MAPPING/ACCOUNTING SYSTEMS FOR THE ANALYSIS OF OUTCOMES OF SOCIO-TECHNICAL ENDEAVORS

The application of this mapping system to the case of the contamination of the blood supply accommodated the following 'accounts':

Fields of contingencies

Communal environment: infected persons, sexual practices, drug use

Organizational environment: Merck, Red Cross, various government institutions, producers of factor VIII; organizational links

Technology: vaccines, factor VIII, blood transfusion, blood testing technologies

Natural environment: coevolution of monkeys and retroviruses; hepatitis viruses and their natural history

'Ring of techno-scientific controls:' screening of blood donors for infectious diseases; viral inactivation of vaccines; licensing.

Decisions and practices: see 'critical paths'

Contingencies of social construction: 'see social construction'

Critical path: Stages in the handling of the spread of HIV and HCA, cohorts of infected people, temporal relationships of various products and testing methods, temporal evolution of dysinformation and its relationship to the handling of the HIV and HCV crises.

Milestones: 'Six critical decisions'

Phases: Clinical Trial phases of vaccine development and use, phases of factor VIII treatment development and operational phases

Fractal segments of critical paths: e.g. the 'Canadian clinical trial'

KNOWLEDGE CONSTRUCTION, MODELING, THEORIZING

Levels of knowledge construction:

Material construction: See above

Social construction: Systems of 'dysinformation'

Sociological explanation: A 'natural history' of the AIDS pandemic, and of the vaccine and transfusion-related outbreak of hepatitis C.

Modeling: Bushmeat and vaccine models; construction and validation of the vaccine and the bushmeat models based on both material facts and observed social constructions. Rejection of the bushmeat model; strengths and weaknesses of the vaccine model for the explanation of the contamination of the blood supply.

Theorizing: Very little. Even the arguments raised as to the characteristics of capitalism such as in the discussion of the 'tragedy of capitalism' is an extension of model construction, by including contingencies of the conditions of competitive

capitalism. The discussion only proposes that this is so, it does not address 'why it is so'. In other words, this study only addresses the external contingencies of human ecology, not the internal, neurocognitive aspects (See Krassnitzky, 1997; in reference to Laughlin 1990). The same can be said about the 'banality of evil and good' and the Bauman's view of 'modernity'; the apparent need to use dysinformation for social control, and the use of ideologies promoting the 'higher good' which can be constructed contingently and on an ad hoc basis by regimes of control; the replacement of older forms of social control under capitalist conditions, changed from outright exploitation and domination to 'managed exploitation and domination'.

Critical path construction is efficient, because it focuses the search for evidence in ways which general theory, or uncoordinated mapping of contingencies cannot. However, there is a risk in using the critical path approach: it requires some assumptions on the functional relationships (tentative model) between events and fields of contingencies. Such assumptions can easily lead to wrong interpretations of individual pieces of information.

For instance (1): The Canadian study on AIDS patients and their hepatitis serological profile published in the WHO *Weekly Epidemiological Record* (1985) looked on first sight as if markers indicative of hepatitis B vaccination would be associated with HIV infections. Only further analysis revealed that the study was designed to give the impression that a) surrogate testing could not have prevented transfusion-related transmissions of HIV; and b) that the vaccine was safe, i.e. it did not transmit live hepatitis B viruses (otherwise the profile would have been different). Thus the author's original impression that this article was meant to inform had to change into the view that this article was really meant to deceive. The author could assume that the suppression of hepatitis B-core antibody really served to suppress discovery of linkages between the vaccine and any live virus transmission, including hepatitis C. Instead of 'proof' of the vaccine hypothesis, it was merely proof of 'dysinformation.'

For instance (2): Aaron Kellner's resistance (he was a former President of the New York Blood Center) to the use of anti-HBc testing did not make sense, if the New York Blood Center was merely testing other developers' vaccines. It made a lot more sense, once the author could find, with some difficulty, the only reference for the New York Blood Center trial vaccine. The reference (a symposium report on viral hepatitis) had disappeared from two major scientific libraries in Ottawa (the interlibrary Loan Service of Carleton University made it

available from the University of Western Ontario). Reports of scores of other symposia were readily available at the National Research Council library. Since the Purcell/NIH trial vaccines already fitted the model, the author did not pursue this finding of this reference until late in the writing. Without it, a key link to the African pandemic would have been missed. This reference provided the only indication that the New York Blood Center had developed its own vaccine, and that it had a laboratory in Liberia (close to one of the AIDS hot spots, Ghana and Cote d'Ivoire), where experiments with chimpanzees were carried out.

However, more severe distortions in the representation of reality can be avoided by the accounting system. For instance, Diane Vaughan wanted to find 'deviance.' She could not find it and settled for 'normalization of deviance'. Horowitz was looking for unlawful behaviors of the CIA and related agencies and companies, and that is what he found. Krever was expected (asked?) to find bureaucratic, cost-focused handling of emergencies, and that is what he found (and was offered). Laurie Garrett wanted to find severe global ecological disturbances, and that is what she found. In every case, the authors focused on certain contingencies, but not on others.

In addition to spatial components of Quarantelli's 'elephant', however, the analysis shows that most authors fall short also on the temporal dimension, i.e. elephants have a life history too, which is particularly problematic for socio-technical disasters. AIDS and hepatitis C were connected by technology development (vaccines). If only the incident and the immediate history and responses are examined (the 'pericalamitous period', as for instance in the analysis of the Challenger launch decision) then important contingencies which originate in the past, often years earlier, get lost. Those authors who do give an historical account restrict the fields of contingency under examination, and such histories serve mostly to re-enforce the expectations, they do not put them into question. Krever's inquiry, for all intents and purposes started in 1981; Vaughan's

analysis is focused on the launch of the Challenger, it covers the period of the operation of the orbiter program, but falls short on the developmental period.

These authors relied primarily on the interpretations of material/scientific knowledge by interviewees. While they all provide impressive bibliographies, on close examination it becomes clear that the original papers and publications were not systematically scrutinized. For instance, Garrett did not pay a great deal of attention to the infections of hemophiliacs, and Horowitz missed, accidentally (or on purpose, or as directed?) that the New York Blood Center had its own vaccine and used a laboratory in Liberia. Thus these authors relied on selected material facts provided by 'trusted institutional experts' (such as Don Francis, John Martin, Max Essex). Both, writers (Panem, Horowitz, Garrett) and informants (Francis, Essex) were close to the Harvard circle of the 'ecological upheaval model' of the AIDS pandemic - which also served as subject for an effective fundraising campaign to boost funding of infectious diseases research.

The ideological/ontological themes used by the various authors include: a dangerous, deranged environment, 'sexual explosion', inept, recalcitrant, cost-obsessed bureaucracies, feuding scientists, homophobic religious right-wingers, a military and a criminal clandestine military intelligence out of control. Very little is said about patents, markets, industrial competition for market position, deregulation, risk management, i.e. all the regular aspects of capitalist enterprising. Zygmunt Bauman in his analysis of the Holocaust (Bauman, 1989) touches on capitalism, but buries it under the blanket of 'modernity' and its rationalism and efficiencies. He does not address the fundamental motivations of World War II: the suppression of Communism which threatened German

capitalism, and the intended conquest of the oilfield of the Caspian Sea (for which Jewish assets and labor provided the necessary resources). Even today, political and strategic activity in and around the Caspian Sea is hidden under the blanket 'stability in the region', i.e. stability for the drilling and shipment of Caspian Sea Oil through a largely Islamic/Turkish territory (including access to the Mediterranean Sea). Garrett briefly touches on capitalism in her reference to medical services in Africa which were started and then abandoned; the financial support of ruthless dictators which used their subsidies to buy outdated military equipment from the US.

The Krever Report shows the blood and plasma enterprise, and hides the many times larger vaccine enterprise. Horowitz shows the vaccine enterprise, but virtually drowns it with vast schemes of global population control. For Panem, Shilts, Garrett, and others capitalism hardly matters. Only Horowitz makes an attempt to address technological development as the most critical phase in capitalist enterprising, which drives university research, bureaucracies and capital markets – not operational production activities. The two examples give some indication, as to how important this phase is, and how little the public has control over those activities.

THE NEED FOR A SOCIOLOGY OF TECHNOLOGICAL DEVELOPMENT

Note: After the completion of the Krever Inquiry, the government of Canada began to set in motion a process of designing a new blood organization for Canada. The process itself was highly secretive, however, it was promised that

the lessons from the AIDS and hepatitis C tragedy had been learned, that the new blood system would be an 'open system', i.e. the public would be informed on emerging risks. The author always had reservations regarding the constitution of the newly formed Canadian Blood Services (CBS), because it more or less reflected the design that had been proposed almost twenty years ago by the Provincial governments (then referred to as the 'Canadian Blood Authority'). Dr. Durhane Wong-Rieger, a psychologist and former President of the Canadian Hemophilia Society, led the Society during the Inquiry, and participated in the design of the new system. Although she had been warned by friends (known to the author) that this new blood organization would be little more than an old puppet in new clothes, she went along with the development and eventually became a board member of the organization.

Mark Kennedy of the Ottawa Citizen reported on July 16, 1999 (page A3) that Durhane Wong Rieger had resigned from the board on July 15, not even 2 years after its formation. Erma Chapman, the president of the Canadian Hemophilia Society suggested that *the agency does not consult Canadians enough about the rationale behind its decisions – such as whether to remove potentially contaminated blood products off the market or ban some blood donors who have visited Britain and may have theoretically contracted the human form of mad-cow disease...The blood agency now holds its board meetings behind closed doors (only one such meeting is held publicly per year), and various reports to the board on ethical and scientific issues are kept secret.*

The response of Lynda Cranston, former hospital administrator and now chief executive officer of the agency was that: *we must carefully balance transparency with scaring the public. And some of the issues that we deal with have a very delicate balance. There are risks and there are risks. We need to make sure that we've got all our ducks lined up before we, in fact, make the information public..... "We are not going to skulk around and shred documents in the middle of the night."*

Obviously, the conditions of secrecy in the Canadian Blood System are still the same as they were during the introduction of factor VIII, the outbreak of AIDS and the spread of hepatitis C. Cranston's remark concerning shredding is missing the point. The shredding during the AIDS crisis only started when the damage had been done and was evident, not during the decision leading up to the damage. Cranston's 'duck argument' is a variant of Sabin's argument that one should not scare the public prematurely. Consultation after the information has been selected and sanitized, after the decisions

have been taken, so as to head off potential litigation, should not be referred to as 'consultation.'

Technological development and its contingencies are today the least accessible and most unaccountable human activity, in particular its corporate variants. In both the case of the contamination of the blood supply and in the case of the Challenger the interests being protected were primarily of a commercial nature. Inquiries into the processes of technological development are not just necessary to prevent 'disasters'. Just because something is 'safe', and is not going to lead to a major disaster does not mean that it is good. Indeed, safety issues may blur larger issues of social change, which may take a turn for the better or for the worse due to the introduction of new technologies. The example of tissue transplants points this out. The main purpose of a disaster sociology would be to investigate the processes, the outcomes of which are being justified to the public after all the decisions have already been taken.

All major trends in sociology, Marxist, Weberian, Parsonian, Durkheimian, feminist or postmodernist deal with the constraints which capitalism (or modernity) imposes on individual life chances and choices, either supporting, accepting or rejecting such constraints. But these are sociologies of production, which view humans as either behaving in an constant and predictable manner (what Foucault refers to as 'disciplined' manner), or resisting control of such behavior.

These are no longer the life conditions of today in Western societies. The production environment has been shifting into developing countries. In developed countries the dominant aspect of capitalism is technological development, i.e., fundamental changes in the ways our life-world is being organized, and the strategies to

get people to accept these changes. For a number of decades now, with accelerated technology development, the main problem for capitalist enterprising has been 'resistance to change', not resistance to discipline, and the development of strategies which overcome such resistance: in particular when such changes are costly in terms of environmental changes, social changes, changes in values, beliefs, norms, security.

The two cases, the hepatitis B vaccine and the Challenger incident, are not merely examples of how developmentally rooted mishaps can be handled, but also of how accelerated change and inevitable mishap can be handled. For a number of reasons mentioned throughout this study, a sociology of development is difficult to establish (competition, proprietary secrecy, protection rather than regulation by government agencies, micro-capitalism). On the other hand, it seems almost pointless to address the problems (i.e. the fallout from development decisions) after the fact, after things go wrong, after socio-technical disasters happen, after new and unfamiliar social problems have been generated. It seems similarly pointless to carry out 'discourse analysis' on discourses which are highly engineered, or reactive to consequences, not to the origins of the consequences. It seems pointless to deal with the fallout of past development decisions, while the next strategic phase has already been decided, and the one thereafter is already on the drawing boards.

However, the last kind of analysis is not entirely pointless, in particular when the fallout is disastrous, or when some other serious consequences have occurred. These are rare occasions when at least some aspects of technological development become accessible, when the shroud of secrecy suffers a few tears. These are occasions when the 'weakest links' become somewhat visible. In the (very) long run, competitive

developmental secrecy will become untenable, or else the 'tragedy of capitalism' discussed earlier will take its full course.

There is currently no other way to access developmental processes. Socio-technical disasters are the only opportunities. It would require a reorientation of disaster sociology towards the genesis of disasters, and continuity between genesis and consequences and responses. In his concluding chapter on the definition of 'disaster', Quarantelli refers to various attempts at defining a disaster sociologically. The metaphor of the 'elephant' has blind people trying to figure out what an object (the elephant) is, by touching selected parts of it. Much of this 'blindness' comes from lack of knowledge of the origins of a disasters. Yet we have not developed strategies that would turn the blindness into 'seeing'.

The proposed superstructure does not eliminate this blindness, but it is suggested to help avoid misconstruction of the elephant, and while it cannot provide perfect vision, it definitely can provide coordinates for identifying visible fields and blind spots, 'terra incognita', missing data, etc. Thus, while different individuals or groups are working on different parts of the elephant, they will not end up having found pigs, fire hoses or tree trunks, or having produced soap bubbles or private constructions of reality.

This study can go no further than to suggest this approach. The main case (the contamination of the blood supply) and the other illustrative cases are not sufficient to prove or disprove the validity or adequacy of the methodology, but rather large numbers of cases studied in this manner are required. It is also necessary, as was discussed in the introductory chapters, to fill the continuum with non-disaster cases, of the same genus.

The continuum should perhaps be stretched further than that. First, since the contingencies of disasters are very similar to the very same contingencies that also lead to 'business' or 'mission success', the origins of what is perceived as positive outcomes of socio-technical activity, should be examined as well; and whether the outcomes of failure or success are entirely contingent (a matter of chance); or whether there are control differences, possibly very small, that determine the outcome one way or the other.

Beyond that, the validation of the superstructure and methodology would not be complete without its application to further extensions of the continuum, namely into phenomenal fields which are not primarily related to technology, failure or success. This includes micro-social process as well as macro-social processes. Although contingency analysis produces 'turtles all the way down', the 10th turtle down may be the one that made all the difference.

THE FEASIBILITY OF THE PROPOSED ACCOUNTING METHOD.

Full accounting of all of these contingencies is an effort that exceeds what can normally be accomplished by a single investigator, as exemplified by Diane Vaughan, who investigated merely the Challenger launch decision and never entered into the large issues of the orbiter program, yet spent almost a decade to complete just that limited task. The sheer extent of such an inquiry is exemplified by the Krever inquiry (which is also very limited), which spent 5 years and millions of dollars to produce hundreds of thousands of pages of documentation, and a 1000 page final report. Without

comprehensive accounting methods and practices, inquiries will do little beyond serving litigating lawyers on both sides of the issues, they will not bring about any fundamental changes in the control of industrial development.

Diane Vaughan's account also shows the problem of the 'lone investigator'. Not only did she buy into the 'cold weather explanation', she also accepted that the contracting with Thiokol was above board. She simply did not know how such contracts are awarded, what the procedures and standards are. She appeared even empathetic towards the NASA and Thiokol engineers, not unexpected after years of talking to them, and sort of becoming 'part of NASA.' Diane Vaughan 'went native'. Similarly, Laurie Garrett, showed no trace of skepticism vis-à-vis the information provided by the group at Harvard University. She also had a fellowship there, and was native by definition.

DISSECTING THE DICHOTOMY, YET CONFOUNDEDNESS, OF EXPLANATION AND JUSTIFICATION

The example of the hepatitis B vaccine shows that human decision-making and action in technological ventures is guided by selfish motivations of gain and avoidance of loss (as in competition for market position; revenues from patent rights; avoidance of liability cost and personal liability); and that, at the same time, these actions are 'justified' with unselfish motivations, of a moral and or material nature (such as avoiding waste of money; freeing the world from hepatitis B; preventing people from becoming vulnerable to epidemics by avoiding vaccinations), which appeal to or arouse motivations in others and garner their approval and support.

This dichotomy applies to individual actions and decision processes (choices) as well as organizational actions and decision processes. While motivations are fairly simple and constant (striving for gain and reward, avoiding loss and punishment), the construction of justifications can be quite elaborate, and is situationally contingent. When Barker, Gerety and Zimmerman distributed their justification of the non-use of ALT as surrogate test for hepatitis non-A,non-B in blood donors, they did not just give one or two justifications, but a list of them, none of which were motivating for the affected public, i.e. people requiring transfusion therapy.

‘Truth’ (as to what happened) is difficult, if not impossible to reconstruct from justificational material without knowledge of the specific motivations, strategies and models used in pursuit of goals.

After the realizations that something had gone awfully wrong with the hepatitis trial vaccines, very specific actions were designed to save the plasma industry from collapse, to ensure the continued sale of the Merck hepatitis B vaccine and to minimize the extent and severity of litigation. Of course, the justifications did not reflect these motivations, but appealed to sentiments and motivations of the public: that blood and Factor VIII concentrate were safe, and that their ‘live-saving’ use should not be discontinued; that the cost of surrogate testing was prohibitive and economically irresponsible; that AIDS was a gay disease and should not concern heterosexuals; that hepatitis non-A,non-B was really not serious illness, and so forth.

Discourse analysis and analysis of social constructions, by themselves, are therefore not a sufficient basis for the analysis of outcomes of social action. It is also not enough to understand how social discourses unfold in the context of power relations.

Without an analysis of underlying material motivations and objectives pursued by organizations and individuals, and a joint analysis of material realities and their respective constructions and communications, conclusions may be wrong, biased or irrelevant. The Krever Inquiry's conclusions on the non-use of surrogate testing is such an example: the conclusions are irrelevant.

Similarly, in the case of the Challenger disaster, the objective after the incident was to save the orbiter program, not to fix the temperature problem. The program (and Thiokol's contract) was threatened by the statistics which showed that seal redundancy in the booster rockets did not exist, and that that none of the launches should have taken place, not only those at low temperatures. However, with the (inadvertent) help of Richard Feynman, the public, to this day, believes that the temperature was the problem, not the overall design and specifications of the orbiter and NASA's contract with Thiokol.

The choice and mix of such justifications is situationally contingent. At various stages of product development and production, and depending on success and failure, different sets of justifications are used to decide the next set of actions. The example also shows that such shifting combinations of justifications are embedded in fundamental shared belief systems, the most prominent of which appears to be the commitment to maintaining the integrity of a social organization to which a social actors belong and which they consider most significant in their lives. This 'significance' translates into the extent to which an organization determines the life conditions of the individual. Under today's conditions of interdependent technologies, this may not be a single institution, or a single corporation, or even a single 'industry', but large networks and systems of

interdependent organizations. As clear boundaries between organizational entities are disappearing, so does identification with such entities, and commitments become more diffuse, abstract, and ultimately ideological: one believes in capitalism or one does not; one believes in religion or one does not; one believes in globalization or one does not; one believes in the principal purpose of science as to be exploited economically, or one does not. In such abstract contexts, specific mishaps, failures, wrong-doings, bad judgements are evaluated on the basis of such ideological orientations and whether or not they are threats or opportunities for one's livelihood. Under such broad ideological terms, specific justifications are easily constructed, deconstructed and reconstructed again, because they do not require moral principles nor rational analysis. What matters is the balance of benefits an individual anticipates from subscribing to such broad ideologies, and the losses or forfeitures incurred from not doing so. This anticipation is neither rational nor moral, but based on experienced life conditions, consequences of actions, and the anticipation of the path of least resistance to reach the benefits.

This is not new. Human history has not been driven by high moral principles or rational analysis, but rather by what people have experienced as working or not working. Hannah Arendt's exposition of the banality of Eichman's 'evil' needs to be complemented with the notion that the 'good' is just as banal. Salk and Sabin are heroes because their vaccine worked, and they were lucky not to have created serious animal virus-induced epidemics (the jury is still out on that). They also competed vigorously.

The hepatitis B vaccine developers were people no different from Salk or Sabin, but apparently their vaccine unleashed a dangerous pathogen into human populations. Their names, in relation to vaccines, are forgotten: today, those who are still around, are

known as 'hepatitis specialists'. Sabin's justification for not revealing the transmittal of SV40 by polio vaccines was probably the model of justification used by those who were motivated to bury the knowledge of the side-effects of the hepatitis B trial vaccines.

THE KREVER INQUIRY ONLY INVESTIGATED THE JUSTIFICATIONAL ASPECTS OF THE CONTAMINATION OF THE CANADIAN BLOOD SUPPLY, NOT THE MOTIVATIONAL ASPECTS, WHILE THE AVAILABLE EVIDENCE WOULD HAVE ENABLED THE COMMISSION TO DO SO

The Krever report is full of records of 'justifications.' We learn nothing about motivations. For instance, we do not learn why scientists proceeded with the conduct of an unethical clinical trial, we only know how they justified it. We know how the use of non-heat-treated Factor VIII when heat-treated Factor VIII was justified, we know nothing about the motivation.

Note: The example of using up heat-treated stock, which involved relatively small amounts of factor VIII, and only small amounts of money saved in the entire scheme of things, looks so absurd, that the author believes that it was done on purpose: as a demonstration case of a bad bureaucracy, single-mindedly pursuing cost savings. These decisions and actions do not make sense, since in 1985 the liability for blood-product related infections with HIV was already on the doorstep of governments. The material was given mostly to hemophiliacs '*who were infected anyway*', so it looks like a case of drawing attention to one kind of misconduct and liability, to divert attention from the larger liabilities. Who, after learning about these horrible decisions, would doubt that everything that had gone wrong with respect to the contamination of the blood supply was due to this obvious, narrow-minded, 'cold-hearted' 'managerial misconduct'?

In the Krever inquiry the questions concerning the material objectives of certain decisions, such as the 1986 decision not to use surrogate testing were never asked. Krever found the decision unacceptable on the basis of the results, not on the basis of (undeclared) material reasons for not using the tests. This is very clear on his conclusions on surrogate testing in Canada.

***Conclusion.** Until the advent of AIDS, blood bankers had come to view the transmission of infectious diseases by transfusion, like hepatitis B, with a certain complacency. The decision to implement surrogate testing in the United States signified that blood bankers in that country had learned a valuable lesson that appropriate and prudent decisions about matters of significant and far reaching public health consequences must sometimes be made on the basis of existing evidence. Subsequent studies proved that the decision was correct. Even after the introduction of HIV-antibody testing, the introduction of either or both of the surrogate tests significantly reduced the incidence of post-transfusion non-A, non-B hepatitis.*

The effect of the failure to implement surrogate testing in Canada is illustrated by the Blajchman-Feinman study itself, which confirmed that surrogate testing would have significantly reduced the incidence of post transfusion hepatitis. The results of the study, published in The Lancet in 1995, support the conclusion that the implementation of both surrogate tests would have reduced the incidence of post transfusion hepatitis by 75 percent, and the incidence of post-transfusion hepatitis C by 85 percent, in the period before HCV-antibody testing in Canada. The decision of the Red Cross not to implement anti-HBc and ALT testing of blood donations in Canada as surrogates for non-A, non-B hepatitis was not an acceptable one. (Krever 1997:707).

This conclusion is pure hindsight judgment (20/20 hindsight), the kind of judgement the Commission in its proceedings tried to avoid, and which was objected to by witnesses and their lawyers whenever it occurred. The following is a list of items which were truly unacceptable at the time they occurred. The Commission touched upon some of those, but they did not come to bear in the conclusions.

The Commission failed to show what was truly unacceptable:

- 1) That Gerety of the US FDA (with Barker and Zimmerman) recommended against the use of surrogate tests in May 1981. It is no business of the FDA ever to recommend against a safety measure;
- 2) Gerety and Barker (a former member of the FDA) were also participants in the NIH trial vaccine development, while they were regulators of that vaccine;
- 3) That half of the members of the ad hoc committee on surrogate testing were representatives of the US military. This committee was everything but representative of blood banking in the US;
- 4) That the FDA/NIH position against surrogate testing was buttressed with additional hepatitis B vaccine developers;
- 5) That the decision of the US not to use surrogate testing was as unacceptable in the US in 1981 as it was in 1986;
- 6) That the Canadian decision not to use surrogate testing was as unacceptable in 1981 as it was in 1986; (because of this failure of the Commission, people transfusion-infected before 1986 cannot get compensation)
- 7) That the US did not conduct any studies after it used their lack as an excuse not to use surrogate testing;
- 8) That after the two decisions not to use surrogate testing (1981,1986) Canada did not conduct studies until 1989;
- 9) That the Canadian study was unethical, including the consent which mislead the participants;
- 10) That the Feinman study of 1984/55 did not do or publish surrogate tests on the donors implicated in the transfusion of study participants;
- 11) That important data of the Blajchman/Feinman study (published in 1995) were not made public, such as the surrogate test status of donors that had a positive test for HCV;
- 12) That profiles of donors implicated in the transmission of post-transfusion hepatitis were never obtained or published, in the US or in Canada;
- 13) That the use of hepatitis B vaccine and hepatitis B immune serum (HBIG), as blood derivatives, were licensed by the Canadian Government in contravention of the Food and Drugs Act;

14) That the hepatitis vaccines (as blood derivatives) were not even mentioned as blood products and as possible sources of infection;

15) That Factor VIII concentrates replaced cryoprecipitate, although the risk of transmitting hepatitis was well understood.

All of these failures in findings make the conclusion of the Commission unacceptable. One needs to ask two questions:

1) Why did so many 'unacceptable' things happen;

2) How was it possible that so many unacceptable occurrences did not find a place in the Commission's conclusions?

The answer is that the true motivations for the various decisions and actions were not to be revealed. In the blood case, the true motivations and goals, i.e. the cover-up and investigation of the effects of various hepatitis B vaccine trials needed to be hidden. In the case of the Challenger disaster, the flawed design and the conditions of NASA's contract with Thiokol needed to be hidden.

5. SUMMARIES AND CONCLUSIONS

5.1 The prima facie case for the role of hepatitis B trial vaccines in the outbreak of the AIDS pandemic and the spread of hepatitis C

5.2 Dysinformation

5.3 The 'tragedy of capitalism'

5.4 Towards a sociology of technological development

5.5 What kind of inquiry?

Halpern, Diane F.: 1984, *Thought and Knowledge. An Introduction to Critical Thinking*. Lawrence Erlbaum Associates Inc. The book contains a chapter on propaganda (Chapter 2, pp. 36-4.) In order to protect oneself effectively from false claims, Halpern stresses, it is not enough to know the subject matter to evaluate messages, claims etc. It is equally important to know the discursive techniques which are used by individuals and institutions of power to get our consent, cooperation, or agreement. It needs to be added that it also is not enough to know the discursive techniques. The subject matter matters.

5.1 THE PRIMA FACIE CASE FOR THE POSSIBLE ROLE OF HEPATITIS B TRIAL VACCINES IN THE OUTBREAK OF THE AIDS PANDEMIC AND THE SPREAD OF HEPATITIS C

THREE MODELS OF THE ORIGINS OF AIDS

Of the three suggested models of the origins of AIDS:

- ❖ The 'vaccine model' of AIDS;
- ❖ The 'bushmeat model' model of AIDS;
- ❖ The 'injectionist model' of AIDS;

only the vaccine model is falsifiable. However, direct evidence for the vaccine model has been destroyed or remains concealed. The available indirect evidence suggests that HIV-1 first entered into human populations (gay men and intravenous drug users) in North-America via one or more hepatitis B trial vaccines contaminated with HIV-1, on more than one occasion (first in the early seventies, and again in 1978/79). In Europe, this may have occurred on one occasion (1978); and on two occasions in Africa (1975, 1978).

The evidence further suggests that only trial vaccines, used during the seventies, are potentially implicated in the outbreak of the AIDS pandemic. While there is no direct

evidence to show that one or more trial vaccines were contaminated with HIV-1 and that their experimental use started the AIDS pandemic, the indirect evidence points to one or more vaccines developed by Prince et al. at the New York Blood Center; and alternatively, to the NIH trial vaccine developed by Purcell and his colleagues. The New York Blood Center vaccine is the more likely candidate of the two. However, there is no evidence which definitely excludes European trial vaccines, such as those of the Dutch Red Cross and those produced in France, or the vaccines of Merck, Sharp and Dohme. All of them may have been used for trial purposes in Africa.

In the seventies, the New York Blood Center had used a laboratory-outpost in Liberia, because imported chimpanzees were too frequently infected with hepatitis B in transit or holding facilities, before their arrival in the U.S. A subspecies of chimpanzees (*Pan troglodytes*, troglodytes), which is the only known natural reservoir of HIV-1-like virus, was frequently used in the US, Africa and Europe for vaccine safety testing; for studying the clinical course of hepatitis B infections in an animal model (which was the only one); for producing a non-human source of hepatitis B surface antigen, since culturing of hepatitis B virus and antigen on tissue cultures had failed; and for supplying livers for the production of anti-HBc tests systems.

The specific modalities of the contamination of the vaccines with HIV-1 from chimpanzees in vaccine laboratories could not be ascertained by the author. It may have been an accident, theft and black market sales, sabotage, scientific interest, or competitive/commercial interest. Assuming that the vaccine hypothesis is correct, all transmissions of AIDS following the use of the vaccines in 1978 were secondary through sexual contact or various blood routes.

The 'bushmeat model' of AIDS, promoted by Harvard University and others (including the U.S. military) as recently as 1999, is an unlikely model because:

1) The habitat of HIV-1 carrying chimpanzee subspecies *Pan troglodytes* troglodytes (Western Zaire), and the epicenter of African AIDS epidemic (Rwanda, Southern Uganda, Northern Tanzania) are nearly 1,000 miles apart;

2) There is no evidence that the retrovirus specific for the chimpanzee subspecies living closely to the epicenter was ever transmitted to humans via the bushmeat route;

3) The model cannot explain the simultaneous massive outbreak of AIDS on three continents and Haiti, and the early cohort formation of reported cases or deaths from AIDS in Haiti, Belgium, and the US;

4) The slow progression of the spread of AIDS amongst intravenous drug users/needle sharers in San Francisco; the late and slow progression in high concentrations of commercial sex workers, such as in Thailand; the lack of drug user networks in Central Africa; stand in contradiction to the claim that AIDS was primarily propagated from central Africa through gay, drug user and commercial sex work networks;

5) The bushmeat model requires at least 4 separate instances, within a period of ten years, of the HIV-1 virus jumping from chimpanzees to human populations. According to the best knowledge available, very few sporadic cases happened before; nor did such an animal-to-human transmission occur with HIV-related viruses carried by chimpanzees belonging to different subspecies and living at least close to the epicenter of the pandemic in Africa.

The 'injectionist' model of the outbreak of the AIDS pandemic is within the range of possibilities, as animal facilities did exist in Africa, and discarded needles used in experiments with chimpanzees could have found their way into the black market. Similarly, during the Central African unrest in the late seventies, facilities might have

been raided, and contaminated materials or even trial vaccines could have found their way into local populations. In this model, foreign AID workers could have picked up the infection from already infected African populations. However, this model is neither provable nor falsifiable.

INDIRECT EVIDENCE SUPPORTING THE VACCINE MODEL

- 1) The implausible and non-falsifiable bushmeat model is being actively promoted, while the plausible, verifiable/falsifiable vaccine model has not been tested;
- 2) The vaccine model can explain features of the pandemic which the bushmeat model cannot explain, such as separate early AIDS cohorts in Belgium, Haiti, and the US; and the simultaneous start of the pandemic in North-America, Africa, Europe and Haiti;
- 3) Chimpanzees were used in large numbers for hepatitis B research and hepatitis B vaccine laboratories in Africa, Europe and in the US;
- 4) Hepatitis B vaccine trials were simultaneously underway in the late seventies in the US, Europe, and in Africa;
- 5) There is good cause to assume that some vaccine trials were not fully inactivated and carried live virus such as HBV, HCV and HIV-1;
- 6) Hepatitis B trial vaccines were never proven or even claimed to be free of HIV;
- 7) The massive onset of the epidemic in the U.S. speaks for a substantial vaccinated initial cohort, rather than for a progressive sexual propagation, as initiating mode of spread; for Africa, the opposite can be said.
- 8) The vaccine model, not the bushmeat model, can explain the absurd resistance of American and European scientists to the use of surrogate testing for the prevention of transfusion-related AIDS and hepatitis non-A,non-B. This is particularly significant with respect to anti-HBc testing (a possible marker for hepatitis B infections or vaccinations containing live virus). Data on anti-HBc testing obtained during the seventies were suppressed the mid-eighties (by then most of the vaccine-infected AIDS cases would have been dead, and thus the most

crucial evidence lost). Surrogate testing could have prevented most of transfusion-related HIV and HCV transmission, and evidence to that effect was available in the early eighties.

It is concluded, therefore, that based on these observations alone, there is a *prima facie* case for investigating the role of hepatitis B trial vaccines in the outbreak of the AIDS pandemic. Additional indirect evidence in support of the vaccine model is as follows:

- o Early cases of anti-HIV positivity were found in US drug addicts in 1971/2;
- o Early cases were also found in Zaire and in the Southern Sudan in or just before 1976, suggesting that early trial vaccines may also have been contaminated with HIV without leading to a major outbreak of AIDS in Africa, Europe, or in the US;
- o Of the three trial vaccines that were possibly tested on gay men in New York around the same time (between 1977 and 1979): The New York Blood Center Trial Vaccines (Prince); the NIH/NIAID vaccines (Purcell); and the Merck trial vaccines (Hilleman); the New York Blood Center trial vaccine was the least conventional, and most ambitious concerning immunogenicity, and the only one which deliberately used full hepatitis B virions (live virus) as starting material for vaccine production;
- o Robert Purcell of the NIH, in his 1985 review of the hepatitis B vaccine development program, does not mention the New York Blood Center vaccine at all: indeed it is the only one he does not mention; neither does Leonard Horowitz in his 1996 discussion of hepatitis vaccines. These conspicuous omissions point in the direction of the New York Blood Center trial vaccine as the likely vaccine(s) associated with AIDS.
- o Comparative statistics on the HIV-status in intravenous drug users in San Francisco and New York/Baltimore indicate that the NYBC vaccine may also have been used on drug users in New York and Baltimore, in addition to gay participants. The San Francisco data indicate that these vaccines were probably not used on drug addicts there, and that HIV did not cross over from gay populations to drug-user populations and vice-versa. Although some gay persons

may also have injected drugs and shared needles, they were not part of the main (heterosexual) drug culture in those cities.

- o The use of more than one trial vaccine explains a seemingly puzzling contradiction: the locations of the AIDS epicenters in the US coincide with the locations of an apparently HIV-free Merck vaccine. Later investigations established that HIV had spread at equal rates in trial participants as well as non-participants, and at equal rates in individuals receiving the vaccine, and those who were given a placebo (up to 70%). This is consistent, however, with the assumption that the initial infections occurred amongst participants in other trials, who then would have spread the virus (evenly) amongst sexually active Merck trial participants and non-participants.

- o Following the clinical trial of the Merck-vaccine in New York, Merck kept upgrading its inactivation protocol, indicating inadequate virus inactivation in earlier trial vaccines, which would have made the transmission of HIV-1 possible.

- o The only New York Blood Center vaccine report presented in the seventies is also the only report that mentions the Peace Corps as potential target group for vaccine trials;

- o Laurie Garrett makes a special point that there were no gay networks in Africa. But that does not preclude a gay presence in locations where aid agencies were operating.

- o In Belgium and Haiti, the earliest AIDS cohort is clearly segregated from subsequently reported cases: those infected spread HIV at home in Belgium or Haiti, after return from their tour of duty. In the US, an equivalent cohort of gay men with AIDS is recognizable by their early death before 1985. Some of the early cases, according to Laurie Garrett, have 'traveled abroad'. Both in France and in Belgium, the early AIDS cohort contained a hundred or so AIDS cases with transmission factor 'unknown'. At the same time, in Belgium, there were hardly any reports of AIDS amongst gay men, which makes those statistics different from any other European statistics at the same time – and unbelievable. One can assume that at least some of these individuals were gay, participated in foreign aid work, and were vaccinated with an HIV-contaminated hepatitis B vaccine.

- o There was a marked difference between the spread of AIDS in Haiti and in the neighboring Dominican Republic. The curve in the Dominican Republic follows the US pattern and can thus be contributed to spread through 'vacational sex'. The curve for Haiti is more consistent with a primary vaccine-infected cohort.

A vaccine-related working model of the origins of AIDS would be as follows:

The New York Blood Center produced a trial vaccine from complete viruses.

In order to maximize efficacy (immunogenicity) of the vaccine, some chimpanzee-derived hepatitis B virus was also used.

Some of that material was HIV-1 infected.

Trial doses were given to drug users in the early seventies; to some Africans in the mid-seventies; to gay persons working for the Peace-Corps in Africa in 1977/8. This may have included French-speaking heterosexual Haitians and some Europeans (Belgium and France).

Gay individuals thus infected propagated the virus several months later, in the gay communities in New York and California.

Trial doses were also given to intravenous drug users in 1978/9 in New York and Baltimore, but not in California.

When the Merck hepatitis B vaccine trials were conducted in 1978/9 in New York and California, some gay participants had already infected with HIV.

By 1979, the first symptoms of AIDS would have been noticed by vaccine researchers in their follow-up of trial participants.

The larger medical community learned about it in 1980.

Alternative explanations include the bushmeat model (as the least likely) and the use of contaminated needles from animal facilities in Africa by injectionists. Gay Peace Corps workers could have been infected there. In that scenario, however, one would expect a significant portion of the US heterosexual workers having been infected as well. The possible role of other trial vaccines cannot be excluded.

1981-1986: THE SUPPRESSION OF SURROGATE TESTING OF BLOOD DONORS AND THE SUPPRESSION OF RESEARCH ON SURROGATE TESTING; THE PRIMA FACIE CASE FOR INVESTIGATING THE

ROLE OF HEPATITIS B VACCINES IN THE SPREAD OF HEPATITIS C IN CANADA

The *prima facie* case for the possible involvement of hepatitis B vaccines in the spread of hepatitis C in Canada is based on the following:

1) The Merck hepatitis B vaccine trial reported on by the New York Blood Center in 1980 suggests that the vaccine may have contained some live virus; and there is no direct assurance that any of the hepatitis B vaccines were free of hepatitis C virus, as hepatitis B vaccines were never tested for freedom from hepatitis C;

2) Positivity of a blood donor for anti-Hbc, who was implicated in non-A,non-B post-transfusion hepatitis, would have been suggestive of a possible link between vaccination and hepatitis infection; while such a link between anti-HBc positivity and infectivity for hepatitis non-A,non-B could also have been associated with gay life-style and intravenous drug use, the possibility of a vaccine-link could not be excluded;

3) There was a substantial increase in hepatitis non-A,non-B in Britain, which did not parallel increases in hepatitis B and A. Such an increase was not observed in the US in the early eighties. In Canada, non-A,non-B post-transfusion hepatitis doubled between 1984 and 1985. Similar observations were made in Germany before and around 1983. The only conceivable change in epidemiological conditions in the early eighties leading to an increase in hepatitis non-A,non-B in Britain and in Canada, but not in the US, would have been a contaminated vaccine. This would have included individuals likely to be blood donors (such as healthcare workers attending hospital blood clinics; of people travelling abroad).

4) Merck hepatitis vaccines were sold in Canada; trial vaccines were used elsewhere; there is a report from Greece that both kinds were used there. Montreal and Vancouver, both mentioned in a WHO report with respect to vaccination of hospital personnel with hepatitis B vaccines, were later excluded from the Canadian clinical trial on surrogate testing in the late eighties, although they would have been logical places to conduct the study (instead, the investigators picked Hamilton and Winnipeg).

5) The only trial report on the New York portion published by Szmuness and others in 1980 provides some hints that the vaccine had some live hepatitis B elements and thus could have contained others as well, including non-A, non B hepatitis, and thus hepatitis C.

6) The results from the two major US studies on surrogate testing were unequivocal as to the efficacy of the tests substantially reducing hepatitis non-A,non-B transmission by blood and blood products;

7) Hepatitis B vaccine were blood products. In 1981, the US, some of the same individuals: 1) Licensed the new Merck vaccine; 2) Reviewed the anti-HBc data on surrogate testing, and suppressed them; 3) Brought up the ALT data on surrogate testing for debate and then advised not to use ALT testing.

8) There was no need for a clinical trial of surrogate testing donors for the presence of hepatitis non-A,non-B virus; the conduct of such a trial was considered unethical in the US;

9) After heat-treated factor VIII products had been introduced as of 1985, the combined lack of donor screening and suppression of surrogate testing cannot be explained with benefits to the plasma fractionation industry. Cutter had started testing its plasma donors for anti-HBc earlier.

10) In a meeting of the Canadian National Action Committee on AIDS in 1985, Dr. Perrault indicated that the 'industry' accepted liability for 'other risks' (presumably hepatitis), but not for transmissions of AIDS. This can be interpreted as the industry feeling responsible for the hepatitis contamination of the blood supply, but not for the contamination with HIV. This in turn is consistent with the suggestion that the New York Blood Center and perhaps other vaccines were linked to AIDS; and that the transmission of hepatitis had been already a risk accepted by the 'industry' when Factor VIII was introduced in Canada in 1978.

11) There was a condition in Canada, different from the US, which prevented Canada from not following the US example and implementing surrogate testing in 1986. Given the sharp increase in non-A,non-B post-transfusion hepatitis in Toronto, the only conceivable reason for such a damaging and liability-laden decision was the avoidance of another (considered more serious) liability associated with the discovery and identification of ALT or anti-HBc positive donors: injury from hepatitis B immunizations amongst those donors.

12) Canada never used surrogate testing, which goes far beyond any links to AIDS and substandard fractionation products. The same condition which stood in the way of using surrogate testing in Canada appears to prevail to this day.

13) Anti-HBc test results on the donor specimens collected during 1984/5 and thereafter in Toronto (over 1,000,000 specimens) were never released;

14) Anti-HBc test results on HVC-positive donors in the larger portion of the clinical trial on surrogate testing in Canada were never released.

The 'vaccine doctor club'. The 1981 decision in the US not to use surrogate testing was spearheaded by the vaccine developers who were also blood product specialists in the FDA and the NIH. The US/European position on the use of ALT as surrogate test was published as an 'International Forum' in *Vox Sanguinis*, the international transfusion journal, in 1983. The vast majority of the participants had been involved in vaccine development and trials:

Gerety (US, FDA),
Holland (US, NIH, Bethesda),
Aach (US, New York Blood Center),
Trepo (France, Lyon),
Reesink (Dutch Red Cross);
Reerink-Brongers (Dutch Red Cross).

The international initiative by vaccine developers had been preceded by vaccine developers in the US:

Barker (FDA, American Red Cross);
Kellner (New York Blood Center);
Purcell (National Institute for Allergy and Infectious Diseases (NIAID, part of the NIH);
Alter (NIH, blood center);
Zimmerman (physician of the US Veterans Administration)
Alling (Scientific director of the NIAID where the Purcell vaccine was developed)

The first statement against surrogate testing was signed by Barker, Gerety and Zimmerman (Red Cross, FDA and a physician affiliated with the Veterans Administration). Half of the undersigned on the subsequent statement published in Transfusion in 1982 belonged to the US Veterans Administration.

Bove of Yale (and the American Association of Blood Banks, AABB), who also signed the statement, was coopted to promote the slogan that the risk of getting AIDS from a transfusion was 1/1,000,000. On the heels of the position taken by this vaccine developer alliance came budget cuts for the FDA and the CDC. This massive defense by the vaccine interests was opposed, without success by members of the CDC (such Don Francis), but half-heartedly, because the CDC (and the office of the Surgeon General) were part of the US military. The policies of not using surrogate testing were propagated by the very people who had the greatest interest in not seeing them used, not by uninvolved, independent, safety-oriented blood bankers.

The use of hepatitis vaccines (trial or routine use) in Canada was illegally permitted by H&W Canada in contravention of the Food and Drugs Act, and therefore, it seems, H&W Canada could not afford to do follow-ups on vaccinated individuals publicly. The blood system may have provided a source of control information – if no systematic screening and exclusion of blood donors donations was carried out. Notably:

The use of HBs-antigen positive blood or plasma, as per the Food and Drugs Act (*'history of a disease transmissible by blood transfusion'*) as raw material for the production of a blood derivative had been illegal in Canada since 1940. All hepatitis B vaccines prior to recombinant DNA products were, without question, blood derivatives; and the presence of hepatitis B antigen was a clear and widely agreed upon indicator of a history of a disease transmissible by blood. The fact that it was a vaccine did not make it any less of a blood derivative.

Regardless of a prima facie case as built in this dissertation, there is a self-evident case for investigating how it was possible that such vaccines were used or sold in Canada. This case arises from the fact that the licensing of any hepatitis B vaccine of human origin, contaminated or not, was in violation of the Canadian Food and Drugs Act. This applies not only to hepatitis B vaccines, but also to passive immune-serum (HBIG). Its use was not merely 'unacceptable', as Krever characterized some of the Canadian decisions, but in contravention of the Act.

The working hypothesis for the prima facie case for the involvement of hepatitis B vaccines in the spread of hepatitis B vaccines is as follows:

Hepatitis B trial (including Merck vaccines) were inadequately inactivated and may have transmitted hepatitis non-A,non-B (part of which was later identified as hepatitis C).

Surrogate tests would not only have prevented most of transfusion-related hepatitis C, but also transfusion-related AIDS. However, surrogate tests would not only have established a possible link to vaccinations with respect to hepatitis non-A,non-B, but also to HIV.

Given the huge liability arising from potential vaccine-related HIV infections, the decision was made by health authorities in most Western industrialized nations (notably members of NATO) to suppress surrogate testing, to gain some time until more was learned about the pandemic, and to wait until the potentially most damaging evidence, the first cohort of HIV-infected persons had died.

This strategy came to an end in 1986 in the U.S.

In Canada this strategy was never terminated, suggesting that problems of vaccine-related hepatitis non-A,non-B had become the dominant concern. The Canadian government was in legal jeopardy for licensing hepatitis B vaccines. An alternative explanation (which is just as plausible) is the possibility that hepatitis B immune-serum (HBIG) was contaminated with hepatitis C, and possibly even with HIV.

THE CLINICAL TRIAL ON SURROGATE TESTING.

The time-table for the clinical trial on surrogate testing was as follows:

1981-1983: The 'vaccine club' decides against surrogate testing and claims that a controlled clinical trial is necessary;

1986: US decision to use surrogate testing without clinical trial;

1986: Canadian Red Cross decision not to use surrogate testing, claiming the a clinical trial is necessary;

1988/9: 'Mini-trial' (only 20% of the planned number of trial participants).

The vaccine developers/surrogate testing evaluators claimed that the two major studies of the NIH and TTVs group studies conducted in the late seventies had not proven the effectiveness of surrogate testing, that the cost of the tests make them a major waste of public funds, that too many blood donors would be lost, and that hepatitis non-A.non-B was not a serious illness. Therefore a clinical trial was claimed to be necessary. In reality:

- 1) The trials of the surrogate tests had proven beyond reasonable doubt that they could effectively reduce hepatitis non-A. non B. Other studies had shown that they would also reduce transfusion transmitted AIDS.
- 2) The cost estimates were exaggerated and based on estimates derived from small purchase orders;
- 3) The loss of donors was truly significant for the Factor VIII (plasma fractionation industry – 50% loss and more; voluntary donor loss would have been in the order of 10%, a loss that could have been easily absorbed with better transfusion practices; however, until 1987, the FDA never required plasma fractionators to use surrogate testing; in 1987 it only required anti-HBs testing.
- 4) Hepatitis non-A.nonB was already known to cause chronic liver disease in a substantial number of cases;
- 5) A clinical trial at that point was ethically already impossible, because it would have required to transfuse patients with surrogate test positive blood units, known to be more risky than negative units. This did not stop Canadian investigators from doing it, the Canadian government from funding it, and Canadian ethics committees from approving it.

The non-use of surrogate testing caused perhaps tens of thousands of patients world-wide to be infected with HIV by blood transfusions and blood products, and

hundreds of thousands with hepatitis C. It provided the following for the parties in jeopardy of liability with the following:

- 1) Plasma fractionators could sell their contaminated stocks; develop heat-treated product, and begin to develop alternative technologies (recombinant DNA);
- 2) The Merck vaccine was approved without further questioning and could begin to develop alternative technologies (recombinant DNA);
- 3) A 'covering of the tracks' of trial vaccines;
- 4) The opportunity to give the public a false sense of safety regarding transfusion products and hepatitis B vaccines and to flood it with theories of AIDS;
- 5) To maintain silence on hepatitis non-A,non-B;
- 6) Time to develop specific AIDS tests and later HCV-tests;
- 7) Time to observe the vaccine cohorts, and eventually estimate when the last one would die from AIDS;
- 8) Time to study vaccine cohorts as to the vaccine related transmission of hepatitis C (hepatitis non-A,non-B);
- 9) Time to prepare legal and public relations defenses.

Given the still high incidence of post-transfusion hepatitis in 1986, such a trial could then have been conducted with very few participants, at a very low cost, in a very short time. But the very conditions which prompted the call for the trial were the very same conditions which would have made such a trial extremely risky for the Canadian government and, at that time, undesirable. The trial was delayed until the specific tests for anti-HCV became available. While its full implementation was delayed with unnecessary (and presumably artificially staged) disputes over ethics, financing, design and funding. Only a mini-version of the trial was conducted (only 1/5 of the needed total participants). By the time funding was approved by the federal government, the risky donors had been

removed from the blood donor base, non-A,non-B post-transfusion hepatitis had been reduced to 2%, and most countries had already implemented the new test for detecting hepatitis C carriers. Key data which might have linked hepatitis C to vaccination were never published. The trial provided a small database, from which the relative effectiveness of surrogate testing and HIV testing could be roughly estimated. As it turned out 75% of hepatitis C (with very wide confidence limits) could have been prevented with surrogate testing. The study is flawed in several ways. The flaws can be explained with the circumstance, that the trial was unethical, should not have been conducted after 1981.

The actual formal result of the study was that surrogate testing would not have significantly reduced hepatitis non-A, non-B(!) The findings that surrogate testing would have significantly reduced hepatitis C was irrelevant to the research question (is surrogate testing efficacious in reducing non-A,non-B post-transfusion hepatitis?) and therefore the conclusion of the Krever Commission are irrelevant also.

THE RELATIVE LIABILITIES FROM CONTAMINATED VACCINES AND BLOOD AND BLOOD PRODUCTS; THE ROLE OF PLASMA FRACTIONATORS AS SECONDARY BENEFICIARIES OF AMERICAN CANADIAN TESTING POLICIES

The plasma industry (and the FDA) had tolerated hepatitis transmission in the seventies. The issue of surrogate testing was primarily related to AIDS, not to hepatitis non-A,non-B. If vaccines had not been involved, the negotiation for safer blood and surrogate testing might still have been fraught with arguments against it. However, there would have been a continuous process of research, negotiation and, yes, haggling over

cost. The 1981 decision not to use surrogate testing (and again in 1986 in Canada) was not an ongoing process, **but a complete shutdown of implementing available safety measures, as well as of the research process, for years.** These initiatives were led by individuals who were not representative of the blood banking business (vaccine developers, government agencies, US military).

In 1985, while heat-treated factor VIII was sitting on the shelf, the Red Cross used up its non-heat treated stocks. This action is so absurd, and the amount of money saved so small, that it led the author to believe that this was a deliberate exposure to liability ('Hit me there!'), rather than bad judgement. Indeed, it did focus public attention and a criminal investigation by the RCMP on those matters, and away from potential vaccine issues. The legal jeopardy with respect to the vaccines was far greater than from the distribution of these products.

The Krever Report goes to great lengths in dealing with the fact that non-heat-treated factor VIII was sold in Canada until the summer of 1985, and that dry-heat-treated Factor VIII was sold by Armour after 1985 in Canada. In general, however, once heat treatment was used for the manufacture of Factor VIII concentrate, HIV-1 transmission was no longer a major issue. Surrogate testing was not a requirement for the plasma industry by the US FDA until 1987, (at the early stages of the AIDS outbreak surrogate testing would have virtually wiped out the industry, as more of than 50% of the commercial donors had one or more surrogate markers positive). By the second half of the eighties, the death of hundreds of the most severe hemophiliacs reduced the demand for Factor VIII.

5.2 DYSINFORMATION

HUMAN-ECOLOGICAL MESS THEORIES

The apparent 'mess'. The origins of the AIDS pandemic and the spread of hepatitis C seem complex. In studying the two outbreaks one encounters:

- ❖ at least three different viruses, two of which were not isolated for years;
- ❖ four different vaccine trial phases;
- ❖ several vaccine developers, in the US and Europe, eventually also in Asia;
- ❖ several Factor VIII manufacturers;
- ❖ markers of one virus infection also being indicators of others;
- ❖ suddenness of the outbreak of AIDS in some places and slowness in others;
- ❖ very long symptom-free periods for both HIV and HCV infections;
- ❖ various modes of propagation for the three viruses;
- ❖ hepatitis B vaccines as ambiguous products (blood derivatives and vaccines);
- ❖ multiple scientific networks;
- ❖ involvement of non-governmental agencies;
- ❖ involvement of the WHO;
- ❖ involvement of the US military;
- ❖ involvement of the International Agency for Research on Cancer;
- ❖ social turmoil (human rights) in the US;
- ❖ political turmoil (Africa);
- ❖ drug user networks;
- ❖ gay networks;
- ❖ unequal regulation of biomedical products in different countries;
- ❖ effective marketing, propaganda and public relations techniques used by manufacturers;
- ❖ conditions of proprietary product information secrecy;
- ❖ sophisticated and complex health bureaucracies;
- ❖ infected patients networks;
- ❖ fear of civil and criminal litigation on the part of responsible individuals and institutions.

These conditions made, and still make, inadvertent as well as strategic, intentional dysinformation possible. The most enduring explanations of the AIDS epidemic and the spread of hepatitis C have been:

- 1) Ecological and social (human ecological) turmoil and the bushmeat model: unexpected things suddenly happen, such as outbreaks of new diseases (e.g. Ebola) and the reactivation of old ones (e.g. tuberculosis);
- 2) Unclear lines of authority; complexity of decision making and bureaucratic bungling, indifference, cost preoccupations; budget constraints;
- 3) Claims of confusion and uncertainty, when such new conditions are encountered by scientists.

The group at Harvard and 'ecology'. The human-ecological mess theory has been promoted by Harvard University and affiliates (Max Essex, Jonathan Mann, Don Francis, Sandra Panem, Leonard Horowitz, Laurie Garrett, Richard Wrangham): but also by journalists (Randy Shilts, who had Don Francis as one of his key informants).

The Krever Report is very much predicated on assumptions of inept, cost-focused, bungling bureaucrats, displaying decisions and behaviors which are characterized in the report as 'unacceptable'. While the report provides a mass of facts (over-information), it has its own methods of dysinformation: for the thousand pages of the report, there is no index, and there is no comprehensive bibliography. Only the best-informed people can find in there what they are looking for. Secondly, it lets the AIDS calendar start in 1981, and treats hepatitis as a separate entity, almost as an afterthought. Thirdly, it ignores the hepatitis B vaccines as blood derivatives. Thus the report omits, misdirects, overwhelms, and does not inform.

These human ecological mess theories are such that they are fairly easily accepted by lay individuals (they seem to make sense). At the same time, they ensure that no specific causes and responsibilities are looked for, let alone found. In addition, they are true in the sense that ecological messes and uncertainty helped spread the diseases, they are most likely not true for the genesis of the two outbreaks. However, few people would be able to make that distinction.

Such ecological constructs not only detract from the true occurrences and decisions, but also appeal to the public's favorite dislikes: the environmental mess, social disintegration, loss of sexual mores, African Americans, gays, brutal African dictators, drug addicts, the CIA, an overwhelming bureaucracy. In the past, the plague, cholera, syphilis would have been consistent with this kind of views. But the outbreaks in question did arise from human interventions and a 'messing up of ecological conditions', and were followed by the actions of very ignorant, confused people and inept officials who were guided by informed professional, military disinformation strategies.

Such 'mess' explanations must never be accepted at face value. Science, technology and the commercial exploitation of a technology or resource intervene in ecological conditions in a strategic and informed manner. The human-ecological model of disasters offered in this study predicts that all human purposive 'organization' (social, technological, information) leads to a disorganization of existing conditions, which may have more or less serious consequences. Thus, if serious disorders are encountered in socio-technical systems (and socio-technical societies), all possible strategic, deliberate decisions and actions of socio-technical organization must be excluded as explanantia,

before some general ecological mess theories of such serious disturbances (and 'true accidents') are to be seriously considered as 'explanation of last resort.'

In the case of AIDS and hepatitis C, the lines of authority and respective responsibilities were clear, at least for Canada's part vis-à-vis hepatitis B vaccines and Factor VIII concentrate. It was clear, that the distribution of hepatitis B vaccines were in contravention of the Food and Drugs Act. It was also clear that cryoprecipitate was a blood derivative, and should have been regulated. It was clear that the development of vaccines (a kind of concentrate) and Factor VIII concentrates were very risky undertakings, at the very least carrying the risk of spreading hepatitis B and what was then known as hepatitis non-A.non-B. In 1981, it also would have been clear to those who had participated in the vaccine development, that vaccines were at last possible culprits in the two outbreaks. Finally, it was clear what measures could have reduced the impact of HIV and HCV on the recipients of blood products: moratoria on vaccines and Factor VIII concentrates; heat-treatment of Factor VIII; restricted use of blood; stringent donor selection procedures; surrogate testing; emergency development of specific screening tests. None of this was done. Instead, the public was served 'dysinformation.'

It was first the strategic development and organization of the vaccine program, and later, the strategic 'damage control' which created all perceived 'messes', confusion and uncertainties. It seems confusing, and indeed absurd, when the scientists contributing to the International Forum in 1983 on surrogate testing vigorously argued against the very means by which the spread of the HIV and HCV could have been minimized. It is not at all confusing, when one knows that at least the majority of these scientists had a major stake in the hepatitis B vaccine development (substantial revenues from vaccine patents).

and then a big stake in concealing the disastrous side-effects of that vaccine (and liabilities): Management of safety of transfusion therapy and public communications were in the hands of the vaccine developers who were in serious jeopardy, not in the hands of safety-oriented blood bankers, in the US and in Europe.

The question of AIDS having been caused by a vaccine briefly erupted in the early eighties. The suggestion that AIDS was caused by a polio vaccine was weak and did not result in a major dispute. It surely did not fit the epidemiological patterns. The suggestion that it was linked to the Merck hepatitis B vaccine was countered with safety experiments, the results and conclusions of which can be shown to be invalid. The theory that HIV was engineered by sinister scientists working for the US military and the CIA, as in Horowitz's book, did not help the credibility or the hepatitis B vaccine trail. Horowitz outlined the trail very superficially, and with no connections to hepatitis C and blood products whatsoever. Laurie Garrett, the main propagandist from Harvard for the 'ecological mess theory', discussed vaccination in a short paragraph, and then ignored it. Yet her account of the AIDS pandemic is full of facts pointing to the hepatitis B-vaccine model of AIDS. She also missed the connection to blood and blood products, and HCV.

OTHER THEORIES

A number of theories of AIDS were floated during the eighties, all eventually discredited. They were effective in confusing the public as to the origins of AIDS and in hiding hepatitis non-A,non-B.

OUTRIGHT MISREPRESENTATIONS

Far more serious instances of 'dysinformation' were false communications by Dr. Perrault and some of his colleagues in Canada (Krever's account is full of such examples); Feinman claiming he only could test a few donor samples (he had lots of them); Bove's announcement the risk of AIDS from blood transfusion was 1/1,000,000, which was based on donors with AIDS, not on donors infected without AIDS symptoms; the withholding of information on the relative risk of surrogate positive and negative blood from Canadian clinical trial participants; the claim that the US surrogate-testing trials were insufficient to prove of the efficacy of the tests; the omission of testing trial vaccines for the presence of HIV material; the withholding of anti-HBc test results for years by both, the NIH and the TTVS group; the Krever Commission not addressing hepatitis B vaccine use in Canada as blood derivatives and starting the true inquiry calendar for AIDS in 1981; the approval of the Canadian clinical trial by ethics committees as being 'ethical'.

These are instances where story telling, 'peshering' and misleading speculation were exceeded. They were instances of serious breaches of the public trust and of rights of the public to be fully and truthfully informed on matters of safety and well-being. Rather than springing out of confusion and uncertainty, these dyscommunications were based on intelligence and certainty available to liable parties and served their defensive strategies.

5.3 'NORMAL BUSINESS': 'THE TRAGEDY OF CAPITALISM'

There is nothing in the vaccine disaster and the Challenger incident that would not be recognizable as 'normal business', i.e. conquest, survival and growth in a competitive market: taking limited risks to maximize returns on investment, including possible consequences of initial design flaws in new technologies; optimizing controls in all the fields of contingencies described; measuring damages to people and the environment in terms of financial liabilities, not in terms of abstract moral principles. The ultimate measure of the soundness of such business decisions is sought in the stock market, in other words, the evaluation of a business by the 'investment community'.

The tolerance of design flaws during the development phase, before product launch, is part and parcel of the competitive business gamble, to enter into the market first and to grab the largest market share (a characteristic of 'excellent companies'). This ensures early strong performance in the stock market, and is followed by strategies which ensure sustained or improving standing in the stock market (sustained return on investment). As long as product failures do not seriously threaten the return on investment, there is no incentive to correct flaws in design, and such liabilities will be tolerated as 'normal' and a cost of doing business.

As it turned out, the Challenger incident did not damage the shuttle enterprise (except for temporary losses) or the Morton Thiokol Company in Utah. The AIDS crisis and the HIV crisis did not damage the plasma industry or the vaccine industry. Ideologies and propaganda of the 'higher good', as well as emphasis on benefits, no matter how

small, and down-playing risks, no matter how serious, tailored to the specific phase in the technology life-cycle (development, marketing and operation), may be readily accepted by politicians, bureaucrats, managers and customers alike, even when the flaws in the technology are serious. The very few dissenters can be handled with bribes (which are difficult to verify if they come in the form of lucrative careers and positions), career manipulation, economic destruction and destruction of personal credibility. Those who 'carry the ball' through the rough times of a product failure, can be expected to be rewarded, and to retain power positions after a crisis. Litigations can be handled with out-of-court settlements, sealing of the records and confidentiality as a condition of the settlement. Public inquiries can be focused on a few segregated issues (to give the impression that *'something is being done about it'*), and thus be used to detract from the main problems. They also provide the 'normal diet' for news media. For instance, the recent developments concerning the use of plasma collected from Arkansas prison inmates by Connaught laboratories in the eighties, during Bill Clinton's reign as governor of Arkansas, are such 'media food'. At that time, any plasma purchased anywhere was probably as contaminated as plasma collected in prison. The Arkansas prison issue is just another 'decoy'.

In the case of the Challenger incident, the O-rings received all the attention (which was enhanced by Richard Feynman's presence). The most important contractual and design issues were not dealt with, and when they came up, they were simply denied. In extreme cases, government can provide cover for the industry and offer compassionate packages as compensation, with the same conditions as out-of-court settlements.

Thus in both, the orbiter case and the vaccine case, nothing happened that would not make good 'business sense', and Diane Vaughan's arguments of 'normalization of deviance' and 'inevitable mistakes' are invalid: because the sequence of decision is precisely what would be considered normal business decisions. In that sense, one would rather agree with Zygmunt Bauman, who would interpret the vaccine disaster simply as a manifestation of modernity and its production ideology. Today, one would perhaps better refer to 'business ideology', in which 'business viability' (with growth and technology development are necessary condition of survival) has displaced older, more limited ideologies. Modernity has become a lot 'faster'.

The regulatory role of government as regulator can be neutralized with 'higher good arguments' (employment, discontinuation of an essential product in short supply), or as in the case of the Canadian government, exposure to severe political liabilities. It can be further neutralized by the shortage of expertise in regulating offices, because most expertise is found in the business enterprises that are being regulated. 'Partnership with governments' and careful stacking of advisory and expert committees, as well as large research and development endowments from industry can complete the breakdown of boundaries between producers and regulators. Secrecy is assured by proprietary information statutes.

The tragedy of capitalism. The case of the hepatitis B vaccine has taught business something new: that even the most horrendous mishaps and the most serious consequences from bad business decisions and gambles can be 'handled', or 'managed'.

so that no serious consequences for the enterprise, cooperating individuals and regulatory agencies arise.

Therefore, the most destructive and lasting damage from not inquiring into the role of the vaccines will be the precedent it sets: consequences from reckless technology development were 'deniable'. The deniability of such consequences can be nothing less than encouraging for those engaged in the capitalist mode of technology development, in which a development project must meet three criteria:

- 1) It must be profitable.**
- 2) It must be doable.**
- 3) Adverse consequences must be deniable.**

Proprietary secrecy already provides an almost impenetrable protection of technology development from public scrutiny. The level of deniability achieved with the contamination of the blood supply, while secrecy could not be kept completely, has set a pernicious precedent. Krever has only revealed what inevitably had to be revealed, and what he was allowed to reveal. He could not object, because he had already compromised himself in the course of the Royal Society study on AIDS in Canada. Loss of a civil suit is not even a cost to a large business corporation, let alone an effective sanction. The architects of the capitalist state (i.e. 'democracy') did not provide a remedial course of action for this 'set of contingencies' of technology development. They never intended to.

The 'tragedy of capitalism' in its production dimension was felt in the 19th century, when business enterprises could not stop child labor even if they had wanted to. The result was the beginning of what become known as the 'capitalist state' of the

'social-democratic state'. The three criteria and the competitive imperative made it impossible for capitalist enterprises to exercise self-restraint, even if they wanted to. Today, under conditions of a vastly accelerated technology development, and as power is shifting increasingly from territorial governments and their constituent citizens to corporate enterprises and their shareholder constituencies, we are slipping back into a modified industrial revolution. The acceleration is experienced as 'risk', and is the basis for what Ulrich Beck termed 'risk society':

There has been a movement away from class society, where the principal preoccupation is equality (obtaining it, losing it, and preventing it), toward a "risk society", whose the basic motive force is safety; there is an emergent solidarity of anxiety about what is, and what is not, safe, although old judgements and values of utility, profit and advantage persist. (Ulrich Beck, quoted by Alan Powell, 1997).

However, once 'risk' becomes inevitable, or a normal aspect of 'doing business', the emergent solidarity of anxiety may well evaporate, and there is nothing to stop the 'tragedy of capitalism.'

5.4 THE CASE STUDY AND DISASTER SOCIOLOGY.

Disaster sociology was shown to be mainly concentrated on events and social impacts after the disastrous occurrence, including observations of how victims, organizations and communities interpret the events and consequences, and how they adjust to the new conditions. With some notable exceptions, very little research has been done on the social conditions and processes engaged in the genesis of a disaster. Even Diane Vaughan, who looked at the contingencies leading to the Challenger launch decision, focused on organizational and other contingencies mainly in the proximity of the occurrence. Critical events in the more distant past, such as design and design approval decision, test results, contracts and requests for proposals, were not in the foreground. As a consequence of that, she rather readily accepted two highly questionable claims: namely the reason given by the engineers why they used only a subset of the O-ring incident data (*'they did not know why'*); and that the contract competition for the booster rockets had been a fair one, on the basis of management evaluation alone, without the technical specifications and risk assessment sections of the proposals. If she had asked, she might have been told that this was proprietary information and thus confidential.

The example of the hepatitis B vaccine teaches that critical events, decisions, actions, may have their origins in a rather distant path, as, for instance, the decision to experiment with hepatitis B antigens harvested from infected chimpanzees; or the illegal distribution of hepatitis B vaccine, which then led to the Canadian clinical trial on

surrogate testing years later; or in the commitment to introduce a known hazardous product (Factor VIII concentrate), that has little, if any advantage, over a product that is already in use, and thus was not introduced for the public good.

It also teaches that public knowledge of such processes could substantially change the social construction of them, as well as the social construction of the consequences and the social actions to be taken. For instance, proprietary confidentiality during clinical trials stands in direct contradiction to the code of ethics to be applied in such undertakings, which requires full disclosure of the risks of the trial drug or vaccine. The Code of Ethics of the Canadian Tricouncil does not address this very serious problem. Since most of the problems of the hepatitis B vaccine were associated with trial versions of it, disclosure of those facts might have resulted at least in some debate on this matter.

Those disaster sociologists who did deal with disaster genesis (e.g. Turner and Pidgeon) are, like Diane Vaughan, too much focused on the immediate operational and technological contingencies (the 'ring of techno-scientific controls' and flaws in it), and do not account for the wider environmental, organizational and communal contingencies: competition, conquest of market share and maintenance, return on investments, environmental disturbance, networks of major share holder interests, softening of the boundaries between business enterprises and regulating government agencies. For instance, there are serious questions to be asked why the NIH in the USA experimented with vaccine development, and did not focus on efficacy and safety testing instead, when Merck already had a full vaccine development program.

THE THEORETICAL SUPER STRUCTURE AND METHODOLOGY

'Levels of knowledge construction'. Disaster sociologists feel that social, purposive constructions of organizations engaged in disaster responses do not provide adequate knowledge of disasters. The vaccine example shows that they may actually produce false information. However, at the same time, these very deficiencies in those constructions may provide important clues as to 'what happened', and 'what is going on'. For instance, the sustained emphasis on Africa as the origin of the AIDS pandemic, on its uncontrollable ecological conditions, and on the bushmeat theory, should raise questions as to the factual realities and how they match up with these claims. As exemplified by Harvard University, an entire institution may play a role in such constructions, in cooperation with parties that have a vested interest in the propagation of 'dysinformation.'

The human ecological case-study methodology developed for this case has served the case-study well, as it forced the author to ask certain question, which he otherwise might not have asked: in particular those questions which are not strictly 'sociological,' but which seek non-sociological evidence in order to understand what it is that is being socially constructed, and how the actions make sense in terms of what has been constructed, and in terms of the material realities to which those constructions make reference.

Critical paths. The temporal dimension and critical path construction ensured that the inquiry went back far enough so as not to miss relevant contingencies in any of the fields prescribed. The data in certain fields have remained incomplete, but it is this

very incompleteness (lack of data, inaccessibility of data) which provided clues as to whether such evidence may exist, why it may be hidden, and what such evidence might contribute if it was accessible. Critical path analysis resulted in an 'unbundling' of the path initially pursued by the author, which was based on factor VIII technology. Some of the paths exposed must remain tentative, as evidence of the decisions and practices along those paths remains concealed.

Fields of contingencies, contingency accounting. This aspect of the methodology was particularly helpful with the analysis of 'dysinformation'. Most of the dysinformation was based on claims concerning contingencies in one or more subfields, but never the entire field. The absence of plausible 'networked contingencies', and lack of validation of claims in one field with contingencies in the others raised questions as to the validity of such claims. It also directed the inquiry to look in subfields which the 'dysinformation' avoided or excluded.

THE NEED FOR A SOCIOLOGY OF THE CAPITALIST MODE OF TECHNOLOGY DEVELOPMENT; THE NEED FOR A SOCIOLOGY OF THE GENESIS OF DISASTERS.

The examples of the contaminated vaccine and the Challenger incident show that consequences, responses, and their analysis of a disastrous occurrence can be seriously flawed, if the genesis of such an occurrence remains unknown, concealed or inadequately investigated.

This case study does not claim to have found conclusive evidence, or the truth, and hence the repeated reference to this study merely making a 'prima facie case' for a formal inquiry. However, the theoretical framework and methodology developed for this case study supplied the accounting tools for exploring the genesis of the contamination of the Canadian blood supply with HIV and HCV. They yielded results which were not obtained (at least officially) by other investigations of this kind, such as the *Krever Inquiry*. Consistency across all fields of contingencies can be demonstrated, and further, the working hypothesis advanced as the prima facie case is testable, verifiable, or falsifiable.

The experience of this investigation suggests that contingencies of the near and more distant past must be explored, if the present is to be understood and properly acted upon. There is no rule, how far back such an inquiry has to go. However, technology development phases are a good target for getting at the roots of a socio-technical disasters.

Hunt's and Wickham's insistence that '*society is always already there*' is useful only in the broadest sense possible. The future cannot be 'observed'. The construction of the present, no matter how we do it, is always a reconstruction of the past, albeit sometimes a very immediate past. The question then is not whether or not the past is relevant for the present, but which aspects of the past and how far back they should be examined to arrive at the best possible interpretation of the present.

Since all operational performance of technologies is rooted in a series of design and development decisions in the past; and since most of technology development is in the hands of commercial enterprises; it is necessary to examine the development of such

enterprises sociologically, from an encompassing, human-ecological perspective: there is a need for a 'sociology of the capitalist mode of technology development'.

A sociology of the 'genesis of the disasters' (or socio-technical disasters) is not just useful for the understanding and prevention of disasters. Mishaps and their material and social contingencies (including the interactions between ideas and materialities) can provide glimpses into the social processes engaged in technology development, which otherwise would remain hidden and shrouded in secrecy. 'Pathology' can convey knowledge of 'normal physiology.'

The 'theoretical superstructure' and methodology of this study were formulated as a spatio-temporal matrix for contingency mapping. Those maps must include both material contingencies and contingencies of social construction and social (power-) relations. In its application to the case-study at hand, it proved to be a suitable framework for conducting such inquiries. In the absence of hard, direct evidence, social constructions of an occurrence, and in particular their flaws, provide valuable indirect evidence for the case. Its effectiveness depends, however, on the amount of resources which can be allocated to such inquiries, and on the political constraints (inevitably) imposed on them. At the present it seems that both circumstances severely curtail the effectiveness of such undertakings. A full inquiry into the vaccines would have to be a 'Krever-plus' inquiry, and the most critical information, even if indirect, is not going to be released.

5.5 WHAT KIND OF INQUIRY ?

THE NEED FOR AN INQUIRY ON THE ROLE OF HEPATITIS B VACCINES IN THE CONTAMINATION OF THE BLOOD SUPPLY

Based on the evidence assembled here (which, is, by no means, exhaustive), it is suggested that there is a *prima facie* case for an investigation into the role of various hepatitis B trial vaccines (American and European) in:

- 1) The outbreak of the AIDS pandemic in the US, Africa, Europe and Haiti;
- 2) The propagation of hepatitis C in Canada and perhaps in the UK and other European states, as well as in selected places in the US, where Merck, Sharp & Dohme and other trial vaccines may have been used; this inquiry should also cover HBIG (used for passive immunization against hepatitis B);
- 3) The 1981/2/3 decisions in the US, Canada, Europe not to use surrogate testing for the prevention of transfusion-related transmissions of HCV and HIV;
- 4) The extended non-screening of blood donors and the extended non-use of surrogate testing in Canada before and after 1986.

In Canada (and perhaps in other countries as well), irrespective of the potential role of hepatitis B vaccines, there two additional issues to be addressed:

- 1) Why did the Canadian government permit the distribution of hepatitis vaccine (a blood and plasma derivative), which was an illegal product in Canada as per Food and Drugs Act (produced from plasma of donors known to have an infection transmissible by blood); and how did that become possible;
- 2) Why did the Canadian government permit the distribution and sale of Factor VIII concentrates (a blood and plasma derivative), which was another illegal product in Canada as per Food and Drugs Act (produced, in part from pools of paid donors, which for more than twenty years were known to contain large numbers of donors with histories of diseases transmissible by blood (10 times more than amongst voluntary donors); and how did that become possible.

The Krever Report addresses neither of the two questions. Only transfusion-related AIDS and transfusion-related hepatitis C, as separate issues, and after 1980, are reported on, although both appear to be linked to hepatitis vaccines; and although the side-effects of Factor VIII concentrate, introduced in 1978/9 in Canada, were well known and understood. The most critical specimens collections and records, i.e. those of the clinical trials in the US, and of the 1984/5 Feinman study and the clinical trial study (Blajchman and Feinman from 1988 to 1991) have not been investigated by the Krever Inquiry. Also, very little information is known on the specific conditions of the earliest cases of AIDS in the US (such as concerning 'travel abroad'). The fact that no such investigations were carried out strengthens the *prima facie* case that trial vaccines may have been responsible for the transmission of HIV and HCV.

The hepatitis B vaccine decisions were taken by regulators who were directly involved in the development of a hazardous product. In addition, the individuals who licensed the Merck products were not vaccine experts, but they were blood product experts. The international forum which recommended against surrogate testing was composed of blood bankers who had a primary interest in hepatitis B vaccines. In other words, the boundaries between manufacturers and regulators, the boundaries between hepatitis vaccines and blood products, the boundaries between blood bankers and vaccine developers, and with them, boundary controls, were dissolved: the ring of technoscientific controls, which normally protects a product from contingencies, which compromise efficacy and/or safety, had become defunct.

Up to the point of Barker's and Gerety's May 1981 stand against surrogate testing, all mishaps could have been interpreted as overzealous competition, recklessness,

unethical conduct and so forth. Barker's and Gerety's announcement against surrogate testing, and all subsequent actions and inactions between 1981 and 1985, had no apparent purpose other than to cover-up what had gone wrong before, and are therefore not at all defensible. Sabin's claim that secrecy is legitimate to prevent people from abstaining from vaccinations does not hold up in the face of the numbers who could be expected to be infected via blood and blood products contaminated with HIV and or HCV.

No less serious was the scape-goating of homosexuals, Haitians and Africans, and even intravenous drug users. It is time to question these stigmatization strategies in the service of dysinformation, and to expose the flawed decisions of business managers and government administrators, who experimented with viral ecological conditions, well-known as risky from precedent (the polio vaccines); who then covered their trails left from the pursuit of a project which, from the very start, could not possibly, not even in their own mind, aim for the 'eradication of hepatitis B' because of limited suitable rawmaterial.

Biotechnology exposes us increasingly to consequences of such ill-conceived bioengineering, its management and its regulation (or non-regulation). The AIDS and hepatitis cases show that such ill-controlled developments can produce serious consequences, if the commercial stakes are high enough, and if the competition for market position is fierce enough. More importantly, the parties involved have learned from the case of the contamination of the blood supply, how to handle and cover-up a worst-case scenario of consequences of such risky ventures, by concealing and mystifying them, by relocating the blame, and by concealing the evidence – at a substantial cost to human life, well-being and reputation of non-co-operative individuals.

By exposing some specific wrongdoings by the Red Cross and by low level bureaucrats in Canada (in particular the withholding of heat-treated Factor VIII concentrate; the non-use of surrogate testing after 1986; also by pointing to the plasma collections at the Arkansas prison for use by Connaught Laboratories in their manufacturing of Factor VIII), Krever and his legal team may have succeeded, by use of these decoys, to divert public attention from the larger, underlying issues of illegal products being licensed and sold to the Canadian public. For the media (and thus the 'public court'), the *Krever Report* has become the 'Gospel', despite the fact that Krever on an earlier occasion was responsible, together with Michel Chretien, the Prime Minister's brother, in suppressing issues related to information on transfusion-related AIDS in their Royal Society report on AIDS (1989).

In talking to two RCMP officers the author is left with the impression that the ongoing RCMP criminal investigation into the contamination of the Canadian Blood supply is showing no signs of going beyond what has already been exposed by the Krever Commission. It does not address the questionable licensing of Factor VIII concentrate for use in Canada in 1989, and, of course there is no trace of any attention being paid to vaccines. Court proceedings in France against blood officials and ministers of the French government also have not resulted in an investigation into the role of French or any other trial vaccines in the spread of HIV and hepatitis C in Europe, Haiti and Africa. Given the transnational synchronization of responses to the HIV and hepatitis C crises within the boundaries of the G7 countries and NATO, the chances for an inquiry into the role of the hepatitis B vaccines are close to zero. Not even the Human Rights Court in The Hague, which increasingly has become a coercive instrument of the NATO alliance, is a realistic

prospect. (The Netherlands Red Cross was also developing hepatitis B vaccines and engaged in the arguments against surrogate testing thereafter in 1983).

The circumstantial evidence strongly suggests that the agencies involved in the vaccine trials should be compelled to release their reference material and records for investigational purposes. Immunity from prosecution should be granted for the benefit of the truth. Short of an inquiry, this study puts on record that a *prima facie* case for such an inquiry indeed exists.

Given the past European/Canadian/US cooperation on these matters, the chances for an inquiry into the role of hepatitis vaccines in the AIDS pandemic and the spread of hepatitis C are not good at all. As to the specific question to be directed specifically to the Canadian Government, such a request may simply be stone-walled: the Justice Department had nearly twenty years to prepare for this eventuality.

Studies of the kind demonstrated in this dissertation may be the only way to counteract the 'tragedy of capitalism' and its inherent developmental recklessness. A slow process of accumulating case studies, extracting common features, pinpointing the inherent risks associated with the capitalist mode of technology development, and exposing disorienting communication methods may be the only form of inquiry possible. However, sociology would have to move beyond its 'perspective and social theory orientation;' begin to address problems that are common to us all; with tools that work and that are acceptable to audiences outside of sociology – not just to sociologists; and most importantly, familiarize itself with the subject matters, the social constructions of which are current, and insufficient, targets of sociological critique.

This will not be an easy task, and it will introduce new levels of complexity into sociological inquiry. One should be reminded by Diane Vaughan's experience that addressing complexity may well be unavoidable.

Appendix 1

(1) Blood and blood component therapy

"One of the earliest transfusions was given to a man who had fallen into a 'Phrensy....occasioned by a disgrace he received.....in some Amours'. It was hoped that the calf's blood used for transfusion, 'by its mildness and freshness might possibly allay the heat and ebullition of his Blood' (Denis, 1667). Even now, blood is sometimes used in this spirit and is given as if it were the elixir of life to patients dying of cancer.. However, transfusion achieves its tangible effects by substitution; for example by supplying red cells which temporarily survive and function in the patient's circulation. (Mollison, 1972:2) (Emphasis by the author).

The essence of blood transfusion and blood component therapy is expressed in the above statement by Mollison (1972(!)): **If a specific substance is lacking in a patient's circulating blood, and if this lack constitutes a serious threat to health and life, then this specific component should be given to substitute for loss or inadequate production by the body. What is not needed should not be given.** Mollison objects strongly (not successfully) to two bad blood transfusion practices:

- * **Blood transfusion is risky**, and if there is no definite need, it should be avoided;
- * **Giving whole blood is wasteful**, since it reduces the opportunity to produce specific components.

To give blood as a 'rosy cheek tonic', as has been the practice by some physicians, is both wasteful and risky, without true benefits. Indeed, with the exception of massive bleeds, when dozens of units of blood may be required to save a life - 'massive transfusion' - whole blood should never be given.

At the beginnings of the 'blood transfusion enterprise', two kinds of risks associated with blood transfusion:

a) Blood group incompatibility between the patient's blood and the donor's blood. This risk was foremost in the minds of blood bankers, because serious reactions were usually immediate, and could be observed in vitro in the laboratory (agglutination-clumping, and lysis-destruction of red cells). This 'immediate danger' shaped the 'culture of blood banking', at the 'banking' level (blood centers) and at the 'pharmacy' level (hospital cross-matching laboratories and blood banks).

b) Transmission of infectious diseases. The second risk was recognized early on. However, there is usually a symptom-free incubation period before the onset of symptoms of infectious disease; and blood center medical personnel or even hospital blood bank personnel would not necessarily see such side-effects. If at all, these cases would be seen by the family physician. While blood group serology became a highly sophisticated subdiscipline in laboratory medicine, which led to the discovery of many rare blood groups, there were, with the exception of syphilis, no laboratory tests available in the early stages of the blood transfusion discipline to even recognize this danger. It became part of the 'blood banking culture' only in the seventies with the discovery of 'HBs antigen' (hepatitis B surface antigen). Before such tests became available, the only safe-guard was to ask blood donors certain question regarding previous exposure to hepatitis risks, or a history of actual illness.

Specific deficiencies can be treated with specific blood components or fractions. For instance, a patient who suffers from bleeding due to a low blood platelet count can be given '**platelet concentrate**'. A patient low on albumin (a protein which, amongst other roles, controlling the water content and volume of circulating blood), as may happen with severe burns can be given a solution of the '**albumin fraction** of plasma. And patients with seriously low red cell counts can be given '**red cell concentrate**'.

- * **Component production.** The idea of giving specific parts of the blood. components and plasma fractions, became a feasible program with the introduction of plastic bags with satellite bags, which allowed easy centrifugation and extraction of plasma supernatants into the 'satellites'.

This was a 'production activity', and again did not fit the blood group oriented 'laboratory culture of blood banks'. For instance, in Canada the work is done by non-professional staff, so-called 'lab helpers'. There is sophisticated equipment available (plasmapheresis, haemapheresis), which allows component separation during a blood donation through 'continuous flow centrifugation'.

- * **Plasma fractionation.** With some exceptions (e.g. the Greater New York Blood Program) this was a commercial, profit-oriented enterprise (the '**plasma fractionation industry**', or short, '**plasma fractionators**') which, in contrast to most blood banks, relies almost entirely on 'commercial', i.e. paid plasma donors. The organization is strictly profit-oriented, and cannot be compared with non-commercial blood banks, who had primarily a medical/clinical laboratory orientation.

There is a 'downside' associated with the benefit of optimal utilization of collected blood though component production and

plasma fractionation: a single contaminated unit of blood may be separated into several products, each one being infectious; and in the case of plasma fractionation, far more seriously, pools of thousands and tens of thousands of units blood hundreds and thousands of finished products may become contaminated by the presence of a single contaminated unit of plasma; and a single infectious donor may infect several plasma pools (usually, blood donors give up to four times year, commercial donors may donate plasma as frequently as once a week). Blood banks (some of which operate for profit also), hospital blood bank laboratories, together with the plasma fractionation industry, commercial plasma collection enterprises, and plasma and blood brokers (who may import blood and plasma from overseas), **are often referred to as the 'blood industry'**.

The risks of 'incompatibilities of blood' from one person and another was overcome by 'typing and matching' donated blood and the blood of the recipient. The main discoveries in this area were as follows (from Race & Sanger, 1975:1):

1875	Landois	Blood from an animal of one species mixed with blood from another may clump
1900	Landsteiner	Serum from blood of some of his colleagues agglutinated (clumped) that of others, later known as ' ABO blood groups '. (Nobel prize received 30 years later).
1910	von Dungern Hirszfeld	Mendelian inheritance of blood groups
1927	Landsteiner Levine	MN and P system
1939	Levine Stetson	Rhesus systems
1940	Landsteiner Wiener	Rhesus system

Table 20: Milestones in blood group serology

Note: A collection of the Landsteiner papers were translated by the US Army : Blood Transfusion Division, US Army Medical Research Laboratory, Fort Knox, Kentucky. 40121. Landsteiner did his research at the Institute for physiology of the University of Vienna. The author studied physiology (and blood groups) there as

part of his medical curriculum, in the same building, which was still in the same condition as at Landsteiner's time.

The main threat from blood group incompatibility is the destruction of transfused cells ('hemolytic reaction'). Similar, but usually less severe reactions occur when plasma with antibody to the transfused patient's red cells is given. The discovery of the main blood group systems eliminated most of these reactions, and rendered, by the onset of WW2 blood transfusion (i.e. the transfusion of 'allogeneic blood') 'safe' (or so people believed). Indeed PTH followed on the heels of the spreading of transfusion practice (on hemolytic transfusion reactions see Mollison 1972:538-70).

plasma. The supernatant plasma can be transfused as such or subjected to further processing and separation. The bulk of cells sedimented by centrifugation are red cells. After centrifugation there is a thin layer of white material ('buffy coat') on top of these 'packed cells', which contains various immune cells ('white' cells and platelets (which are essential for blood clotting)). Through differential centrifugation plasma can first be separated with the blood platelets suspended, followed by another sharp spin to sediment the platelets and produce 'platelet concentrate'. Buffy coats (for white cell transfusion) are normally not collected in this fashion, but by a mechanized process referred to as haemapheresis.

(2) Blood components

The cellular components have a different specific density than blood plasma, in which they are suspended. Therefore cells can be sedimented by centrifugation and thus separated from the liquid portion, the blood

The routine spinning and separation is facilitated by plastic bags, consisting of a main bag and satellite bags connected by plastic tubing. After the blood is spun, the plasma can be expressed into a satellite bag which is then separated from the main bag (see figure below).

Fig. 20: Separation of blood and extraction of plasma

Plasma free of red cells, buffy coat and platelets can be used to produce so-called cryoprecipitate: if plasma is frozen rapidly and then thawed slowly at +4 degrees Celsius, it does not dissolve completely, but a white precipitate remains undissolved, which contains blood clotting factors, most importantly

Factor VIII (the clotting factor lacking in hemophilia A). The thawed plasma can be extracted and the precipitate frozen for use when needed. (Pool and Shannon, 1965). In summary, the following products can be produced with low-level technology from a unit of whole blood:

- **red cell concentrates (RCC)**
- **platelet concentrate (PC)**
- **fresh frozen plasma (Factor VIII not removed) (FFP)**
- **cryoprecipitate**
- **frozen plasma (Factor VIII removed, but some remaining) (FP)**
- **'stored plasma' (frozen plasma from blood with extended storage of blood before separation)**

Table 21. The most important blood components.

(3) Plasma fractionation

Plasma can be processed further and specific protein fractions can be separated. They are commonly referred to as 'plasma derivatives'. The fractionation process was developed by E. Cohn in the 1940's at Harvard University. The processes uses various

concentrations of alcohol and levels of acidity at cold temperatures to achieve a differential precipitation of plasma and thus a separation of major plasma protein fractions. There are several intermediate steps, and several purification processes can be applied. The main products derived from these processes are:

- **Albumin:** a protein which provides blood with 'onkotic pressure, i.e. it keeps water in the blood vessels (at low levels of albumin people suffer from edema).
- **Immunoglobulins:** this fraction contains antibodies against a large number of infectious agents. Some specific sera for passive immunization are [produced by this fractionation process (rabies, varicella, hepatitis B rhesus antiserum).
- **Factor VIII concentrate:** a product which contains Factor VIII in a more pure and concentrated form than cryoprecipitates.
- **Factor IX concentrate:** Hemophilia B requires this factor. The disease is also referred to as 'Christmas disease' after a Canadian named Christmas. He succumbed to an HIV infection as result of his treatment in the eighties.
- **Other protein fractions.**

Table 22: Some important products from plasma fractionation.

(4) Hepatitis ('H') and hepatitis viruses ('HV')

Hepatitis ('H') is an 'old' disease. For instance, Ludwig van Beethoven died from the sequelae of a hepatitis infection (and we cannot be sure whether it was B or C, more likely B and perhaps acquired in a sexual encounter). Beethoven developed chronic hepatitis, and later cirrhosis of the liver, which became the cause of his death. A popular account suggests that he stayed unmarried so that he would not pass on his infection.

The propagation of hepatitis through medical intervention received increasing attention during and after World War II. It soon became known that it could be transmitted via blood and vaccines: immunizing material was suspended in pooled human serum, and hence its first name: '**serum hepatitis**' (SH). It was realized later that it could also be transmitted through the use of poorly sterilized injection needles and syringes, a circumstance which eventually led to the use of disposable needles and syringes (in the sixties). Serum hepatitis appeared to be different from another kind of hepatitis which affected mostly children and young people, Ihas an uncomplicated, short course and rarely leads to chronic liver disease and acute liver coma. This kind of hepatitis used to be referred to as '**infectious or epidemic hepatitis** (IH) - now known as **hepatitis A**. It is transmitted through close social contact and drinking water (there has been a recent epidemic in the US should caused by contaminated imported strawberries distributed with school lunches).

Serum hepatitis became the most serious side-effect of blood transfusion, the clinical application of which expanded during and after the war. In the fifties, in the US, it became evident that paid donors carried a much higher risk of hepatitis transmission than voluntary donors. However, other than asking the donor whether he ever had hepatitis or jaundice remained the only method of excluding potentially infectious donors. The usefulness of this screening method was limited, because many cases of hepatitis remain '**subclinical**', i.e. there may be no signs of jaundice at all (jaundice being the only 'tell-tale sign' of acute hepatitis).

In the late sixties, Saul Krugman and others carried out inoculation experiments on

children of a New York institution for retarded children. (The ethics of this project are discussed in the course of the documentation). They clearly demonstrated two distinct kinds of hepatitis and associated strains of virus. In 1965, Baruch Blumberg discovered an antigen ('**Australia antigen**') in an Australian aboriginal. This antigen was later recognized by Alfred Prince (1968) as being associated with PTH, and it was shown to be the same strain which Saul Krugman had associated with serum hepatitis. Thereafter, tests were developed to identify carriers of this antigen, and to identify cases of acute and chronic hepatitis of the type B (HB). For a while it was considered equivalent to the older term 'serum hepatitis' (that is until there was incontrovertible evidence of yet another kind of hepatitis and associated virus).

In the seventies, **hepatitis A virus**, associated with '**infectious hepatitis**' and distinct from the B virus, was isolated. There is no indication that it is a significant hazard in blood transfusion. However, while mass-screening of donated blood for hepatitis B was implemented in almost all transfusion services, there remained a substantial number of PTH cases which could be shown not to be associated with A or B virus. In the mid-seventies, these cases were referred to by Alfred Prince as **hepatitis non-A, non B** (HNANB) and the respective post-transfusion hepatitis as **NANB-PTH**. A major portion of these Non-A non-B cases was shown much later (1989) to be associated with a third virus, **hepatitis C virus (HCV)**. Mass screening tests for hepatitis C become available by 1989. Additional hepatitis viruses have been identified since, but they have not been shown to be significant in transfusion medicine. An exception is the so-called **Delta-agent** (**hepatitis D**) which only occurs in association with hepatitis B and with a particularly severe courses of the disease.

Hepatitis A, B and C differ in their tendency of leading to chronic liver disease. Very few A cases become chronic, about 20% of B cases become chronic, and more than 50% of C cases turn chronic. There have been claims that it was unknown in the early eighties whether hepatitis C (or at the time, hepatitis non-A, non-B) would take a chronic course. However, there is substantial evidence (including the author's own research) that a considerable number of known chronic cases of hepatitis were neither A nor B, and

therefore had to be of the non-A, non-B variety, including C. Also a number of cases of liver cirrhosis, for which an alcoholic etiology could be excluded, were not of the B variety.

A small percentage of hepatitis infections may lead to **acute fulminant hepatitis and death**, others may be subacute and led to death within months. **Chronic hepatitis** leads to severe fatigue, and may eventually lead to a hardening of the liver (**liver cirrhosis**), and liver insufficiency (**liver coma**); also, the hardened liver causes blockage and changes in the intestinal blood circulation ('portal circulation') and eventually to and **esophageal varices** which, when ruptured, may result in massive, life-threatening bleeding.

Immunization is effective for hepatitis A and B. No vaccine has been developed for hepatitis C to-date. It must be noted that HIV became an '**epidemiological companion**' of hepatitis viruses in the late seventies, because of similar routes of transmission (in particular the blood route). However, how HIV entered into certain populations and into the gay population, and later into the blood supply remains obscure or, **perhaps, obscured**. (See

Horowitz, 1997). Since studies which could have shed light on this matter were never conducted (although important specimens had been kept in storage), **there remains a suspicion yet to be satisfactorily refuted, that HIV was propagated via certain immunization programs.**

Hepatitis remains a significant health problem world-wide, a substantial portion of which has been contributed by vaccinations and later blood transfusion and blood component therapy. Because of its almost obligatory fatal course, HIV has taken the frontstage in blood-borne diseases. However, the hepatitis problem is far greater in terms of numbers. **The handling of this partially iatrogenic/nosocomial disease, and the implications of that 'handling' for the spread of HIV (and not just via blood and blood products), not its occurrence per se, constitute perhaps the darkest chapter in modern medicine.**

Acronyms:

HAV	for hepatitis A virus
HBV	for hepatitis B virus
HCV	for hepatitis C virus
HA	for hepatitis A
HB	for hepatitis B
HC	for hepatitis C
HNANB	for hepatitis which is not A or B.
HNABC	for hepatitis which is not A or B or C; probably due to another virus responsible for infections in hospitals, but not via blood

Table 23: Abbreviations for types of viruses and hepatitis.

Note: The NANB (non-A, non-B) terminology came into use at a time when a form of hepatitis was identified which appeared to be viral, which was neither A nor B PTH, and for which no specific markers or viruses had been identified. NABC needs yet to be investigated.

(5) Post-transfusion hepatitis ('PTH'); formerly 'serum hepatitis' ('SH'); the history of its prevention

Terms and abbreviations: Post-transfusion hepatitis is a **iatrogenic** (i.e., physician-induced) or **nosocomial** (i.e., hospital-induced) **inflammatory condition of the liver**. It is observed as a group of sequelae to the injection of whole blood obtained from a donor, or a variety of blood components of

plasma derivatives produced from collected blood.

A variety of agents, viruses and micro-organisms have been implicated in inflammatory reactions of the liver following the injection of blood and blood products. For the purpose of this dissertation, the focus will be on only two, now identified and isolated viruses and their effects on the health of the recipient: hepatitis B virus and hepatitis C virus; and the respective diseases: hepatitis B and hepatitis C. In the text the following abbreviations are used:

PTH	for post-transfusion hepatitis
PTH-A	for post-transfusion hepatitis A
PTH-B	for post-transfusion hepatitis B
PTH-C	for post-transfusion hepatitis C
NANB-PTH	for post-transfusion hepatitis which is neither A nor B.

Table 24: Abbreviations used for post-transfusion hepatitis

Three technological phases (Bergman, 1970) and a 'social/economic controversy' can be identified in the history of blood donor selection or donor-blood screening programs designed to reduce post-transfusion hepatitis. The three technological phases are:

a) Clinical phase: questions directed at the donor as to a history of hepatitis or contact (and possible contact) with hepatitis.

b) Biochemical phase: the use of measuring liver enzyme activity in donor blood as indicator of active liver disease.

c) Immunological phase: the use of specific immunological tests to detect past or current infections in donor blood.

A 'socio-economic issue' concerns **voluntary blood donations and paid blood donations**. Blood donation with material incentive tends to attract people living in poverty and poor hygienic conditions. Many transfusion services moved towards a

voluntary system (including the US). However, the introduction of Factor VIII concentrate for hemophiliacs was associated with such high losses of Factor activity during production, that a purely voluntary supply of plasma did not meet the plasma volumes product required for an adequate supply of Factor VIII. Plasma collection (and importation) from paid donors started on a grand scale. (Note: The assumption of inadequacy of voluntary plasma supply has been challenged in Canada). Shortly after the introduction of tests for anti-HBs (known as the test for hepatitis B surface antigen), it became clear that only a portion of cases of transfusion-related infections could be explained with this virus.

(6) The state of knowledge of sequelae of PTH up to 1970.

The reluctance of using liver enzyme tests or even to investigate their significance for transfusion services must be seen in the light of the consequences from PTH infections.

Lethal outcome from acute, 'fulminant' or 'subacute necrotizing' hepatitis. In 1965, Chalmers et al. gave an overview of 23 publications on lethal outcomes of serum hepatitis. The reports varied between 0 and 62 %. Later, the mortality from serum hepatitis was estimated between 1-2%.

Chronic hepatitis and cirrhosis. Once cirrhosis has been diagnosed, the mean survival interval is about 5 years (with a rather wide variance). Chronic hepatitis has various protracted courses, and may progress to liver cirrhosis. By 1969, there was a substantial body of literature on chronic hepatitis and liver cirrhosis, only a portion of which could be attributed to Hepatitis B. As discussed earlier, there was another virus involved in the genesis of these disease states. **Hepatitis B related chronic liver disease had demonstrated beyond doubt the possible outcome of such infections, and there was no reason to believe that HBV negative cases would be vastly different.** It was not known how many cases of acute hepatitis would progress to chronic hepatitis and chronic liver disease. Furthermore, it had been known for some time that many cases remain anicteric (without jaundice). The onset of the disease is difficult to differentiate from flu-like syndromes. But it was clear that the observed cases were only the tip of a "Berg" of unknown size.

Anicteric, subclinical infections. The author himself went through a course of anicteric subclinical hepatitis B, with the only symptoms being a two week period of extreme fatigue. The infection was later confirmed by the emergence of an antibody to Hepatitis B surface antigen. (The author had incurred a laboratory infection).

"The possibility that anicteric, and even symptom-free hepatitis might persist has often

been suggested. This seems to have been confirmed by observations from Korea and Taiwan. Symptom-free soldiers, on the basis of hepatomegaly or raised serumtransaminase values, were subjected to needle biopsy of the liver. A hepatitis was shown, sometimes with all the features of virus hepatitis, but sometimes with only some of them. This lesion persisted and in some patients appeared to progress to macronodular cirrhosis". (Sherlock 1968:332).

The studies mentioned were: Chung et al. 1964 (Korea); Chung et al. (1965) (Korea); Cooper et al. (1966) (Taiwan). (Note: of course at that time it was not known which of the virus strains had caused the epidemics); consequently, the US military had substantial data (and specimens) on anicteric and chronic hepatitis transaminase elevation. The US military did commission various studies, in particular the one which Krugman conducted in New York State on retarded children. **It must be borne in mind that during those years the US became increasingly engaged in Vietnam, and had more influence in many public affairs than might have been the case under peace conditions. National interest and security tend to become an excuse for all kinds of atrocities.**

Whereas by 1968 immunological testing for HBV resolved some of the problems, it was also clear that only a portion of hepatitis, PTH and chronic liver disease, would be explained with that test. Thus the old problems had not disappeared, they had only become somewhat diminished, while further knowledge on chronic liver disease and hepatitis transmission was accumulating.

(7) Surrogate tests

The central issue of this dissertation is the legitimacy of a clinical trial, the only major trial of its kind, planned and conducted in Canada in the late eighties. It was designed to study the efficacy of surrogate testing in the prevention or reduction of post-transfusion hepatitis (PTH), in particular those cases which could not be identified as hepatitis A and B by respective laboratory tests. As mentioned, the balance of these PTH cases were therefore referred to as non-A, non-B PTH (and non-A, non-B hepatitis in cases other than related to blood transfusion). The term *surrogate-tests* stems from their non-specificity, and their use in absence and in lieu of a specific test. These surrogate tests were:

a) **The ALT (alanine aminotransferase) test** is a test which measures the level of an enzyme in circulating blood. It is elevated when damage to liver cells has occurred. The rationale for using the ALT test in the prevention of PTH is as follows: a positive test (elevated level of ALT) is indicative of damaged liver cells, and individuals so afflicted carry a higher likelihood of being carriers of acute or chronic viral infection of the liver than is the case for those with normal ALT levels. This test had become available as early as the late fifties.

b) **The Anti-HBc test (hepatitis B-core antibody)**, detects an antibody to hepatitis B which is elevated during all stages of hepatitis B, and which is therefore a universal indicator for past and present hepatitis B infections. The rationale for using the anti-HBc test is as follows: individuals with that antibody may also carry otherwise undetectable hepatitis B virus or have history of hepatitis; and secondly, that a history of hepatitis B is often associated with a lifestyle or life conditions which, in turn, are associated with a higher likelihood of carrying other viruses (hepatitis C, also HIV) than individuals without a history of hepatitis B and without such lifestyles and life conditions. The life-styles and life conditions in question may be cultural, sexual or involve intravenous drug use, but they also include a number of health occupations. The common factor of these epidemiological conditions is the exchange of

body fluids (in particular blood and saliva). Hepatitis B, hepatitis C and HIV infections have been linked, in varying degrees, to these lifestyles and life conditions. The transmissibility via blood also includes a possible transmission from mother to fetus.

In addition to its properties as a marker of possible viral infections, a positive anti-HBc test in a blood donor would also be an extension of an existing policy to exclude donors with a history of hepatitis. ALT elevations, on the other hand, can be indicative of liver damage arising from conditions other than viral infection of the liver. Not testing for hepatitis B was therefore equivalent to not asking the blood donor during the interview whether he or she had hepatitis in the past, and thus a violation of an existing donor selection standard. This test had become available in the late seventies.

(8) Clinical epidemiology

A brief review of clinical epidemiology is introduced here for four reasons:

a) The 'clinical trial' is now the methodological 'gold standard' in the decision stream leading to the use or non-use of a therapeutic in clinical medicine;

b) The Canadian clinical trial on surrogate testing is an example of the use this decision tool (albeit not a legitimate use, as is demonstrated in this dissertation).

c) It is important to identify the state of the art in clinical epidemiology at the time of the US decision (198/82) not to use surrogate testing. 'State of the art' is a key technical contingency of the 'critical path' and the clinical trial on surrogate testing.

Synchronicity between Fletcher's text and the US decision not to test (1981/2): Clinical epidemiology came of age in the eighties. It was promoted by the Rockefeller Foundation through the International Clinical Epidemiology Network (INCLEN), which trains clinical epidemiologists around the globe. The publication of the first edition of Robert H. Fletcher, Suzanne W. Fletcher and Edward H. Wagner in 1982 (*Clinical epidemiology. the essentials*) preceded and was a contributor to this change in practice and education in clinical epidemiology.

This date of publication is important for this dissertation, as it coincides with the time when a position which was taken by American scientists not to use surrogate tests in the prevention of post transfusion hepatitis. One can safely assume that **the reference standard for the decisions taken in the US in 1981/2), and the standard of practice in clinical epidemiology in the US at that time would have been Fletcher's book (or an equivalent)**. In the author's own experience, the beginnings of this standard were noticeable during the author's work in clinical medicine in the early seventies in Austria (e.g. a clinical trial of various breast cancer treatment combinations, a study in which the author briefly participated in 1969. Around the same time, computers were introduced in the assembly and analysis of such trial data, and made large scale, multivariate clinical investigations possible).

Since 1982, when Fletcher first published his text, clinical epidemiology has become more sophisticated, in particular with respect to statistical methods, as is evident in the publication of the Canadian clinical trial on surrogate testing. It lists a statistician as one of three authors (although the added benefit for the study - from the statistical methods, not from the statistician - remains dubious).

Appendix 2

The switching of hemophilia A treatment from cryoprecipitate to Factor VIII concentrate and the contamination of the Canadian blood supply with HBV, HCV and HIV.

Purpose of this section:

This sections seeks to show that:

- 1) Factor VIII concentrate at the time of its introduction into hemophilia treatment was not only known to be hazardous (transmitting hepatitis), but it was also extremely wasteful in its production processes and offered only trivial advantages over the far safer product already in use: cryoprecipitate;
- 2) The loss of activity in production made the use of plasma obtained from paid donor populations inevitable. Paid donors carry a much higher risk of disease transmission than voluntary donors;
- 3) The sustainability and profitability of the production of Factor VIII concentrate made from plasma of paid blood donors was kept feasible only by maintaining the lowest possible standards of donor selection and donation screening, with acquiescence of government regulators;
- 4) The policy level of the medical specialty of hematology, and in particular of the subspecialty of blood banking played an important mediating and product promoting role in this business strategy: creating a 'demand' instead of meeting a 'need'; **exaggerating the benefits and trivializing the risks;**
- 5) When HIV had entered the blood supply, the contamination of the factor VIII concentrate was so extensive that the implementation of

timely and reasonable safety measures would have bankrupted the industry;

- 6) At the same time recombinant technology was on the rise, and in preparation to replace the older technology using human plasma.

The failure of the Krever Report in addressing these issues.

In the early eighties, individuals, organizations and institutions responsible for the safety of the Canadian and US blood supply with hepatitis C virus (HCV, then only known as NANB hepatitis - non-A, non-B hepatitis) and with human immune deficiency virus (HIV, then only known as AIDS-related agent) were, almost without exception, against the introduction of 'surrogate testing'. This study proposes that this opposition was the result of attempts to hide the role of an HIV-contaminated vaccines in the origin of AIDS and the spread of hepatitis non-A, non-B.

Surrogate testing offered an inexpensive, and by 1981, proven **effective** measure, which would have reduced the risk of contracting hepatitis and AIDS through blood and blood products, and thus would have prevented thousands of HIV and hepatitis C infections of patients and a number of their spouses. The peculiar avoidance of a substantial 'good' by the blood industry was the result of the blood industry taking advantage of the vaccine situation and selling contaminated inventories and material in process, rather than withdrawing and destroying the contaminated goods.

The *Krever Report* fails to make reference to both issues: the unnecessary replacement of an effective, safe product with an unsafe product (Factor VIII concentrate replacing cryoprecipitate); and the possible role of hepatitis B vaccine and HBIG (as blood products) in the contamination crisis.

Note: On a different occasion, the author pointed out that Krever was in conflict of interest as Commissioner, because of his role in the 1988 **Royal Society Report on AIDS**, which he chaired together with Dr. Michel Chretien, the brother of Prime Minister

Jean Chretien. This report failed to recommend that patients who had been infected with HIV positive blood should be notified. Yet the report indicated that a substantial number of Canadians had been infected and the possibility of spousal infection was known. The report did recommend some kind of assistance and compensation for infected hemophiliacs, but not for individuals who had been infected by blood transfusions. The author also pointed out that Krever's interim report on his assessment of the (then) current safety of the Canadian blood supply was invalid, since it did not account for the institutional conditions which had led to the contamination of the blood supply in the seventies and eighties, and the fact that these conditions were still operative at the time of the report. Dr. R. Perrault was one of his 'colleagues' in the Royal Society project. Dr. N. Aye, the successor of Dr. Perrault in the role as national director of the Canadian Red Cross Blood Services after the publication of the Royal Society report, had actually written the report (he was then in a Deputy Director role at the Ottawa Blood Center). He is again listed and thanked as an advisor to Krever in the *Krever Report*.

The question of foresight in the seventies; the author's background relative to these issues

In the writing of this study, the author drew on his own professional experience and research in hematology, transfusion medicine, hemophilia treatment and consulting for a commercial plasma fractionator, in Austria and in Canada, during the years 1969-1974 (a list of publications of the author is attached). This was the time when the plasma fractionation industry began to aggressively market Factor VIII concentrate and when the Canadian Hematology Society (founded in 1970) exerted pressure on the Red Cross the introduction of Factor VIII concentrate in Canada (1973; Krever 1997:60-61). The first concentrate had been licensed in Canada in 1968 (Krever, 1997:166).

In the author's own experience, 'aggressive marketing' meant: he had a relative lucrative (dollars earned for the work done) consulting contract with a commercial plasma fractionator (Immuno AG, Austria); there was ample money to go to conferences; he had a rather lavish travel budget to attend the hemophilia conference in Tehran, which allowed him to travel in Iran, to feast on Persian caviar on the shores of the Caspian Sea, to visit Athens and Istanbul (his colleagues also visited Baghdad and Tel Aviv); and the fractionation industry sponsored hemophilia and hemophilia related events and conferences. In the sixties, hemophiliacs began to depend on 'a convenient product assuring normal life'; their parents, and in particular their mothers (who carry the defective gene and pass it on to half of their sons), were made to look forward to a relief of their guilt feelings; researchers were given research and travel opportunities; the various hemophilia organizations which had formed around the world could count on financial support for events and programs; and governments were promised that the new product would reduce the need of in- and out-patient services for hemophiliacs.

In retrospect, the author realizes that he was in conflict of interest at the time, but he does not believe that interfered in any way with his work, research and publications. His last publication in Europe was a co-authorship of a position paper in the new German publication *Forschungsergebnisse der Transfusion-medicin und Immunehaematologie*. (Deicher et al., 1973). This was follow-up on a similar publication in the *Deutsche medizinische Wochenschrift*. (Krassnitzky et al., 1972).

At the time of publication, the author was working in Toronto for Dr. Feinman, gastroenterologist at the Mount Sinai Hospital. The position paper was a response to group of German blood bankers from Kiel, who had questioned in 1972 the wisdom of using Hepatitis B surface antigen testing in the absence of 'proof of specificity and infectivity'. The same argument resurfaced with respect to the use of ALT testing in 1981 in the US.

The authors of the position paper were: H. Deicher, R. Müller (Hannover); O. Krassnitzky, F. Pesendorfer, F. Wewalka (Vienna) and Schober (Goettingen). All but one author were internists, Schober was a virologist. There was

no participation from blood bankers in this position paper. All three groups had been active in promoting safety in transfusion therapy, some of them since 1969. The split between 'blood bankers' and internists-gastroenterologists-hepatologists was ominous then, the blood bankers being against testing and the clinicians being in favor of testing. **Of course, the blood bankers never saw the acute and chronic infections following transfusions.**

The same pattern arose in the late seventies and early eighties in the US and Canada. However, there were three blood bankers in Canada (Dr. T. Stout, Medical Director of the Vancouver Blood Center, Dr. Damiana Wrobel, Medical Director of the Toronto Blood Center (for whom the author worked from 1974-1989), and Dr. Andrew Kaegi, Medical director of the Calgary Blood Center), who, in the seventies were deeply concerned over the hepatitis risks from blood and blood products. The *Krever Report* mentions only Dr. Andrew Kaegi. Dr. Feinman, a gastroenterologist at the Mount Sinai Hospital in Toronto, worked for many years closely with Dr. Wrobel on the issue of post-transfusion hepatitis. The German position paper foreshadows the debate of letting safety prevail in uncertainty, and the debate on cost-effectiveness, which dominated North-American transfusion medicine in the early eighties. The following is a translation from the position paper (*Transfus. & Immunehaem*, 1: 71 (1973)):

.....The Au/SH antigen is a specific marker for an infection with the hepatitis B agent. Origin and history are not clarified beyond doubt. [Emphasis by the author]. Until there is proof to the contrary we must assume for every Au/SH carrier, sick or not, that he or she is infected with hepatitis B and a potential source of infection.

This viewpoint is supported by transmission and immunization experiments by Krugman, Prince and Soulier. We deduce the medical duty to proceed with mass-screening and to oppose any attempt to fabricate 'uncertain conditions'. The question of funding is irrelevant to this debate. [Emphasis added by author].

The remark on funding surely did not go over well with German health authorities and the fractionation industry. Thus the history of playing 'uncertainty' against expenditure goes back to the early seventies.

The same arguments of uncertainty and cost were raised and sustained without action from 1981-1986 in the US with respect to surrogate testing and well into the nineties in Canada. **Unfortunately, there was no group who came out unambiguously in insisting that physicians, when in doubt, must come down on side of safety for the patient.**

There is a serious contradiction between the justification of introducing an unsafe product (Factor VIII concentrate) and arguing against uncertainties regarding a test, which could improve the safety of the product.

In an 'International Forum' on whether surrogate tests should be introduced, published by *Vox Sanguinis* in 1983 (*Vox Sang.* 44:48-64) R. Müller of Hannover made the only contribution amongst a total of 9 position papers, which clearly advocated for surrogate testing on safety, economic and legal grounds. He and Aach were the only internists in that group (Aach, who had been associated with Szmuness in New York, had considered a clinical trial as a viable option, but he did favor the use of surrogate testing). **No liver specialist participated in that forum. In other words, the 'forum' was stacked with blood bankers and affiliated professions, who were willing to argue against testing.** The anti-testing group also included Dr. Gerety of the Division of Blood and Blood Products, Bureau of Biologics, FDA, Bethesda, Maryland. It must be noted, however, that by then ALT surrogate testing was a legal requirement in Germany, and Behringwerke A.G. had begun to heat-treat (disinfect) Factor VIII concentrate and tested them in clinical trials (Krever, 1997). Müller could have restricted his comments on the legal requirements. The group was essentially composed of individuals who had been involved in the development of hepatitis B vaccines.

Past decisions can only be viewed and appraised fairly in the light of knowledge and information available at the time when the decisions were made. For instance, Factor VIII concentrate was introduced in significant amounts in Canada in 1978, which means that respective discussions needed to take place in 1976 and that their results were promulgated in respective budget proposals in 1977. Thus the relevant information would have to be from the time before 1976/77. Planning decisions were taken years before that. For instance, recommendations of the Canadian Hematology Society to the Red Cross regarding the introduction of Factor VIII concentrate and the prospects of a second fraction plant. On this time scale the industry **planning** decisions would have been made in the mid sixties, and negotiations with governments (as founders of hemophilia treatment), blood services and hematologists would have taken place in the early seventies, just about when hepatitis B moved to the front stage. The discovery of the hepatitis B markers and the massive literature arising thereof should have been a warning sign to reconsider the plans. **Yet there was no hesitation to move the business strategy forward and produce Factor VIII concentrate in total disregard of the lessons which hepatitis B was teaching, in terms of epidemiology and modes of transmission, clinical course of hepatitis, chronicity following acute infection, and an unidentified additional agent responsible for hepatitis and post-transfusion hepatitis (PTH).**

Yields of Factor VIII in fresh frozen plasma, cryoprecipitate and concentrate

Fresh Frozen plasma: Fresh frozen plasma is plasma extracted from units of whole blood ('recovered plasma'), or from plasma collected by plasmapheresis (a process by which blood is processed in a machine connected to a donor: the outflowing blood is separated into red cells and plasma by continuous centrifugation; the red cells are returned; and the plasma is collected. Volumes of plasma equivalent to the plasma of two separate blood donations can be collected in one session. While blood can only be given

every three months, plasmapheresis can be carried out at weekly or biweekly intervals (i.e. a single donor may make up to 50 donations a year). Fresh frozen plasma, if designated for Factor VIII substitution therapy, needs to be stored at -30 to -40 degrees C. Fresh frozen plasma seems to be more susceptible to activity loss under such conditions than is cryoprecipitate (Pool and Robinson, 1959; Pool 1970: Cryoprecipitate can be stored at -20 degrees C for two years without significant loss of factor VIII activity; in fresh frozen plasma half the activity disappears after 4 months at -20 degrees C; see also Mollison, 1972:90-1). However, fresh frozen plasma is no longer a treatment of choice, because of the large volume load (for instance, in order to infuse Factor VIII equivalent to 10 bags of cryoprecipitate, an entire liter of plasma would have to be infused).

'Cryoprecipitate': is a Factor VIII-rich cold-precipitate derived from fresh frozen plasma which is produced in blood centers by rapid freezing of blood plasma extracted from individual units of whole blood and subsequent slow thawing. The thawed (supernatant) plasma can be separated from the very small amount of white precipitate. The precipitate can be frozen and stored at -20 degrees C. (Pool, 1970; see also Mollison, 1972:91). Freeze-drying of this material is possible. Approximately 50% of the factor VIII present in collected plasma can be recovered by this method of cryoprecipitation (Pool, 1970).

Factor VIII concentrate: is a Factor VIII concentrate produced from pools of thousands of liters of plasma collected by plasmapheresis or by extraction from collected blood units. This product is manufactured commercially in fractionation plants, and freeze-dried in vials. It can be stored at +4 degrees C. Approximately 25% (only half of what can be recovered by cryoprecipitate production) of the Factor VIII present in the original plasma can be recovered by these methods.

Recovery of Factor VIII after infusion of Factor VIII preparations. Mollison (1972:91-2) summarizes recovery of infused Factor VIII preparations *in vivo* as follows (from Rizza and Biggs, 1969):

Fresh frozen plasma:	82%
Cryoprecipitate:	70%
Factor VIII concentrate:	60%

Table 25: Recovery *in vivo* of Factor VIII preparations.

Heat-treatment of Factor VIII containing materials another 40% of activity would be lost by heat-treatment which would effectively eliminate active virus materials ('wet-heat treatment', (Krever, 1997:856). Accordingly, the relative efficiencies of the three kinds of factor VIII preparations would be as follows:

Factor VIII levels				
	Level in plasma	Recovery in product before heat-treatment	Recovery in product after heat-treatment	<i>in vivo</i>
Fresh frozen plasma	100%	100%	N/A	82%
Cryo-precipitate	100%	50%	N/A	35%
Factor VIII conc.	100%	25%	15%(!!!)	9%(!!!)

Tab 26: Recovery rates for the Factor VIII preparations. All rates are relative to the level in raw plasma of 100%.

The table shows that only approximately 15% of the original Factor VIII present in plasma could be recovered in heat-treated (disinfected) Factor VIII concentrate (about a third of what can be harvested with cryoprecipitate). The same recovery rates can be applied to the total plasma and factor VIII raw material resource. In addition to the 85% loss of Factor VIII present in raw material plasma, a full implementation of all safety measures, i.e. donor exclusion and surrogate testing, could have reduced that yield by another 50% for the commercial sector utilizing commercial donor plasma, **bringing the final harvest of Factor VIII (effective *in vivo*) down to roughly 5%**

of what was available in the original donor pool. Such massive losses could not be compensated from the North American population, but rather massive imports of plasma from abroad was needed. Accordingly, testing and donor exclusion was the last resort, and heat-treatment was the preferred method as in this fashion there was some hope that infectious agents in imported plasma might have been inactivated. The precariousness of the whole venture is apparent in the attempt to use dry heat treatment of factor VIII (Armor) which would have resulted in less loss of factor VIII activity. However, dry heated material also remained at least partially infectious.

What actually happened: At an average use of 40 000 units of Factor VIII per hemophiliac and year (Krever's estimate of actual usage; a total Canadian consumption of 53 million units of Factor VIII), roughly a million units or less of blood collected would have been adequate to supply the hemophilic population with that level of Factor VIII. **In other words, Canada was self-sufficient for Factor VIII during the period when cryoprecipitate was used.** By switching to concentrate, the demand for such plasma would have been double or higher which, at an annual collection of a million units of blood in Canada would not have been enough, even without heat treatment: some cryoprecipitate was required for von Willebrand's disease, some fresh frozen plasma was required for reconstitution of red cells, and a considerable amount of blood collected in rural areas was not suitable for production since it stayed too long in contact with the cellular material and could not be **freshly** frozen. In addition, the additional *in vivo* loss required higher dosage than cryoprecipitate. Without heat treatment, a rough estimate would have been that half of the plasma required for Factor VIII production could have come from voluntary whole blood collections, whereas the other half needed to be substituted from other sources. This other source was plasma collected from paid donors.

On page 384, Krever presents data which confirm that only 50% of the total plasma demand could be met from Canadian recovered plasma. In other words, the reality matched what would have been estimated in the seventies to be the situation for supplying Canadian hemophiliacs with Factor VIII. Similarly, Krever's data on yield match what

might have been estimated before Canada was converted to Factor VIII concentrate: for instance, Canada was able to supply 112 000 liters of fresh frozen plasma, which yielded 50 % of the total factor VIII production, 26.5 million units, which is equivalent to a recovery of 23.5% of the Factor VIII available in the original source plasma (fresh frozen plasma). (The estimate used in above was 25%).

In comparison, the less pure cryoprecipitate, which could be produced without the need for fractionation plants and technology, yielded enough factor VIII activity for any Western industrialized nation (like Canada) to meet all the factor VIII required for hemophilia prophylaxis and treatment - entirely from its voluntary blood donors. (Factor needed in excess of that could be relatively easily supplemented from a limited voluntary plasmapheresis program). This crucial relationship between type of Factor VIII preparation, safety measures, plasma and donor requirements is not made explicit anywhere by Krever.

In summary: Canada had enough blood from voluntary blood donors to meet the factor VIII needs of its hemophiliacs with cryoprecipitate. It could meet only half the needs with factor VIII concentrate. This would have been estimated before the factor VIII concentrate program started, and the actual practice matched such estimates of the reduction in Factor VIII yield. The loss was substituted with plasma from paid donors, a then known high risk group. Any safety measures (donor selection, testing of collected plasma, heat-sterilization) would have reduced the available factor VIII concentrate far below limits that could still be met from donors recruited in the North American population. Also the costs per unit of Factor VIII would have become a multiple of the original costs.

To bring this product to the market, the marginal benefits of concentrate over cryoprecipitate had to be exaggerated, and the risks trivialized. At the same time the low standards of safety applied to plasma needed to be maintained for all other blood products. In other words, the entire population was put at risk, for no tangible benefit, which could not be done without

deliberate non-intervention by the regulating government: i.e. the federal government.

Relative benefits of Factor VIII concentrate over cryoprecipitate.

One would assume that sacrificing approximately 25,000,000 units of Factor VIII (i.e. half of the total Canadian requirement for factor VIII) derived from voluntary blood donors; and replacing it with a product that had to be purchased and was derived from a risky paid donor population, and on top of it, was pooled from thousands of donations, would be balanced with an offer of a rather substantial benefit, in addition to and over the benefits already available from the existing product, cryoprecipitate. Cryoprecipitate was administered in small pools of four bags, a single treatment being anywhere a pool of four to twenty bags.

The *Krever Report* mentions three main benefits of concentrate over cryoprecipitate:

	Cryoprecipitate (frozen)	Concentrate (freeze-dried)
Storage	-40°C	-4°C
Reconstitution for injection	cumbersome, slow	easy fast
Dosage	imprecise	precise

Table 27: Advantages of Factor VIII concentrate over cryoprecipitate.

The *Krever Report* mentions that concentrate would have allowed hemophiliacs to participate in sports and travel without restrictions. Thus the main benefit of concentrate over cryoprecipitate was claimed to be convenience, as cryoprecipitate could have performed therapeutically almost as well as concentrate. Even some travel would have been possible if

cryoprecipitate was transported in dry ice and then stored in household freezer at the place of destination.

Storage: There is one important inaccuracy in the *Krever Report* which is rather crucial in these considerations. On page 166, he claims that cryoprecipitate needs to be stored at -40 degrees C, meaning that no household freezer or hotel freezer would have been adequate to store the materials. However, the inventor of cryoprecipitate, Judy Pool, published in 1970 that Factor VIII activity is fully preserved at -20 degrees C for at least 2 years. The -40 degree C storage requirement applies to fresh frozen plasma, not to cryoprecipitate. Accordingly, the most critical claim in the entire convenience debate presented in the *Krever Report* is false.

The question of precise dosage is a bit of 'red herring', because hemophiliacs would never be injected or inject themselves with a single dose of cryoprecipitate but with one or more small pools of, say, four doses. Even large variabilities in Factor VIII activity between individual doses would thus be substantially reduced. If this was done on a prophylactic basis with regular injections, the differences between individual units would have been practically immaterial. Considering the large differences in Factor VII consumption described by Krever (p.169-70: 1982 average 18,250 units in Regina and 63,200 in Montreal per hemophiliac) standardized treatment does not appear to have been a goal which was pursued with great vigor.

For example: a common range of Factor VIII activity is 75 - 125 units of factor VIII per bag of cryoprecipitate. A child weighing 40 kg would require approximately 25Units/kg of body weight, i.e. 1000 Units of factor VIII to raise its level of factor VIII to 50% of normal. This would require 10 bags of cryoprecipitate. Even with a large variance amongst the ten bags, the total number of units transfused would still be close to 1000 units. A considerable (and unpredictable variability) exists in the half-life of transfused factor VIII which can vary between 8 and 12 hours. A safety margin can be achieved by raising the

estimated dose to 30 Units/kg (or 1200 Units). (This is a typical regimen for a 'one-shot therapy' for the most common bleeds, such bleeding into a joint. Adapted from Behrman and Vaughn, 1987:1068). In younger children fewer bags would be required, there would be more variability, but then the safety margin could be raised higher.

Reconstitution and injection. It is true that the reconstitution of cryoprecipitate is more cumbersome than that of concentrate. However, this was matter of pure convenience, in particular for a prophylactic program.

Krever's 'transfer' of the effect of cryoprecipitate treatment onto concentrate. Krever reports that by 1980, the median life - expectancy of severe hemophiliacs was near normal.

"The benefits were so pronounced that factor concentrate quickly gained acceptance as the product of choice for treating persons with clotting factor deficiencies. The combination of therapeutic advantage and personal convenience eventually brought about an almost universal abandonment of cryoprecipitate in favor of concentrates." (Krever, 1997:166)

Of course the normal life expectancy in 1980 could not be attributed to concentrate treatment which had been in use in Canada only for 2 years (since 1978), but rather it had to be attributed to earlier fresh frozen plasma treatment and since 1965, to cryoprecipitate. Since Krever goes on to point out the risks from hepatitis right after, he gives the impression that tremendous benefits from concentrate had to be weighed against unknown or what was alleged to be assumptions of minor risks from hepatitis infection at the time. In these sections Krever echoes the rhetoric of the fractionation industry and the scientific advisors which carried this rhetoric forward to the patients. Krever had promised that "We intend to get to the bottom of that issue". His 'fact reporting' did not get anywhere near 'the bottom'.

In summary: The benefits are almost entirely a matter of convenience, not of life expectancy, and very little in terms of 'quality of life. Thus the surrender of 25,000,000 units of factor VIII (which is rather substantial resource) and low risk product is not balanced at all by improved convenience. Krever's report uncritically and with the inclusion of false information echoes the seductive and deceptive arguments used by the plasma industry to get hemophiliacs to use Factor VIII concentrate. This was not a case of a human need being met, but a demand created and commercially exploited, while a substantial safe resource was wasted, and substituted with far more hazardous product.

Relative risks of factor VIII concentrate over cryoprecipitate (hepatitis).

Note: To avoid unnecessary complexity the issue of Factor VIII inhibitors will not be discussed here. It affects about 10 % of severe hemophiliacs and generates a whole new set of cost-benefit considerations. Inhibitors are gammaglobulins ('antibodies') which inactivate infused Factor VIII. They arise from Factor VIII therapy. Certain Factor IX preparations have properties which can bypass factor VIII in the blood clotting chain.

This section only deals with the hepatitis risk. However, as will be shown, the non-attention to the hepatitis risk led to an extreme HIV risk, and the resistance to using surrogate testing for hepatitis also lead to a large number of unnecessary infections with HIV, even after the HIV-risk for hemophiliacs had been recognized.

The *Krever Report* indicates that, in the late 1970's, Dr. Agnes Bishop had conducted a study at a hemophilia treatment clinic in Winnipeg, and presented at a symposium sponsored by the Canadian Hemophilia Society in 1980. She reported that 50% of hemophiliac patients treated with concentrate had elevated liver enzymes (indicative of possible hepatitis), while only

15% of patients on a cryoprecipitate regimen showed abnormal live tests.

At an international symposium on hemophilia on the occasion of the Vita Congress of the World Federation of Hemophilia in 1970 (ten years earlier than Dr. Bishop's report) the author had already presented similar findings:

"Among 52 patients with hemophilia, 12 had a history of hepatitis. In another 20 patients slight elevations [between 2x and 5.5 times the upper limit] of transaminases were observed." (Krassnitzky, Pesendorfer, Wewalka, 1970:385-90) **Note:** in the major American PTH studies the criterion for 'hepatitis' was a transaminase elevation of 2.5 the upper limit.

These hemophiliacs had received a variety of partially purified products from Immuno A.G., the Austrian plasma fractionation company which has recently been bought by Baxter (US). The rates of liver abnormalities might have been higher in Vienna, since hemophiliacs there were never exclusively treated with cryoprecipitate but were supplied with Immuno products during the late sixties, during more years than those in Winnipeg. While the paper was presented in German, the brief English summary said enough. Thus the knowledge of the hepatitis risks dates back to 1970, and the data appeared in a widely circulated conference report. Notably, the data were published two years before the Canadian Hematology Society pushed for the introduction of Factor VIII concentrate in Canada, and even suggested a second fractionation plant. This opened the door for the Bayer corporation and its North American subsidiaries Miles and Cutter; how much 'Bayer interest' was behind that recommendation from the Canadian hematology profession is unknown. It is a fact that Bayer worked with Dr. Perrault, national director of the Canadian Red Cross Blood Transfusion service since 1974 and whose sole major interest was the building of the fractionation plant. Bayer continued its efforts right up to the end of the Krever Inquiry. Bayer (Miles, Cutter) would have been acutely aware from the Hemophilia symposium of the hepatitis problems which beset Immuno products.

At the 7th congress in Teheran in 1971, the author (Pesendorfer, Krassnitzky and Wewalka, 1971) reported that there had been an apparent decline in titers and frequencies of antibodies to Hepatitis B, since the routine screening of blood donors for hepatitis B had been implemented; further, that the surface-antigen frequency amongst paid blood donors had dropped from 1.8 % to 0.2%; and finally that antigen positive donors may have normal liver tests, but upon liver biopsy show significant liver damage. It should be noted that the high frequencies observed in paid plasma donors had been observed in prison populations in Canada. The only two reports on the use of concentrate at that conference (Factor IX) came from Sweden, and this report also pointed out that 3 of 18 patients had developed hepatitis (16%); and the Netherlands.

By 1971, the Austrian experience with the new factor VIII preparations, including Cohn fractions, had shown that the use of purified material produced from pooled plasma taken from paid donors was associated with a very high incidence of hepatitis. The experience also pointed to hepatitis B as not being the only contributor to hepatitis infections, and that paid donor plasma was particularly risky. Thus the industry was well aware of the consequences of developing more purified products, years before they came into wide-spread use in Canada or anywhere else. Hepatitis was recognized as a potentially serious risk associated with concentrate therapy, long before the first hemophiliacs in Canada were supplied with concentrate (1978). The Krever report fails to point this out.

The promotion of Factor VIII concentrate in Canada is that the concentrate was pushed by the very profession, the hematologists, on whom the hemophiliacs depended, despite the fact that there were increasing numbers of warning signals indicating that contamination of Factor VIII concentrates with one or another hepatitis virus was virtually certain. Internists and hepatologists had very little say in this matter. Canadian hematologists supported a second fractionation plant in Canada (in addition to Connaught Laboratories), which seems to indicate that the long arm of business had 'thrown some chips on the table'. Two years later, with the arrival of Dr. Perrault as national director of the National Blood

Transfusion Service of The Canadian Red Cross Society, this 'long arm' became known to belong to the Bayer corporation, and its North-American subsidiaries Cutter and Miles-Canada.

The *Krever Report* also fails to point out that the ad hoc committee of the Canadian Hematology Society was the main source for members of the Scientific Advisory Committee of the Canadian Red Cross Blood Transfusion Service, which became the Blood Services Committee in 1986. Thus the hematological profession was in a key position of promoting and monitoring the risks and benefits surrounding the use of blood and blood products, ever since its meeting of its ad hoc committee in 1972. They, like the executive committee of the Red Cross, were never held accountable by the Krever Inquiry.

Sources of risk of hepatitis transmission via Factor VIII preparations

- 1) The pooling of plasma from large numbers of donors (thousands to tens of thousands); and the possibility that such a pool could be contaminated with plasma from a single infectious donor;
- 2) The possibility that a single infectious donor could donate plasma weekly or biweekly for years, and thus could contaminate many pools;
- 3) The high-risk populations (low socio-economic status) from which commercial donors were drawn.

The *Krever Report* introduces the first two sources of risk, and gives two specific examples: Connaught Laboratories using plasma from the Irvin Memorial Blood Bank in California, and plasma from Arkansas prisoners. The report skirts the issue of the level of contamination of plasma collected from paid donors. The *Krever Report* quotes data from one of the major studies on the use of surrogate testing in the US, but does not point out the disastrous test results which this group obtained from commercial blood donors. Although the numbers are small, they are

nonetheless alarming: **44%** of patients receiving blood from commercial agencies developed signs of hepatitis, as compared to **7%** who received blood from community agencies. The actual risk of contracting hepatitis from a commercial blood source may actually have been higher: patients who were given blood from commercial agencies may also have received blood from community agencies.

This means that at least in some places in the US the risk of developing signs of hepatitis from receiving blood of paid donors was roughly 1/2, without any pooling! The implication for Factor VIII concentrate is that virtually all commercial factor concentrate supplies were contaminated with multiple sources of infection in the late seventies, i.e. when factor VIII became available to all hemophiliacs in Canada. These aspects of the Aach study are not quoted in subsequent studies, *including the Krever Report*.

Thus the distribution of factor VIII concentrate was associated with **certainty of multiple infection, from multiple sources, and possibly with more than one infectious agent**. The Austrian experience surely conveyed this outcome as early as 1970, and at least the German fractionators (notably Immuno, Bayer and Behringwerke) would have known about these data.

The argument that the medical profession was not sure about the long-term consequences of acute hepatitis has two meanings (in the sense of whether a glass is half- full or half-empty): was their uncertainty concerned with the expected danger; or was their uncertainty concerned with expected safety? **Evidently, only a small minority dealt with expected danger, while the vast majority chose to frame the question in terms of expected safety.** And further, everybody who had some gain from the sale of Factor VIII concentrate (hemophiliacs, treaters, families, manufacturers, governments) would have framed the question in terms of expected safety.

To make this sales strategy really work, the industry had to **vastly exaggerate the benefits** of concentrate over cryoprecipitate. It also had to **trivialize the risks** of commercial plasma, and even the *Krever Report* does not

deal with the full depth and breadth of this issue. Finally, while the 'possibility' of a hepatitis infection had to be acknowledged, **its significance and long-term consequences needed to be trivialized**. To this end it was important to keep the blood banking and hepatological specialties separated as much as possible. As suggested, this was noticeable to some extent (see the notes regarding the author's engagement in the debate in Germany 1972, and 1973).

Had there been a recognition that the consequences were indeed serious, at the level of certainty of infection from Factor VIII concentrate, this meant that:

1) Either the product had to be removed entirely from the market;

2) Or safety measures (donor selection, testing, heat-sterilization) would have had to be instituted which made the entire venture economically non-viable.

In either case the fractionation industry would have been 'out-of-business'. The industry, government and the medical scientific politicians chose to keep fractionation 'in business', and to follow a strategy of 'foot dragging', trivialization of risk.

There was also tremendous resistance to using hepatitis surrogate tests for exclusion of blood potentially infected with an AIDS-related virus. First, the hepatitis B issue in the infection of hemophiliacs was ignored, then NANB hepatitis was spread, and finally AIDS was spread. The motivations for not using surrogate tests for screening out potential HIV-infected donors are discussed at length in the main body of this study. It is reasonable to assume that an emerging realization in 1981, that AIDS might have entered the blood supply, and the sudden and then protracted opposition to surrogate testing, led by the US Food and Drug Administration, was not a mere coincidence. While foot-dragging was still possible with respect to hepatitis, AIDS was such an 'imminent and real danger' that, once the connection between positive testing results and the epidemiology of AIDS had been made in public awareness, the industry would have come to a sudden standstill. As is argued further, the liability risk with respect to vaccines

may have been so vast, that the contamination of the blood supply could be used later as a smoke-screen and decoy in inquiries and lawsuits in the late eighties and during the nineties. On the other hand, had hemophilia treatment not been switched to Factor VIII concentrate, the debate on the use of surrogate testing on regular, voluntary blood donations might have taken a very different turn.

The hands-off position of the federal regulators in the US and in Canada was not a matter letting the industry regulate itself, but it was a matter of letting the industry do whatever it deemed necessary to survive - and for governments, to cover their own tracks.

Most importantly perhaps, all those committed to Factor VIII concentrate from the start (other than the hemophiliacs themselves and their families), those who had preferred to see the glass as 'half-full', including the medical-scientific policy advisors, found themselves in a potentially very serious liability situation: **in such a case lawyers would normally advise silence and to avoid that might lead to self-crimination.** Since the professional and institutional exposure to liability was so extensive, the expected reaction could be expected to be a 'closing of the ranks'. And finally, since plasma fractionation is a corporate, transnational venture, and since the blood banking profession had extensive international links, the 'closing of the ranks' occurred on an international scale.

The *Krever Report* does provide extensive international data, but does not provide a detailed technical-scientific-economic-legal fact presentation and analysis. The important link between hepatitis risk and AIDS risk from transfusion is pointed out only, en passant, in a couple of places. Rather it seem that the international exposé in Volume 3 serves to show that Canada 'was not all that different from other countries or worse than other countries'. Under conditions of transnational corporatism, it would be a fallacy to conclude that if a country's standards of care are roughly at the same level as in others that therefore the right things were done in this country. **The low standards may be merely a measure of compliance with a systematic lowering of standards in all countries under the influ-**

ence of a specific transnational corporate interest.

The most general implication is as follows: under conditions of transnational corporatism, comparisons between countries or populations as to their standards of care, program success etc, may no longer be measure of their genuine efforts, politics, successes and failures, but instead, a measure of compliance with corporate strategy.

Acute and long-term consequences of viral hepatitis.

It has been argued that, in the early eighties, post transfusion hepatitis was not considered a serious disease. In particular, it was claimed the relationship between acute hepatitis and chronic liver disease was not well understood.

In her 1968 edition of *Disease of the Liver and the Biliary System*, at the time the standard text on liver disease, Sheila Sherlock had this to say:

Cryptogenic Cirrhosis. In Britain, half the patients seem to have no ascertainable cause for their cirrhosis. These patients do not give a history of hepatitis and have never been jaundiced. Alcoholism cannot be incriminated and protein intake has been adequate. The cirrhosis might have followed unrecognized virus hepatitis, but this supposition must wait the introduction of diagnostic tests for such previous infection. The pathology is that of a macronodular cirrhosis.

On chronic hepatitis following acute hepatitis: *The progression of virus hepatitis to cirrhosis is probable but is still not unanimously accepted. Serial liver biopsies are certainly strongly suggestive of this course. In Britain, a surprising proportion of patients, about a third give a past history of jaundice, presumably virus hepatitis. There are however, great geographic differences in the importance of hepatitis as an aetiological factor in cirrhosis. In a predominantly alcoholic group in a city*

such as New York, a past history of hepatitis is rare, whereas in a predominantly rural community a history of previous hepatitis is more common. In the tropics, hepatitis may be an important antecedent to cirrhosis. The absence of a past history does not exclude hepatitis for anicteric attacks will not be recorded. Nine patients with post-necrotic cirrhosis. Eight of them middle aged or elderly women, had a preceding attack which seemed to be anicteric hepatitis for all showed hepatic histological features considered diagnostic of this disease. Chronic liver disease followed 2-18 months later, jaundice only appearing 23-55 months from the onset. Serial hepatic biopsies in a further five cases have shown well-documented progression from acute hepatitis to a post necrotic (macronodular) cirrhosis. The ultimate proof of the progression of virus hepatitis to cirrhosis must await the development of specific tests for the virus infection.

The sequence must be exceedingly rare. This allows reassurance of most patients who, after hepatitis, believe they are developing cirrhosis. In a study of 367 patients who had hepatitis 4-6 years before, hepatic functional abnormalities were no greater than in a control group of healthy young males. A follow-up of 1293 cases of hepatitis occurring in British forces in the Middle East 7 years before showed that apparently no one had subsequently developed cirrhosis. Follow up of 304 persons suffering hepatitis in the Delhi epidemic of 1955/56, has shown no clinical evidence of persistence of liver damage. In those who showed minor biochemical abnormalities liver biopsies were within normal limits. However, following the epidemic in Denmark in the mid 1940s an increased incidence of cirrhosis, in particular in women, has been noted. The natural history is very variable. The acute hepatitis may proceed through a subacute stage until it becomes indistinguishable from cirrhosis. These patients show all the

features of liver cell inadequacy, and either die or revert to an inactive cirrhosis. More usually, apparent recovery is followed about 5 years later by portal venous hypertension, usually shown by bleeding from esophageal varices or symptomless splenomegaly. During the intervening period there no clinical symptoms and physical findings are confined to hepatomegaly and splenomegaly and these are not constant. The development of liver cell failure (ascites, coma) is later

The relation of hepatitis to the active cirrhosis which predominantly affects young people, especially females, remains obscure. Certainly many such patients seem to commence their illness with typical hepatitis, often with contact history.

Such was the state of the art in 1968. The epidemics without long-term consequence described by Sheila Sherlock seem to resemble outbreaks of hepatitis A, (such as the one that was recently caused by imported berries in the U.S.); whereas the epidemic in Denmark may well have been caused by a different virus. (at least two types of hepatitis were recognized at the time). Overall, however, Sheila Sherlock made the connection between acute (possible without jaundice) hepatitis and cirrhosis and chronic hepatitis appear probable. Her argument that this is exceedingly rare must be seen in the context that hepatitis A is indeed a by and large benign disease and if these cases are included in the overall picture of acute hepatitis leading to chronic liver disease, then of course patients could be 'reassured'. On the other hand, it was also known that many acute cases of hepatitis were subclinical (i.e. the patients may not have had any awareness of it).

The author reported in 1970 that 20 percent of cases of liver cirrhosis are hepatitis B surface antigen positive, and 60 % of chronic aggressive hepatitis. (Krassnitzky, Pesendorfer and Wewalka, 1970) This left little doubt that a significant portion of acute hepatitis of the Type B would progress to chronic liver disease of different severity. But since only 50% of acute hepatitis were positive for Hepatitis B marker, another virus was suspected to cause acute hepatitis and possible chronic progression. While these data did not represent population

statistics, they nevertheless left no doubt as to the link between chronic liver disease and hepatitis B; and were highly suggestive that another viral agent was responsible for a number of the hepatitis B negative acute and chronic cases. The results were first presented at a meeting of the European Gastroenterological Society in 1969, and subsequently published in German and English, including *Vox Sanguinis* (1970) (Krassnitzky et al. 1970, (a), (b); updated Wewalka et al. 1970); In the paper published in *Vox Sanguinis*:

1) the total number of cases (presenting in one hospital) with acute hepatitis examined was 180; the total number of cases with chronic liver disease was 62 with chronic hepatitis; and 246 with cirrhosis of the liver. All chronic cases were verified with liver biopsy;

2) Only 45% of acute hepatitis were verifiable hepatitis B;

3) 53 % of cases of chronic hepatitis had a positive hepatitis B marker;

4) 19.5% of liver cirrhosis had a positive hepatitis B marker;

5) The paper points out the cases of chronic hepatitis were known to be rare in England, and hence Sheila Sherlock's discussion;

6) Several cases of transmission of hepatitis from close contacts with relatives suffering from chronic hepatitis B, some of which, in turn, also developed chronic hepatitis.

Wewalka F., Gnan F., Krassnitzky O. and Pesendorfer F. *Vox Sang.*, 19:311-317 (1970)

One could then extrapolate that another 50% of all cases of (clinically verifiable) acute hepatitis might contribute to chronic liver disease, and taking into account subclinical cases of acute hepatitis, half of all cases of cirrhosis of the liver may have been preceded by an episode of acute viral hepatitis.

These results left no doubt that acute hepatitis had to be considered as an important contributor to chronic liver

disease, first in the form of chronic aggressive hepatitis, eventually leading to cirrhosis. The lower number of cases of chronic hepatitis would be consistent with the limited period within which the diagnosis of chronic hepatitis can be made before they must be recognized as active cirrhosis. *Vox Sanguinis* was the leading international journal for transfusion medicine at the time, and these findings would or should have been known to the hematologists who recommended factor VIII concentrate and the building of second fractionation plant in Canada. Acute hepatitis clearly was not a trivial condition, there were many cases which would develop chronic hepatitis and pass the infection on to their spouses; and therapy of hemophilia A with Factor VIII concentrate would present a substantial known risk together with an unknown, but potentially similarly substantial risk (i.e. hepatitis non-B) of developing chronic liver disease. Outcome and life-expectancy associated with chronic liver disease was also understood at the time.

The knowledge described existed three years before the Canadian Society of hematology pushed for the introduction of factor VIII concentrates. The Krever Report makes no reference to this early state of knowledge.

Summary

If the business strategy of selling factor VIII concentrate was to succeed:

a) Safety had to be minimal, to make the venture commercially viable;

b) The benefits had to be exaggerated;

c) The risks had to be hidden or trivialized;

d) The federal government had to be committed to non-intervention;

e) The medical-scientific policy advisors had to be kept 'happy,' cooperative and silent or made 'accessories' of some kind;

f) Blood-bankers and hepatologists had to be separated;

g) Actual and potential resisters had to be silenced;

h) The hemophiliacs and their families had to be committed with seductive advertising and promises.

Deception, etc. regarding drugs -Drugs labeled or packed in contravention of regulations.

9. (1) *No person shall label, package, treat, process sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.* (Rodrigues 1996, FDA). (Underscore by the author).

The *Krever Report* echoes the same kind of deception which was used by the plasma fractionation industry and their promotional cohorts.

To embark on a program:

❖ that had no significant benefit for the patients over an existing program;

❖ that would spread residual hepatitis B virus (i.e. not eliminated by hepatitis tests) as a matter of certainty (not 'possibility') ; and other yet unknown viruses through large pools of plasma from high risk, paid donors;

❖ that, with the full knowledge of such risks, is implemented without any risk-countervailing measures (donor selection, additional tests, sterilization);

must be considered as

❖ **reckless and ruthless**, in the context of the commercial interests;

❖ **negligent**, under conditions of law;

❖ **deceptive**, with respect to the hiding of the potential consequences from hemophiliacs and their families, while wildly exaggerating the benefits;

❖ **perhaps worse**, from the viewpoint of governments creating conditions for, and supporting, such endeavors, which put an entire population at a known risk.

❖

In his submission to the parliamentary subcommittee on AIDS (the 'Wilby hearings;') The author expressed his opinion that the Red Cross and its humanitarian mission was the only thing that stood between the population at risk and HIV - and failed. He is now convinced, that the medical scientific establishment (outside of the Red Cross and government bureaucracies), had a real option and the necessary information to push for safe-guards in blood transfusion - since 1970. Its handling of the scientific evidence and its acquiescence was the cornerstone of the business strategy to proceed. The hematologists (at least at the policy level) acted as promoters and guardians of the business strategy, and were the key agents in 'erroneous impressions' of the merits and safety of the factor concentrate.

While Krever goes to great length how the bureaucracy supported the business strategy by inaction and then dealt with the fallout of this strategy, nowhere does he summarize coherently the underlying fundamental scientific-economic conditions and the key role of the medical scientific policy establishment in this strategy. He not only fails to demonstrate the lack of incremental merit of concentrate, but exaggerates the benefits in the same manner as it was done at the time of the introduction of the product, and trivializes what was known before and at the time of implementing the factor VIII concentrate program.

Appendix 3

The Food and Drugs Act and the sale of cryoprecipitate, Factor VIII concentrate and hepatitis B vaccines in Canada.

Early in 1998, during the writing of this dissertation, the author was interviewed by two RCMP officers. By then the RCMP had stated that there was enough evidence to warrant a criminal investigation of the contamination of the Canadian blood supply with HIV-1 and HCV. Public announcements and the interview gave the author the impression that the investigation had been restricted to events exposed in the *Krever Report* (1997), starting with events in 1981, the year the first AIDS case was formally reported by the US CDC (Centers for Disease Control). The author believed at the time of the interview (and still believes) that this timeline was artificial and designed to avoid more serious issues. At the time of the interview, he believed that, independently of that timeline, two products (cryoprecipitate, Factor VIII concentrate) had been illegally distributed by The Canadian Red Cross Society, as a result of failure of the federal government in carrying out its regulatory duties in accordance with the Food and Drugs Act (FDA) and its regulations. He has added two products (hepatitis B vaccine; HBIG) since:

Cryoprecipitate was produced from blood donations of voluntary Canadian blood donors, and had been in use in Canada since the late sixties. The product was not licensed, but should have been licensed.

Factor VIII concentrate was imported from the United States, which was produced from large pools of plasma obtained from commercial plasma donors. This product was licensed and sold in Canada in 1978. (The RCMP focused the questioning on Factor VIII concentrate.)

Hepatitis B vaccines were produced from relative small pools of donated plasma in the US and in Europe. According to a WHO report at least one vaccine was brought to the Canadian Market in the early eighties.

HBIG (Hepatitis B Immunoglobulin) was produced by fractionation from pools of

plasma from donors with high levels of hepatitis B surface antibody.

These products were subject to the same standard provisions of the Act as any other drug:

Prohibited Sales of Drugs.

No person shall sell any drug that:

- (a) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or*
- (b) is adulterated.* (FDA, S.8; Rodrigues, 1997)

"unsanitary conditions" means such conditions or circumstances as might contaminate a food, drug or cosmetic with dirt or filth, or render injurious to health a food, drug or cosmetic. (FDA, S.2; Rodrigues, 1997).

"sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration; (FDA, S.2; Rodrigues, 1997).

"drug" includes any substance of mixture of substances manufactured, sold or represented for use to:

- (a) the diagnosis, treatment, mitigation, or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,*
- (b) restoring, correcting or modifying organic functions in human beings or animals, or*
- (c) disinfection in premises in which food is manufactured, prepared or kept;* (FDA, S.2; Rodrigues, 1997).

The three products listed were at least potentially subject to additional regulatory requirements under Division 4: Preparations from human sources, specifically when listed in Schedule D. Schedule D did not include collected blood and fresh components until September 1989. During the Krever Inquiry, what was and wasn't in Schedule D served as a smokescreen for members of the Health Protection Branch for failures of requiring measures to ensure safety of blood during the AIDS crisis.

The following is quoted from the Krever Report (1997:128):

Manufacturers of "preparations from human sources" were subject to additional regulatory requirements set out in Division 4. These "preparations" were not included in Schedule D and were not therefore "drugs" within the meaning of that word in Division 4. However, manufacturers were subject to stringent requirements when these preparations were used in the production of a drug listed in Schedule D. "Preparations from human sources" were defined as "pooled plasma or pooled blood serum, or fractions or either separated by a method satisfactory to the Minister." Manufacturers were permitted to obtain human serum or plasma only from persons who had been certified by qualified physician as healthy. They could not use blood donors who had a history of a disease transmissible by blood transfusion, including syphilis, infectious hepatitis, and malaria. [Emphasis by the author.] The drawing of blood from a donor was to be conducted under the supervision of a qualified physician, in a "suitable bleeding room" under the manufacture's control. A manufacturers of preparations from human sources was required to maintain a complete record of all its donors, including their certificates of good health.

The question whether any of the four products were unlawfully sold in Canada as a result of regulatory failure boils down to **two central criteria** (there are others):

- 1) Were they products regulated under Division 4, preparations from human sources;
- 2) Did the products contain material from one or more donors that had a history of a disease transmissible by blood.

Cryoprecipitate, in the author's opinion, is a plasma derivative, by virtue of additional steps in the processing of plasma (freezing, thawing, centrifugation, expression of supernatant plasma). However, the Bureau insisted that it was a 'fresh blood component' and therefore not regulated. The issue remained unresolved.

Factor VIII concentrate is a blood derivative to which the regulations applied, a fact that was not challenged by the Bureau or the manufacturers. Indeed, these products were licensed. **The question whether a donor had a history of a disease transmissible by blood could not be answered if the donor lied, and if certain tests were not obligatory.** Clearly, in the seventies, a donor who was a carrier of hepatitis B virus, and was so identified by laboratory tests, was a donor with a history of a diseases transmissible blood. Such donors were excluded from donating. If, however, the manufactures chose not to use certain tests (such as surrogate tests), then they could not be formally accused of using plasma from a donor 'with history of a diseases transmissible by blood'.

Hepatitis B vaccines. Hepatitis B vaccines manufactured from plasma of human donors were, unquestionably, blood derivatives (extensive purification procedures, chemical and other viral inactivation procedures). **They also came from donors, by specification of the product, with a history transmissible by blood** (i.e. the donors carried hepatitis B surface antigen, and possibly complete hepatitis B virus).

HBIG. The same arguments as those concerning hepatitis B vaccines apply.

The sale (and licensure) of hepatitis vaccines would have violated the letter of the Act and its regulations, with regard to both criteria: 1) as products equivalent to Factor VIII concentrate (sera and drugs analogous to blood; as of 1982, blood derivatives (Krever 1997:124)); and 2) they were manufactured exclusively from the plasma of donors with a history of a disease transmissible by blood. As both of these criteria apply, it is irrelevant whether the vaccines were 'safe' or not.

Whereas with respect to cryoprecipitate and Factor VIII concentrate the Federal government could argue in litigation that the Health Protection Branch stayed within the letter of law, in the case of the hepatitis B vaccine it is self-evident that it did not.

GLOSSARY

Active Immunization Inoculation of antigenic material of disease causing organisms to induce immunity (antibodies)

AIDS (Human) Acquired immunodeficiency syndrome

ALT Alanine-leucin-amino-transferase. Enzyme evaluated if liver cells are damaged; large specific for liver damage, but not for any particular kind of damage

Antigenicity Property of a molecule or particle inducing production of antibodies

Anti-HAV Antibody to hepatitis A virus

Anti-HBc Antibody to HBV core antigen. Appearing early in disease, persisting during disease and during convalescence; does not confer immunity

Anti-HBs Antibody to HBV surface antigen. Appearing late in disease, confers immunity

Anti-HIV Antibody to HIV, does not confer immunity

Anti-HCV Antibody to hepatitis C virus, does not confer immunity

Armour Plasma fractionator supplier for Canada

Alpha American plasma fractionator

Arman-Frappier Canadian Biologics manufacturer

Baxter American plasma fractionator

B.o.B. Bureau of Biologics; in the US part of the Food and Drug Administration; in Canada, part of the Health Protection Branch of Health and Welfare Canada

Blood components Major constituents of blood such as white cells, platelets and plasma

Blood derivative Any blood product that is manufactured from human blood and involves industrial process (e.g. Factor VIII concentrate). Also referred to as plasma derivatives

Blood donor screening Testing of donor blood for the presence of infectious disease markers

Blood donor selection A process by which blood donors are accepted or rejected for donation by a set of criteria

Bushmeat Game from the bush which includes monkeys, also those adult monkeys whose young have been captured or for sale to laboratories

Clades Subtypes of HIV-1 thought to have radiated from Africa from a single source of HIV-1

CDC (US) Centers of Disease Control. US epidemiology center. Atlanta. affiliated with US military and Surgeon General (Navy).

Chronic hepatitis Chronic inflammation of the liver, persistent destruction of liver cells (chronic liver disease)

Cirrhosis of the liver Nodular regeneration and hardening of liver tissue (chronic liver disease)

Clinical trial Controlled experiments of treatment methods, and diagnostic methods on humans

Connaught Laboratories Canadian biologics manufacturer (plasma, fraction, and vaccines)

Contamination Presence of infectious or toxic agents in substances or instruments used for therapy

Contingency Any occurrence which is linked in some way to another occurrence

Critical path Events and activities sequentially leading to a particular outcome

Cutter/Miles Vaccine manufacturer and plasma fractionator, subsidiary of Bayer in Germany

Dysinformation In this study referring to incomplete, false, or misleading information

Ebola Viral disease caused by a group of so-called filiform viruses leading to haemorrhagic fever

Effectiveness Measurement of therapeutic effect under non-controlled non-experimental conditions

Efficacy Measurement of therapeutic effect under controlled experimental condition

ELISA test Screening test for HIV.

Endemicity Prevalence of a disease in high frequency at all times within a region

Experimental vaccines Vaccines which are tested for efficacy and safety in humans and laboratory animals

Factor VIII concentrate Factor VIII rich fraction of blood plasma, industrially produced from large pools of plasma

FDA (US) Food and Drug Administration). American regulating and licensing agency of drugs, biologics and medical devices

Formaldehyde A chemical compound used for inactivation of viruses

Fractionators Enterprises carrying out plasma fractionation

GIMGM Global industrial/military/government/medical complex. A term coined for this study, describing the multi-institutional collaboration in certain health projects

Gradient centrifugation Spinning of biological material layered on density gradients to separate molecules and particles by their specific gravities

Haemorrhagic fever Usually virus induced illness, which leads to damages in the lining of blood vessels and generalized bleeding. Fluid loss may lead to pulmonary edema and shock.

HA Hepatitis A. Mild, short incubation, transmitted by food, water, contact, etc; mostly young age

HA-PTH Post-transfusion hepatitis A. Not common, mild

HAV Hepatitis A virus

HB Hepatitis B. Acute, chronic; long incubation; transmitted by body fluids; recognized as STD

HBc-Ag Hepatitis B core antigen. Core protein of HBV

HBIG Hepatitis B immune globulin. Preparation for passive immunization against hepatitis B derived from the plasma of donors with high levels of antibodies against hepatitis B

HB-PTH Post-transfusion hepatitis.

HBs-Ag Hepatitis B surface antigen. Coat protein of HBV; appearing late in incubation period, disappearing during acute stage, or persisting in chronic cases; may be present in healthy individuals (asymptomatic carriers)

HBV Hepatitis B virus. Causing acute or chronic liver disease, endemic in Africa, amongst some Australian aboriginals and China; where endemic, commonly associated with primary liver cancer

HC Hepatitis C. A large portion of hepatitis non-A,non-B was identified as hepatitis C. Often subclinical (no signs of liver damage, no jaundice); tendency to become chronic; transmitted mainly through blood routes (transfusion, IV drug users, pregnancy, some sexual transmission is suggested, also vaccination)

HC-PTH Post-transfusion hepatitis C

HCV Hepatitis C virus

Hemophilia A Sex-linked hereditary disease affecting males; lack of one factor (protein) required for blood clotting: Factor VIII

Hepatitis A Mild, short incubation, transmitted by food, water, contact, etc; mostly young age

Hepatitis non-A,non-B Hepatitis not caused by HAV or HBV. Until 1988, all hepatitis that was not identified as A or B

Hepatitis Inflammation of the liver induced by organisms (viruses, bacteria, parasites) or toxins

High risk population Populations which are at high risk of damages due to damaging agents, or lack of protection, or both

HIV Human immunodeficiency virus

HIV-1 Subtype of HIV, responsible for AIDS pandemic

HIV-1,M Main subtype of HIV-1 in the AIDS pandemic

HIV-1,O Subtype causing of HIV-1, observed in Cameroon and Gabon

HIV-2 Subtype of HIV, endemic in West equatorial Africa; transmitted from the sooty managbey (a macaque species), which is commonly eaten in these regions

HTLV-1 Human T-Lymphotropic virus type I. Retro-virus found in humans, the same as or similar to STLV-1 (simian T-Lymphotropic virus type I) carried by mandrills, a sub-species of baboons

HTLV-III Human T-Lymphotropic Virus type III, Robert Gallo's notation for HIV-1

IARC International Agency for Research on Cancer. Centers in Lyon, France, and in Bethesda, Maryland, USA

Iatrogenic infections Infections propagated through medical intervention

Immune serum Serum extracted from the blood of individuals who have antibodies against a disease-causing organism

Immunogenicity Property of molecule or particle associated with a pathogen which induces immunity if injected

Immunoglobulin Class of plasma protein comprised of antibodies

Injectionists Individuals in Africa without license or qualifications administering injectable drugs, vitamins, vaccines, etc. to Africans

Inoculum Immunogenic material that is being injected (e.g. vaccination)

JAMA Journal of the American Medical Association

LAV Lymphadenopathy virus. Notation used by Montagnier's lab at the Institute Pasteur in Paris for HIV-1

League of Red Cross Societies Assembly of representative of national Red Cross Societies and their governments

NANB-PTH Non-A,non-B post-transfusion hepatitis

NATO North Atlantic Treaty Organization

Natural reservoir Animal species which carries pathogens without becoming sick

NBRL the US Navy's biomedical research laboratory

NCI National Cancer Institute, part of the US NIH

Needlestick Term used by epidemiologists, referring to skin penetration with sharp instruments such as an injection canula. This used to be a common occurrence amongst

physicians, nurses, laboratory workers and handlers of animals in an experimental animal facility. In hospitals it was often associated with nosocomial hepatitis infection.

NEJM New England Journal Of Medicine

NHLBI National Heart Lung and Blood Institute, part of the US NIH

NIAID National Institute for Allergies and Infectious Diseases, part of the US NIH

Nosocomial infections Hospital-stay-related infections: this includes infections of staff working in hospitals

NIH (US) National Institutes of Health. US centers for medical research, Bethesda

NYBC New York Blood Center

Oncogenic viruses Tumor-causing viruses

Pan troglodytes troglodytes Chimpanzee sub-species, habitat in coastal Western Central Africa; a natural reservoir of HIV-1

Pandemic Epidemic of global proportions; simultaneous occurrence of a disease in numbers far exceeding expectations within a region or country

Passive Immunization Injection of antibodies which protect against the disease causing organisms

Pepsin Digestive enzyme used for vaccine purification and inactivation

Perinatal Refers to time period immediately before, during and immediately after birth

Placebo An inactive ingredient used as control for the testing of presumed therapeutically effective substances or treatment in humans

Plasma Liquid portion of blood

Plasma Derivatives see blood derivatives

Plasma Fractionators see fractionators

Plasma Fractions Specific proteins preparation produced by a fraction process of plasma

Plasmapheresis Collection process by which blood is drawn from a donor, and the cellular elements are returned, while the plasma is harvested

Post-transfusion hepatitis Viral hepatitis transmitted by blood components of plasma derivatives

Prospective study A study which generates data for the specific study purposes

PTH Post-transfusion hepatitis. Viral hepatitis transmitted by blood components of plasma derivatives

Realism Any epistemology that assumes that life world processes can become known and understood by human sensory, perceptual and cognitive processes

Retrospective study A study of data which were not generated for the specific study purposes

Retroviruses RNA viruses which contain transcriptase which can make DNA copies of the viral RNA

Rhesus factor A blood group on red blood cells

Schistosomiasis Disease caused by liver flukes (worms)

Serum hepatitis Old term for hepatitis B, perhaps, C; associated with transmission of viral hepatitis by vaccines, which used human serum as diluent for the immunogenic material (such inactivated virus)

SH Serum hepatitis; old term for hepatitis B, perhaps, C; associated with transmission of viral hepatitis by vaccines, which used human serum as diluent for the immunogenic material (such inactivated virus)

Social constructionism Any epistemology that assumes knowledge to be dependent on social processes

Socio-technical disaster Disaster with a genesis that involves both technical and social organizations

STD Sexually transmitted disease

Surrogate testing The use of non-specific tests when specific tests such as for the detection of infectious disorder are not available. In this study surrogate testing refers to ALT and Anti-HBC testing for the detection of hepatitis C and AIDS themselves

Theoretical superstructure A system of concepts, models, theories and methods proposed as necessary for the investigation of disasters by E.H. Quarantelli

T-Lymphocytes White blood cells involved in amplifying or suppressing immune responses; T-4 cells (helper cells) are reduced in AIDS patients

Trial vaccines Vaccine tested in clinical trials

VA Veterans' Administration in the US

Vaccine Live/attenuated or inactivated viruses; if injected, it elicits production of antibodies and immunity; also portions of viral or other microbial components may be injected for this purpose; bioengineered viral or microbial proteins; also nucleic acids

Vector Normally, an animal species which transports an infectious agent from one organism to another

Viral inactivation A process by which viruses in a vaccine are rendered non-infectious while antigenicity is preserved

Western blot Confirmatory test for HIV, more specific than ELISA test

WHO World Health Organization

Zoonose Infectious diseases of animal origins transmissible to humans

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This is one of the two US studies (the other by Alter et al., NIH, fall of 1981, published 1986) which proved that ALT testing should have substantially reduced the transmission of non-A,non-B hepatitis). At the time Aach was working at the Sinai Hospital of Baltimore. This is significant, because Baltimore was one of sites which a high prevalence of AIDS amongst needle-sharing Intravenous drug users. Participating Institutions: New York Blood Center; the New York Hospital; the Hospital for Special Surgery, New York; Washington University School of Medicine-Barnes Hospital; Ben Taub General Hospital Houston. The Methodist Hospital, Houston; the UCLA Center for Health Sciences, Los Angeles.

The advisory for the study committee had Paul Holland of the NIH Clinical Center Blood Bank as chair (a colleague of Harvey Alter), also William Bancroft of the Walter Reed Army Institute of Research in Washington, and Hyman Zimmerman of George Washington University Medical Center. These three scientists authored the editorial on the Aach study in the New England Journal of Medicine (same issue as the study paper). Since Holland was also co-author of the NIH study, and since the study was supported by an grant from the National Heart, Lung and Blood Institute (NHLBI, NIH, N01-HB 42972) the conclusions of the two study were not reached independently from one-another. Holland was a member of the ad hoc committee against surrogate testing and participated in the NIH/Purcell vaccine development; Zimmerman co-signed the Barker memo against surrogate testing; and Bancroft cosigned the NEJM editorial against surrogate testing. At the time, Szmunes was also consultant to Barker at the American Red Cross (formerly FDA, and participant in the NIH/Purcell vaccine development project).

Mosley was one of the 'expert witnesses' at the Krever Inquiry – the other being Donald Francis of the CDC. Szmunes was the chief epidemiologist at the New York Blood Center, and principal investigator of the Merck hepatitis B vaccine trial in New York. Cladd Stevens of the New York Blood Center eventually published the data on the other surrogate test (anti-HBc) in December of 1984. He also was one of the authors who defended the Merck vaccines as being free from HIV contamination.

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Memorial Bank in San Francisco, which became infamous for the number of HIV transmissions by blood transfusion. However, it was one of the first to press for the use so surrogate testing in donor screening. Vyas's findings confirmed Stevens findings of the efficacy of anti-HBc testing. A small study carried out by Cossart (see ref.) in Australia, reached exactly the same conclusions. None of this, however, could overcome the resistance of the 'vaccine developer club' to surrogate testing.

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