

Gramsci and the Ghost-Management of Medical Research:
Revisiting Medical Journal Conflict of Interest Policies in
an Age of Neoliberal Science

by

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Abstract

Medical research, particularly with respect to pharmaceuticals, has become intertwined with marketing techniques (such as ghostwriting and the use of publication planning strategies) that systematically leverage conflicts of interest in an effort to exert greater control over the creation and dissemination of medical knowledge to support the commercial interests of industry. Drawing on a theoretical framework informed by the works of Robert Merton and Antonio Gramsci, this thesis seeks to explore how the current organizational form of medical research reflects a neoliberal conception of science characterized by its distinct normative structure. Examining these issues in the form of medical journal conflict of interest policies, this thesis seeks to evaluate the impact and efficacy of such policies in addressing the problem posed by a neoliberal conception of science.

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List of Abbreviations

CRO:	Contract Research Organization
DIN:	Drug Identification Number
FDA:	U.S. Food and Drug Administration
ICMJE:	International Committee of Medical Journal Editors
JAMA:	Journal of the American Medical Association
KOL:	Key-Opinion Leader
MECC:	Medical Education Communication Companies
NAS:	New Active Substance
NEJM:	New England Journal of Medicine
NME:	New Molecular Entity
PhRMA:	Pharmaceutical Research and Manufacturers of America
PMPRB:	Patented Medicine Prices Review Board
RCT:	Randomized Clinical Trial
R&D:	Research and Development
WAME:	World Association of Medical Editors

1 Chapter: Introduction

Science does not exist in a vacuum. Rather, it is the subject of an ongoing negotiation between a variety of social, economic and political interests each of which exerts variable levels of influence on the objectives and processes governing scientific research. The extent to which each of these forces guide scientific research can readily be seen in the specific policies responsible for governing both the creation and resulting dissemination of scientific knowledge. While the process of scientific discovery is often portrayed as a so-called ‘Republic of Science’ guided by Mertonian norms emphasizing the pursuit of objective knowledge that is seen to be universally accessible and serving a broader social purpose,¹ a cursory examination reveals that the presence of external influences call into question this perceived reality. Among such influences, perhaps none is more pervasive than the entrenched belief that neoliberal ideals of competition, individualism, and market-oriented decision making function as the optimal guiding principles for economic activity,² and summarily can be applied to scientific research in those areas that can be readily commercialized. While these values have come to be portrayed as accurate depictions of reality, such practices are in fact nothing more than theoretical ideals. In reality, scientific research particularly within medicine has largely been shifted to a private, increasingly consolidated and controlled corporate sphere

¹ Robert K. Merton, “The Normative Structure of Science,” in *The Sociology of Science: Theoretical and Empirical Investigations*, ed. Norman W. Storer (Chicago: University of Chicago Press, 1973), 267-414; Sheldon Krinsky, “The Changing Ethos of Academic Science,” in *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research* (Lanham: Rowman & Littlefield Publishers, 2003), 73-89; John Ziman, “Academic Science,” in *Real Science: what it is, and what it means* (Cambridge: Cambridge University Press, 2000), 28-52.

² Wendy Larner, “Neo-liberalism: Policy, Ideology, Governmentality,” *Studies in Political Economy* 63 (2000): 5.

separate from the market. Consequently the realities of corporate science stand in stark contrast to the theoretical market utopia that exists at the heart of neoliberalism, leaving these theoretical ideals to instead serve as the primary means by which to justify the ongoing reconfiguration, and resulting privatization of formerly public scientific research.³ The result of this reconfiguration of scientific research is the fundamental alterations to the basic values driving scientific discovery. No longer is scientific discovery socially oriented so as to preserve the values of the Republic. Instead highly desirable fields of scientific discovery including those related to medical research and pharmaceutical development have come to be defined by the further encroachment of market-based values emphasizing profit and private ownership as the “foundational precepts concerning knowledge and how it is best organized,”⁴ yielding a new form of social organization that has come to define a form of ‘neoliberal science’. It is through an examination of the specific fields of science pertaining to medical research and pharmaceutical development that offers a means to understand how the spread of neoliberal ideology has come to reshape and redefine the broader social understanding as to the purpose and associated processes of scientific inquiry.

The impact of this increasing reliance on market logics to act as the sole steering mechanism for scientific activity is a subject of ongoing study. Despite rigorous academic investigation, existing research is often focused primarily on an examination of

³ David Harvey, *A Brief History of Neoliberalism* (New York: Oxford University Press, 2005), 19.

⁴ Rebecca Lave, Philip Mirowski, and Samuel Randalls, “Introduction: STS and Neoliberal Science,” *Social Studies of Science* 40, no. 5 (2010): 661.

changing institutional practices within the academy and how this impacts researchers.⁵

While such research is useful, it alone is insufficient to link these processes to the broader ideological shifts occurring within science itself. Adopting the terminology of ‘neoliberal science’, while not necessarily novel in itself, remains underutilized within the existing literature as a means of describing the ongoing process of transformative change that is taking place within specific scientific disciplines and within the ethos of science itself. Drawing on such terminology offers a way to describe the ongoing renegotiation of scientific values by looking beyond institutional boundaries in order to recognize the changing social relations that ultimately define both the objectives and related processes that drive scientific inquiry. Consequently, by embracing the terminology of neoliberal science it becomes possible to explore not only changing institutional structures, but perhaps more importantly how these changes themselves can be understood as part of a broader ideological shift within the social foundations of science itself. As such, neoliberal science does not simply represent a process of bringing an increasing number of institutions and actors under the purview of the market, but more importantly a change in the consciousness of these same actors such that the market becomes naturalized as the sole steering mechanism to direct scientific inquiry and discovery.

The ideological and structural shifts within the ethos of science that have precipitated the ongoing naturalization of neoliberal science can best be understood by utilizing the theoretical and conceptual tools offered by Antonio Gramsci. Among such conceptual tools, the notion of cultural hegemony and the corresponding notions of good

⁵ For one such example of the impact specifically on the academy see Bronwyn Davies, Michael Gottsche, and Peter Bansel, “The Rise and Fall of the Neo-liberal University,” *European Journal of Education* 41, no. 2 (2006): 305-19.

sense and common sense are of primary importance. For Gramsci, “all men are philosophers”⁶ capable of producing a specific understanding of the world. However, such understandings are often subjected to the ideological influence exerted by more dominant groups such that this imposed conception becomes the perceived reality that is reinforced by one’s own submission and subordination.⁷ The imposed philosophy of others becomes instilled in one’s consciousness replacing the potential for critical self-reflection and evaluation such that it becomes the sole ‘common-sense’⁸ approach to understanding the material realities of the surrounding world. This process as described by Gramsci can be applied to the ongoing transformation of science and its corresponding ethos within medical research. By recognizing the importance of ideas as a means to alter our understanding of the norms that guide scientific activity, the theoretical concepts offered by Gramsci present an opportunity to understand the connection between the ideological extension of neoliberal science and the material realities that come to shape the processes and objectives of medical research.

Despite a shift within the guiding principles of medical research, the naturalization of market success has become but one of the primary characteristics of a broader discursive shift within the ethos of science itself. This shift has diminished, yet has not fully replaced the ideals attributed with the Republic. Rather, the current ethos of

⁶ Antonio Gramsci, *Selections from the Prison Notebooks of Antonio Gramsci*, eds. and trans. Quintin Hoare and Geoffrey Nowell Smith (New York: International Publishers, 1971), 323.

⁷ Gramsci, *Selections from the Prison Notebooks*, 327.

⁸ Harvey, *A Brief History of Neoliberalism*, 39-41; Benedetto Fontana, “State and Society: The Concept of Hegemony in Gramsci,” in *Hegemony and Power: Consensus and Coercion in Contemporary Politics*, eds. Mark Haugaard and Howard H. Lentner (Lanham: Lexington Books, 2006), 39; Mark Haugaard, “Conceptual Confrontation,” in *Hegemony and Power: Consensus and Coercion in Contemporary Politics*, eds. Mark Haugaard and Howard H. Lentner (Lanham: Lexington Books, 2006), 7; Gramsci, *Selections from the Prison Notebooks*, 323-28.

science can be seen as the ongoing contestation between the contradictory ideals representative of both the Republic of Science and neoliberal science. The shift towards more market oriented models as the primary means of governing medical research has not completely displaced science's social purpose, instead facilitating the reconfiguration of existing social processes to increasingly intertwine the operational dynamics of science and its corresponding institutional structures with market-based logics. This has led to the presence of two distinct yet intertwined conceptions of science, each possessing contradictory objectives and methods yielding conflicting approaches on how to best expedite the creation and dissemination of scientific knowledge.

Such contradictory ideals are embodied in what has come to characterize 'conflicts of interest' within scientific research and can be expressed through the conflicting scientific ideals espoused by both the Republic of Science and neoliberal science. Drawing on each set of values to guide current research practices, conflicts of interest can be viewed as the direct by-product of a process whereby the objectives of scientific research do not share similar values to those guiding the research process. Therefore, it is through the study of the specific policies put in place to govern the issues associated with conflicts of interest that it becomes possible to illustrate how modern scientific practice within medical research has been subjected to two contradictory ideals while exploring the resulting impact this has on the ethos of science itself.

1.1 Exploring Issues of Authorship and Ghostwriting

Existing literature on conflicts of interest can be grouped into two broad categories emphasizing either financial or non-financial matters. While such categories offer an overly simplistic and inherently problematic method of categorization, they do

provide an ideal starting point to begin any substantive analysis. This starting point is useful as it provides a readily accessible means of recognizing a number of general problems associated with conflicts of interest. While useful, it is also equally problematic given the tendency for such overgeneralizations to exclude the equally important structural and ideological factors that sustain such conflicts of interest. Thus while such categories may offer an ideal starting point, alone they are grossly insufficient to fully explore the structural and ideological influences that not only define what is deemed a conflict of interest but the resulting policy response employed to address the root of such conflicts.

One of the most prominent issues involving conflicts of interest centers on the recent need to address questions regarding how to best handle the rise of corporate sponsored ghost-authorship within medical publishing and its impact on traditional notions of authorship. The practice of ghostwriting involves contracting a third party to develop and draft publications without properly recognizing the extent of their contributions in the final product or published manuscript. Within medical research, the practice of ghostwriting is characterized by the corporate financing of specialized medical writers who craft a carefully planned and managed manuscript to supplement the marketing strategies of specific products while relying on the authority of trusted academics to legitimize and assume authorial ownership over the final publications.⁹

⁹ Sergio Sismondo, "Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry," *PLoS Medicine* 4, no. 9 (2007): 1429-33; Barton Moffatt and Carl Elliott, "Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles," *Perspectives in Biology and Medicine* 50, no. 1 (2007): 18-31; Philip Mirowski and Robert Van Horn, "The Contract Research Organization and the Commercialization of Scientific Research," *Social Studies of Science* 35, no. 4, (2005): 503-48.

While such practices may be a relatively recent development, they offer a unique insight into the problems posed by conflicts of interest within medical research. The practice of ghostwriting is directly rooted not only in issues surrounding what are deemed to be acceptable authorship practices particularly with respect to deciding which actions warrant acknowledgement in a published manuscript and the reasons behind masking specific contributions, but also exhibits significant financial motivations for all parties involved. As such, the intersection of both financial and non-financial motivations within the practice of ghostwriting allows it to serve as an ideal case study when examining conflicts of interest in medical research. The presence of both financial and non-financial motivations within ghostwriting challenges a great deal of the existing literature on conflicts of interest, which has thus far focused largely on either the financial or non-financial dimensions of the practice. By acknowledging the importance and intrinsic connection between both of these aspects within the practice of ghostwriting, it becomes possible to develop new accounts of the practice that have thus far been largely overlooked by framing conflicts of interest from either a financial or non-financial standpoint.

Therefore, while ghostwriting as one facet of the issues related to conflicts of interest provides an ideal topic of study, it becomes necessary to identify the point at which these practices intersect with and have a transformative effect on the normative structures of science itself. One approach to answer to this question lies in examining the editorial policies, particularly those elements related to ghostwriting and authorship, employed by medical journals governing conflicts of interest in the publication process. Using these policies as the basis of a more detailed examination provides the necessary

focal point to examine how the fundamental norms governing medical research embodied in the policies of individual journals have evolved and changed as a result of pressures exerted by neoliberal science. While the struggle over the ethos of science may be ongoing, the perceived ineffectiveness of existing policy measures to combat the ongoing practice of ghostwriting and related issues impacting scientific authorship would appear to indicate a tendency towards the increasing naturalization of neoliberal science in the minds of scientific researchers and journal editors.

Ultimately, the underlying theme this thesis seeks to address is to examine how changes within the ethos of science can be explained through the specific policies enacted by medical journal to govern conflicts of interest and the practice of ghostwriting. As this thesis will demonstrate, such policies have failed to adequately address the growing structural and ideological influences exerted by neoliberalism within what has become an increasingly market-oriented model of scientific research more akin to project management than more traditional notions of scientific inquiry.¹⁰ Consequently, scientific research and the knowledge it produces, particularly when confined to the domain of medical research can no longer be seen to be driven by the pursuit of a universal truth or the development of novel explanations of our physical world, but instead as a tool to be carefully controlled and marketed in order to achieve an optimal financial return.¹¹ As a result, it is through this implied need to satisfy market demands that places medical

¹⁰ Bruce Charlton, "Figureheads, ghost-writers and pseudonymous quant bloggers: The recent evolution of authorship in science publishing," *Medical Hypotheses* 71, no. 4, (2008): 475-80.

¹¹ Gaile S. Cannella and Lisa L. Miller, "Constructing Corporatist Science: Reconstituting the Soul of American Higher Education," *Cultural Studies ↔ Critical Methodologies* 8, no. 1 (2008): 24-38; Maria Nedeva and Rebecca Boden, "Changing Science: The Advent of Neo-liberalism," *Prometheus* 24, no. 3 (2006): 269-81.

journals and their respective editorial policies at a crucial nexus in exploring the ongoing contestation surrounding the ethos of science and the larger struggle concerning what is deemed to be an optimal means of organizing both the creation and dissemination of scientific knowledge.

With medical journals serving as the primary conduit in the dissemination of newly acquired clinical knowledge, the editorial policies of each journal provide a glimpse into the underlying and often uneven power relations exercised by various actors in shaping the conditions of what is deemed acceptable scientific conduct. This allows medical journal conflict of interest policies to represent one focal point where it becomes possible to examine the physical embodiment of the ethos of science and explore how particular ideological currents crystalize in the form of policy enabling one to identify the particular normative standpoints they represent. As such, this thesis seeks to examine how conflict of interest policies in medical journals can be viewed as part of the ongoing contestation between two conflicting notions of science encapsulated by the more traditional conception embodied by that of the Republic of Science and its neoliberal infused alternative. From this, two primary research questions emerge:

- Are existing conflict of interest policies effective in mitigating the problems such conflicts pose to medical research?
- Do these same policies challenge a neoliberal ethos of science or rather do they serve to further entrench such ideals and aid in the construction of neoliberal science as common sense?

1.2 Constructing the Argument

This thesis will begin by first exploring how science must be understood as a social process in Chapter 2. Recognizing the social character at the heart of scientific

inquiry makes it possible to conceptualize how the current ethos of science is the direct product of a set of historic and contemporary tendencies present in society. It is through this interplay of both historic and contemporary social relations that yields potentially conflicting objectives as to how and why scientific inquiry takes place. This second chapter will explore how this underlying conflict has been exacerbated by the shift towards a neoliberal conception of science resulting in a set of inherently incompatible ideals with those held by the more historic vision postulated by Merton and characterized by the Republic of Science. Understanding how these conflicting ideals come to be negotiated within society is ultimately dependent on the theoretical and conceptual tools available to inform the analysis. By utilizing a theoretical framework informed by Antonio Gramsci, it becomes possible to understand the dynamics governing not only the ongoing negotiation between the contrasting conceptions of science but also how this contestation plays out within the conflict of interest policies implemented by medical journals. Employing Gramsci's conceptual notions of cultural hegemony (and with it the corresponding ideas of common-sense and good-sense) alongside the role and function of intellectuals, this chapter seeks to explore the spread of neoliberal science as a dominant form of consciousness within contemporary medical research both with respect to how researchers envision the process of scientific inquiry and the specific policies used to govern conflicts of interest. By adopting a theoretical framework informed by Gramsci it is possible to examine how the tensions between contrasting social conceptions of science have left both the agents of science, primarily researchers, and the products of science, namely the knowledge generated through research, with conflicting roles and responsibilities that must be negotiated. It is the role of medical journal conflict of

interest policies to effectively intercede between these conflicting roles by establishing codified standards of acceptable scientific conduct; thereby promoting specific scientific ideals characterized by the individual policy prescriptions that are adopted. By exploring how conflicts of interest emerge within science it becomes possible to then examine their current manifestations and potential problems they present in the pursuit of medical research.

Chapter 3 serves to establish the necessary foundation with which to understand the central importance attributed to marketing and promotion within the pharmaceutical industry by demonstrating how the industries' core business model has come to rely on the use of such strategies to overcome the fiscal challenges posed by modern drug development. Confronted with rising research and development (R&D) costs alongside marked declines in the therapeutic value of new drugs, the integration of marketing and promotional strategies into the pharmaceutical business model has become an increasingly necessary means of ensuring the industries' continued financial success by offering the requisite ability of differentiating between the range of available products in an increasingly competitive marketplace. By first problematizing the widely accepted narrative that portrays the pharmaceutical industry and its continued financial success as tied to the production of innovative new medicines, it becomes possible to explore how rising R&D costs alongside the declining therapeutic value offered by new medicines fails to adequately account for the ongoing financial success exhibited by the industry. It is by recognizing this underlying discontinuity between what is seen to be the industries' accepted public image and the realities of modern drug development that requires the range of activities that define the industries' core business model be expanded to not only

recognize, but account for the central importance of marketing and promotional strategies such as ghostwriting that help elucidate the ongoing structural and normative shifts within medical science that will be discussed in later chapters.

Building on this understanding, Chapter 4 seeks to outline the manner in which conflicts of interest have become central to understanding the core business model of the pharmaceutical industry by developing a thorough account of the specific strategies that define the most recent iteration of pharmaceutical marketing and promotion. Beginning with a cursory overview of the historical evolution of marketing and promotion, Chapter 4 seeks to exemplify the shift that has seen medical research come to function in an explicit marketing capacity. Central to this shift has been the ongoing structural transformation to core elements of the research process in an effort to afford greater control to industry over the production and dissemination of medical knowledge. As a result, the next section of this chapter focuses on the way in which the production of medical knowledge has been able to conform to the marketing and promotional needs of industry by analyzing the critical role held by contract research organizations as the dominant means of conducting medical research and the related importance afforded to key areas of medical knowledge such as randomized clinical trials (RCTs). With each of these components facilitating the production of favorable forms of medical knowledge, the next section of this chapter seeks to examine the way in which this knowledge can be actively mobilized to support the commercial goals of industry by exploring the strategic function of publication planning and its reliance on ghostwritten research supported by key-opinion leaders. With the extent of medical research functioning in a marketing capacity well documented, the chapter will briefly review some of the proposed solutions

to these issues found within the established body of literature focused on ghostwriting and medical conflicts of interest. The chapter will then conclude by reaffirming the need to recognize the importance of structure and ideology as a means of more fully understanding the problems posed by conflicts of interest in medical research.

In order to understand the significance of medical research functioning in a marketing capacity and the intrinsic connection between practices such as ghostwriting and publication planning with conflicts of interest, Chapter 5 will serve to establish the methodological principles that will be used to guide the subsequent analysis of medical journal conflict of interest policies. The chapter will begin by first clearly outlining the underlying rationale behind analyzing medical journal conflict of interest policies and explain why this focus presents an ideal case study with which to examine the efficacy of existing approaches to address conflicts of interest. With the choice of this specific case study fully outlined, the next necessary step is to frame the scope of the analysis by identifying a group of key journals and organizations based on one or more of the following criteria: policies that can be seen to offer a representative sample of existing approaches to address conflicts of interest; possess significant economic value and therefore serve as key targets for publication planning strategies; or have a documented history critical of the involvement of the pharmaceutical industry. Resulting in the inclusion of six key journals and two organizations whose individual qualities each satisfied one or more of these criteria, the next element of this chapter involves operationalizing the key principles of qualitative content analysis in order to establish the specific processes that will be used to guide the actual analysis. Involving three sequential phases of immersion, reduction, and interpretation, the final sections of the

chapter will be used to implement the first two phases of qualitative content analysis in order to develop a series of key questions for the purpose of focusing the collection of relevant data followed by a cursory overview of the principle results such that the final interpretative phase can be employed in a forthcoming chapter.

Chapter 6 will serve to incorporate the central elements of each of the proceeding chapters in order to develop a substantive analysis of the relevant findings in keeping with the interpretative phase of qualitative content analysis. Utilizing the key questions developed in the proceeding chapter, Chapter 6 will begin by first relaying the key research findings concerning the central issues present in each of the examined journal and organizations respective conflict of interest policies. Beginning with a detailed account as to the individual definitions employed by each set of policies as to what constitutes a conflict of interest, it becomes possible to shift focus and explore in greater detail the specific issues related to the key distinctions employed by individual journals concerning authorship and contributorship. From this point the next issue that will be discussed concerns the role of disclosure and the subsequent ramifications of its use to address conflicts of interest. It is also necessary to include a discussion concerning any substantive differences that may exist between each journal and organizations respective policies in order to highlight potential points of contestation pertaining to how best to address the challenges posed by conflicts of interest in medical research.

With this substantive overview of the key findings covered, the next phase of this chapter will serve to revisit the theoretical framework discussed in Chapter 2. Exploring the impact of existing conflict of interest policies through a new theoretical lens allows such policies to be understood as a microcosm of the larger structural and ideological

changes occurring within scientific research and illustrate how such changes have been largely overlooked by existing studies. This new theoretical approach to understanding conflicts of interests and the policies governing them will be heavily informed by the ideas of Antonio Gramsci and begin by defining neoliberal science as the established form of common sense. From this point, it is possible to draw on the theoretical and conceptual offerings of Gramsci in order to develop a more theoretical account concerning the use of disclosure and the resulting challenges posed by neoliberal science. The final key issue discussed within this chapter concerns the distinction between authorship and contributorship and how existing approaches employed by medical journals exemplify Gramsci's conception of intellectuals via the use of key opinion leaders.

The thesis itself will then conclude with a brief chapter summarizing the relevant findings in order to synthesize how the contributions offered by Gramsci provide a novel understanding of existing conflict of interest policies and how such policies relate to the ongoing negotiation occurring within the ethos of science. The final portion of this conclusion will introduce a potential alternative model as a means of discussing possible areas of further scholarship that seek to build off of the findings of this thesis.

2 Chapter: Formulating a Theoretical Framework

Approaching problems from a theoretical perspective makes it possible to not only understand, but also analyze the conceptual and material dimensions of a problem while developing an appreciation of the wider social and historical processes at work. This chapter seeks to outline the key concepts that will establish the foundation of a theoretical framework capable of examining the emergence, and subsequent reaction to conflicts of interest pertaining to medical ghostwriting contained within the editorial policies adopted by medical journals that will be examined in later chapters.

This theoretical framework begins first by recognizing the need to reevaluate many of the common preconceptions concerning the relationship between science and society. Approaching science in a more social manner serves to clarify that the process of scientific inquiry is a dynamic and ever evolving operation characterized by the ongoing discovery and the creation of knowledge. Understanding this continued evolution becomes possible by drawing on the theoretical concepts offered by Robert Merton whereby science is seen to be guided by an overarching ethos encapsulated by a distinct normative schema. While the theoretical insights offered by Merton shed light onto understanding the social dynamics underscoring science, they alone are insufficient to address the way particular norms are elevated such that they come to define the character of science. It is here that the works of Antonio Gramsci pertaining to the formation of culture and the elaboration of specific ideological positions can help fill this gap.

Integrating the theoretical insights offered by both Merton and Gramsci enables the development of a working theoretical framework capable of offering expanded

insight into the formation and naturalization of a new neoliberal ethos of science representative of both the rise and subsequent reaction to conflicts of interest and medical ghostwriting within the pharmaceutical industry that will be examined in later chapters.

2.1 Towards a More Social Understanding of Science

Science is fundamentally concerned with the creation of knowledge. Such knowledge is most often embodied in the form of what are seen to be generalized laws seeking to explain our material surroundings. While such explanations offer a means of constructing knowledge so as to understand the material world, the attributed sense of universality and truth such knowledge comes to possess fails to recognize the impact and influence exerted on science and its requisite processes by broader social forces. It is this broader social framework that is not only responsible for shaping the construction of scientific knowledge, but perhaps more importantly how such knowledge comes to be organized and privileged within society. In a sense, the production of specific forms of scientific knowledge can be seen as the direct product of distinct sets of social relations which serve to privilege certain scientific practices and institutions at the expense of others. It follows then that scientific knowledge must be understood as the product of what is fundamentally a series of social processes that are continually subjected to the ongoing negotiation between various social dynamics and power relations. Consequently, it is through this ongoing negotiation that establishes the boundaries of acceptable and seemingly proper scientific practice are established while legitimizing the specific institutional forms wherein such conduct occurs.

With the social prestige and perceived objectivity afforded to scientific knowledge, the ability to demarcate the boundaries of what is deemed proper scientific

practice, and by doing so explicitly influence the creation of specific forms of scientific knowledge, allows the social institution of science to possess tremendous power. The extent of this power is rooted in the ability of science to construct knowledge that is seen to serve not only an explanatory purpose, but more importantly do so in a way that is deemed credible and universal. It is this ability for scientific knowledge to construct generalized meanings that has served to promote its use not as a method of pursuing greater collective knowledge, but instead as a key tool to aid the reproduction and redirection of ideological imperatives on behalf of an economic and political elite.¹² Drawing on these ideological imperatives further reinforces the need for science to be understood not as a series of independent processes devoid of a larger social context, but instead to recognize that these social elements are central to understanding not only what science is, but also what it produces and the specific form it assumes to do so.

By treating science as a social process it becomes possible to examine not only how specific forms of scientific knowledge are constructed but also the potential motivations that influence the creation of such knowledge. Adopting this view allows science to not be understood solely as a rigid methodological process leading to what is essentially a fixed end, but instead as a fluid and dynamic series of negotiations that is representative of the ongoing struggles between competing power relations and efforts to reconceptualize and repurpose the meaning and products of various scientific processes. Conceptualizing science in this contested state serves to reinforce not only the need to acknowledge the often neglected social elements of science, but also recognizes the

¹² Dominique Pestre, "Regimes of Knowledge Production in Society: Towards a More Political and Social Reading," *Minerva* 41 (2004): 250.

importance of history as a primary means by which to trace the ongoing evolution of scientific inquiry through accompanying social structures. It is only by understanding science within a social context that enables one to analyze the broader structures at work both in a contemporary and historical context.

Acknowledging that science may act as a vehicle to advance set ideological imperatives defined by the social tendencies of a given period of history yields the opportunity to study the influence such specificities have in shaping the most recent articulation of dominant scientific practices. While a social understanding allows for greater insights into the processes that come to define the specific nature of science, they also serve to reinforce the variable and often contested nature of these same processes. Although science may be influenced in a way such that dominant frameworks governing its practice emerge, such structures do not necessarily represent the totality of scientific practice. Despite this perceived limitation, it is still both possible and productive to examine the emergence of a dominant conceptual form of scientific activity associated with a particular temporal period. Rather than serving to limit the value such an analysis may offer, the emergence of a dominant organizational form within science at a given time serves to reinforce the underlying presence of social elements responsible for shaping the development of science's governing practices. As a result, the emergence of a dominant organizational form within science can be seen to act as an extension of the social and ideological preferences represented in society such that they become the driving force in deriving the institutions and processes governing acceptable scientific practice and conduct. In other words, the wider structural and ideological elements that guide science become representative of specific social preferences at a given historical

juncture which in turn privilege both a particular scientific form and the resulting knowledge it generates. Citing the perceived benefits that such arrangements offer the production of knowledge, the distinct form science assumes as a result of specific social processes helps to solidify the original social values that led to its formation. In this way, a dominant form of science may emerge as a result of specific sets of social relations that yield an organizational form responsible for reinforcing the same social values that went into its production.

It is the social specificities that serve to construct and reinforce a dominant conception of science that in turn can be understood to constitute a generalized ethos of science. This so-called ethos of science can be envisioned as a “complex of values and norms, which is held to be binding on the man of science.”¹³ However, expanding the original focus of the ethos of science beyond strictly its’ role in governing individual action to also focus on the impact to the structural and ideological dimensions of science provides added insight into the ongoing development of scientific practice. In this way, understanding science and its continued evolution, particularly with respect to ongoing structural and ideological changes, can best be achieved by examining them through a social lens that is cognizant of the impact social norms can have in directing scientific activity.

2.2 Revisiting Merton’s Ethos of Science

Building off of Max Weber’s original insights regarding the cultural aspects of science, the normative structure proposed by Merton recognized that the development of

¹³ Robert K. Merton, “The Ethos of Science” in *On Social Structure and Science*, ed. Piotr Sztompka (Chicago: University of Chicago Press, 1996), 267.

science was rooted not in nature, but instead in specific cultural forms. Recognizing the distinct cultural characteristics that served to promote the development of science allowed Merton to question why certain cultural forms resulted in the development of science while others did not.¹⁴ The answer to this question for Merton lies in the elaboration of an ethos of science that serves to promote a set of social values and norms responsible for guiding individual activity through the promotion of a proper set of “institutional imperatives, in that rewards are given to community members who follow them, and sanctions are applied to those who violate them.”¹⁵ These norms, and the corresponding reward structure that facilitates their operation, provide the necessary incentives to advance the development of specific forms of scientific activity in order to satisfy what Merton recognizes as the true function of science.

Science for Merton is concerned with the creation of a set of cultural values and methodological processes capable of creating, governing and aiding the accumulation of certifiable forms of knowledge.¹⁶ It is the function of the ethos of science and its accompanying norms to establish the “prescriptions, proscriptions, preferences, and permissions” internalized by individual scientists necessary to facilitate the optimal creation of new forms of certifiable knowledge.¹⁷ Also important to note is that not only norms, but also the products and discoveries of science itself continue to support science being conceptualized as a socially oriented process. Instead of seeing science concerned

¹⁴ Robert K. Merton, “Science and the Social Order” in *The Sociology of Science: Theoretical and Empirical Investigations*, ed. Norman W. Storer (Chicago: University of Chicago Press, 1973), 254.

¹⁵ Sergio Sismondo, *An Introduction to Science and Technology Studies* (Walden: Wiley-Blackwell, 2010), 23.

¹⁶ Merton, “The Normative Structure of Science,” 268.

¹⁷ *Ibid.*, 268-69.

with the production of truth, Merton envisions science to be concerned with the creation and extension of certifiable knowledge. This conceptual distinction between truth and the idea of certifiable knowledge reinforces the impact and importance of social structures and their participants in defining and ultimately legitimizing the end products obtained through scientific inquiry.¹⁸ To achieve this, Merton identifies four distinct norms that are seen to constitute an ideal ethos that provides the most effective and optimal means for both the development of science and the extension of certifiable knowledge.

The first norm Merton points to is the need for science to display a sense of communism, or more appropriately communalism so as to recognize the level of social collaboration necessary for the production of scientific knowledge and the resulting need for not only the public ownership of scientific products but also public dissemination of scientific knowledge. Communalism challenges recent portrayals of science as an individualized process whereby issues such as individual property rights and knowledge production are replaced by those emphasizing the communal ownership and involvement in the production of scientific knowledge. For Merton, newly discovered scientific knowledge must not only be treated as a common good that is made readily available to the public domain, but must also recognize that all scientific discoveries are predicated on a historical foundation of previous scientific findings. Thus, all new and existing scientific knowledge can be seen to effectively stem from the actions of the preceding

¹⁸ Sheldon Krinsky, *Science in the Private Interests* (Lanham: Rowman & Littlefield Publishers, 2003), 74.

scientific community and its preexisting cultural heritage, which must be recognized and embraced in order to effectively produce new scientific knowledge.¹⁹

This communal structure of scientific knowledge production is reinforced by the cultural rewards afforded in lieu of private ownership over scientific discoveries. Rather than relying on private ownership of individual discoveries, Merton points to the function of cultural prestige and its use by science as the primary means of attributing ownership to a discovery in a way that does not exclude access to the knowledge being produced.²⁰ Attributing ownership of scientific discoveries through socially recognized naming rights allows the act of discovery rather than the resulting idea to serve as the principle object of ownership. Evidence of this can be found in many famous scientific theories with Einstein's theory of relativity providing one notable example. By rewarding scientific discoveries through the social prestige afforded by naming rights it remains possible to reward the act of discovery in a way that does not necessarily infringe on the collective ownership of the idea by the scientific community.

In order for scientific knowledge to be considered truly public and communal, simply ensuring non-exclusionary forms of ownership through means of social recognition is not enough. To satisfy the sense of communalism identified by Merton, it is also necessary to promote the ready dissemination of newly created scientific knowledge. Academic publishing acts as the primary communications medium for the dissemination of scientific findings by functioning to translate specific scientific claims

¹⁹ Merton, "The Normative Structure of Science," 274-75.

²⁰ *Ibid.*, 273.

into communally accepted knowledge.²¹ While the current practices that define academic publishing may not actively serve to promote truly public knowledge, the practice of disseminating scientific knowledge via publication is seen to possess the potential capacity to achieve the communal emphasis emphasized by Merton.

Universalism is the second key norm constituting the ideal ethos of science identified by Merton. Seeking to subject scientific claims to “pre-established impersonal criteria...consonant with observation and with previously confirmed knowledge,”²² emphasizing universalism as a scientific norm attempts to avoid potential conflicts arising from the innate individual and social character of scientists themselves. Recognizing the potential influence impacted by impersonal criteria such as nationality, class, religious, and personal motivations on the claims advanced with scientific knowledge, the need for universalism Merton emphasizes functions as a requirement for science to sustain its largely impersonal nature. Lacking this impersonal quality, science itself can be readily used not for the creation of certifiable knowledge as Merton originally envisioned, but instead as an extension of existing power structures within society.

Writing during a period of intense ideological hostility towards science originating from Nazi Germany and the Soviet Union,²³ Merton recognized the ability for the role of individual scientists to be unduly influenced by prevailing social structures.

²¹ John Ziman, *Real Science: what it is, and what it means* (Cambridge: Cambridge University Press, 2000), 35.

²² Merton, “The Normative Structure of Science,” 270.

²³ The failure to recognize the contributions of Jewish scientists in Nazi Germany and the corresponding push for science to conform to the perceived ‘national’ character of Soviet ideology epitomized a shortcoming in promoting the universality of science emphasized by Merton. See Merton, “Science and the Social Order,” 254-60; Merton, “The Normative Structure of Science,” 271.

Consequently, science when lacking adherence to universalism has the potential to become less about the pursuit of certifiable knowledge and instead become highly politicized and militarized serving to not only privilege but also actively discredit specific scientific claims, or as Merton puts it, the “man of science may be converted into a man of war – and act accordingly.”²⁴ Utilizing individual and social characteristics to assess the validity of scientific knowledge serves to effectively alienate potentially credible findings from scientists deemed socially undesirable. This in turn places tremendous pressure on the ethos of science to effectively pursue the formation of scientific knowledge in a way that attempts to be autonomous from external influence wherever possible. If scientific knowledge comes to be judged based on the criteria of individual scientists and not on impersonal preexisting criteria, science can no longer be seen as being primarily concerned with the creation of certifiable knowledge. Rather, science when judged in this manner becomes nothing more than a body of knowledge serving to reinforce particular cultural representations emphasized by existing power dynamics in society.

The third norm identified by Merton builds on the emphasis of ensuring science is a universal process and extends this to the level of individual scientists. In addition to the need to ensure that scientific claims are not evaluated based on individual merits of scientists, the norm of disinterestedness emphasizes that scientists themselves must approach scientific knowledge without personal biases. This serves to make extraneous individual factors, such as “considerations of personal gain, ideology, or fidelity to any

²⁴ Merton, “The Normative Structure of Science,” 271.

cause other than the pursuit of truth”²⁵ irrelevant when attempting to verify the authenticity of scientific claims. It is by promoting a sense of disinterestedness in the outcomes and processes utilized to validate scientific claims that functions to ensure individual scientists transcend their personal vested interests and motivations while acting to ensure that claims are evaluated based solely on their scientific merit.

Disinterestedness therefore serves to ensure that scientific claims adopt an impersonal and seemingly objective standpoint by allowing scientists to serve as “disembodied instrument[s] of factual observation or logical inference.”²⁶ This level of personal detachment affords both science and the community of scientists an aura of social legitimacy and trust that scientific claims represent replicable observations of the material world and not simply reflections of individual interpretations and beliefs.

The norm of disinterestedness is essential to develop a wider sense of social legitimacy for scientific claims and science itself. Ensuring this sense of social legitimacy is of paramount importance in order to effectively translate scientific claims from their highly technical state to a form that can be readily understood by the general populace. Given the specialized nature of scientific claims, only those with sufficient technical training are able to validate their legitimacy and accurately reproduce the findings. This places scientists and the knowledge they produce in both a privileged and unique social position. It is this privilege that affords scientists such tremendous power, and it is this power that in turn reinforces the need to pursue disinterestedness as a core normative value for Merton. To this extent, the expert authority of science “can be and

²⁵ Krimsky, *Science in the Private Interest*, 77.

²⁶ Ziman, *Real Science*, 38.

[often] is appropriated for interested purposes, precisely because the laity is often in no position to distinguish spurious from genuine claims to such authority.”²⁷ As a result, the promotion of disinterestedness is of supreme importance not only to prevent the potential abuse of expert authority afforded to science, but perhaps more importantly to sustain the public’s trust in science and scientific knowledge. It is this trust and the resulting public relationship with science that is facilitated by the disinterestedness of individual scientists. Without such trust, it is unlikely that the general population would come to accept scientific claims and instead adopt those that can be readily proven without reliance on the expert authority and technical training of scientists.

Where the norm of disinterestedness seeks to ensure that individual scientists evaluate scientific claims on impersonal grounds, the final norm addressed by Merton seeks to ensure that science is structured in a manner sufficient to provide methodological and institutional checks in the event that disinterestedness fails.²⁸ These checks for Merton take the form of subjecting new scientific claims to a sense of organized skepticism. This entails that novel scientific claims undergo rigorous scrutiny prior to being accepted as certifiable knowledge by the wider scientific community. Such scrutiny takes the form of communal processes that serve to reinforce the repeatable and testable nature of scientific validation while fostering the development of communal ties within the broader institution of science itself. It is these broader communal ties within science that are fundamental in order to promote the creation and resulting validation of certified scientific knowledge.

²⁷ Merton, “The Normative Structure of Science,” 277.

²⁸ Ibid.

Adopting an inherent sense of skepticism within science ensures that new scientific knowledge is subjected to communal scrutiny prior to being accepted as certified knowledge. In a similar fashion to the way in which disinterestedness seeks to prevent scientific claims from reflecting the self-interest of individual scientists, organized skepticism functions in a similar manner but on a broader institutional scale. This serves to reinforce the reproducibility and testability of scientific claims by implementing a means of insulating the institution of science from being seized by a singular authority.²⁹ Reinforcing the need to extensively test and reproduce the validity of scientific claims as both methodological and institutional mandates, organized skepticism promotes scientific knowledge that actively reflects observations informed by the wider social processes that have come to define science, rather than a more individual interpretation.

Endorsing organized skepticism as a fundamental norm of science promotes the need for scientists to be “held accountable to their community, rather than to their superiors or [to] themselves.”³⁰ In this way, the inherent sense of skepticism directed towards novel scientific claims serves to ensure that the certification of such knowledge is deemed acceptable in the eyes of a wider community rather than single individuals. The need for the communal acceptance of such knowledge in turn satisfies the requirement that scientific knowledge is seen to be certifiable set out by Merton. Drawing on communal scrutiny as means of certifying scientific knowledge, organized

²⁹ Krimsky, *Science in the Private Interest*, 79.

³⁰ Ziman, *Real Science*, 43.

skepticism acts as a barrier to prevent the abuse of scientific knowledge and deviation from the norms set out by Merton.

The combination of each of these four norms, the abbreviated CUDOs, serves to constitute a distinct ethos of science for Merton that represents the ideal social structure and optimal means of ensuring the continued development of science.³¹ This ethos emphasized by Merton reinforces the need to treat science as a socially oriented public process that can readily be conceptualized in a manner that is seen to constitute a so-called Republic of Science. While this terminology was first utilized by Michael Polanyi to describe the necessities of communal organization and collaboration for scientific endeavors to be successful, the label can be readily extended to the institutional structure of science envisioned by Merton's CUDOs.³² The imagery of the Republic offered by Polanyi serves to further support the fact that the success of science is intrinsically tied to the wider community, both in terms of like-minded scientists and the general public. In this way, the specific ethos that can be attributed to the norms offered by Merton to describe scientific practice in many ways mimics the Republic outlined by Polanyi. By adopting this terminology, the norms set out by Merton become an integral part of the ethos of science that is consistent with science possessing both a broader public and social purpose.

From the beginning it has been quite easy for critics to point to an absence of these norms in everyday reality as a point of failure for Merton's analysis. The lack of institutional structures with which to codify these norms alongside the inherent variability

³¹ Merton, "The Normative Structure of Science," 269-70.

³² Michael Polanyi, "The Republic of Science: Its Political and Economic Theory," *Minerva* 38, (2000), 1-32, reprinted from *Minerva* I, 1 (Autumn, 1962), 54-73.

associated with individual interpretations of the norms themselves serves to challenge the analytical use Merton's functionalist framework as a means to understand the evolution of science.³³ While the inherent variability present in translating and interpreting norms as a means by which to dictate specific actions does present challenges to a social framework governing scientific practice, the functional framework offered by Merton cannot be written off entirely. Rather, the value of Mertonian norms is in their ability to offer precepts concerning the idealistic operation of science, whereby such norms characterize an optimal ethos of science for the advancement of certifiable knowledge. In this sense, while such norms may offer an inherently idealistic view of science, such idealism is not without some analytical merit.

While the realities of science may not necessarily match the idealistic norms set out by Merton, they nonetheless provide guidance for the scientific community concerning the continued development of science while establishing what can be seen to be an effective method of producing certifiable knowledge.³⁴ Functioning in this idealistic manner, Mertonian norms do not need to directly reflect reality but act simply as a means of guiding the ongoing social development of science in a proactive way. This guidance is primarily embodied in the consciousness of individual scientists and facilitates the development of acceptable scientific practice. Nevertheless, the true analytical value provided by Merton can be traced to understanding how the existing ethos of science and its accompanying normative framework differs from the idealistic vision of the Republic by providing a benchmark against which alternative normative

³³ Sismondo, "Introduction to Science and Technology Studies", 27-31.

³⁴ Ibid., 34-35.

structures may be measured. Recognizing the analytical importance afforded by this difference allows for broad shifts within the ideals and values that shape the current social configuration of science to be understood as part of the ongoing negotiation surrounding how society conceptualizes and interacts with science itself. In this way, while Merton offers direct prescripts concerning the most effective method of constructing certifiable knowledge, his analytical value comes from expanding this framework to understand how shifts within the ethos of science can come to reflect different social conceptions of science.

Despite the analytical value offered by Merton, understanding the social development of science through norms alone is insufficient. It is also necessary to understand how in the absence of Merton's CUDOs, alternative norms instead come to be reinforced by both the institutional and cultural practices of science. To this end, it is necessary to supplement a theoretical foundation built on Merton with the theoretical concepts offered by Antonio Gramsci in order to explain how and why specific norms have come to shape current conceptions of science.

2.3 Constructing Common Sense: Gramsci's Relevance to the Ethos of Science

While the contributions offered by Merton better allow the social nature of science to be understood as the product of a generalized ethos and its accompanying normative structure, the analytical scope of his idealism is limited by its inability to explain the realities of modern science. It is necessary to not only recognize the formative function of norms in shaping the ethos of science, but also how specific norms themselves come to develop. To this extent, while Merton offers an idealistic account pertaining to the role and function of norms with respect to the production of certifiable

knowledge, there is little said about the development of these norms and the manner in which they are actively integrated into the wider scientific community. In order to address these limitations it is necessary to expand upon this existing framework with the theoretical offerings of Antonio Gramsci. Doing so offers an expanded theoretical foundation capable of examining the emergence of hegemonic forms of consciousness, ideology, and social practice in order to understand the production and integration of alternative sets of norms than those identified by Merton.

With the social norms envisioned by Merton serving as generalized guiding principles informing a specific conception of science, these norms can also be explicitly linked to Gramsci's understanding of philosophy and ideology. Where Merton sees the primary purpose of social norms in their ability to define a particular ethos of science, such norms can also be seen to constitute a particular philosophical conception of science. Philosophy for Gramsci is seen to constitute a particular worldview arising out of the historical and social processes that shape our individual understandings of the world.³⁵ Understanding philosophy in this manner can be readily translated to conceptualizing a socially grounded interpretation concerning the formation of science. By recognizing the importance of history and society in shaping individual understandings of the world, and the way in which individual philosophy in turn translates to larger ideological frameworks, the centrality of philosophy as a defining element for Gramsci's thought offers a means by which to explain why specific norms have come to guide the development of scientific practice. In this way, the theoretical

³⁵ Gramsci, *Selections from the Prison Notebooks*, 324.

contributions offered by Gramsci advance an expanded theoretical framework than one reliant solely on Merton; by offering the conceptual tools capable of exploring the development norms that are absent from the foundations offered by Merton. Such additions offered by Gramsci serve to provide a more analytically robust framework to approach an analysis of the normative structure of modern scientific practice.

Although the function of norms is critical in guiding the development of scientific practice, the specific historical and social contexts from which they emerge are also of paramount importance to inform any understanding as to their ongoing evolution. It is only by recognizing the extent to which these social and historical processes act in shaping scientific norms that allows for an explanation of not only why, but also how the current ethos of science reflects a specific understanding of science. In this sense, by understanding not only the role of norms in guiding the development of a scientific ethos while appreciating the how such norms serve as the products of distinct ideological frameworks, it becomes possible to understand the ethos of science through a more Gramscian lens. It is the ability of ideology as Hall notes to define “the mental frameworks – the languages, the concepts, categories, imagery of thought, and the systems of representation”³⁶ that allows specific norms and the philosophical meanings they generate to define and clearly elaborate a particular ethos of science in light of potential alternatives. As a result, understanding the ethos of science by relying solely on the role of norms alone is insufficient. Instead, it is necessary to recognize and embrace the importance of ideology as a central means for promoting specific norms so as to

³⁶ Stuart Hall, “The Problem of Ideology: Marxism without Guarantees,” *Journal of Communication Inquiry* 10, no. 28 (1986): 28-30.

identify the way in which particular ideological currents are elevated above others and come to be institutionalized and accepted as the prominent way society understands science.

The foundation of this tacit acceptance can be readily expressed through Gramsci's conception of cultural hegemony. For Gramsci, the definition of hegemony centers on the necessary balance between coercion and consent, which presents a fundamentally different view from more conventional accounts that often emphasize more explicit forms of power. Gramscian hegemony is instead premised on, and can be appropriately defined as the use of more indirect methods of control and domination premised on fundamentally altering the way society envisions and interacts with its material surroundings. By shaping individual understandings of the world it becomes possible to establish a form of power that is no longer reliant solely on the direct administrative control of political and economic structures of power. Rather, cultural hegemony reaffirms the importance of an expanded socio-cultural footing that "encompasses the critical domains of cultural, moral, ethical, and intellectual leadership"³⁷ each of which become requisite components necessary for the realization of a cultural hegemonic social order.

Incorporating these added social and cultural dimensions necessitates hegemony be understood not simply as the product of isolated economic, political, or cultural forces, but instead as a relationship between the underlying economic structure of society and the related social and political superstructure. The nature of this relationship facilitates not

³⁷ Stuart Hall, "Gramsci's Relevance for the Study of Race and Ethnicity," *Journal of Communication Inquiry* 10, no. 5 (1986): 16-17.

only the formation of hegemony, but also the conceptual means by which to understand it. As Gramsci notes:

It is the problem of the relationships between the structure and superstructure which must be accurately posed and resolved if the forces which are active in the history of a particular period are to be correctly analysed, and the relation between them determined.³⁸

It is by recognizing the importance of this relationship between the underlying economic structure of society and the prevailing superstructure consisting of various sociocultural and political institutions that it becomes possible to understand the true nature of hegemony for Gramsci. Rather than controlling either area independently, cultural hegemony is instead premised on the reciprocal relationship between structure and superstructure that seeks to promote a historically contingent unity between each sphere. This unity is premised not only on the transformation of the economic structure and socio-political superstructures, but also on the unification of cultural and intellectual values across social divides within what Gramsci terms a historic bloc.³⁹

The successful realization of hegemony for Gramsci requires the formation of a historic bloc to bridge opposing class forces through the dissemination of a common ideological worldview. It is the formation of this common ideology that provides the requisite component necessary for the emergence of a historic bloc as it serves to subjugate subaltern class interests under the perceived leadership of a dominant class. Such subjugation is achieved not through the forcible repression of subaltern thought, but

³⁸ Gramsci, *Selections from the Prison Notebooks*, 177.

³⁹ Hall, "Gramsci's Relevance for the Study of Race and Ethnicity," 14-15.

rather through the proliferation of consent from the subaltern classes. Consent in this manner is achieved through the reshaping of political struggle such that a dominant ideological current unifies previously discordant interests through the diffusion of a new form of consciousness across existing social institutions. Utilizing ideology to this end, hegemony is able to effectively reshape political struggles in such a way that they no longer explicitly challenge the solidity of the historic bloc and instead actively reinforce it. Ideology thus becomes a central point of mobilization around which hegemony is devised, disseminated, and disputed for Gramsci. In other words, hegemony is at heart an ideological and philosophical struggle over the ability and methods used to produce particular forms of knowledge.⁴⁰ The importance of this struggle over the ideological specificity of such knowledge comes about as a direct product of Gramsci's distinct approach to philosophy.

Philosophy for Gramsci is a broad theoretical concept due in part to its highly individualized potential given the opportunity for every individual to possess the ability to elaborate a unique understanding of the world.⁴¹ It is this capacity to construct individualized meaning that outlines the primary definition of philosophy for Gramsci. However rather than defining philosophy strictly in terms of such individual expression, Gramsci instead points to the ways in which it becomes possible to define "the limits and characteristics of the 'spontaneous philosophy' which is proper to everybody."⁴²

⁴⁰ Hall, "The Problem of Ideology," 42-3; Fontana, "State and Society", 43.

⁴¹ It is important to note that Gramsci recognizes two distinct forms of philosophy. Philosophy itself is rooted in the meanings that are ascribed to an individual's surroundings while the more recognizable philosophy of praxis is the more radical and revolutionary set of meanings that seek to challenge and make critical existing philosophy.

⁴² Gramsci, *Selections from the Prison Notebooks*, 323.

Recognizing the ability of philosophy to not only reflect individualized meaning, but also address the imposition of limits and boundaries serves to identify the greater importance associated with philosophical meaning for Gramsci. As a result, while philosophy recognizes the importance of individual experience, it is the emergence of a more communal worldview that serves to embody philosophy in the Gramscian notions of ‘good sense’ and ‘common sense’.

The foundation of Gramsci’s conception of philosophy is predicated on the assumption that every individual possesses the capacity and ability to express their own particular understanding of the world. This individual capacity to experience and understand their material surroundings in a specific fashion is of the utmost importance in ones’ ability to conceptualize a distinct philosophical explanation of reality. Elaborating on Gramsci, Fontana remarks that:

Knowing is not simply an abstract activity, it is a conscious engagement with reality, such that the very act of knowing gives form, meaning and ‘personality’ to the object. Thus reality is not passively perceived, but it is actively and passionately seized, captured, and possessed by the subject.⁴³

Thus, even the relatively intangible and metaphysical experience of knowing has the potential for something more. It is a process that necessitates individual action and reflection such that an experiential moment of knowing may effectively be translated into a distinct and individualized philosophical form.

However, such insights are not necessarily the product of conscious engagement with the world itself. Often, individual philosophy is nothing more than an unconscious

⁴³ Fontana, “State and Society,” 41.

reproduction of pre-existing dominant cultural forms that arise from particular social and historical processes that have come to “share the same mode of thinking and acting.”⁴⁴ It is this appropriation of individual philosophy to reflect a set of dominant cultural beliefs that characterizes Gramsci’s notion of common sense. Nevertheless, the formation of common sense goes beyond simply reaffirming the common assumptions and beliefs advanced through the historic and social specificities of a given period. Instead, common sense comes to function in a transformative sense whereby consciousness itself is altered allowing the foundational precepts of reality to reflect those offered and actively reinforced by common sense itself.

Acting to shape the demarcated bounds of thought and reality, common sense entails the creation of a philosophical worldview that becomes defined not only by collective individual experiences, but more importantly by the distinct cultural expressions of the particular historic and social processes that are seen to define it. In this way, the formation of common sense is as Gramsci recognizes:

not to be conceived solely as the “individual” elaboration of systematically coherent concepts, but also and above all as a cultural battle to transform the popular “mentality” and to diffuse the philosophical innovations which will demonstrate themselves to be “historically true” to the extent that they become concretely – i.e. historically and socially-universal.⁴⁵

Constructing common sense thus requires more than a simple aggregation of collective beliefs, instead promoting the creation of a specific socially and historically contingent cultural form. By doing so, the formation of common sense transcends simply reshaping

⁴⁴ Gramsci, *Selections from the Prison Notebooks*, 324.

⁴⁵ *Ibid.*, 348.

individual philosophy, and instead acts as a comprehensive reconfiguration of the social and historical truths that come to inform ones individual conception of the world. In this way, common sense functions to not only reshape individual consciousness, but to alter the very parameters and possibilities that come to define it. Common sense therefore comes to foster the creation of “a new ideological terrain, [which] determines a reform of consciousness and of methods of knowledge”⁴⁶ in order to actively create a new social and historical worldview.

Reshaping the ideological terrain to reflect newly defined social and historical lines allows common sense to serve as the requisite element for Gramsci in the realization of cultural hegemony. Redefining individual beliefs and perceptions to reflect a particular worldview, it becomes possible to elicit consent from the general populace as a means of justifying a particular course of action. Establishing hegemony in this manner therefore requires “the formulation and elaboration of a conception of the world that has been transformed into the accepted and ‘normal’ ensemble of ideas and beliefs that interpret and define the world.”⁴⁷ This ability for hegemony to act as the sole semblance of normalcy imbues it with the power to effectively reshape individual philosophy into a collective form of consciousness reflecting the particular ideological influences that are seen to be socially and historically true at a given juncture.

However, the diffusion of common sense requires more than just the realignment of individual philosophy with hegemonic ideals. Rather, the successful diffusion of common sense beyond individual consciousness is predicated on its ability to manifest

⁴⁶ Ibid., 365.

⁴⁷ Fontana, “State and Society,” 20.

itself in the operational capacity of various social institutions effectively seizing their ability to construct and disseminate particular forms of social knowledge. In this way, social institutions assume a productive role in society through their ability to perpetuate and promote not only the social relations that underpin everyday interactions but also the normative structures that guide this behavior. Understanding hegemony in this manner must begin as Cox points out by recognizing that production must:

be understood in the broadest sense. It is not confined to the production of physical goods used or consumed. It covers the production and reproduction of knowledge and of the social relations, morals and institutions that are prerequisites to the production of physical goods.⁴⁸

Social institutions maintain an active involvement in the production and reproduction of particular forms of social knowledge as a result of their related educative capacity to inform and structure the general public's subjective understanding of the world. In this way, social institutions act to construct "the 'material structure of ideology' in civil society" allowing common sense to transcend the bounds imposed by individual philosophy. Social institutions constituting the "material structure of ideology in civil society" such as "publishing house[s], newspapers, journals, literature, libraries, museums, theatres, art galleries, schools, architecture, or street names"⁴⁹ all serve as key centers of knowledge production allowing a particular understanding of the world to be disseminated as common sense and thus become central to the continued struggle for and

⁴⁸ Robert Cox, "Production, the State and Change in World Order," in *Global Changes and Theoretical Challenges: Approaches to World Politics for the 1990s*, eds. E-O. Czempel and J.N. Rosenau (Toronto: Lexington Books, 1989), 39, quoted in Adam David Morton, *Unravelling Gramsci: Hegemony and passive revolution in the global economy* (London: Pluto Press, 2007), 116.

⁴⁹ Adam David Morton, *Unravelling Gramsci: Hegemony and passive revolution in the global economy* (London: Pluto Press, 2007), 92.

against particular hegemonic forms. As a result, the importance of social institutions and the forms of knowledge they reproduce become critical sites not only to aid the emergence of hegemony but also the resultant struggles and contestations that emerge to contest it.

Despite this power to actively reshape social and historical truths, hegemony and the construction of common sense is far from everlasting.⁵⁰ Rather, it is the solidification and entrenchment of hegemony and the resulting diffusion of common sense that can be seen to sow the seeds responsible for its potential downfall. In effect, the development of hegemony produces its own counterhegemonic forces arising from the internal tensions and contradictions that emerge within a hegemonic social order.⁵¹ Such tensions and contradictions become the basis of a larger transformative force offering the potential to challenge the emergence of a hegemonic social and historical order. The basis of this challenge lies in a renewed critical engagement with the adopted philosophical ideals consistent with common sense in order to promote a return to the more general notion of philosophy achieved through realization of critical self-consciousness. Challenging the diffusion of common sense by promoting a critical re-engagement of philosophy requires the creation of a contrasting worldview characterized by Gramsci as ‘good sense’. Good sense is seen to function as the embodiment of emergent counterhegemonic tensions functioning to either transform or replace common sense through the restoration of critical thought and a renewed ability to formulate individual philosophical meaning. In

⁵⁰ While Gramsci recognizes the duality of coercion and consent as constitutive elements of establishing hegemony, the theoretical framework being presented here will look exclusively at the later consensual aspects that accompany the construction of common sense and the related concept of good sense.

⁵¹ Robert Cox, ‘Approaches from a Historical Materialist Tradition’ in Christopher Chase-Dunn et al., “Hegemony and Social Change,” *Merston International Studies Review* 38, no. 2 (1994): 366.

this way, good sense serves as the functional antithesis of common sense by promoting a renewed sense of critical introspection regarding the very assumptions held about the material world rather than the simple tacit acceptance of a set of preconceived explanations offered as part of common sense.

It is often during moments of crisis and contradiction that this transformation of common sense takes place. Arising through a reintroduction of critical philosophy and criticism so as to question the perceived social and historical truths imposed by common sense, good sense is seen to promote a higher conception of life beyond the “primitive philosophy of common sense.”⁵² It is through the interjection of criticism and critical thought back into common sense that it becomes possible to develop a new separate and distinct form of thinking that encompasses good sense and fundamentally distinguishes it from the existing roots of common sense.⁵³ Good sense in this way can be seen to parallel Gramsci’s original conception of philosophy in that it recognizes the inherent necessity of critical thought and seeks to reintroduce this as a means of challenging the imposition of pre-established socio-historical truths associated with common sense.

Critical thought forms the central component necessary to challenge the accepted truths associated with common sense so as to produce a new conception of reality that exists outside of imposed bonds of hegemony. In other words, good sense seeks to actively challenge the imposition of a distinct philosophical worldview by actively challenging the social and historical truths responsible for reproducing a distinct form of common sense through a reassertion of critical self-consciousness. Challenging these

⁵² Ibid., 332.

⁵³ Ibid., 333-34.

accepted truths, good sense seeks to provide the necessary conceptual tools to create an intellectual cleavage capable of contesting the formation and further entrenchment of hegemony and produce a new philosophical conception of reality.

While the role of philosophy and critical thought are central to the formation of hegemonic and counterhegemonic cultural practices, ideas and ideology are only able to offer a partial explanation of this process. If ideas act as the means to express a particular understanding of the world, then these same ideas also require substantive direction in order to translate them into hegemonic cultural forms. To this end, Gramsci recognized the necessity of a social function held by what he referred to as the intellectual(s) in order to address the directional absence of strictly philosophical thought. This direction is achieved by the elevation of a particular group from within or alongside the social class responsible for directing production in order to organize and mobilize wider forms of social consciousness and culture. Therefore the primary social function for intellectuals is to act in “the capacity to be an organiser of society in general, including all its complex organism of services, right up to the state organism, because of the need to create the conditions most favourable to the expansion of their own class.”⁵⁴ Functioning in this organizational capacity, intellectuals serve as the primary means by which to guide the development of social consciousness, but to do so in a way that comes to reflect a particular form of thinking. This resulting direction is the product of the organizational capacity afforded to an intellectual caste that makes possible not only the emergence of

⁵⁴ Ibid., 5-6.

hegemony through the formation of common sense but also the potential means by which to contest it.

Recognizing the inherent revolutionary tendencies present in Gramsci's thoughts, it becomes necessary to differentiate the role of intellectuals into two separate, yet fundamentally similar groups. Membership into each of these particular intellectual castes is determined not by their similar social function, that is to act in a leadership role so as to organize social activity, but instead by their relationship with the ideas they serve to organize and how these ideas relate to either the existing or emerging mode of production. To this end, intellectuals are seen to "either align themselves with the existing dispositions of social and intellectual forces ('traditional' intellectuals) or align themselves with the emerging popular forces and seek to elaborate new currents of ideas ('organic' intellectuals)."⁵⁵ Acting to either reinforce or challenge existing ideological and cultural practices, traditional and organic intellectuals act to either preserve common sense or challenge it through the formation of good sense. Each of these courses of action is made possible by defining each strata of intellectual activity based on their alignment with either the prevailing or emerging social structures. This serves to reinforce the organizational role afforded to intellectuals while linking this practice to either cement or contest existing ideological currents.

While understanding the role of intellectuals on the most basic level to be the product of their relationship with a particular mode of production is useful, a more complete understanding becomes necessary to examine how the succinct nuances that

⁵⁵ Hall, "Gramsci's Relevance for the Study of Race and Ethnicity," 433.

define this relationship further demarcate the roles and responsibilities of each intellectual caste. To this end it is necessary to further explore the social and cultural specificities that define the roles of both traditional and organic intellectuals.

With the role of traditional intellectuals being characterized primarily by their intrinsic connection to existing ideological and cultural currents, this relationship serves to form a starting point from which to understand their true social and political significance for Gramsci. As a result of this attachment to established modes of production, traditional intellectuals serve a more ancillary political function in society. Rather than actively seeking to organize public consciousness, traditional intellectuals instead function to indirectly promote the further entrenchment of a particular form of common sense defined by their surrounding structural conditions. In this way, the organizational capacity of traditional intellectuals is exercised in a way that seeks to ensure the continuation of the current mode of production of which they form an integral, albeit indirect part.

The organizational function of traditional intellectuals can therefore be characterized in this indirect fashion primarily due to the way in which their social form has been perceived. Primarily, the position of traditional intellectuals is characterized through an occupational attachment to various positions of prestige and traditional authority. Gramsci points to the intellectual function held by priests and lawyers as prime examples of this occupational connection to intellectual activity. As a result of this, traditional intellectuals come to view themselves, and become perceived in a manner that bestows upon them with an aura of ahistorical freedom that serves to seemingly

position them outside of the current class structure.⁵⁶ In this sense, traditional intellectuals come to be seen and see themselves as both “autonomous and independent of the dominant social group”⁵⁷ such that their actions are seen to be independent and not simply a reflection of dominant interests.

However, this perceived autonomy is fundamentally misplaced as the actions of traditional intellectuals come to reinforce, rather than criticize, the very system that elevates and legitimizes the social positions they occupy. It is this illusory sense of autonomy that promotes the crystallization of a single group of intellectuals that “sees itself as continuing uninterruptedly through history [...] rather than as the expression of a dialectical process through which every dominant social group elaborates its own category of intellectuals.”⁵⁸ In this way, traditional intellectuals come to envision themselves as a social group that exists independent of their immediate historical context whereby they neglect to recognize the conditions (and resulting subjugation) that led to their formation at the behest of dominant social forces. As a result, their actions unknowingly serve to reinforce and preserve the already existing social framework set out by the dominant social forces responsible for their perceived independence. In this way, traditional intellectuals act as one of the primary means by which to reinforce existing cultural hegemonic practices through their unknowing support for established forms of common sense.

⁵⁶ Quintin Hoare and Geoffrey Nowell Smith, “The Intellectuals: Introduction,” in *Selections from the Prison Notebooks of Antonio Gramsci*, (New York: International Publishers, 1971), 3.

⁵⁷ Gramsci, *Selections from the Prison Notebooks*, 7.

⁵⁸ *Ibid.*, 452.

Contrasting the role and social function of traditional intellectuals for Gramsci is that of the organic intellectual. Rather than acting to reinforce existing dominant social and cultural arrangements to preserve hegemony, organic intellectuals instead serve to champion emerging forms of critical thought that seek to contest and challenge the existing dominant social order. In this way, the organic intellectual for Gramsci functions as a true philosopher, capable of elaborating truly critical individual forms of thought and consciousness capable of developing new ways of understanding their material surroundings. This allows organic intellectuals to consciously act so as to develop a new form of counter-hegemonic thinking outside of accepted social and cultural arrangements thereby challenging the established form of common sense. For Gramsci, the ability to challenge common sense is heavily dependent on the organic nature and resulting class awareness that underpins the social and political function of the organic intellectuals.

In order to define the distinguishing elements of this organic character, the conditions necessary for the formation of organic intellectuals are of central importance. Where the production of traditional intellectuals is contingent on their connection to previously dominant forms of social thought often expressed through specific occupational and professional connections, organic intellectuals instead emerge alongside and from within new forms of social consciousness. In this way, organic intellectuals do not possess the same obligations to existing modes of production and therefore cannot be characterized as the historical remnants of previous social forms. Rather, their organic character can be defined based on the connection and representative function to advance

a particular set of philosophical ties, which for Gramsci are attributed to the social class that they seemingly represent.⁵⁹

However, directly translating Gramsci's emphatic use of class as a defining characteristic is problematic given the lack of clearly differentiated class roles assumed by scientists. The organic character of intellectuals within science can instead best be attributed to the development of a distinct ethos that can be seen to inform and guide the behavior of individual scientists. In this way, where Gramsci envisions each social class to possess the ability to organically produce its own intellectual strata, this same function can be applied to science by extending the concept of class to apply to the competing normative structures that guide the creation of scientific knowledge. By doing so, the concept of class is able to transcend a simple reflection of the organization of the more material means of production envisioned by Marx and embraced by Gramsci. This provides a more accurate description of the social organization of science by recognizing competing ideals and understandings with respect to the optimal means of production pertaining to the creation of scientific knowledge. Class as a theoretical concept therefore becomes a means of describing not just the relation of social groups to the means of production, but also the organization of different ideas and normative values alongside their accompanying groups concerning to the logistical operation of science itself. Envisioning class in this manner reflects the same analytical purpose intended by Marx as a means of describing the organization of productive forces but does so in a manner that can be applied to the production of scientific knowledge.

⁵⁹ Hoare and Smith, "The Intellectuals: Introduction," 3.

The importance of this fundamental relationship allows organic intellectuals to represent the ideas of a particular class or related ethos they actively represent, rather than those necessarily imposed by existing social and cultural structures. This allows organic intellectuals to act as the progressive catalyst to promote social change by championing the creation and promotion of counter-hegemonic structures through the elaboration of a new form of thinking defined by particular class interests. As Gramsci notes:

It can be observed that the "organic" intellectuals which every new class creates alongside itself and elaborates in the course of its development, are for the most part "specialisations" of partial aspects of the primitive activity of the new social type which the new class has brought into prominence.⁶⁰

It is the purpose of these intellectual specializations that serve to organize new forms of social consciousness that allows a particular social class or set of ideals to then be elevated into a coherent understanding of ones' material surroundings. Without the involvement and continued connection to a particular class or scientific ethos, as is the case with traditional intellectual activity, the creation of new philosophical and social forms is not possible leaving intellectual activity to simply reinforce and cement the existing array of dominant social and cultural practices.

While the organizing capacity of organic intellectuals is a necessary component to foster the development of counter-hegemonic social and cultural forms, it is important to note that such actions do not necessarily align with particular political viewpoints. In other words, the organizational and leadership capacities of organic intellectuals do not

⁶⁰ Gramsci, *Selections from the Prison Notebooks*, 6.

possess any particular innate normative or political values. Rather, their actions serve to organize the strict elaboration of a particular set of beliefs and philosophical ideas extended by a particular class that presents a novel philosophical outlook beyond that expressed by the existing hegemonic structure. For Gramsci, it is the underlying social relations that serve to determine the normative values imbued in a particular counter-hegemonic viewpoint rather than the function of intellectuals alone. However, the importance of such normative attachments to the theoretical usefulness of the organic intellectual is at best secondary to the primary purpose they serve. Regardless of the political affiliations or normative values held by a particular class, the end result of any form of counter-hegemonic action is to replace existing hegemonic social and political structures with the specific ideas elaborated by the organic intellectuals they raise up. As a result, no matter the political affiliations held by a particular class and the organic intellectuals they create, the end result and underlying process remains the same.

Successfully replacing hegemonic social and cultural practices with those presented in a counter-hegemonic fashion cannot be achieved by relying solely on the function of organic intellectuals. While the organizational and leadership capacities of the organic intellectuals form the initial spark allowing for the formation of counter-hegemonic thought, its successful ascendancy into a place of social and cultural dominance is predicated on the ability of a class or way of thinking

to assimilate and to conquer 'ideologically' the traditional intellectuals, but this assimilation and conquest is made quicker and more efficacious the more the

group in question succeeds in simultaneously elaborating its own organic intellectuals.⁶¹

Thus, the emergence of a new hegemonic form is not predicated solely on the elaboration of a new way of thinking but also on the ability for this way of thinking to disperse itself amongst prominent social actors and institutions. In this way, the promotion of a new counter-hegemonic philosophy is characterized in a similar fashion to that of existing hegemonic practices. In both cases, the development of counter-hegemonies and the entrenchment of existing hegemonic practices are dependent on the ideological conversion of principal agents who subsequently act to disperse and solidify particular philosophical points of view. In this way, the success of a counter-hegemonic struggle can be viewed as the potential transition from counter-hegemony to hegemony itself provided that traditional intellectuals who underpinned previous hegemonic social and cultural arrangements intrinsically adopt these new philosophical tenants.

It is by expanding the understanding of hegemony into the ideological and cultural realm that allows Gramsci's theoretical contributions to be applied so that it becomes possible to understand the social development of particular scientific cultures and their governing normative frameworks. In this way, the theoretical concepts proposed by Gramsci in many ways complement and help supplement those put forward by Merton. Where Merton offers the foundations by which to understand the underlying social context of science exemplified by a distinct normative structure, the theoretical concepts offered by Gramsci pertaining to the role of intellectuals and the formation of

⁶¹ Ibid., 10.

cultural hegemonic social practices offer a means by which to conceptualize how particular norms come to be accepted as the representative portrayal of a general philosophic conception of science. Gramsci in this sense lends added theoretical credence to a framework grounded on Mertonian norms by offering the ability to understand not only the role and purpose of norms, but also how they emerge and become rooted in social consciousness through the formation of common sense and the social function held by both traditional and organic intellectuals. Where the concepts advanced by Merton are able to describe the social state of science in a static sense, the additions offered by Gramsci lend a certain sense of historicity with their ability to examine changing trends associated with social consciousness. By combining the theoretical insights advanced by both thinkers it becomes possible to formulate a set of theoretical tools capable of examining the means and motivations behind the construction of a new scientific ethos and the accompanying values that serve to guide corresponding scientific action.

2.4 Synthesizing a Neoliberal Ethos of Science

Acknowledging the norms that inform the current iteration of science do not reflect those of the Republic, it becomes necessary to examine the formation of a new ethos of science and its accompanying normative structure. Analyzing this new ethos of science requires utilizing a theoretical framework that draws on the insights offered by both Merton and Gramsci in order to understand not only how new norms come to demarcate acceptable scientific practice but also the processes that have privileged their capacity to guide scientific action. By examining both the production of norms and their resulting social function, a theoretical framework informed by both Merton and Gramsci

is able to yield greater insight into conceptualizing the current iteration of the relationship between science and society allowing for the recognition of a new ethos of science consistent with neoliberal ideals.

This new form of neoliberal science can be linked to the growth of neoliberal ideology and the resulting empowerment of markets that has occurred since the 1980s. While science regardless of its normative structure is focused principally on the creation of new forms of certifiable knowledge, this has not served to isolate it from shifting ideological currents within society. Despite the argument that scientific knowledge is endowed with some form of objective truth, the spread of neoliberalism as a seemingly doctrinal cornerstone of economic and political theory and policy formation has had a profound influence on the ongoing evolution of science. As a result, neoliberal ideology has brought forth its own normative structure that serves to inform and direct what is deemed to be appropriate scientific practice. This so-called normative structure of neoliberal science reflects three of the central tenets of neoliberalism.

The first key element of neoliberal science is the way in which it advances the centrality of markets in all areas of life. As a result, neoliberalism comes to value “market exchange as ‘an ethic in itself, capable of acting as a guide to all human action, and substituting for all previously held ethical beliefs.’”⁶² Consequently, markets come to be perceived as the sole efficient and acceptable means of guiding both economic and scientific activity within society such that market exchange comes to define standards of efficiency, accountability, and applicability. By placing such prominent emphasis on the

⁶² Harvey, *Brief History of Neoliberalism*, 3.

centrality of markets, neoliberalism advances a number of interrelated assumptions that ultimately reinforce this core belief in market exchange.

These assumptions function to secure the legitimacy of the market as a sole means of decision making within neoliberal science. In order to achieve this, neoliberalism facilitates the reconstitution of success by altering the way in which decisions and their resulting outcomes are measured. This entails decision-making is seen as efficient and productive only in instances that conform to the underlying logics of market exchange. In this way the purpose of the market exchange within a scientific context functions to produce an optimal means of processing new information whereby the market functions not only as the means to distribute material goods, but more importantly as a means of constructing particular forms of knowledge. Building on the centrality of market exchange, Lave, Mirowski, and Randalls note that:

At an even more fundamental level, neoliberalism reifies the primary function of an ideal economy as a ‘marketplace of ideas’. The fundamental role of the market is not, according to neoliberalism, the mere exchange of things, but rather the processing and conveyance of knowledge or information.⁶³

Thus the market assumes a pivotal role in promoting and prioritizing specific forms of knowledge advanced by science within a neoliberal context. As a result, questions surrounding scientific innovation become defined not by a grander pursuit of certifiable knowledge, but instead by their orientation, and subsequent ability to satisfy market expectations. This realignment of decision-making within neoliberal theory is deemed justifiable given the core assumption that markets act as the optimal method of

⁶³ Lave, Mirowski, and Randalls, “Introduction: STS and Neoliberal Science,” 662.

organizing all forms of human activity due to their intuitive promotion of competition and free choice.⁶⁴ Given this innate sense of efficiency purported by markets, the social structures responsible for guiding scientific decision making come to conform to both market-oriented processes and the resulting outcomes they entail that exist at the core of neoliberalism.

This harmonization of scientific decision making with market-oriented outcomes is deemed to promote an underlying sense of accountability within science. Science therefore becomes measured not by its ability to contribute to the archives of knowledge, but instead based on its perceived commercial value and potential contribution to the marketplace. In other words, the emphasis on market-oriented decision-making within neoliberalism serves to restructure the boundaries of scientific knowledge by shifting their focus away from the production of knowledge for its own sake and towards the production of knowledge whose value can be determined by the market. By doing so, neoliberalism “fosters (and privileges) forms of science that are accountable to [...] the financial ‘bottom line’”⁶⁵ set out by market-established metrics of success. As a result, neoliberal science comes to internalize and reflect the innate values that prioritize commercial success and allow scientific progress to be guided increasingly by the potential ease of a discoveries future commodification and resulting sale. This process of commodification serves as one of the principle elements to ensure neoliberal science is

⁶⁴ Larner, “Neo-liberalism: Policy, Ideology, Governmentality,” 5.

⁶⁵ While the label of ‘hypercapitalism’ is used by Cannella and Miller to describe this process, it highlights many of the same dynamics as neoliberalism. For a more detailed account see Cannella and Miller, “Constructing Corporatist Science,” 25.

held accountable to the market while simultaneously acting to sustain the very concept of a knowledge economy.⁶⁶

The potential for scientific knowledge to be readily commodified serves to reinforce a requisite need for market accountability as mandated by neoliberal science. In addition to the potential financial returns, market accountability implies that science is seen to possess a sense of applicability. Applicability in this manner serves to promote the development of tangible product oriented discoveries that can be readily translated to forms suitable for commodification and later market exchange. In this way, neoliberal science possesses a decidedly material outlook of scientific discovery such that it becomes a preferred “route for constructing new products for the market.”⁶⁷

Each of these measures serves to privilege and prioritize the market as a principle means of influencing decision making within science while also redefining what is deemed to be appropriate scientific knowledge. Satisfying the metrics of market accountability and applicability functions to alter the scope of scientific activity such that the knowledge it creates is only appropriate and proper when it is deemed economically useful.⁶⁸ Such judgment serves to artificially constrain the scope of scientific activity and discovery whereby science comes to be defined predominantly by market success and less by the pursuit of certifiable knowledge. As a result of placing markets at the center of scientific activity, science increasingly comes to reflect a decidedly neoliberal set of guiding principles and objectives and comes to reflect the particular structural imperatives capable of realizing these goals.

⁶⁶ Nedevea and Boden, “Changing Science,” 272.

⁶⁷ Cannella and Miller, “Constructing Corporatist Science,” 34.

⁶⁸ Nedevea and Boden, “Changing Science,” 271.

These principles and objectives are further tempered by the second key element of neoliberal science. In addition to the empowerment of markets and the resulting impact on decision-making and accountability in science, neoliberalism is also premised on the construction of individuals as rational actors who seek to advance their own personal self-interest, liberty, and freedom above all else. Analogous to the effect that empowering markets has in structuring decision making, the rational pursuit of liberty and freedom serves to define and reconstruct individuals into ideal neoliberal subjects whose actions are guided by the relentless pursuit of their own seemingly rational self-interests.

The construction of the neoliberal subject is inherently tied to the core assumption previously outlined concerning the empowerment of markets. With markets acting as the primary means of ensuring individual freedom and replacing society as the primary means of managing social interaction, individuals are left to act on behalf of their own rational self-interests.⁶⁹ These individual actions in turn are managed through competitive market transactions that are seen to yield optimal results for all parties involved. While this may appear to enhance the apparent freedoms of each individual, the reliance on the market as a central means of conveying the wants and desires of an entire population serves to reduce each rational transaction made on behalf of an individual into nothing more than a series of market exchanges. This allows neoliberalism to effectively reconstruct individuals as singular entrepreneurial actors whose entire lives come to be driven and defined by the market transactions in which

⁶⁹ Harvey, *Brief History of Neoliberalism*, 7.

they willingly participate.⁷⁰ Thus in a similar fashion to how markets delineate the boundaries of appropriate decision-making within science, individual experiences as neoliberal subjects become defined by a similar entrepreneurial mentality consistent with the supremacy of the market.

Accordingly, neoliberal science embraces this construction of the individual entrepreneurial spirit by channeling it so as justification to drive the belief that markets provide the most effective means of promoting innovation. Given this endorsement of the innovative capacity of markets, the function of individual entrepreneurs is seen to align with the goals of scientists such that the two roles often become indistinguishable. This has led to the reconfiguration of the (successful) scientist into a new form that augments the more traditional notions of scientific knowledge production with an entrepreneurial drive to commercialize and commodify their discoveries.⁷¹

Reconstituting social relations in this way to solely encompass the individual actions of neoliberal subjects serves to further transfer risk out of a more communal context and into the realm of the individual.⁷² With risk often being addressed in a collective fashion by the state or other communal bodies, neoliberalism instead focuses on reallocating risk onto individuals as a means of encouraging and reinforcing ones entrepreneurial identity. As rational individuals assume the central decision making

⁷⁰ Wendy Brown, "Neo-liberalism and the end of liberal democracy," *Theory and Event* 7, no. 1 (2003): 38, quoted in Davies, Gottsche, and Bansel, "The Rise and Fall of the Neo-liberal University," 307.

⁷¹ Warde refers to the construction of the professor-entrepreneur as a distinct role, a similar process can be seen to extend to individual scientists whose own roles and responsibilities are often either directly involved with, or have been previously involved in academic research. See Ibrahim Warde, "For sale: US academic integrity," *Le Monde diplomatique (English edition)*, March 2010, <http://mondediplo.com/2001/03/11academic>, par. 11.

⁷² Davies, Gottsche, and Bansel, "The Rise and Fall of the Neo-liberal University," 307.

function within neoliberal theory (under guidance from the market), the associated risks accompanying any decision are deemed the responsibility of the individual in question while ignoring the overarching social conditions that determine ones access to necessary information to ensure market transactions truly benefit all parties involved. The resulting failure to recognize asymmetrical flows of information available to each actor due to variable social conditions produces situations whereby risk may be transferred to individuals, but not all individuals may share the same exposure to and level of risk. As such, the transference of risk onto individual subjects while pursued under the guise of individual empowerment does little to promote the additional freedoms that often accompany discourses of neoliberal rationality.

However, the transference of risk onto individual subjects is but a microcosm of a larger process occurring within neoliberalism. This process entails the hollowing out of publicly oriented services and social functions in favor of those provided exclusively by private actors for economic means. Serving to not only reallocate risk out of the collective public and onto private individuals, this process also entails the ongoing concentration of wealth, power, and influence within a neoliberal context. It is this shift from a framework emphasizing the importance of the public to one that valorizes the private, which forms the third key element of neoliberal science. Underpinned by the belief that freeing individuals from the regulatory burden imposed by a public mandate serves to enhance their economic efficiency, methods emphasizing deregulation and privatization have become common policy prescriptions associated with neoliberalism. Justified by the perceived economic benefit such policies are seen to offer, their explicit purpose is not to enhance economic efficiency as is claimed, but instead “to open up new

fields for capital accumulation in domains formerly regarded off-limits to the calculus of profitability.”⁷³

The resulting expropriation of previously public goods by neoliberalism has in turn reshaped the social understanding surrounding the ownership of scientific knowledge. Neoliberal science ceases to recognize the historically public character of science, instead coming to reflect a set of institutional imperatives and organizational mandates emphasizing private ownership. The shift from public to private ownership within the realm of science is achieved through the extension of individual property rights into the intellectual domain. Allowing individuals to claim exclusive ownership over scientific discoveries has fundamentally altered the underlying incentives that guide scientific activity by radically altering the normative structures responsible for delineating acceptable scientific practice. Previously, innovative discoveries were rewarded through the social recognition of a scientist’s contribution while the requisite knowledge was dispersed throughout the community in return for public support.⁷⁴ However, neoliberal science has instead prioritized the potential financial returns afforded by private ownership as the primary incentive fueling scientific innovation and discovery. In this way, neoliberal science defines an ideal form for scientific knowledge that is characterized by its decidedly private character that effectively ignores the long public history of science.

It is important to note that neoliberalism does not present a single unified understanding of any particular activity. Rather it is characterized by a high degree of

⁷³ David Harvey, “Neoliberalism as Creative Destruction,” *Annals of the American Academy of Political and Social Science* 610 (2007): 35.

⁷⁴ Nedeava and Boden, “Changing Science,” 271

contextual variability as part of a broader ideational project. Despite the inherent variation and uneven applicability of neoliberalism as a theoretical concept, it is still possible to identify some of the core guiding principles that come to influence the specificities associated with the development of particular neoliberal contexts. This inherent variability found in neoliberalism is perhaps best articulated by Peck who notes that:

neoliberalism exhibits a context-specific form, with high degrees of path dependency, albeit one keyed into a known – if unevenly observed – set of ideational coordinates. It defines a broad vision and strategic priorities, together with a way to make, interpret and respond to policy ‘problems’, licensing the continuous restructuring of regulatory regimes and the state apparatus.⁷⁵

In this way, the construction of neoliberal science exemplifies but one specific contextual form that shares many common elements with a broader neoliberal project.

Characterized by a particular framework of beliefs and assumptions to underpin its foundational ethos, neoliberal science can be defined as the extension and application of the guiding principles advanced by neoliberal theory to purposefully reshape science through the advancement of a private, market-oriented, individualistic normative structure.

The impact of this shift towards a neoliberal form of science becomes clear when drawing on the normative dimensions of science expressed by Merton, and the function of intellectuals and common sense in constructing cultural hegemonic social orders recognized by Gramsci. Utilizing these theoretical concepts it becomes possible to

⁷⁵ Jamie Peck, “Remaking laissez-faire,” *Progress in Human Geography* 32, no. 1 (2008): 33.

recognize how the concept of neoliberal science can be applied to the current business model of the pharmaceutical industry and the gauge the effectiveness of reactionary policy measures designed to address problems associated with conflicts of interest and the growing corporate influence over the perceived objectivity of medical science.

Applying the concepts outlined in this chapter will help demonstrate that contrary to their intended purpose, the extent of existing policy approaches undertaken by medical journals, which often emphasize disclosure and transparency, have done little to alter the foundational ethos from its decidedly neoliberal standpoint and instead have served to further entrench neoliberal science as the current common sense conception of science.

3 Chapter: Scrutinizing the Pharmaceutical Business Model

Sticking to the present course of action is simply not an option. Those companies which cannot dramatically increase both the number and quality of drugs they produce will go the way of the dinosaurs.

Dr. Steve Arlington,
Head of Pharmaceutical R&D Consulting,
PricewaterhouseCoopers⁷⁶

Pharmaceuticals have come to form one of the principle cornerstones of modern medicine. With the ability to translate scientific knowledge into material therapies, considerable advances in the promotion of patient health and quality of life have served to reinforce the dependence of modern medicine on chemical and biological methods of treating disease. Realizing this social importance has imbued the pharmaceutical industry as a whole with a distinct social purpose whereby public health has come to depend not only on the material products that are produced, but also on the continued capacity to innovate and develop novel treatments. Such innovative capacity is arguably as important, if not more so, than the material products it yields given the ongoing evolution of disease and changing pathology of illness. Innovation in this sense can therefore be defined as the processes responsible for the production of truly novel chemical and biological products, which possess the ability to expand on, or improve the range or efficacy of existing therapeutic options to improve the lives of patients. Given the central

⁷⁶ PricewaterhouseCoopers, "Pharma 2005: An Industrial Revolution in R&D," (Report, 1998): 2, accessed February 28, 2014, http://www.trinity.edu/sbachrac/drugdesign/Drug%20Costs%20Articles/PWC_Pharma_2005.pdf. This report was originally available directly through the PricewaterhouseCoopers website but has since been removed. The included URL is an alternate location to obtain the original report.

role pharmaceutical products have come to occupy in modern medicine, the need to harness the innovative capacity of individual firms has never been greater.

However, in light of the need for the continued development of novel therapeutics, this chapter seeks to outline how the pharmaceutical business model has come to rely less on the real scientific innovation that often punctuates the industries' espoused narrative and instead has come to focus on marketing and promotional strategies to fuel its ongoing financial success. Marketing and promotion has become a central means of differentiating between a growing number of comparable products allowing the pharmaceutical industry to bolster demand in the absence of actual therapeutic gains. Consequently, this has allowed the industries' emphasis on innovation to instead focus on implementing novel marketing strategies such as ghostwriting that seek to leverage conflicts of interest as a means of influencing physicians prescribing habits in order to maximize product revenues.

Understanding the emergence of these marketing strategies as a core element of the pharmaceutical business model requires first problematizing and deconstructing the industries continued focus on innovation and how this emphasis fails to account for the industries continued financial success. By first outlining how the pharmaceutical industry actively utilizes innovation in shaping its public image, it becomes possible to explore how the changing realities of drug development do not correspond to the continued financial success exhibited by the industry. Arising from this discontinuity is a direct need to identify alternate processes responsible for influencing business decisions within the pharmaceutical industry that are able to account for the rising R&D costs and the declining therapeutic value of new medicines. It is by clearly demonstrating the

industries' financial reliance on marketing and promotion that provides the necessary foundation to facilitate a more in-depth analysis as to the rise of particular practices such as ghostwriting in later chapters alongside the subsequent policy measures enacted by medical journals to address the corresponding rise of conflicts of interest.

3.1 Deconstructing the Dominant Industry Narrative

The important function afforded to pharmaceuticals within modern medicine and the resulting emphasis on innovation and the development of novel therapies requires the pharmaceutical industry to satisfy two often-opposing directives. On the one hand, firms face an implied public obligation through added social pressures to provide their products in a timely fashion and at a minimum cost in order to ensure that important discoveries are made widely available to the public. At the same time, the activities of individual firms must also conform to the fiduciary responsibilities that accompany any major corporation. Consequently, this entails that each stage of pharmaceutical production must be organized in a manner capable of satisfying the private obligations imposed by individual shareholders requiring that business decisions be made in a manner that is deemed efficient, cost effective, and above all else, profitable for each firm. As a result, the decisions that underscore the pharmaceutical business model must be predicated on implementing a proper balance capable of satisfying this combination of public and private obligations.

With such a seemingly contradictory set of responsibilities, the pharmaceutical industry has come to occupy an intersecting nexus whereby business decisions must satisfy both public and private obligations. The apparent solution to this conflict lies in the ability of the pharmaceutical industry to satisfy their public obligations by

championing their ability to develop new and more effective treatment regimens that can ultimately command a premium price as a result of patent protection. This reliance on innovation serves to facilitate the construction of a narrative and public image that portrays the pharmaceutical industry as a thriving example of a research centric, knowledge-intensive industry whereby the high prices of branded drugs are deemed a necessary social cost in order to promote the development of novel therapies. Innovation therefore functions as the primary means of satiating the social obligations of the industry by promising future products capable of expanding the range and improving upon the efficacy of available therapeutic treatments in exchange for temporarily higher prices to offset the costs associated with such clinical advances. This promise of innovation serves to effectively bridge the gap between the industries' public and private obligations by facilitating an exchange that seemingly benefits all parties.

The success of this commitment to innovation is ultimately dependent on successfully altering public perceptions regarding the industries' daily operations that lie in stark contrast to the realities of their core business model. This process entails actively reinforcing the dominant narrative that maintains the pharmaceutical industry is chiefly concerned with facilitating R&D above all else so as to produce a continually evolving array of novel therapeutic drugs. As a result, this core emphasis on innovation has become accepted as the dominant activity of the pharmaceutical industries' public image, whereby the industries' future growth and continued success is contingent on successfully harnessing the innovative capacity of individual firms. This in turn reinforces a public narrative offered by the pharmaceutical industry whereby innovation is not only portrayed as the key activity of the industry, but also as a predominant

institutional objective capable of guiding and influencing the specific business decisions made on behalf of individual firms.

However, the centrality of R&D as a core component of the branded pharmaceutical business model is less of a factual reality than a means of favorably shaping the regulatory terrain on which the industry operates.⁷⁷ In reality, innovation has become less an objective of the industry, and instead a crucial discursive element functioning to privilege the pharmaceutical industries underlying financial motivations by acting to justify the premium prices commanded by branded pharmaceuticals. Drawing on the discursive power of innovation, the pharmaceutical industry has been able to sway public perception to support more stringent intellectual property protections so long as such changes are believed to aid the development of innovative medicines.

It is this subsequent disconnect between the public perception and the realities of pharmaceutical innovation that become readily apparent when examining the current state of the industry. Citing the high-costs of initial drug development and the low-costs associated with reproducing a discovery, the pharmaceutical industry has been able to draw on its perceived innovative capacity to push for more stringent regulatory assurances that legally enshrine its own ability to extract further financial returns from existing products regardless of the therapeutic value they may possess. While firms have come to portray this activity as a necessary safeguard to offset the financial risks associated with the upfront costs of drug development, the increasing reliance on the extension of time-limited monopoly rights has done little to enhance the state of

⁷⁷ Marc-André Gagnon and Joel Lexchin, “The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States,” *PLoS Medicine*, 5, no. 1 (2008): 29.

innovation within the industry. Rather, the promise of innovation (or threat of its absence) has functioned to not only favorably shape regulatory bodies but has provided an effective means of concealing the true business model of the pharmaceutical industry.

3.2 Confronting the Realities of Rising R&D Costs

It has become widely accepted that the costs associated with all phases of the drug development process have become increasingly costly for all parties involved. With these rising costs forming one of the primary justifications to impose more stringent intellectual property legislation, their impact on the long-term financial viability of drug development is well recognized and accounted for by the pharmaceutical industry. As a result, the oft cited \$802 million price tag to successfully develop and bring to market a new molecular entity (NME)⁷⁸ has been frequently revised, and now sits at an estimated \$1.32 billion, a 64 percent increase from 2000 to 2006.⁷⁹ While the accuracy of these estimates has been met with scrutiny, there is sufficient data to demonstrate continued growth in the costs of drug development even in the absence of a more precise figure.⁸⁰ As a result of the continued growth in costs related to drug development, pharmaceutical firms face added financial pressures to not only maximize the financial returns on the

⁷⁸ The Food and Drug Administration (FDA) defines a new molecular entity as “an active ingredient that has never before been marketed in the United States in any form.” This definition therefore entails a certain sense of novelty for these particular drugs. See U.S. Food and Drug Administration, “FDA Glossary of Terms,” last updated February 2nd, 2012, <http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm#NewMolecularEntity>.

⁷⁹ PhRMA, “Pharmaceutical Industry Profile 2009,” (Washington: PhRMA, 2009) referenced in Donald W. Light and Rebecca Warburton, “Demythologizing the high costs of pharmaceutical research,” *Biosocieties* 6, no. 1 (2011) 36.

⁸⁰ Similar criticisms regarding these figures have been raised by not only Light and Warburton but also by the former editor-in-chief of the *New England Journal of Medicine* Marcia Angell. However, through a systematic review of additional estimates, Morgan et al. are able to offer a more generalized historic outlook on the costs in the absence of more precise estimates concluding that no precise standard currently exists. See: Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* (New York: Random House, 2004); Steve Morgan et al., “The cost of drug development: A systematic review,” *Health Policy* 100 (2011): 4-17.

select products that ultimately receive regulatory approval, but to also ensure that there remains a continuous supply of new drugs in development.

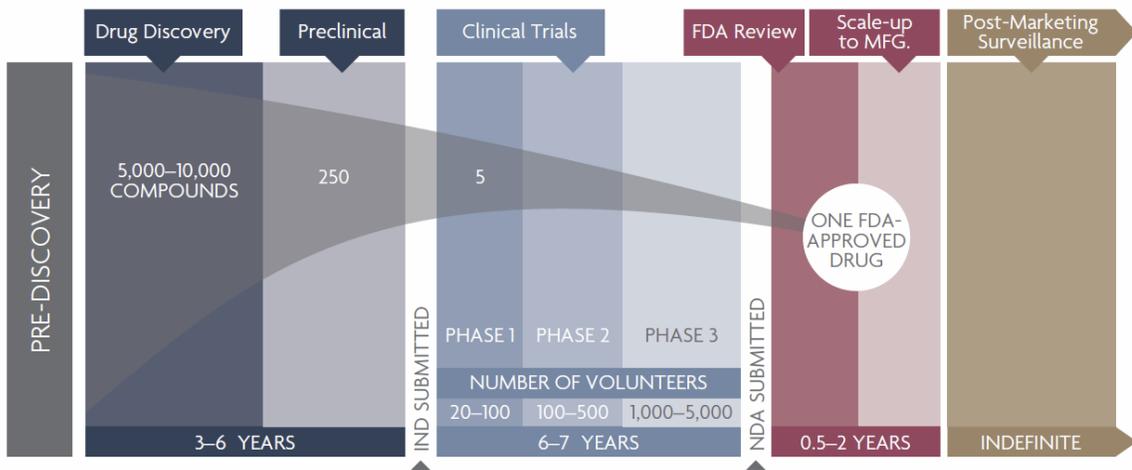
Ensuring that firms are able to fully utilize this so-called ‘pipeline’ (see Figure 1) has become a crucial method of combating rising drug development costs. Referring to the various stages each prospective drug must complete before receiving regulatory approval, navigating the pipeline requires not only a substantial monetary commitment from firms, but also a significant amount of time spent in each of the pre-clinical, clinical, and post-clinical phases.⁸¹ With the average drug requiring between ten and fifteen years of clinical testing and regulatory review prior to being granted approval for sale in the United States, there is a significant upfront investment required before a potential discovery can even begin to realize a financial return for its respective firm.⁸² While this period of clinical testing is unavoidable, the ability for a firm to maximize its potential profits depends on the continual utilization of its full R&D capacity. Idle resources allocated to R&D translate into costly delays when bringing a potential drug to market resulting in reduced periods of market exclusivity and lower earnings potential. To avoid this, a continuous supply of potential drugs is necessary in all phases of the pipeline in

⁸¹ While the pre-clinical phase is broken down into both the drug development and preclinical testing to assess the initial safety of a drug, it is helpful to refer to this entire phase of drug development as a pre-clinical phase due to the lack of testing on human subjects. While it is important to acknowledge that preclinical testing has a specific function, the lack of focus on this portion of the drug development process allows for it to be considered alongside the initial drug discovery process to constitute a broader pre-clinical phase.

⁸² Pharmaceutical Research and Manufacturers of America, *Drug Discovery and Development: Understanding the R&D Process*, (Washington: PhRMA, 2007), available at http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf; Marc-André Gagnon, “The Nature of Capital in the Knowledge-Based Economy: The Case of the Global Pharmaceutical Industry” (PhD diss., York University, 2009): 103.

order for the industry to actively utilize the full extent of its R&D capacity and maximize the potential financial returns available to individual firms.

Figure 1: PhRMA R&D Process Chart



Source: Pharmaceutical Research and Manufacturers of America, “Drug Discovery and Development: Understanding the R&D Process,” (Washington DC: PhRMA, 2007). Available at: http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf

However, filling the pipeline with prospective drugs is not necessarily as straightforward as it seems. While such measures require a continual stream of chemical and biological compounds to evaluate, the number of compounds that successfully pass through the pre-clinical phase onto actual human clinical trials is quite small with each subsequent phase of clinical testing screening out even more prospective compounds. With each successful compound that is approved for sale representing only a small fraction of those under consideration in earlier phases of drug development, the infrequent success of having a potential drug receive regulatory approval has come to condition the expectations that arise from the pipeline itself. As a result, while the

pipeline continues to maintain its focus on promoting drug discovery, it has done so by primarily “favor[ing] the development of ‘successors’ to existing drugs, instead of radically new medicines.”⁸³ Narrowing the focus to the short-term, the development of successor drugs serves to establish an enhanced sense of certainty in the drug discovery process by offering quicker and more predictable development timelines alongside more reliable financial returns.⁸⁴ This certainty, while financially beneficial for the industry, comes at the direct expense of the more socially oriented therapeutic goals and innovative focus intrinsic to the development of new medicines.

Even with the pipeline favoring those drugs that offer a quicker development trajectory, it still takes considerable time and money to satisfy the regulatory requirements involving clinical testing. While the time spent on randomized clinical trials offers a systemic means by which to evaluate the safety and therapeutic efficacy of new medicines, it is difficult for firms to place an explicit financial value on such benefits. Locating these benefits becomes even more difficult when confronted by the growing costs associated with clinical testing itself. According to the most recent internal survey conducted by the Pharmaceutical Research and Manufacturers of America (PhRMA), the association representing leading pharmaceutical companies in the United States, the costs associated with the clinical testing phase of drug development now account for over half of the R&D budgets of their respective members.⁸⁵ The extent of

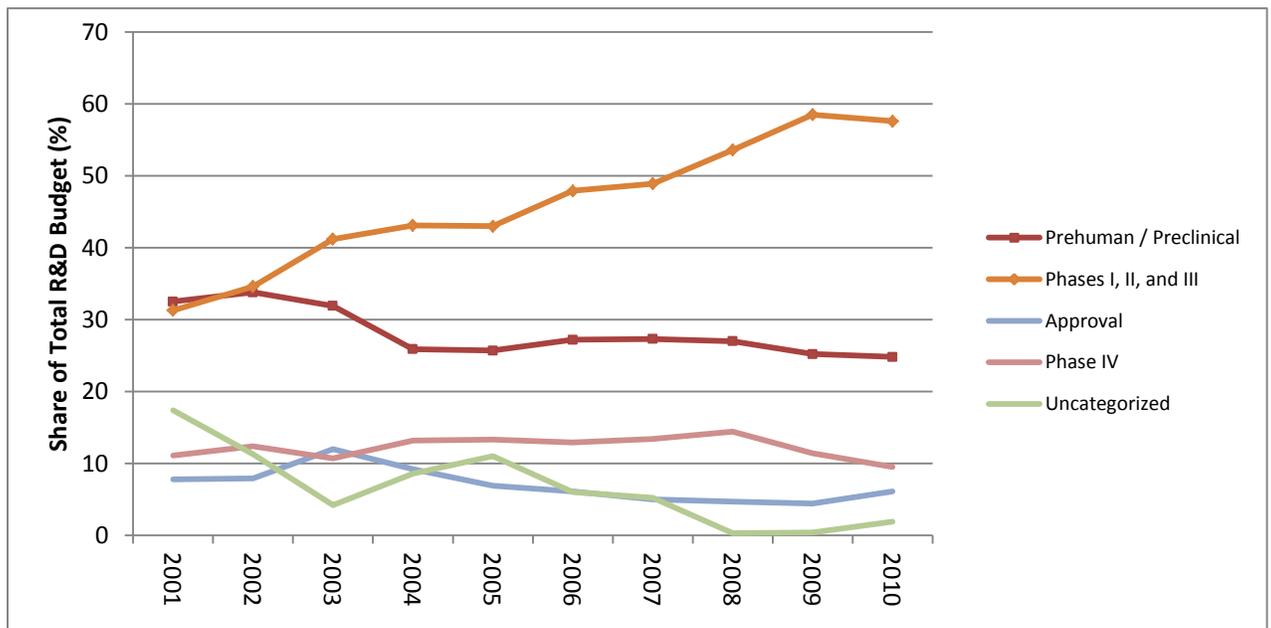
⁸³ Gagnon, “The Nature of Capital,” 105.

⁸⁴ Bernard Munos, “Lessons from 60 years of pharmaceutical innovation,” *Nature Reviews Drug Discovery* 8 (2009): 966.

⁸⁵ PhRMA, *Pharmaceutical Industry Profile* (Washington: PhRMA, April 2012). While the PhRMA survey also includes data for Phase 4 clinical trials, it is important to note that these trials take place after marketing approval has already been granted and is intended to gather additional information regarding

this increase however becomes even more pronounced when examined alongside the costs associated with other phases of the drug development process. As seen in Figure 2, while the industry has been able to reduce many of the costs associated with drug development, there has been continued growth in expenditures allocated to clinical trials. Accordingly, while total R&D costs may be rising, it appears that the extent of such increases has largely been isolated to those costs associated with the clinical testing phase of drug development with the most pronounced increments coming from Phase III trials.

Figure 2: R&D by Function, PhRMA Member Companies: 2001-2010



Source: PhRMA Industry Profiles 2003-2012.

safety and therapeutic efficacy of the drug in question. As such, given their irrelevancy for securing regulatory approval, these trials have also come to function as an extension of the marketing efforts of the industry by helping to popularize newly launched drugs. As such, despite being labeled as a phase of clinical testing, they are not included in the calculations for the clinical phase of drug development. For a more detailed explanation outlining the role and purpose of Phase 4 trials see Angell, *Truth About the Drug Companies*, p. 161-66.

It is difficult to point to any single factor that offers a complete explanation concerning the growing costs associated with RCTs. Navigating the intricacies of the drug discovery process involves negotiating a complex range of factors each of which has a direct impact on how individual trials are run and their definitive financial cost. As such, it is necessary to explore a range of potential explanations to account for the rising costs associated with RCTs. One common explanation revolves around the theory that medical research is dealing with increasingly complex and chronic medical problems that require equally complex and therefore costly solutions. For this reason, “[c]urrent areas of unmet medical need are increasingly those in which diseases are more complex and more difficult to understand and control, and drug targets more difficult to attack.”⁸⁶ However, this also influences the degree to which clinical testing is necessary for a drug to receive marketing approval. The added complexity of a potential drug may require further trials that are larger in size or longer in duration to successfully satisfy the individual requirements set out by regulatory agencies with respect to safety and therapeutic efficacy. This added complexity in turn leads to higher costs and greater time spent recruiting and retaining trial subjects who often constitute an increasingly specific subject population necessary to evaluate the safety and efficacy of the drug in question.⁸⁷

The potential need for additional and more complex RCTs in turn raises another possible explanation to account for the continued cost increases present in the clinical testing phase of drug development. With regulatory bodies such as the Food and Drug

⁸⁶ Iain M. Cockburn, “The Changing Structure of the Pharmaceutical Industry,” *Health Affairs* 23, no. 1 (2004): 12.

⁸⁷ Kenneth I. Kaitin, “Deconstructing the Drug Development Process: The New Face of Innovation.” *Clinical Pharmacology and Therapeutics* 87, no. 3 (2010): 358.

Administration (FDA) in the United States relying entirely on industry funded and managed clinical trial results to evaluate drug safety and efficacy, added public and institutional pressures to ensure greater patient safety may require more precise tolerances in trial findings prior to a new drug receiving final marketing approval. As a result, regulatory bodies may require additional trial data or more complicated trial methods to verify the therapeutic safety and efficacy of new medicines.⁸⁸ Alternatively, this need for more precise trial data may also be the indirect result of the preeminent focus of the pipeline itself in producing successor drugs that offer only marginal therapeutic improvements. With such drugs often requiring larger samples to provide adequate evidence of a therapeutic advance, the focus of individual firms in producing more predictable comparator drugs may present an additional factor to consider when examining the growth in expenditures related to clinical testing.

While the costs associated with RCTs continue to grow and form a more substantial portion of the respective R&D budgets of individual firms, the ability to offset such costs is ultimately dependent on a firms' ability to offer a steady supply of novel therapeutic discoveries. With new medicines expected to represent the primary source of revenue for the industry, the potential to address rising R&D costs is ultimately dependent on the ability of firms to either expand the existing range of available treatment options or to present some form of therapeutic advance capable of improving patient health. It is this underlying innovative quality possessed by new drugs, particularly those offering first-in-class treatments or made available immediately to

⁸⁸ PhRMA, *Industry Profile 2012*, 16-17.

global markets, that enables them to justifiably command premium prices based on the enhanced quality of new drug discoveries.⁸⁹ However, contrary to assurances by the industry that it remains a source of continued therapeutic innovation — a narrative consistent with their established public image — a more critical assessment reveals far more exigent circumstances that would appear to directly impact the long term financial sustainability of the industry.

3.3 Assessing the State of Therapeutic Innovation

Assessing the state of innovation within the pharmaceutical industry requires evaluating the therapeutic potential offered by new drugs when compared to the range of existing treatment options. While new medicines are required to demonstrate their therapeutic efficacy during clinical testing as part of the conditions to receive regulatory approval, such testing only serves to evaluate the efficacy of a new drug versus a placebo and does little to assess the therapeutic value of the drug in question with respect to existing treatment options.⁹⁰ As such, clinical testing when conducted for regulatory purposes offers little in the way of assessing the impact, and resulting therapeutic potential new medicines can offer in terms of expanding or improving upon the range of treatment options available to patients. Rather, all such testing methodology offers is demonstrate that the drug in question does something with little evidence as to the scale or impact it has on patients.⁹¹ Therefore, additional means of assessing the importance of

⁸⁹ Henry G. Grabowski and Y. Richard Wang, “The Quantity and Quality of Worldwide New Drug Introductions,” *Health Affairs* 25, no. 2 (2006): 458.

⁹⁰ Angell, *Truth About the Drug Companies*, 240.

⁹¹ David Healy, “Shaping the Intimate: Influences on the Experience of Everyday Nerves,” *Social Studies of Science* 34, no. 2 (2004): 235-36.

a new drug in terms of its ability to expand or improve upon existing therapies are necessary to properly assess the state of innovation within the pharmaceutical industry.

Despite the failure of clinical testing to offer a systematic means of assessing the quality of new drugs with respect to existing treatments, many of the international regulatory bodies do make attempts to distinguish between drugs offering potential therapeutic breakthroughs and those of lesser social importance. Such differentiation often comes in the form of various categories that selectively demarcate the perceived therapeutic value a new drug possesses at the time marketing approval is granted. In turn, this allows regulatory agencies the ability to gauge not only the therapeutic value of new drugs, but also provide an indirect measure pertaining to the state of innovation within the pharmaceutical industry.

One example of this is the two separate approval streams offered by the FDA that are dependent on the perceived therapeutic value offered by a new drug. Drugs with the potential to provide either a first-in-class treatment or significant improvement upon existing treatment options receive an expedited priority review while all others are subject to the standard review process.⁹² The creation of a priority review system serves to differentiate new medicines based on their perceived quality and potential ability to expand or improve upon the range of existing therapeutic treatments available to patients. It is therefore possible to identify the expected impact a new medicine may have based on which approval process a drug is subject to with priority review status representing

⁹² U.S. Food and Drug Administration, “Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review,” last modified June 26, 2013, <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm#priorityreview>.

medicines that possess a higher perceived therapeutic value than that of the standard review process. As Kaitin and DiMasi rightly point out there has been an increase in new drug approvals receiving priority review (40% to 49%); however this alone does not conclusively indicate that these new drugs are effective in translating the eligibility criteria for priority review into effective treatments for patients.⁹³ Despite having established criteria determining eligibility for priority review, the FDA is still subject to political and social pressures to hasten the approval of drugs making such metrics at best an imperfect assessment concerning innovation within the industry.

Delayed regulatory approval attributed to the standard review process has become a prominent focal point around which political pressure on behalf of organizations such as patient groups mobilize to push for quicker drug approvals and the more generous application of priority review.⁹⁴ Exposing the FDA to this kind of political pressure effectively undermines the validity of utilizing priority review as a metric of assessing the therapeutic value of new drugs. Rather than representing a means of assessing drugs that possess the ability to expand available treatment options, priority review instead comes to represent “how well those who demand drugs can press their case before the agency,

⁹³ Kenneth I. Kaitin and Joseph A. DiMasi, “Pharmaceutical Innovation in the 21st Century: New Drug Approvals in the First Decade, 2000-2009,” *Clinical Pharmacology and Therapeutics* 89, no. 2 (2011): 185.

⁹⁴ It is important to note that many patient groups are heavily funded by the pharmaceutical industry effectively transforming them into lobbyists for their sponsor effectively supplementing their intended advocacy function. See Ray Moynihan and Alan Cassels, *Selling Sickness: How the World’s Biggest Pharmaceutical Companies are Turning Us All into Patients* (Vancouver: Greystone Books, 2005), 61-81; Susannah L. Rose, “Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 680-87; Barbara Mintzes, “Should Patient Groups Accept Money from Drug Companies? No,” *BMJ* 334 (2007): 935.

Congress, the media, and other public fora.”⁹⁵ Consequently, while drugs selected for priority review may still possess the novel therapeutic benefits in line with the criteria originally set out by the FDA, the presence of political pressure increases the likelihood that priority review selections are the result of factors exogenous to the therapeutic benefits offered by the drug under examination.

An additional method of assessing the therapeutic impact of new drugs is possible by examining the categorical assessments offered by the Patented Medicine Price Review Board (PMPRB). Concerned primarily with the regulation of patented pharmaceutical prices and tracking R&D spending within the pharmaceutical industry, the PMPRB offers a categorical assessment of the therapeutic benefits offered by new medicines introduced to the Canadian market. While such categories function primarily as a means to ensure that new drug pricing is comparable to that of existing treatments, these categories also offer a means to qualitatively assess the innovative and therapeutic advances offered by the pharmaceutical industry.

The PMPRB has historically utilized three categories based on the recommendation of a scientific advisory panel as a means of assessing the therapeutic contribution of new drugs. These categories were defined by medicines that were deemed to be comparable to an existing product (Category 1), a new or existing drug seen to offer either a breakthrough or substantial improvement over existing treatments (Category 2), or a new or existing drug that offers moderate, little, or no added

⁹⁵ Daniel P. Carpenter, “The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy,” *Health Affairs* 23, no. 1 (2004): 56.

therapeutic benefit (Category 3).⁹⁶ Since 2010, these categories have been expanded in order to offer a more detailed assessment of the potential therapeutic value of new medicines with new drugs classified as providing either: a breakthrough, substantial improvement, moderate improvement, or slight or no improvement.⁹⁷ As a result, the classifications offered by the PMPRB offer an expanded range with which to assess the therapeutic impact of new medicines by clearly differentiating those treatments that are able to expand and improve upon existing treatment options for patients from those that offer little in the way of added therapeutic benefit.

Despite utilizing the above-mentioned categories as a means of assessing the therapeutic contributions offered by new medicines, the institutional mandate of the PMPRB prevents them from drawing explicit conclusions about the state of innovation within the pharmaceutical industry. As a result, the assessment offered by the PMPRB is limited to the annual totals of new drug identification numbers (DINs) assigned to each category. Simply adopting these numbers at face value serves to under report the significance of drugs deemed to offer therapeutic breakthroughs to patients by artificially inflating the number of drugs classified as either Category 1 or Category 3. The root cause of this problem lies with the assignment of DINs based on the approved dosages of a particular medicine. Consequently, it is common for a single NME to be assigned multiple DINs each corresponding to each separate approved dosage. As such, it is necessary to compile the data offered by the PMPRB in a more selective and prudent

⁹⁶ PMPRB, *Compendium of Guidelines, Policies and Procedures* (Ottawa: Patented Medicine Prices Review Board, revised October 2003), section 3.2, accessed February 28, 2014, <http://www.pmprb-cepmb.gc.ca/CMFiles/2004compendium-e21LTW-152004-1350.pdf>.

⁹⁷ PMPRB, “Compendium of Guidelines, Policies and Procedures,” revised June 2013, section C.5, accessed February 28, 2014, <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1733&all=true>.

manner in order to provide a more accurate assessment concerning the innovative capacity of the pharmaceutical industry within a Canadian context.

The most straightforward means of compiling the data provided by the PMPRB in order to account for the presence of multiple DINs is to purposefully exclude the additional dosages of a particular medicine. By excluding these additional dosages, the data offered by the PMPRB can more accurately reflect the actual therapeutic value offered by new medicines. In order to achieve this, each new drug examined by the PMPRB is included for each individual classification provided that it is not an alternate dosage of an already included medicine with exceptions being made for different dosages that have been granted different therapeutic assessments. The end result is an annual total of new drugs for each therapeutic category utilized by the PMPRB. In addition to ruling out multiple dosages, any drugs deemed by the PMPRB to be Under Review or Investigation and which did not possess an explicit categorization were cross referenced with later annual reports and any matching Voluntary Compliance Undertakings for the drug in question.⁹⁸ This allowed the classification of a number of drugs listed as being either under investigation or review to be categorized based on data made available after the publication of the initial annual report in order to minimize the number of drugs lacking a classification. Utilizing this approach when compiling the raw data provided by the PMPRB, ascertaining a more complete picture as to the therapeutic value of new drugs and the corresponding state of pharmaceutical innovation is made possible.

⁹⁸ A full list of Voluntary Compliance Undertakings is available online from the PMPRB. See “Voluntary Compliance Undertakings,” last modified February 18, 2014, <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=126>.

Adopting a purposefully conservative approach to evaluating the PMPRB's findings, the image of the industry presented is one that is less than promising from an innovative standpoint. This is perhaps most readily apparent with the number of new medicines that successfully satisfy the requirements for a Category 2 classification. As shown in Table 1, between 1992 and 2011,⁹⁹ the PMPRB deemed that only sixty-three drugs have offered a substantial improvement or have been deemed a potential breakthrough to patients.¹⁰⁰ This represents only 5.3% of the total number of drugs examined by the PMPRB during this same period with 449 (37.9%) and 617 (52%) new medicines grouped in Categories 1 and 3 respectively and fifty-seven remaining under review or investigation. While it is unreasonable to expect all new drugs to offer a significant breakthrough to patients, the sheer volume of new drugs deemed to offer only moderate therapeutic improvements presents cause for serious concern given the accepted industry narrative that emphasizes the central importance of innovation.

An alternate measure of pharmaceutical innovation may instead choose to focus solely on the development of new active substances (NAS) as the desired metric to gauge the innovative capacity of the industry. Defining innovation based solely on a NAS entails a broader definition than that utilized by NMEs.

⁹⁹ 1992 was selected as a starting point as it was the first year in which individual categorizations for new drugs was made available through the PMPRB's Annual Reports.

¹⁰⁰ With the PMPRB adopting new therapeutic categories to assess new medicines beginning in 2010, it is necessary to transpose these new categories to fit with those previously utilized. As such, based on the definitions for each category offered by the PMPRB, drugs deemed to offer either a breakthrough or substantial improvement were treated as Category 2 with all others being treated as Category 3.

Table 1: Patented Drug Products Introduced by Year in Canada – Totals Adjusted for Multiple DINs

	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Category 1	16	25	22	22	22	26	28	24	26	22	27	26	43	12	26	19	38	24	1	0
Category 2	12	4	3	1	3	6	2	1	3	3	3	2	0	1	4	3	5	1	3	3
Category 3	28	23	18	30	25	30	29	45	30	19	24	32	35	17	49	20	34	25	40	63
Under Review / Under Investigation	0	0	2	0	0	0	0	0	0	10	13	5	7	4	10	0	1	0	5	0
Total	56	52	45	53	50	62	59	70	59	54	67	65	85	34	89	42	78	50	49	66

Source: PMPRB Annual Reports 1992-2011.

Note: With the PMPRB adopting a new system for classifying drugs beginning in 2010, a decision was made to utilize the previous classifications given the ability to more readily translate the data provided for 2010/2011 to fit with these categories. Drugs classified as either breakthroughs or significant improvements were deemed to satisfy the criteria for Category 2 with all other classifications unless explicitly noted being classified as Category 3. The original totals were as follows:

- 2010: 2 – Breakthrough, 6 – Moderate Improvement – Primary, 2 – Moderate Improvement – Secondary, 30 – Slight or No Improvement.
- 2011: 1 – Breakthrough, 2 – Significant Improvement, 7 – Moderate Improvement – Primary, 9 – Moderate Improvement – Secondary, 43 – Slight or No Improvement, 4 – Category 3.

In addition to recognizing the importance attributed to the initial marketing of the product in question, the definition of a NAS offered by Health Canada also recognizes previously approved products that have undergone substantive alterations such that they require additional safety and efficacy testing among other factors.¹⁰¹ Utilizing this definition presents a more favorable portrayal of innovation given the pharmaceutical industries' penchants for producing therapeutically similar drugs based on minor chemical alterations. Nonetheless, similar concerns surrounding the lack of innovation within the pharmaceutical industry continue to be relevant, albeit to a lesser degree when looking solely at the introduction of NAS within the Canadian market.

Even when utilizing this more stringent means of compiling the data offered by the PMPRB as shown in Table 2, only thirty-eight new medicines were assessed a Category 2 classification between 1993 and 2009 representing 10 percent of all NAS examined during this period.¹⁰² While this may demonstrate that NAS have a greater likelihood of being declared innovative, over 80 percent of NAS remain classified as Category 3 resulting in the vast majority offering little to no added therapeutic benefit over the existing range of medicines available to patients. Consequently, even when compiling the data in a manner to purposefully accentuate the production of Category 2 medicines, the state of innovation within the industry remains unchanged.

¹⁰¹ Health Canada, "Notice of Compliance (NOC) Database Terminology," last updated August 19, 2010, http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/notices-avis/noc-acc/term_noc_acc-eng.php.

¹⁰² The PMPRBs 1992 Annual Report does not explicitly list NAS and only includes the drugs individual categorization. NAS information is first available in the 1993 Annual Report.

Table 2: Patented Drug Products Introduced by Year in Canada - New Active Substances Only

	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Category 1	0	0	0	0	0	1	0	1	2	1	0	0	0	0	0	0	0
Category 2	4	3	1	3	3	2		3	3	2	1	0	1	4	3	4	1
Category 3	15	15	19	18	21	18	29	19	10	19	16	23	15	18	17	14	19
Under Review / Under Investigation	0	0	0	0	0	0	0	0	4	3	0	2	1	6	1	1	0
Total	19	18	20	21	24	21	29	23	19	25	17	25	17	28	21	19	20

Source: PMPRB Annual Reports 1993-2009.

Note: While data is available from the 1992, 2010 and 2011 Annual Reports, there is no specific distinction granted to new medicines actively utilizing a New Active Substance. As a result, these years have not been included.

While NAS may be more likely to produce a therapeutic advance, they remain a small portion of total pharmaceutical production. Examining both the introduction of NAS alongside the introduction of all newly patented medicines to the Canadian market, it is evident that contrary to the pharmaceutical industries common narrative, innovation is far less pronounced than one would expect.

Reinforcing these conclusions are similar findings offered by the independent French medical journal *Prescrire* who conduct annual reviews to evaluate the therapeutic benefits offered by newly approved drugs in France. Drawing on the available literature, expert knowledge concerning particular drugs, and purposeful attempts to ascertain information from unpublished studies sourced from the manufacturers and various regulatory agencies, the reviews offered by *Prescrire* contribute an additional perspective into gauging the therapeutic potential new medicines may offer patients. Utilizing these methods, *Prescrire* assigns new drugs a rank based on one of seven categories, ranging from drugs offering a major therapeutic advance to those that possess the potential to seriously harm patients.

Closely resembling the newly adopted categories of the PMPRB, there are two key points of departure in the set of classifications utilized by *Prescrire*. The first being the utilization of two separate categories for drugs deemed possibly helpful and those that offer nothing new in terms of their therapeutic function. Expanding upon the single category of slight or no improvement (SN) utilized by the PMPRB, the reviews offered by *Prescrire* are better able to recognize the incremental improvements that some medicines exhibit in rare circumstances. The second key difference is the utilization of a supplementary category for drugs deemed not acceptable based on the additional risk

they present to patients while offering no corresponding therapeutic benefit.¹⁰³ By including this additional category, Prescire is able to not only evaluate the therapeutic potential of new medicines based on their ability to expand the existing range of treatment options, but also gauge the efficacy of these same treatments based on a balanced approach to the potential harm they present to patients. Despite these categorical differences, the assessment offered by Prescire shown in Table 3 further challenges the dominant industry narrative that implies innovation, when measured in terms of therapeutic benefit, remains a central element of the pharmaceutical business model.

Culminating from these three separate appraisals, one must conclude that the state of pharmaceutical innovation when assessed in therapeutic terms fails to support the innovation-centric image purported by the industry. The inability for new drugs to improve and expand upon the existing range of therapeutic treatments available to patients serves to raise serious concerns that the therapeutic quality of new drugs is indicative of a systemic failure of the pharmaceutical business model to adequately promote innovation. It is from this realization that serves to problematize what has come to be the dominant narrative espoused by the pharmaceutical industry. Faced with declining productivity and a dwindling number of truly novel medicines, the continued economic success of the pharmaceutical industry requires one to reevaluate the foundations on which it supposedly rests. In the absence of real therapeutic innovation to drive the sale of new drugs, the pharmaceutical industries' continued financial success

¹⁰³ "Prescire's Drug Ratings," *Prescire*, accessed March 4, 2014, <http://english.prescire.org/en/115/540/49140/3136/3133/SubReportDetails.aspx>.

Table 3: Prescrire's Therapeutic Ratings of New Products and Indications 1987-2010

	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Bravo	1	2	2	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	1	0	0	0
A real advance	3	5	1	2	7	1	1	1	3	16	3	2	1	2	2	4	4	0	1	1	2	0	0	1
Offers an advantage	6	8	11	10	9	15	8	12	15	8	12	17	17	11	11	9	5	6	4	8	14	6	3	3
Possibly helpful	11	30	19	12	20	44	15	27	15	25	38	23	20	17	17	18	23	12	20	31	27	25	14	22
Nothing new	23	40	36	38	51	69	61	65	52	85	125	193	165	157	36	35	34	41	38	69	79	57	62	49
Not acceptable	2	5	7	1	3	8	2	6	1	3	0	4	3	9	9	6	7	7	19	17	15	23	19	19
Judgement reserved	5	5	8	4	4	7	4	10	5	16	6	4	9	7	7	0	6	4	2	8	3	9	6	3
Total	51	95	84	67	94	144	91	121	91	154	184	243	215	203	82	72	79	70	84	135	141	120	104	97

Source: Prescrire, "Drugs in 2001: A number of ruses unveiled," *Prescrire International* 11, no. 58 (2002): 60; Prescrire, "New drugs and indications in 2010: inadequate assessment; patients at risk," *Prescrire International* 20, no. 115 (2011): 106.

has instead come to rely on carefully honed marketing strategies capable of enhancing the therapeutic value of new drugs by directly influencing the content of medical literature. It is from this focus on influencing the underlying literature pertaining to new drugs that has allowed strategies such as ghostwriting to assume prominent roles in the pharmaceutical industries' business model and provide a source of revenue that is able to account for the ongoing decline in innovation throughout the industry.

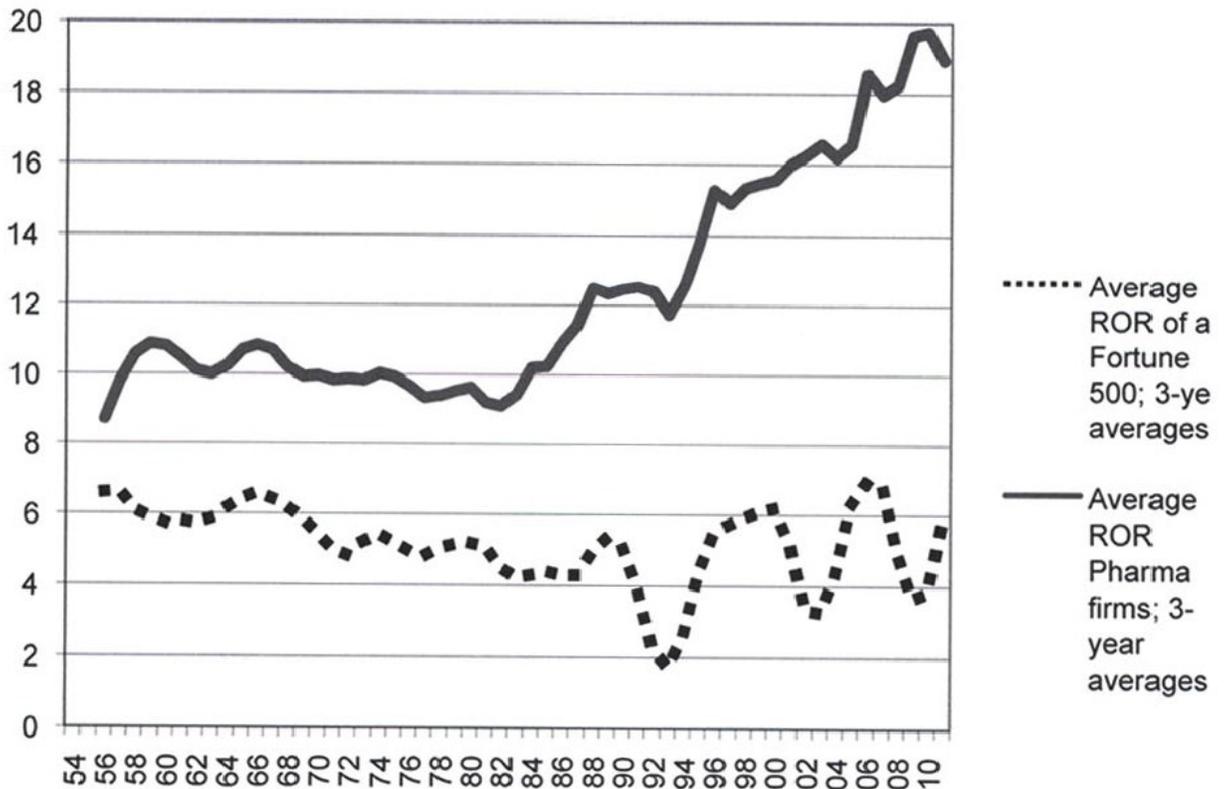
3.4 Reconciling Pharma's Continued Success – Revealing the Industries' True Business Model

If the claim that innovative drugs function as the primary means of generating revenue within the pharmaceutical industry is true, then simple economics would dictate that an increase in costs (primarily with respect to R&D expenditures) without a corresponding increase in revenue (sourced from the production of new drugs) will reduce the net profits of an individual firm. However, the case of the pharmaceutical industry seems to defy conventional economic logic by continually posting not only sizeable, but growing profits despite an apparent absence of new innovative medicines. Confronted by this fact, it becomes necessary to identify additional revenue streams available to individual firms in order to develop an adequate explanation for the industries' continued profitability in light of serious challenges to the long-term viability of their alleged business model.

Historically, the pharmaceutical industry has outperformed other leading sectors with respect to profitability. When the average profits of the 500 largest U.S. companies are calculated, the performance of pharmaceutical firms dramatically outpaces all other

industries combined. As Figure 3 illustrates, beginning in the early 1980s, the average profits of industry leading pharmaceutical firms began to markedly surpass those of the average Fortune 500 firm.

Figure 3: Net Return on Revenues of an Average U.S. Major Pharmaceutical Company Compared with That of an Average Fortune 500 Company (1954-2011, three-year averages)



Source: Marc-André Gagnon, “Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 573.

This exemplary performance by leading pharmaceutical firms is indicative of not only the sizeable earnings capacity of the industry, but also a certain fiscal resilience to the

negative impact associated with rising R&D costs and declining therapeutic innovation. With R&D costs continually compounding over time, the sustained growth of pharmaceutical profits would seemingly point to a source of revenue that is independent of the industries expected focus on innovation and the production of novel therapeutic products.

Without continual therapeutic improvements, individual payers retain little incentive to continue to comply with the premium prices commanded by branded drugs, resulting in increased use and more frequent substitution of cheaper, therapeutically equivalent generic alternatives. As the likelihood of generic substitution continues to rise with a record number of blockbuster drugs facing lapsing patent protection and mounting pressures to reduce healthcare expenditures, it is simply no longer feasible to reconcile the continued growth of pharmaceutical profits with a business model whose primary focus rests on innovation and the production of novel therapeutic products. Rather, in order to explain the continued success of the pharmaceutical industry requires adopting a new set of methods whose financial viability is unaffected by the real threat posed by heightened generic competition and the declining therapeutic contributions offered by new medicines.

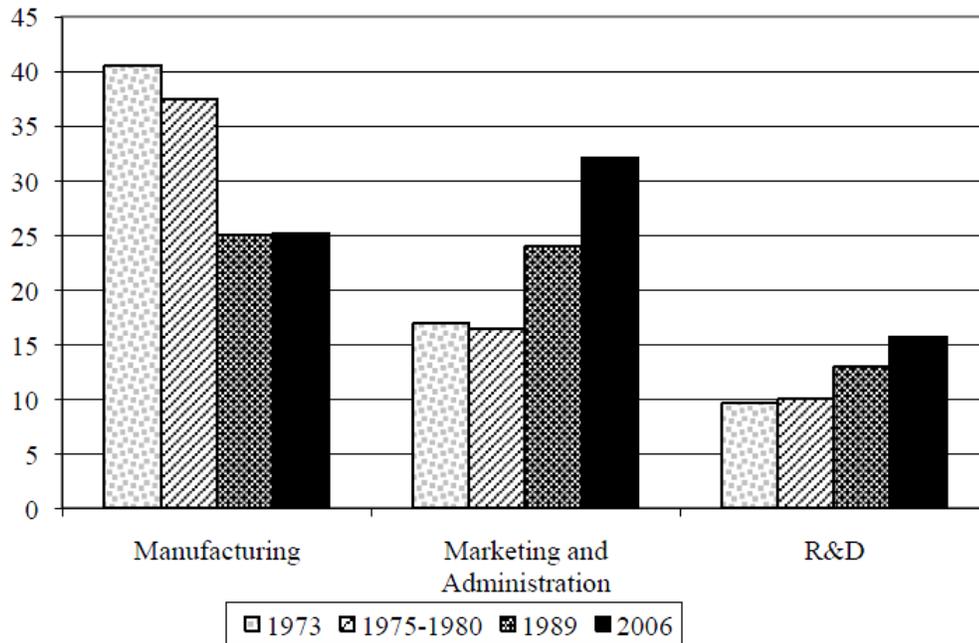
Displacing innovation in this manner is a growing emphasis on the careful construction and dissemination of medical knowledge through the implementation of well-honed marketing and promotional strategies. Designed specifically to maximize the earning capacity of new drugs, these promotional strategies seek to enhance the perceived therapeutic efficacy of new drugs while also downplaying potential adverse reactions in an effort to positively influence the prescribing habits of individual physicians while

building consumer brand awareness. Doing so has allowed the pharmaceutical industry to expand their individual market share while developing new market niches for their products irrespective of the therapeutic value they possess. By utilizing marketing and promotional strategies in this manner, the pharmaceutical industry has been able to develop an additional stream of revenue independent of the costs associated with the traditional drug development process. It is by recognizing the importance of marketing and promotion in the pharmaceutical business model that it becomes possible to offer an explanation of the industries' continued financial success in light of the ongoing challenges presented by an approach reliant solely on innovation.

Functioning as an alternative source of revenue, the use of marketing and promotional strategies has served to redefine what constitutes value within the pharmaceutical industry. No longer is value defined solely by a firms' innovative capacity with respect to the production of novel therapeutics, but is instead based primarily on the successful development of new and more effective methods of honing individual product messages and the ability to reinforce them through the targeted dissemination of supporting 'evidence' across a variety of mediums. As a result of redefining value in this way, the financial success of individual firms has become reliant on their ability to harness and develop marketing proficiencies as opposed to skills more commonly associated with scientific innovation and traditional R&D processes. Expenditures allocated to marketing related activities have come to greatly exceed those earmarked for R&D both in terms of their total value and rate of growth as made apparent by Figure 4. In the U.S. alone this translates to roughly \$61,000 spent per physician on

marketing and promotion, resulting in individual firms now spending almost double what they do on R&D in an effort to positively influence physicians prescribing habits.¹⁰⁴

Figure 4: Changing Cost Structure in Dominant Pharmaceutical Firms (1973, 1975-1980, 1989 & 2006; % of sales)



Source: Gagnon, “The Nature of Capital,” 315.

Rationalizing the scale of these expenditures on marketing is possible by accepting that while pharmaceuticals may possess the capacity to improve the health and well-being of patients, the primary focus of the pharmaceutical industry remains no different from any other business. With the pharmaceutical industries’ paramount concern being the creation of value for individual shareholders by any means possible,

¹⁰⁴ Gagnon and Lexchin, “Cost of Pushing Pills,” 32.

the continued investment in marketing and promotion must logically offer a greater return than comparable investments in R&D related activities.

The result of this growing gap between marketing and R&D expenditures makes it increasingly difficult to claim that innovation remains the core focus of the pharmaceutical business model. Rather, the industries' continued profitability is better explained by recognizing the growing importance of marketing and promotion and the integration of such strategies into the core business model of the industry. Consequently, the industries' continued financial success has become less about novel discoveries and instead about exerting greater control over the development of new forms of medical knowledge. It is through the integration of marketing and promotional strategies into the core of the pharmaceutical business model that has served to not only provide the necessary source of revenue to address declining levels of therapeutic innovation, but to fundamentally restructure the industries' R&D capacity to satisfy the objectives consistent with this new business model. It is by restructuring the R&D capacities of individual firms to reflect this underlying emphasis on marketing that has provided the industry as a whole the necessary means of alleviating the financial pressures stemming from rising R&D costs and declining therapeutic productivity that have come to afflict the pharmaceutical industry.

4 Chapter: Managing and Marketing Medical Knowledge

This is an industry that in some ways is like the Wizard of OZ—still full of bluster but now being exposed as something far different from its image. Instead of being an engine of innovation, it is a vast marketing machine. Instead of being a free market success story, it lives off government-funded research and monopoly rights.

Marcia Angell, M.D.
Former Editor-in-Chief
New England Journal of Medicine¹⁰⁵

As outlined in the previous chapter, marketing and promotion have become necessary measures to ensure the continued financial success of the pharmaceutical industry. With this point established, it becomes possible to begin a more substantive analysis as to what such techniques entail. Alongside the rise of marketing and promotional strategies within the pharmaceutical industry has been a pronounced intensification of conflicts of interest throughout the research process. While conflicts of interest have long been recognized by academics and medical professionals, the resulting issues they pose for the advancement of modern medicine have until recently been largely overlooked by the general public.¹⁰⁶ However, the growing frequency of litigation involving major blockbuster drugs produced by a number of different pharmaceutical companies has produced a renewed sense of public concern surrounding not only the extent to which marketing strategies have been able to influence the objectivity of physicians, but also a greater sense of public scrutiny pertaining to the

¹⁰⁵ Angell, *Truth About the Drug Companies*, p. 20.

¹⁰⁶ A PubMed search utilizing either the terms “Conflict of Interest” or “Conflicts of Interest” shows the first significant mention occurring in 1960 in the journal *Science*. It is not until the 1970s that references to the term begin to exhibit significant growth with the most sizeable increases occurring from 1989 until a peak in 2007.

general business practices of the pharmaceutical industry as a whole. Perhaps the most telling example of such litigation has been the recent plea agreement, and subsequent record setting \$3 billion settlement on behalf of GlaxoSmithKline related to the off-label promotion related to three of its blockbuster drugs: Paxil, Wellbutrin and Avandia.

While this particular settlement involves only those actions undertaken by GlaxoSmithKline, there is no shortage of comparable lawsuits alleging similar actions undertaken by other leading firms in the past.¹⁰⁷ Among the most notable cases have been those directed at Merck (Vioxx), Pfizer (Zolofit), Wyeth (Fen-phen) and Parke-Davis (Neurontin) with each sharing a common focus in that they sought to examine the role and purpose of marketing and promotional practices that played a central role in the commercial success of each drug. Each of these lawsuits and subsequent media attention they attracted has culminated into a renewed sense of public skepticism leveled at the pharmaceutical industry and served to shed added light into the growing prevalence and financial value associated with the marketing and promotional efforts of industry. Consequently, the impact of conflicts of interest has taken on new meaning allowing the very relationships and actions that define these conflicts to become a direct product of a pharmaceutical business model that places a core emphasis on marketing and promotion.¹⁰⁸

¹⁰⁷ For further information regarding the settlement involving GlaxoSmithKline see “GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data,” U.S. Department of Justice, last modified July 2, 2012, <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>. For a more detailed examination of legal settlements involving the pharmaceutical industry as a whole see Sammy Almashat and Sidney Wolfe, “Pharmaceutical Industry Criminal and Civil Penalties: An Update,” Public Citizen, 2012, accessed March 4, 2014, <http://www.citizen.org/documents/20731.pdf>.

¹⁰⁸ References to the pharmaceutical industry refer only to those actions and incentives pursued by the portion of the industry responsible for the production of branded pharmaceutical products. While similar findings may apply to other areas such as the generics industry, they are beyond the scope of this project.

However, in order to fully understand the central importance conflicts of interest have come to play in realizing the continued commercial success of the modern pharmaceutical industry requires first examining the particular context from which they emerge. While there is no shortage of literature exploring the nature and impact of conflicts of interest and the medical profession,¹⁰⁹ much of this literature fails to appreciate the extent to which a neoliberal phase of capitalism has dramatically intensified the existing array of market-oriented incentives at work within the industry. Such incentives serve to transform the underlying normative structure responsible for guiding the very nature of medical research and allow a set of ideological precepts consistent with neoliberalism to become the dominant social conception of science. Realizing this transformation is premised on the purposeful restructuring of medical research and its accompanying normative structure to conform to pre-established marketing strategies whereby both the creation and dissemination of medical knowledge is pursuant to the commercial goals of the pharmaceutical industry. In this way, the very processes guiding medical research become synonymous with the same market-oriented values and ideological imperatives that characterize a neoliberal ethos of science. It is this transformation of medical research that allows conflicts of interest to become viewed as the natural and expected byproducts of the pharmaceutical business model rather than simply insular deviations of accepted scientific practice.

¹⁰⁹ For an in-depth overview of some of the most prominent issues concerning conflicts of interest see Bernard Lo and Marilyn J. Field, eds., *Conflict of Interest in Medical Research, Education, and Practice* (Washington: National Academies Press, 2009), 97-188; Jerome P. Kassirer, *On the Take: How America's Complicity with Big Business Can Endanger Your Health* (New York: Oxford University Press, 2005).

This chapter seeks to contextualize the form and function conflicts of interest have assumed within the modern pharmaceutical business model by outlining how the transformation of medical research to function in an explicit marketing capacity has come to both actively produce, and subsequently rely on conflicts of interest as a defining element of a drugs commercial success. Beginning with an examination of the historical evolution of pharmaceutical marketing and the resulting public scrutiny directed towards more material methods of promotion, it becomes possible to examine how the evolution of pharmaceutical marketing strategies have come to rely the control over medical research through the use of publication planning strategies reliant on ghostwriting as a prominent means of constructing and disseminating new forms of medical knowledge. With this foundation in place it is possible to explicitly define and situate the growth of conflicts of interest and the problems they pose, particularly those related to the rise of medical ghostwriting, as expected outcomes of a distinct set of individual incentives and institutional imperatives that exist at the core of the pharmaceutical business model. The chapter will conclude by briefly outlining some of the responses to conflicts of interest proposed within the existing body of literature and evaluate the limitations such solutions face.

4.1 Historicizing the Evolution of Medical Marketing

Characterizing the form and function assumed by modern pharmaceutical marketing requires first understanding the longer historical evolution of marketing practices within the industry. Recognizing that marketing is not historically unprecedented, it becomes possible to analyze how changes within the social and institutional organization of medical knowledge effectively demarcates distinct periods of

pharmaceutical promotion defined through the utilization of particular promotional strategies. Recognizing this periodization affords one the ability to analyze how the current iteration of pharmaceutical marketing is the product of a distinct set of historical contingencies that have guided its development while conversely functioning to define what are deemed to be appropriate business decisions within the pharmaceutical industry. Thus, it is only by accounting for the historical evolution of marketing and promotion that it becomes possible to understand how its current phase draws on a novel set of strategies with which to exemplify a range of normative values and ideological precepts consistent with a neoliberal conception of science.

While marketing and promotion have come to form cornerstones of the modern pharmaceutical business model, their initial rise to prominence dates back to the period following the Second World War. Between 1951 and 1961, the pharmaceutical market expanded rapidly with the introduction of 4,562 new medicines,¹¹⁰ many of which offered far more targeted solutions than existing treatment options and represented the initial development of key therapeutic categories for treatments involving antidepressants and products to treat hypertension.¹¹¹ These new medicines would quickly come to command the majority of pharmaceutical spending during this period effectively displacing previously available medicines. It was during this period that the economic value of marketing and promotional activities became readily apparent to the pharmaceutical industry by offering a means of differentiating between the growing numbers of available

¹¹⁰ Scott H. Podolsky and Jeremy A. Greene, “A Historical Perspective of Pharmaceutical Promotion and Physician Education,” *JAMA* 300, no. 7 (2008): 831.

¹¹¹ Andrea Tone and Elizabeth Siegel Watkins, “Introduction,” in *Medicating Modern America: Prescription Drugs in History*, eds. Andrea Tone and Elizabeth Siegel Watkins (New York: New York University Press, 2007), 2.

products in an increasingly competitive marketplace. Such differentiation was made possible through a concerted effort by industry for the first time to foster the development of individual brands for specific pharmaceutical products.

Prior to this emphasis on brand development, marketing strategies focused largely on promoting individual chemical names for the express purpose of developing wholesale markets through individual pharmacies.¹¹² However with the passage of the Durham-Humphrey Amendments in 1951 restricting patient access to drugs through the need for prescriptions,¹¹³ the successful development of pharmaceutical brands hinged on the purposeful restructuring of existing marketing efforts to more precisely target and influence the prescribing habits of individual physicians rather than targeting pharmacies alone. Marketing strategies thus began to develop and leverage methods better suited to target individual physicians resulting in a growing prevalence of drug advertisements appearing in medical journals alongside more frequent in person visits to physicians from a burgeoning force of pharmaceutical sales representatives.¹¹⁴ Serving to solidify newly constructed brand identities and offering a means of educating physicians about the availability and therapeutic value possessed by new drugs, the success of pharmaceutical marketing during the post-war period was heavily dependent on the educative role held

¹¹² Jeremy A. Greene and Scott H. Podolsky, "Keeping Modern in Medicine: Pharmaceutical Promotion and Physician Education in Postwar America," *Bulletin of the History of Medicine* 83, no. 2 (2009): 338; Jeremy A. Greene, "Pharmaceutical Marketing Research and the Prescribing Physician," *Annals of Internal Medicine* 146, no. 10 (2007): 742.

¹¹³ Tone and Watkins, "Introduction," 3.

¹¹⁴ Greene, "Pharmaceutical Marketing Research," 742-3.

by the sales representatives or ‘detail men’ who were often viewed by physicians as the most important source of new therapeutic information during the 1950s.¹¹⁵

Over time the primary role of the pharmaceutical sales representative has remained relatively unchanged, despite their daily responsibilities becoming increasingly streamlined and efficient as modern sales representatives “stepped more confidently into those positions so carefully negotiated by early detail men.”¹¹⁶ With the commercial success of individual drugs depending increasingly on the willingness of physicians to prescribe them, realizing a drug’s commercial success came to rely on the ability for pharmaceutical sales representatives to not only educate physicians with respect to the potential therapeutic benefits afforded by a particular product, but to foster the development of deeper social relationships “forged and strengthened through repetitive and calculated acts of giving.”¹¹⁷ Where such acts of giving previously centered on the exchange of knowledge related to physician education, over time such practices evolved to increasingly rely on the dispensation of branded material products such as pens, mugs, and other trinkets alongside industry funded meals, trips, and educational events to help strengthen the pre-existing social relationships between physicians and sales representatives. It is the sense of reciprocity developed through this exchange of gifts that allowed such acts to not only further the development of brand loyalty and product recognition by means of increased exposure of physicians to sales representatives, but to do so in a manner that “creat[ed] relationships and interests on the part of recipient

¹¹⁵ Podolsky and Greene, “A Historical Perspective,” 831.

¹¹⁶ Jeremy A. Greene, “Attention to ‘Details’: Etiquette and the Pharmaceutical Salesman in Postwar American,” *Social Studies of Science* 34, no. 2 (2004): 286.

¹¹⁷ Michael J. Oldani, “Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices,” *Medical Anthropology Quarterly* 18, no. 3 (2004): 332.

physicians that conflict[ed] with their primary obligation to act in the best interest of their patients.”¹¹⁸

The role of the pharmaceutical sales representative has therefore come to involve more than a strictly educative function by engaging directly in the everyday operation of what Oldani terms the pharmaceutical gift economy. With their involvement serving as a means of “limiting and disguising the play of economic interest and calculation that exists at every level of pharmaceutical product promotion”,¹¹⁹ the success of gifting has been dependent on the constructed sense of reciprocity that is developed with physicians through even the most trivial series of exchanges.¹²⁰ Thus, it is the act of “gifting itself, rather than the amount given [that] creates a sense of loyalty and indebtedness”¹²¹ that ultimately comes to shape the relationships between medical professionals and industry representatives allowing gifting to assume a decisive role in the successful realization of the marketing objectives set out by industry. Facilitating both the flow of information from industry to individual physicians while acting as an effective means of influencing and guiding resultant actions, the growth of medical marketing during this period was made possible through the relationships forged with gifts.

Nonetheless, as marketing and promotion became a more prevalent and widespread means of educating and influencing physicians about new therapeutic products, so too did the social criticisms leveled against the pharmaceutical industries’

¹¹⁸ Dana Katz, Arthur L. Caplan, and Jon F. Merz, “All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift Giving,” *American Journal of Bioethics* 3, no. 3 (2003): 42.

¹¹⁹ Oldani, “Thick Prescriptions,” 343.

¹²⁰ Kassirer, *On the Take*, 69-71.

¹²¹ Michael Camilleri, Eric C. Dubnansky, and Anil K. Rustgi, “Conflicts of Interest and Disclosures in Publications,” *Gastroenterology* 132 (2007): 841.

growing influence over the contents of medical knowledge. While a growing number of academic publications began to express serious concerns pertaining to the extent of commercial influence over the professional autonomy of the medical profession, perhaps the most important public challenges came in the form of U.S. governmental hearings between 1959 and 1962. Led by then Senator Estes Kefauver, the ongoing series of hearings sought to initially examine the monopolistic pricing practices utilized by the pharmaceutical industry but was later expanded to target the role and content produced by marketing and promotional strategies.¹²² While the Kefauver hearings represented one of the first public critiques of pharmaceutical marketing, the subject has continued to be revisited with similar hearings led in the early 1990s by the late Senator Edward Kennedy, and more recently in 2010 by Senator Charles Grassley. While the individual issues addressed in each set of hearings have evolved to focus on the specific issues of their time, recurring concerns regarding the prevalence of marketing and promotion to enhance the sale of prescription drugs and the resulting impact such practices have on the objectivity of individual physicians have remained central elements in each of the respective hearings.

In spite of the enhanced levels of public scrutiny afforded by such hearings, pharmaceutical sales representatives have continued to enjoy a prominent place in the marketing strategies employed by individual firms. With a significant portion of firms' marketing budgets remaining allocated to maintaining a sizable sales force, growing public scrutiny has not done away with the pharmaceutical sales representative, but has

¹²² Greene and Podolsky, "Keeping Modern in Medicine," 357-62.

instead forced the industry to adopt novel strategies dependent less on their ability to translate pens into pills.¹²³ Driven by the same sense of materiality, the ready disbursement of highly visible gifts has functioned not only as an effective marketing tool, but also as a rallying point for social criticism of the pharmaceutical industries' use of marketing and promotion as a means of influencing physicians' prescribing habits. In this way, the materiality of gifting has functioned not only as a ready reminder to physicians of their relationships with industry, but has done so in a way that is highly visible and can be readily scrutinized by the public. As a result, the inquiries originating with Kefauver and Kennedy have crystalized into real social momentum spearheaded by groups such as the No Free Lunch campaign¹²⁴ and codified into the legal structures of six U.S. states that have seen significant restrictions placed on the pharmaceutical industries use of gifts in attempts to manage the potentially problematic relationships involving physicians through greater transparency surrounding the actions and involvement of industry.¹²⁵

Although there have been pronounced changes governing responsible conduct concerning the relationships between physicians and the pharmaceutical industry, marketing and promotion remains commonplace with sales representatives retaining a prominent albeit evolving role. While the distribution of more recognizable material gifts

¹²³ Greene, "Attention to 'Details,'" 271.

¹²⁴ The No Free Lunch campaign is a dedicated effort by medical practitioners to embrace an open pledge to not accept gifts and other donations from or on the behalf of the pharmaceutical industry in order to avoid wherever possible potential conflicts of interest. More information about the movement can be found online at the No Free Lunch website, accessed March 4, 2014, <http://www.nofreelunch.org/aboutus.htm>.

¹²⁵ Susan Chimonas, Natassia M. Rozario, and David J. Rothman, "Show Us the Money: Lessons in Transparency from State Pharmaceutical Marketing Disclosure Laws," *Health Services Research* 45, no. 1 (2010): 99.

has been ultimately scaled back to satiate public concerns, the pharmaceutical industry has instead focused on implementing new marketing and promotional strategies better able to hold up to public scrutiny while meeting the range of restrictions now imposed on more material forms of gifting. The result has been the purposeful reshaping of medical research itself to function in an explicit marketing capacity and provide a new avenue of profitability for pharmaceutical marketing strategies. Made possible through the purposeful restructuring of the individual roles and institutional processes governing the research process to conform to the predetermined marketing objectives of industry, the research process itself has now become central to the marketing strategies employed by the pharmaceutical industry. Acting not only as a source of producing new clinical information for physicians, but also providing the resulting method for its dissemination, utilizing the research process as a marketing tool has presented an optimal solution capable of appearing objective while providing physicians with information formerly made available through sales representatives. It is this appropriation of the research process to function in an explicit marketing capacity that can be seen to define the most recent iteration of the ongoing evolution of marketing and promotional strategies employed by the pharmaceutical industry.

4.2 The Restructuring of Medical Research

The ability of medical research to serve as an extension of the pharmaceutical industries' marketing and promotional efforts is premised on the establishment of more complete control over the production and dissemination of favorable forms of medical knowledge. Facilitating this control has been the purposeful restructuring of the organizational processes and individual incentives governing medical research whereby

the intrinsic qualities associated with contract research organizations (CROs) have allowed each phase of the drug discovery process to be successfully tailored to produce medical knowledge in accordance with the marketing objectives imposed by industry. Thus it is through greater control over each phase of the drug discovery process that medical research functioning in an explicit marketing capacity has come to actively produce conflicts of interest by embracing specific corporate strategies such as ghostwriting as a means of ensuring research reflects the imperatives of industry rather than more publicly oriented objectives. Understanding how the current organizational form of medical research has come to function as an integral component of the marketing strategies employed by industry can be effectively broken down into two interrelated elements: those activities related to the production of medical knowledge in keeping with specific marketing objectives, and the related actions pertaining to its subsequent dissemination to a targeted audience in order to maximize economic returns. It is only by recognizing each of these constituent elements that it becomes possible to examine the contextual specificities that define the current form assumed by medical research, and by doing so analyze the significance associated with the rise of specific marketing practices such as medical ghostwriting and the use of publication planning strategies. To this end, it is important to examine not only the way in which the research process has been actively restructured to satisfy the commercial interests of industry, but to recognize how this same process has led to the growing prominence of conflicts of interest through the implementation of specific marketing practices such as medical ghostwriting that signify broader changes occurring within the social organization of science itself.

Successfully translating medical research into a viable marketing tool requires that medical knowledge actively conform to the financial objectives set out by industry. While medical research has always functioned in some capacity as a means of marketing the new forms of knowledge emerging from a laboratory setting, it is the explicit transformation of both the productive and demonstrative qualities present in research to satisfy the commercial marketing obligations of the pharmaceutical industry that has yielded a more direct and controlled approach pertaining to the creation and dissemination of medical knowledge. As a result of this greater control, each stage of the research process is now subject to industry influence ensuring that wherever possible, research outcomes can be readily integrated into a larger strategic marketing plan. It is the extent of control over the research process that affords the pharmaceutical industry the ability to craft and hone not only specific marketing messages, but to do so in a way that also provides the underlying data and supporting clinical evidence that comes to inform and validate such findings. Medical marketing is therefore uniquely positioned given that it is often accompanied by an abundance of supporting scientific data developed through a set of institutional processes that increasingly make use of CROs.

Reshaping medical research to function as an explicit marketing tool has entailed a full reconfiguration of the dominant organizational form governing research within the pharmaceutical industry. In addition to the steady stream of mergers and acquisitions that have come to further centralize corporate power without enhancing the innovative capacities of firms,¹²⁶ the research capacities possessed by individual firms have been

¹²⁶ Gagnon, "The Nature of Capital," 197-242.

realigned to increasingly rely on contract based research organizations as the dominant means of satisfying core elements of the drug development process. Since the 1980s, CROs have become the prevailing means by which to organize pharmaceutical research and conduct clinical trials. As of 1998, CROs were responsible for 60 percent of pharmaceutical research, up from a paltry 20 percent just seven years earlier, a shift that has occurred primarily at the expense of academically affiliated medical research institutions.¹²⁷ Although individual estimates as to the magnitude of this decline vary, there remains a consistent outlook as to the limited role academic health centers will play in conducting industry funded research in light of the growing prevalence of CROs that were projected to handle 90% of clinical research by 2006.¹²⁸ The growing presence of CROs in medical research has produced a highly specialized industry drawing on an estimated \$17.8 billion of revenue in 2007, a figure more than double the nearly \$8 billion valuation offered in 2001.¹²⁹ Such dramatic growth over a relatively short period demonstrates not only that contract research organizations have rapidly emerged as the standardized means of conducting clinical research but have also become critical and socially accepted institutions for the production of medical knowledge.¹³⁰

On the surface, the growth of this contract research model can be seen to correspond directly with the pharmaceutical industries' need to proactively reduce

¹²⁷ David Henry and Joel Lexchin, "The pharmaceutical industry as a medicines provider," *The Lancet* 360 (2002) cited in Ross Brennan, Lynne Eagle, and David Rice, "Medicalization and Marketing," *Journal of Macromarketing* 30, no. 8 (2010): 15.

¹²⁸ For a more in-depth breakdown concerning the estimates of the changing scale of research conducted in academic health centers see Mirowski and Van Horn, "The Contract Research Organization," 506.

¹²⁹ Miriam Shuchman, "Commercializing Clinical Trials – Risks and Benefits of the CRO Boom," *NEJM* 357, no. 14 (2007): 1365.

¹³⁰ The social acceptance of contract research organizations as prominent institutions in medical research is evident by the recent IPO and subsequent public listing on the NYSE by industry leading contract research organization Quintiles on May 8th, 2013.

expenditures stemming from rising R&D costs. Supporting this view is the belief in the direct cost-saving measures afforded through the removal of in-house laboratories and research staff offered by targeted outsourcing measures to shift these functions to less costly alternatives located in CROs. In addition to these measures, the successful adoption of a contract research model was seen to also offer greater efficiencies and the development of organizational advantages established through the creation of “specialized boutique firms offering narrowly targeted outsourcing services.”¹³¹ This highly specialized research function was deemed to offer a viable solution to facilitate added expediency and efficiency throughout the drug development process by employing the ability of CROs to quickly launch new trials or cancel ongoing research projects when necessary. Reducing the time research capacities spent idle, the ability of CROs to sustain a perpetual state of action was seen to present an obvious strategy for reducing the rising costs associated with the drug development process.¹³²

However, while the initial emergence of CROs has focused on their ability to assume highly specialized roles within the research process, over time these roles have evolved significantly expanding both their form and function. While this specialization allowed CROs to offer initial cost savings measures realized through outsourcing, their ongoing development has allowed the pharmaceutical industry to dramatically reduce both the time and costs associated with introducing new drugs to market by offering a more seamless and fully integrated drug development process. This has allowed CROs to now actively participate in all phases of drug development with many of the largest

¹³¹ Mirowski and Van Horn, “The Contract Research Organization,” 505.

¹³² *Ibid.*, 511.

companies acting more as full-service supplements to existing R&D capacities by serving to not only conduct clinical trials, but also developing additional areas of expertise including managing patient recruitment efforts,¹³³ data and statistical analysis services,¹³⁴ and targeted publication strategies.¹³⁵ While these additional responsibilities yield a more integrated and connected method with which to organize the productive structures of pharmaceutical research, the intended purpose of such integration is far from sustaining the economic efficiencies that underpin the more common explanations accounting for the rise of this contract research model. Rather, the development of CROs to offer full-service research services has instead facilitated greater control over the production and controlled dissemination of favorable forms of medical knowledge in keeping with the commercial marketing objectives of the pharmaceutical industry.

Originating with the transition of research out of academic health centers, the ascendance of CROs has facilitated the production of medical knowledge devoid of the institutional constraints imposed by a more traditional academic setting. Where the production of medical knowledge previously emphasized authorship and academic publishing as the desired outcomes of the research process, CROs have instead come to

¹³³ The ability to rapidly recruit clinical trial subjects has been one area of tremendous cost savings offered by contract research organizations. When handled internally within pharmaceutical firms, human subject enrollment presented a serious challenge to the realization of expedited clinical trial results. With the restructuring of pharmaceutical research to rely on the targeted specializations offered by contract research organizations, the rise of pseudo-marketing efforts and identification of “ready-to-recruit” patient populations within clinical trials have offered a seemingly effective solution to this problem. For a far more detailed explanation and analysis regarding patient recruitment efforts and the resulting social issues that arise see Jill A. Fisher, *Medical Research For Hire: The Political Economy of Pharmaceutical Clinical Trials* (Rutgers University Press: New Jersey, 2009), 128-55.

¹³⁴ Robert M. Califf et al., “Task Force 2: Investigator Participation in Clinical Research,” *Journal of the American College of Cardiology* 44, no. 8 (2004): 1731-2.

¹³⁵ Raymond De Vries and Trudo Lemmons, “The social and cultural shaping of medical evidence: Case studies from pharmaceutical research and obstetric science,” *Social Science & Medicine* 62 (2006): 2696; Moffatt and Elliott, “Ghost Marketing,” 19.

locate the core focus of research principally on satisfying the predefined contractual obligations necessary to secure future clients.¹³⁶ Departing from more academically oriented research models allows success to be framed by the external obligations imposed by a contracting party rather than those participants actively involved in the production of medical knowledge. As a result, the success of individual CROs and the individual scientists who they employ is no longer dependent on the scientific merit of the knowledge produced, but rather success, and with it the potential for future research contracts, is instead evaluated on metrics emphasizing issues exogenous to the quality of research being conducted and comes to emphasize elements such as trial subject enrollment rates and the ability to satisfy trial quotas in a timely fashion.¹³⁷ Consequently, the work undertaken by CROs comes to be structured in such a manner so as to actively reinforce the production of medical knowledge capable of conforming to these explicit evaluative metrics whereby the “predominant interest is simply to deliver a product on time and under budget.”¹³⁸ With such obligations determining the future success of individual CROs, the pressures to satisfy the budgetary and temporal constraints imposed by industry come to shape not only the activities of the institutions conducting research, but also condition the research process itself.

It is the underlying distinction between the intrinsic public purpose imbued within medical knowledge and the commercial desires of industry to maximize profitability that allows the dominant role of CROs to provide one of the most succinct and real world

¹³⁶ Mirowski & Van Horn, “The Contract Research Organization,” 530.

¹³⁷ Fisher, *Medical Research for Hire*, 140; Carl Elliott and Amy Snow Landa, “What’s Wrong with Ghostwriting?,” *Bioethics* 24, no. 6 (2010): 284.

¹³⁸ Mirowski & Van Horn, “The Contract Research Organization,” 522.

examples of how conflicts of interest have become a systemic byproduct of the structural changes occurring within medical research. With the intrinsic qualities present in this contract research model requiring scientists satisfy these two often-conflicting objectives, the pharmaceutical industry has been able to successfully leverage its sizable power and influence to ensure that realizing these objectives occurs as part of a larger overall marketing strategy that is well supported with accompanying clinical evidence.

Central to commercial marketing objectives of industry is the need for marketing claims to be supported by an accompanying array of medical knowledge with the most desirable and economically fortuitous being those results generated through RCTs. Portrayed as the principle means by which to validate therapeutic efficacy and ensure patient safety, the intended role of clinical trials is to enact regulatory safeguards while functioning as a springboard for further scientific discovery. Accordingly, clinical trials and the knowledge they generate have become perceived as the most important and reliable form of medical knowledge, a fact that has become well recognized and employed by the pharmaceutical industry.¹³⁹ However, despite their intended purpose, clinical trials have also become a useful tool that can be actively mobilized to fuel therapeutic bandwagons by offering what is deemed to be an unbiased assessment of a drug's therapeutic efficacy and general safety for the express purpose of seeking regulatory approval.¹⁴⁰ As Healy points out, clinical trial results have come to be “sold as evidence that the treatment works (actually does good) rather than evidence that

¹³⁹ Sergio Sismondo, “How pharmaceutical industry funding affects trial outcomes: Causal structures and responses,” *Social Science & Medicine* 66 (2008): 1910.

¹⁴⁰ Healy, “Shaping the Intimate,” 236.

treatments have an effect (which may be put to good use in judicious hands).”¹⁴¹

Consequently, new drugs when backed by clinical evidence have come to possess a therapeutic expectation as a result of clinical testing that may not necessarily reflect the realities of their actual therapeutic value. It is this expectation when attached to clinical evidence that comes to possess tremendous economic value for the pharmaceutical industry by serving as the principle means of evaluating and distinguishing new drugs from alternate treatments. As a result, the evidence generated through clinical trials has become central to the marketing objectives of industry, acting to bolster the therapeutic claims accompanying a particular drug while downplaying potential adverse reactions in order to distinguish between new and existing treatment regimens.

One key element influencing the production of clinical evidence necessary to achieve these goals is the methodological limitations associated with the placebo-controlled trial designs necessary to secure regulatory approval. As RCTs are only able to confirm a new drug yields some measurable effect versus a placebo, there is little evidence offered to ensure long-term patient safety and therapeutic efficacy.¹⁴² This comes to reinforce a systemic bias with respect to the production of medical knowledge capable of satisfying the regulatory requirements necessary to receive market approval but to do so in a way that favors the temporal constraints favored by the pharmaceutical industry. Given that the majority of clinical trials are sponsored and run by, or on the

¹⁴¹ David Healy, “The dilemmas posed by new and fashionable treatments,” *Advances in Psychiatric Treatment* 7 (2001): 322.

¹⁴² Healy, “Shaping the Intimate,” 235-36.

behalf of the pharmaceutical industry,¹⁴³ there are tremendous commercial pressures during the drug development process to prioritize expedited regulatory approval at the expense of long-term safety concerns in an effort to further reduce costs while maximizing the duration of patent exclusivity afforded to new drugs.

Further compounding this issue is the existing practice of relying predominantly on industry to fund such studies. It is well established that there is a direct connection between the source of research funding and the production of results favorable to the funder.¹⁴⁴ As such, it logically follows that with industry funding the majority of clinical trials; trial design will often reflect an innate desire to produce the particular types of knowledge necessary to satisfy the objectives set out by industry. This is made possible by altering “[c]ore aspects of trial design with respect to the choice of comparators, study size and duration, treatment regimens and outcome measures such that results generally favour the sponsored product.”¹⁴⁵ These same issues hold true for those clinical trials that are not directly related to securing regulatory approval and may not necessarily involve a placebo instead choosing to focus on a comparative approach to evaluate the therapeutic efficacy of a new product versus existing treatment options. In a similar fashion to placebo-controlled trials, the pharmaceutical industry continues to be able to

¹⁴³ Nikolaos A. Patsopoulos, Apostolos A. Analatos, and John P.A. Ioannidis, “Origin and funding of the most frequently cited papers in medicine: database analysis,” *BMJ* 332, published May 4, 2006, <http://www.bmj.com/content/332/7549/1061>.

¹⁴⁴ Thomas E. Finucane and Chad E. Bolt, “Association of Funding and Findings of Pharmaceutical Research at a Meeting of a Medical Professional Society,” *The American Journal of Medicine* 117 (2004): 842-45; Joel Lexchin et al., “Pharmaceutical industry sponsorship and research outcome and quality: systematic review,” *BMJ* 326, published May 29, 2009, <http://www.bmj.com/content/326/7400/1167>.

¹⁴⁵ Alastair Matheson, “Corporate Science and the Husbandry of Scientific and Medical Knowledge by the Pharmaceutical Industry,” *BioSocieties* 3 (2008): 359-60.

utilize clinical trials of this variety as a means of producing favorable results. As Moffat and Elliott note:

Drug companies get the results they want not by outright fraud or manipulation of data, [...] but by asking the right questions. For example, a company might conduct a trial of its drug against a treatment known to be inferior, or against too low a dose of a competitor drug (making their drug appear more effective), or against too high a dose of the competitor (making their drug appear less toxic). A company might conduct multi-center trials and select results only from centers that are favorable, or conduct subgroup analyses and select only those that are favorable for publication.¹⁴⁶

Acting to not only serve as evidence of therapeutic efficacy, but to do so in a way that favors a particular product that allows the results of clinical trials to be readily integrated into the marketing strategies laid out by the pharmaceutical industry. In this way, the results afforded by clinical trials provide the evidentiary burden capable of supporting the specific marketing claims intended to enhance the sales and financial performance of newly launched products through the appearance of rigorous scientific validation.

Clinical trials have come to assume the necessary productive function accompanying the rise of medical research as a marketing tool. Acting as a seemingly unbiased method of producing medical knowledge, clinical trials and the knowledge they generate have been elevated to a position of relatively unchecked authority in medical research. Successfully translating this authority into a viable marketing tool however requires more than a tacit acknowledgement that the knowledge produced from clinical trials possesses some economic value. While clinical trials serve as the primary means of generating the necessary scientific evidence supporting pharmaceutical marketing

¹⁴⁶ Moffatt and Elliott, "Ghost Marketing," 27.

strategies, ensuring that such knowledge continues to support the commercial objectives set out by industry requires altering not only the methods of producing medical knowledge and the particular organizational form responsible for its creation, but also the accompanying manner in which this knowledge is disseminated to a wider (and specifically targeted) audience. In other words, while the restructuring of medical research to rely on contract research organizations has afforded the pharmaceutical industry the necessary means of producing medical knowledge to support its marketing objectives, such efforts are ultimately futile if such information never reaches its intended audience.

4.3 Publication Planning - Marketing the Message

While the proliferation of CROs as the dominant organizational form for conducting medical research has introduced a more flexible and compliant laboratory setting to facilitate the creation of new forms of medical knowledge, successfully realizing the full economic value of medical research as form of marketing has required greater coordination and control pertaining to the targeted dissemination of newly constructed medical knowledge. These carefully crafted and coordinated corporate messages have come to replace therapeutic innovation as the primary economic means with which to extract, rather than create new areas of profitability in the pharmaceutical industry. As a result, the industries' emphasis on 'innovation' can better be characterized by the ongoing effort to introduce new and more effective marketing strategies capable of seizing market exclusivity through greater product differentiation and ensuring that new products are not only the first to reach market but do so accompanied by a series of well-timed publications extolling the virtues and benefits of the drug in question.

This new form of ‘innovation’ is not based on therapeutic value and is instead entirely constructed through the controlled creation and dissemination of medical knowledge. With “new drugs consist[ing] primarily of ‘copycat’ or ‘me-too’ drugs: molecules which do not differ very much from previously existing drugs... [and] possessing similar therapeutic benefits”¹⁴⁷, innovation can no longer be defined solely by the ability to develop new drugs, but increasingly by the ability to differentiate these treatments from their therapeutically similar counterparts. The principal focus of this new form of innovation therefore rests on implementing new ways to market what are essentially pre-existing drugs so that they appear to not only possess new therapeutic benefits, but offer a renewed source of financial revenue for the pharmaceutical industry. To this end, the rise of medical research as a marketing tool has depended on the parallel development of so-called ‘publication planning’ strategies crafted by specialized firms that are often owned and operated by larger CROs and publishing companies.¹⁴⁸ Produced by so-called medical education and communication companies (MECCs), publication planning strategies function as the virtual guide with which to chart research progress, coordinate product communiqés, specify target audiences, all while seeking to bolster product demand in order to extract the maximum economic value from newly created medical knowledge.

The primary purpose of such plans according to an internal draft of a publication plan prepared for Wyeth is to provide “the tactical recommendations necessary to

¹⁴⁷ Mirowski & VanHorn, “The Contract Research Organization,” 533.

¹⁴⁸ Sergio Sismondo, “Ghosts in the Machine: Publication Planning in the Medical Sciences,” *Social Studies of Science* 39, no. 2 (2009): 176; Carl Elliott, “Pharma Goes to the Laundry: Public Relations and the Business of Medical Education,” *Hastings Center Report* 34, no. 5 (2004): 20.

develop a scientific platform within the biomedical literature to support the market positioning of an established product or an existing product.”¹⁴⁹ Although the specific strategies to achieve this goal vary based on the market dynamics that accompany a specific product, the common elements of publication planning can be found in the attempt to exert greater control over the production and resulting dissemination of medical research through the integration of all phases of drug development into an overarching marketing strategy. Integrating both the creation and dissemination of medical knowledge into the marketing objectives of individual firms results in communication taking precedence above all else leading to “research [that] is created with publication and marketing in mind”¹⁵⁰ as Sismondo and Doucet rightly recognize. This resulting emphasis placed on communication by publication planning strategies allows MECCs to harness the untapped economic value of scientific publications in an effort to facilitate the dissemination of favorable scientific data in a way that appears not only unbiased and objective, but more importantly reinforces the underlying commercial goals of the product in question. Relying on scientific publications to serve as the principle means of disseminating medical knowledge, the use of publication planning strategies offer a means for firms to mask their explicit marketing efforts and the public scrutiny that accompanies them under the veil of scientific objectivity by relying on accepted institutional safeguards such as peer review and community scrutiny that accompany academic publishing.

¹⁴⁹ OCC North America Inc., “Publication Plan 2002: Premarin/Trimegestone HRT Version 1,” prepared July 19, 2002: 1, <http://dida.library.ucsf.edu/tid/wpc37b10>.

¹⁵⁰ Sergio Sismondo and Mathieu Doucet, “Publication Ethics and the Ghost Management of Medical Publication,” *Bioethics* 24, no. 6 (2010): 275.

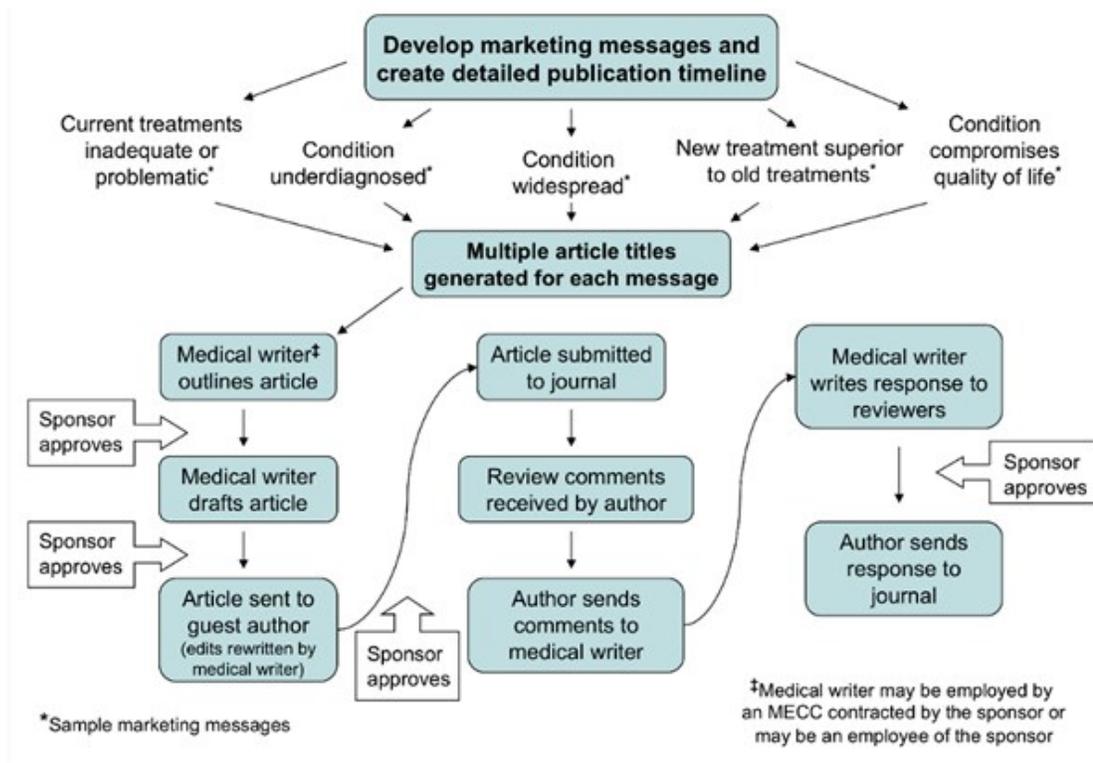
While the intersection of medical research and commercial interests exemplified by the rise of publication planning is in no way a novel development, it is the greater influence afforded by such methods that signifies an important shift within both the conduct of medical research and its corresponding ethos. As Elliott notes, while the involvement of MECCs in medical research may not be new, it is the growing scope of publication planning and the magnitude of such plans' influence over all phases of the drug development process that has been made apparent through litigation that demarcates a new direction in the development of pharmaceutical marketing.¹⁵¹ The growing influence of publication planning on medical research is apparent when looking at the end results of the process. With recent estimates identifying “roughly 40% of articles on recent drugs [being] managed by publication planners,”¹⁵² it is no coincidence that this new direction coincides with the structural reforms that have resulted in the dramatic expansion of contract research as an accepted industry standard.¹⁵³ This transformation has enabled publication planning strategies to draw on the structural flexibility incorporated into CROs in order to exert more direct influence over the research process in order to provide the evidentiary support necessary to support the marketing claims accompanying a particular product.

¹⁵¹ Elliott, “Pharma Goes to the Laundry,” 19.

¹⁵² Sismondo and Doucet, “Publication Ethics,” 281.

¹⁵³ Sismondo, “Ghosts in the Machine,” 176.

Figure 5: The Publication Planning Process



Source: Adriane Fugh-Berman and Susanna J. Dodgson, “Ethical considerations of publication planning in the pharmaceutical industry,” *Open Medicine* 2, no. 4 (2008), <http://www.openmedicine.ca/article/view/118/215>.

With direct involvement from marketing departments now beginning at the earliest phases of the drug development process, the commercial expectations accompanying individual publication plans are well established prior to a prospective molecule even being discovered. Further research into prospective compounds thus becomes contingent on their ability to satisfy commercial marketing goals and structured in such a manner that reflects a consistent focus on advancing key product messages that have been selected based on their appeal to targeted audiences and likelihood of future

publication.¹⁵⁴ Thus, many of the decisions made throughout the research process come to have little relevance with respect to the actual research being conducted and are better described according to Charlton as a form of risk averse project management where decisions are conditioned by external concerns and are unlikely to challenge the status-quo.¹⁵⁵ These concerns are defined principally by the marketing objectives laid out early on as part of publication planning strategies and function to ensure the remaining portions of the research process continue to operate within the accepted framework of the plan itself.

Although the range of activities employed by publication planning strategies may differ throughout the research process, what is important to consider is not necessarily the actions of a specific plan, but instead adopt a more holistic view of the process itself. The function of publication planning is not to define a set of ideal actions that can be uniformly applied to each stage of the research process, but rather to ensure that the entirety of the research process functions to produce favorable forms of medical knowledge that can be used to support and enhance the marketing claims and commercial interests of industry. This is of particular importance given the vital role clinical trials play for physicians when establishing the therapeutic efficacy of new drugs and the highly structured journal publications that announce their results.¹⁵⁶ It is this structure that further emphasizes the need for publication planning strategies to exert control over each phase of the research process in order to ensure that the knowledge produced is not only consistent with the marketing objectives of industry, but also that it will ultimately

¹⁵⁴ Ibid., 175.

¹⁵⁵ Charlton, "Figureheads, ghost-writers," 480.

¹⁵⁶ Sismondo, "Ghosts in the Machine," 190.

meet established standards for reporting clinical trials in medical journals. While such requirements are reduced for other types of publications¹⁵⁷ that remain important to publication plans, the preeminent focus on generating clinical evidence that can support specific marketing claims remains paramount. This importance when coupled with the highly structured manner of conducting and reporting clinical trials necessitates the involvement of publication planning from the beginning of the research process if such strategies are to be commercially effective.

Accompanying the influence of publication planning within the research process is a pronounced effort to also shape the effective demand for a product under development by promoting both pills, and the diseases they treat.¹⁵⁸ Employing the use of educational awareness campaigns backed by a body of supporting literature, these strategies seek to change the way both patients and physicians understand, experience, and approach treatment to particular ailments by presenting either a problem or medical puzzle alongside an obvious solution.¹⁵⁹ The solution presented is the particular product being primed for launch, be it a new or simply modified version of an existing drug; while the problem or puzzle is brought forth from the perceived unmet need of individual patients, the source of which will often stem from marketing efforts that seek to draw attention to the insufficiency of existing treatment options, an ongoing adjustment of the

¹⁵⁷ According to Lexchin and Light, journal supplements have far lower standards regarding their content and thus come to function as a more explicit form of advertising for particular drugs. While such articles offer an additional source of revenue for individual medical journals, they lack the scientific prestige that accompanies direct reports on clinical trial results. See Joel Lexchin and Donald W. Light, "Commercial influence and the content of medical journals," *BMJ* 332, (2006): 1445.

¹⁵⁸ Ray Moynihan, "Doctors and drug companies: Is the dangerous liaison drawing to an end?" *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen* 103, no. 3 (2009): 146.

¹⁵⁹ Healy, "Shaping the Intimate," 221; Matheson, "Corporate Science," 361.

acceptable limits of various biological indicators, the need to manage certain risk factors, and so on.¹⁶⁰ It is through the creation of a problem, and the provision of an effective solution that these activities function to both develop and expand markets for new and existing drugs. In turn, such efforts produce greater fiscal returns for the pharmaceutical industry provided that this expanded demand can be translated into increased prescription volumes of which publication planning plays an integral role.

As previously noted, publication planning relies on the production of supporting scientific evidence as a key element of the marketing strategies produced for specific drugs. This is particularly important considering that individual physicians possess no direct obligation to prescribe a particular brand of medication when treating patients. Thus, while the launch of a new drug may be primed through efforts to expand the effective demand of a product by demonstrating an unmet therapeutic need, this does not inherently lead to a larger volume of prescriptions. With many leading drugs facing significant competition in their respective therapeutic class and physicians retaining the professional autonomy and ultimate discretion when it comes to the products they prescribe, the true test for pharmaceutical marketing strategies is their ability to craft both a lasting brand identity and accompanying sense of physician loyalty to prescribe that particular brand. In other words, while the end goal of publication planning may be to maximize the financial returns from a given drug, this can only be achieved by persuading physicians that the product in question is in some way superior to the range of

¹⁶⁰ Activities such as these are often described utilizing the terminology of ‘disease-mongering.’ For a more detailed discussion about practice and the some of the techniques used see Moynihan and Cassels, *Selling Sickness*; Moynihan, “Doctors and drug companies,” 145-46.

available alternatives and that it can be seen to represent the best available treatment option for their patients regardless of the actual therapeutic value it may possess.

It is therefore necessary for publication planning strategies to not only focus on ensuring the creation of favorable medical knowledge that can support their claims, but to also ensure that this knowledge is made readily available to physicians. To accomplish this, another key area of publication planning is focused on recognizing and employing optimal communication strategies to ensure that favorable clinical knowledge reaches its' ideal audience. Within medical research, the communications strategies employed by publication plans center on their ability to favorably shape the contents of medical journals by ensuring the timely publication of clinically relevant manuscripts. With new claims dependent on the acceptance of the wider scientific community before being seen as valid, targeting medical journals as the means of communicating strategic marketing messages allows publication planning strategies a means of embracing the sense of authority afforded to science by society. Representing a perceived “stamp of approval from its most influential audience... [and] an automatic validation unmatched by any other medium”¹⁶¹, medical journals can be seen to offer publication planners an optimal means by which to not only disseminate knowledge consistent with the commercial interests of the pharmaceutical industry, but to do so in a way that becomes embedded in the socially accepted archives of medical knowledge.

This ability to shape the archives of medical knowledge and by doing so influence physicians attitudes towards particular treatments is dependent on the ability of

¹⁶¹ Adriane Fugh-Berman and Susanna J. Dodgson, “Ethical considerations of publication planning in the pharmaceutical industry,” *Open Medicine* 2, no. 4 (2008): par. 3, accessed March 4, 2014, <http://www.openmedicine.ca/article/view/118/215>.

publication planning strategies to not only craft supporting medical knowledge through the structural reorganization of the research process, but to ultimately disseminate it in such a way that it becomes accepted as the dominant means of understanding a particular drug. To achieve this, the successful dissemination of medical knowledge for publication planning strategies can be reduced to two basic operations: a focus on compounding the number of positive and supporting studies appearing within the medical literature particularly when timed to coincide with the launch of a new product;¹⁶² efforts to minimize the corresponding number of negative or unfavorable studies often by claiming that such studies contain valuable trade secrets protected by intellectual property legislation or simply withholding the results from the scientific community by not seeking opportunities to publish the final results.¹⁶³ Employing both of these operations allows the resulting discourse surrounding a particular drug to be directly influenced by publication plans in such a way that makes it easier to market the drug in question.

Compounding the number of positive studies allows for publication planning strategies to create the appearance that the therapeutic properties of a new drug are far more pronounced than those demonstrated during clinical testing or when compared to alternative treatments. Allowing a new drug to assume the appearance that it is therapeutically superior to available alternatives yields fairly obvious results in terms of

¹⁶² Angell, *Truth About the Drug Companies*, 111-3; Sismondo and Doucet, "Publication Ethics," 278; Marc-André Gagnon, "Corporate influence over clinical research: considering the alternatives," *Prescrire International* 21, no. 129 (2012): 191-194.

¹⁶³ Gagnon, "Corporate Influence."; Wayne Kondro and Barbara Sibbald, "Drug company experts advised staff to withhold data about SSRI use in children," *CMAJ* 170, no. 5 (2004): 783; Erick H. Turner et al., "Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy," *NEJM* 358, no. 3 (2008): 252-60; Drummond Rennie, "Trial Registration: A Great Idea Switches from Ignored to Irresistible," *JAMA* 292, no. 11 (2004): 1359-62.

the actions undertaken by physicians, most noticeably a direct boost in prescribing the particular drug(s) in question. Consequently, the ability to bolster the number of positive studies appearing in the medical literature — particularly when timed to coincide with the launch of a new product — enables publication planning strategies to directly influence and sway the prescribing habits of individual physicians based on criteria that may not necessarily be supported by actual clinical evidence, relying instead on the appearance of superior therapeutic quality derived from the timely publication of supporting articles within the medical literature.¹⁶⁴ With physicians dependent on medical journals as a primary source of information to inform their clinical decisions, the presence of articles that effectively misrepresent via the selective disclosure of trial results the true therapeutic potential of a drug has a direct impact on the ability of individual physicians to ensure patients receive informed care. Magnifying the extent of this further are concerted efforts to minimize the impact or eliminate entirely potentially negative studies, either through the outright omission or failure to publish unfavorable data,¹⁶⁵ controlling the analysis of and access to necessary data,¹⁶⁶ pressuring and discrediting independent researchers,¹⁶⁷ or simply failing to include certain findings in relevant

¹⁶⁴ For one documented case of this concerning hormone replacement therapies, see Adriane J. Fugh-Berman, “The Haunting of Medical Journals: How Ghostwriting Sold ‘HRT,’” *PLoS Medicine* 7, no. 9 (2010): 1-11.

¹⁶⁵ One of the most notable cases involving the omission of relevant data pertains to the overall lack of mention of the potential link between the use of Sertaline and increased suicidal ideations in articles involving Current Medical Directions (a MECC working with Pfizer). For a more detailed analysis of this see David Healy and Dinah Cattell, “Interface between authorship, industry and science in the domain of therapeutics,” *British Journal of Psychiatry* 183 (2003): 22-27.

¹⁶⁶ Califf et al., “Task Force 2,” 1731.

¹⁶⁷ Arthur Schafer, “Biomedical Conflicts of Interest: A Defence of the Sequestration Thesis: Learning from the Cases of Nancy Olivieri and David Healy,” *Journal of Medical Ethics* 30, no. 1(2004): 8-24.

discussions such that they become detached from the relevant discourse involving a particular drug.¹⁶⁸

However, the ability of publication planning strategies to successfully market a product within the medical literature is ultimately dependent on the appearance of scientific objectivity and impartiality. While targeting medical journals as the principle means of communicating strategic marketing messages offers some level of institutional certitude in this regard, additional measures are necessary to ensure that publication planning strategies are able to capture the maximum economic value associated with their actions by downplaying the involvement of industry. Due to the readily apparent connection between research funding and supporting outcomes, without an appearance of objectivity, the ability of medical research and the accompanying body of literature it produces to function in a marketing capacity would be unable to withstand public scrutiny and be seen to act undoubtedly to advance the interests of the pharmaceutical industry. Thus, in order for medical research to be successfully employed as a marketing tool, publication planning strategies have needed to utilize supplementary methods capable of concealing wherever possible the influence and involvement of industry in the construction and resulting dissemination of medical knowledge. It is from this need that publication planning strategies have come to rely extensively on more ghostly means by which to shape medical knowledge and influence physicians in order to not only make medical research appear more objective and impartial, but to also exert greater control over the production of medical knowledge.

¹⁶⁸ Matheson, "Corporate Science," 367.

4.4 Ghosts in the (R&D) Machine

The ability of publication planning strategies to mask the extent of corporate influence over the creation and dissemination of medical knowledge hinges on the successful use of systematic ghostwriting and the resulting misattribution of academic authorship. Integrating these methods as part of a larger publication plan, or what Sismondo refers to as the ‘ghost-management’ of medical research, offers a means of directly influencing the creation and dissemination of medical knowledge in a way that can satiate public scrutiny and appease institutional safeguards such as peer review. This form of ghost management is premised not only on the ability of “pharmaceutical companies and their agents [to] control or shape multiple steps in the research, analysis, writing, and publication of articles” as is expected through the use of publication planning strategies, but also for the articles produced to assume what can be best described as a “ghostly” character with many of the “signs of their actual production [remaining] largely invisible— [allowing] academic authors whose names appear at the tops of ghost-managed articles [to] give corporate research a veneer of independence and credibility.”¹⁶⁹ In this way, the successful utilization of medical research as a marketing tool has required the pharmaceutical industry to actively embrace the strategic advantages afforded by ghostwriting and the development of so-called ‘key-opinion leaders’ in order to distance their involvement in shaping and controlling the research process so as to realize their underlying commercial objectives.

¹⁶⁹ Sismondo, “Ghost Management,” 1429.

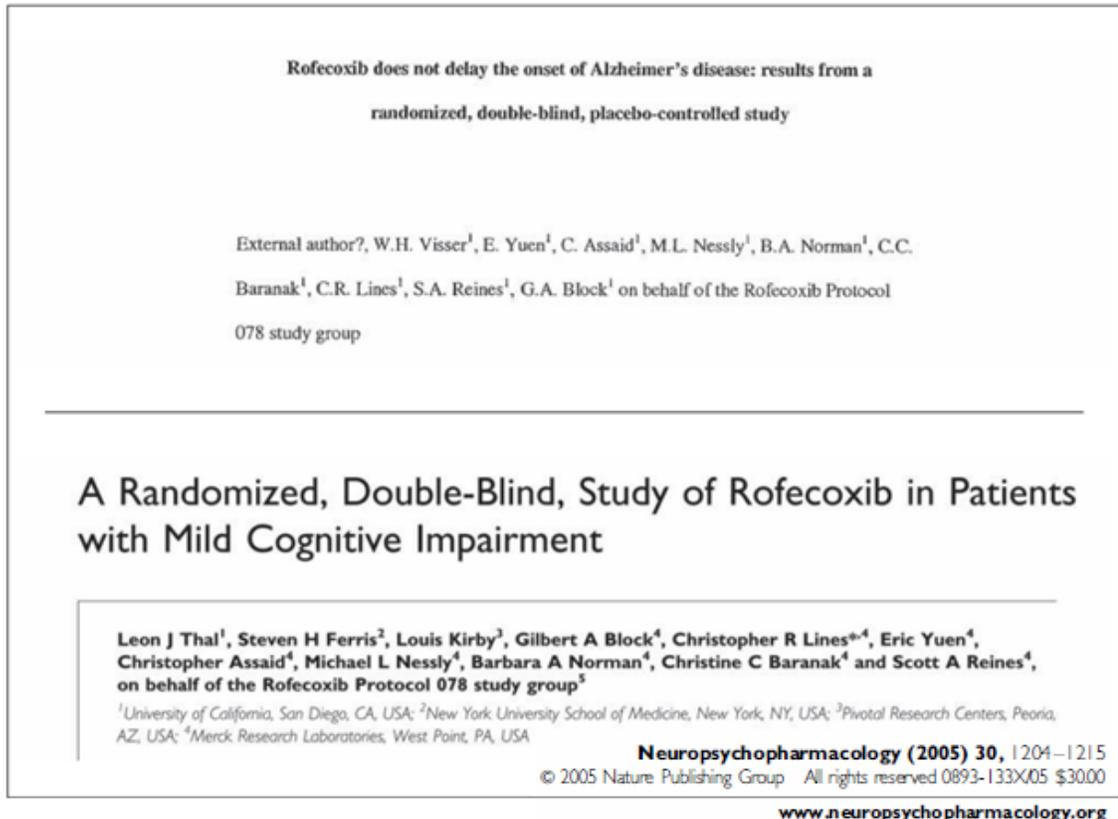
Ghostwriting entails the contracting of a third party to draft and construct publications without mention or proper recognition of their actual contributions in the final manuscript.¹⁷⁰ Within medical research, ghostwriting is characterized by the corporate financing of medical writers, often working for or on the behalf of MECCs,¹⁷¹ who are responsible for developing a draft manuscript consistent with the marketing messages advanced through the publication planning process with the aim of producing a tailored manuscript fit for publication in leading medical journals. These articles are ultimately published with authorship being accredited to prestigious academics or other well-known and influential researchers while the contributions of the true author(s) remains absent in an effort to seemingly legitimize and distance the findings being presented from their industry sponsored roots.¹⁷² This process is exemplified through the comparison of a draft manuscript and the final published article as shown in Figure 6. Where the draft manuscript specifically references an unnamed external author and properly notes the contributions of W.H. Visser, the final published article fails to recognize this while listing Leon J. Thal as the new principal author of the published article. While the final published article does acknowledge corporate funding provided by Merck, there is no mention of what contributions were made by W.H. Visser to either the research being presented or production of the manuscript in question.

¹⁷⁰ Thomas J. Liesegang, Daniel M. Albert, and Andrew P. Schachat, "How to Ensure Our Readers' Trust: The Proper Attribution of Authors and Contributors," *American Journal of Ophthalmology* 146, no. 3 (2008): 338.

¹⁷¹ Moffatt and Elliott, "Ghost Marketing," 19.

¹⁷² See Sismondo, "Ghost Management," 1429-32; Moffatt and Elliott, "Ghost Marketing," 19-22.

Figure 6: Ghostwriting at Work: Draft Manuscript vs. Published Article



Source: Joseph S. Ross et al. “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation,” *JAMA*, 299, no. 15 (2008): 1803.

By falsely accrediting authorship in this manner, the involvement of external authors such as Leon J. Thal in this specific case can be portrayed to have greater impact over the final document than is truly the case. Often the scope of this involvement rarely involves any significant contribution to the final article beyond minor editorial contributions that remain conditional on industry approval.¹⁷³ Arising from the lack of substantive involvement by external author(s), ghostwritten publications are able to

¹⁷³ Joseph S. Ross et al., “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents From Rofecoxib Litigation,” *JAMA* 299, no. 15 (2008): 1800-12.

function in a way that reinforces the marketing messages set out as part of a broader publication plan. Serving to not only deflect social criticisms that have come to accompany industry sponsored research, the use of ghostwriters to develop manuscripts within publication planning strategies provides the pharmaceutical industry a direct means by which to develop a publication that can be directly tailored to reflect the specific marketing objectives that accompany a particular drug.

Medical ghostwriting is dependent on the secrecy associated with the practice to escape public scrutiny. Without its ghostly quality, the involvement of ghostwriters would likely be unable to achieve the appearance of objectivity necessary to quell public criticism. However, as the practice has become increasingly widespread and has been linked to several public controversies attracting prominent media coverage,¹⁷⁴ ghostwriting has effectively become one of the worst kept secrets of the pharmaceutical industry and occurrences can no longer be simply treated as isolated occurrences, but instead as systemic components in the construction of corporate medical knowledge. The integral role afforded to ghostwriting within the current structural configuration of medical research has led to the presence of ghostwritten articles no longer being isolated simply to peripheral or supplemental journals. Rather the scope of ghostwriting has expanded to include publications in prestigious industry leading journals with MECCs claiming acceptance rates of 80% by journals whose rejection rates are over 90%.¹⁷⁵ It is the veracity of such claim that makes it incredibly difficult to treat recognized instances of ghostwriting simply as isolated incidents. Rather, it is far more productive to

¹⁷⁴ Moffat and Elliott, "Ghost Marketing," 19.

¹⁷⁵ Sismondo and Doucet, "Publication Ethics," 282.

recognize ghostwriting as a logical and expected outcome of a set of social and institutional processes that have seen control over the research process be subjugated to commercial imperatives consistent with the pharmaceutical industries underlying emphasis on marketing and promotion.

Notwithstanding the apparent need to recognize the structural causes that have helped ghostwriting become an integral component to the marketing strategies that accompany individual drugs, it remains incredibly difficult to estimate just how prevalent the practice is. This should come as no surprise however considering it is the very secrecy associated with the practice that allows it to offer added economic value to publication planning strategies. Despite these limitations there have been a number of attempts attempting to shed light on the practice in order to provide an estimate as to just how prevalent the practice of ghostwriting has become.

Drawing on confidential surveys, Flanagan et al. were able to establish that between 7% and 16% of journal articles involved ghostwriting allowing them to conclude that “that a substantial proportion of articles in peer-reviewed medical journals have honorary authors and ghost authors.”¹⁷⁶ While this particular study focuses on a variety of publication types, Gøtzsche et al. instead choose to focus on the extent to which ghost authorship is prevalent in industry sponsored clinical trials through a comparison between trial protocols and final publications. Recognizing that the findings offered by Flanagan

¹⁷⁶ Annette Flanagan et al., Prevalence of Articles With Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals,” *JAMA* 280, no. 3 (1998): 223-24. Similar results were also found in studies conducted by *Nature* and a survey published in the Cochrane reviews which found the prevalence of ghostwriting to be 10% and 9% respectively. For more information about this see Graham Mowatt et al., “Prevalence of Honorary and Ghost Authorship in Cochrane Reviews,” *JAMA* 287, no. 21 (2002): 2769-71 referenced in Moffatt and Elliott, “Ghost Marketing,” 22.

et al. may present a rather conservative estimate based off of the methodological limitations associated with self-reporting, the results offered by Gøtzsche et al. portray ghostwriting as a far more common occurrence, particularly in light of the economic importance in reporting the results of RCTs. Evidence of ghost authorship was found in 75% of articles reporting clinical trial results, with the most prominent omission being a failure to properly attribute the involvement of individuals conducting data or statistical analyses. These results enable Gøtzsche et al. to conclude that ghostwriting is very common in industry sponsored clinical trials and that ghostwriting also serves an explicit commercial purpose.¹⁷⁷ Wislar et al. provide a third estimate such that nearly 8% of articles published in high-ranking medical journals during 2008 may not properly attribute authorship to all contributors and concluding that while the prevalence of ghostwriting may appear to be declining between 1996 and 2008, added measures are necessary to ensure the proper attribution of authorship.¹⁷⁸

It is important to note that while for the most part the magnitude of these findings may present ghostwriting as a relatively minor occurrence, one critical aspect of publication planning concerns ensuring the proper timing of published results in order to saturate the available literature with favorable manuscripts at the time a new drug is launched in order to establish a positive first impression with physicians. In this way, while the magnitude of such findings does not necessarily reflect the importance of

¹⁷⁷ Peter Gøtzsche et al., "Ghost Authorship in Industry-Initiated Randomised Trials," *PLoS Medicine* 4, no. 1 (2007): 48-50.

¹⁷⁸ Joseph S. Wislar et al., "Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey," *BMJ* 343, published October 25, 2011, <http://www.bmj.com/content/343/bmj.d6128>.

timing, they do offer an initial means of assessing the prevalence of ghostwriting within medical journals.

In addition to making up a sizeable portion of the medical literature, particularly those articles documenting clinical trial results, the associated impact of ghostwritten articles is also important to consider when determining the totality of their influence. To this end, Healy and Cattell offer a rigorous examination as to the comparative literature profiles of ghostwritten articles and the potential impact this has on subsequent publications. Comparing publications related to Sertaline authored through the MECC Current Medical Directions and those without industry ties, Healy and Cattell are able to offer the following conclusions regarding the comparative literature profiles of each set of articles:

- The authors of ghostwritten papers are among the most highly Medline-cited authors in the field; with upwards of 200 other Medline listed papers per author.
- The listed authors of ghostwritten papers have a citation rate three times greater than that of non-ghostwritten authors.
- The ghostwritten papers appear in journals with an impact factor three times greater than that of the journals in which non-ghostwritten papers appear.¹⁷⁹

These findings make apparent that the impact of ghostwriting cannot be calculated solely by examining the sheer prevalence of the practice in terms of the number of impacted manuscripts. Rather, as Healy and Cattell make clear, ghostwritten articles often possess greater citation rates, appear in more impactful journals, and are more likely to draw on the prestige of their authors effectively allowing for the marketing strategies they advance to be continually revisited after their initial publication allowing for the continual

¹⁷⁹ Healy and Cattell, "Interface between authorship," referenced in Healy, "Shaping the Intimate," 231.

recursion of a particular drug narrative. It is precisely these qualities that help set ghostwritten papers apart from those produced through more traditional means while also making them highly desirable for journals to publish despite the attached stigma of doing so. With the ability for ghostwritten manuscripts to easily pass peer review and help supplement a journal's revenue through reprints, it is increasingly difficult to willingly crack down on such practices given the commercial interests held by many journals themselves. As such, even in situations where the prevalence of ghostwriting may appear to be on the decline, the ability of ghostwritten articles to maximize their potential exposure and shape public consciousness through higher citation rates, the purposeful targeting of high impact journals, and a potential willingness of journals to publish ghostwritten studies helps to ensure that the dissemination and adoption of particular marketing messages is possible even if the total number of ghostwritten publications is reduced.

The comparative literature profiles offered by Healy and Cattell illustrate that the commercial strength of ghostwriting is not tied solely to the prevalence of impacted articles, but also the individual and institutional prestige that can be drawn on to help perpetuate the marketing claims at the heart of the respective publications. An important element for establishing this prestige originates from the purposeful targeting and development of so-called 'key-opinion leaders' (KOLs) by the pharmaceutical industry to serve as the surrogate authors of ghostwritten publications. Portraying KOLs as active participants in the production of medical knowledge allows individual claims to assume an appearance of objectivity effectively distancing research from the perceived influence that accompanies corporate funding. Creating this perception of objectivity further

enhances the commercial value of corporate research through what effectively amounts to a celebrity endorsement as to the quality and rigor of the manuscript.¹⁸⁰ These endorsements provide a further mechanism of persuasion for other physicians who look to the individual prestige and institutional affiliations of KOLs when evaluating newly published research. Thus, the collective reputations that accompany the attribution of authorship enables not only the appearance of objectivity, but when coupled with individual and institutional prestige of listed authors acts as an additional means of selling the research at hand. In other words, the economic value of KOLs for the pharmaceutical industry is not necessarily based off of their potential contributions to the research itself, but rather the authoritative presence that their name commands when it is listed in the byline of a published manuscript.

It is important to note that while KOLs may effectively lend their support through the tacit approval afforded by authorship to claims made in ghostwritten articles, this does not necessarily entail that KOLs do not value scientific ethics, objectivity, and the importance of clinical evidence. Rather, the most convincing, and therefore economically valuable KOLs are those whose own research interests come to coincide with the marketing objectives of the pharmaceutical industry. The most ideal marketing strategies are those that are able to simply employ “convincing science, [and] not conspicuous marketing”¹⁸¹ to achieve their goals. To this end, the most convincing and therefore economically valuable KOLs are those who need no convincing about the

¹⁸⁰ Sergio Sismondo, “Pharmaceutical Maneuvers,” *Social Studies of Science* 34, no. 2 (2004): 152.

¹⁸¹ Matheson, “Corporate Science,” 370-71.

information they attach their name and reputation to and can be seen to genuinely believe in the therapeutic advantages offered by the product they come to represent.

While the pharmaceutical industry actively utilizes KOLs in a way that furthers the commercial marketing objectives of industry, their role and function is not intrinsically tied to a particular normative standpoint. Rather, the social function held by KOLs instead serves as a focal point for disseminating the views of any persuasion to reach a captive audience attracted through the appeal of expert authority. For this reason, KOLs can be mobilized to not only back the marketing claims that drive the production of ghostwritten research but also act as highly vocal critics of the drugs being marketed and the marketing techniques employed by the pharmaceutical industry itself. Thus, in order for the pharmaceutical industry to maximize the ability of KOLs to disseminate ghostwritten research, there has been a requisite need to identify ‘advocates’ for particular products while conversely acting to ‘discredit’ or ‘neutralize’ the voices of dissenting KOLs.¹⁸² Drawing on a range of motivational techniques including but not limited to the material dispensation of financial incentives including research honoraria, distributing invitations to corporate events, and engaging existing networks of supportive KOLs and sales representatives, the pharmaceutical industry possesses a tremendous array of resources that can be readily mobilized to quell potential dissenting voices that may be seen to undermine the marketability and economic success of their products.

¹⁸² As part of the selection process for key opinion leaders who will disseminate ghostwritten research, the pharmaceutical industry identifies potential researchers who can function not only as ‘advocates’ to advance the commercial interests that accompany a new product launch, but also academics and researchers who may hinder this success resulting in efforts to either convert them into supporting voices or to ‘neutralize’ and ‘discredit’ their work. For a more detailed look into how this is achieved see Merck & Co., “List of doctors – Neutralize/discredit,” accessed March 4, 2014, <http://dida.library.ucsf.edu/tid/oxx02y10>.

While the social function held by KOLs does not inherently reflect a particular set of interests, their use by the pharmaceutical industry to provide the authorial support for ghostwritten research further amplifies a contradictory set of responsibilities that exist between the public and private obligations that emerge within a neoliberal ethos of science. With research increasingly functioning in an explicit commercial capacity to satisfy the marketing objectives of industry, the use of KOLs further stresses the boundaries between the seemingly public obligation of doctors and healthcare professionals to provide the best possible care for patients and the private impetus towards profitability and personal success. Drawing on prestige alongside the professional and societal expectation that accompanies the role of a physician, the pharmaceutical business model has come to systematically exploit this divide relying on the public perception regarding the roles and responsibilities of physicians to facilitate private gain on behalf of industry.

4.5 Revisiting Conflict of Interest Policy

With greater commercial influence over the production and dissemination of medical knowledge made possible through the rise of CROs, the implementation of publication planning strategies, and the successful development and mobilization of KOLs to validate ghostwritten research, there is a pressing need to reassess the role of conflicts of interest in an era where medical research assumes a direct commercial function. While the impacts of conflicts of interest, particularly with respect to ghostwriting have become well documented as of late, there remains a distinct failure to appreciate the ideological and structural transformation that has occurred within medical science to allow the research process to function in an explicit marketing capacity. With

many existing studies constrained by the disciplinary boundaries of their respective researchers, there has been at best a cursory understanding of what needs to be understood as a larger structural problem underscored by the spread of neoliberal ideology. While many existing studies investigating the nature of conflicts of interest correctly recognize the negative impact associated with practices such as ghostwriting, there remains a seemingly obvious oversight concerning how the broader social understanding of science and with it the particular normative values that define acceptable scientific practice ultimately reflect the dominant ideological currents of a given period. In this way, while existing accounts examining the impacts associated with conflicts of interest raise a number of key issues, it is the absence of a more substantive discussion as to the formative power held by the material and ideational influences associated with a neoliberal conception of science that represents the most serious deficiency within this body of literature. As such, in order to develop a more robust account as to role and impact conflicts of interest have on modern medical research it is necessary to first outline the dominant themes proposed to address conflicts of interest provided by these existing accounts. Only then does it become possible to demonstrate how these existing approaches can ultimately be improved upon by incorporating a distinct recognition as to the structural processes guiding medical research and the direct impact of neoliberal ideology in shaping a broader social conception of science.

One of the most common themes to emerge within the literature on medical ghostwriting focuses on addressing the relationship between researchers and their research. While this approach does little to address the structural influences that help guide individual behavior, it does frame the debate on ghostwriting around individual

researchers and how their relationship to research needs to be fundamentally altered. Such alterations take on a number of different forms depending on the specific author. Among these is a consistent call for a clarification of the rules governing authorship in medical publications. This emphasis on ensuring more exacting standards to facilitate the proper accreditation of authorship according to Liesegang et al. is necessary in order to be able to promote a sense of “ethical responsibility... [that] assures accountability and responsibility”¹⁸³ in both the production and dissemination of medical knowledge so as to introduce a greater sense of transparency to the research process. The belief is that in turn, this sense of ethical responsibility and the resulting transparency afforded by the proper attribution of authorship will serve to allow ghostwriting to become a legitimate practice rather than one that is veiled and masked in secrecy.¹⁸⁴

While this solution may draw ghostwriting out of the shadows, it ultimately does little to address the issues associated with honorary authorship whereby authorship is accredited to those whose actions provide minimal substantive content to the final publication and are instead included simply to provide an added element of prestige to the published byline. In this way, the effect of recognizing the contributions made by ghostwriters does little to challenge the use of key opinion leaders and their underlying prestige as a means to drive marketing efforts allowing authorship to become as much a part of the problem as it is a solution. According to Anekwe, the practice of falsely attributing authorship in this manner accounts to nothing more than plagiarism and as

¹⁸³ Liesegang, Albert, and Schachat, “How to Ensure Our Readers’ Trust,” 337

¹⁸⁴ Max Lagnado, “Haunted Papers,” *The Lancet* 359 (2002): 902

such should be “subject to federal and academic policies on research misconduct.”¹⁸⁵

However, this proposal yet again fails to appreciate the structural dynamics that have effectively hollowed out and severely diminished the institutional capacity of universities and professional societies to function in both a disciplinary and regulatory capacity given the elevated role afforded to CROs within the research process. While recognizing authorship is an important element to consider, solutions that look solely at authorship as a means of addressing conflicts of interest provide but a single approach with which to understand the multifaceted problems associated with ghostwriting and how this practice impacts the relationship between researcher and research.

While the focus on authorship within the literature ultimately recognizes the importance of the relationship between researchers and their research, it fails to account for the underlying fact that this relationship has been fundamentally altered with the internalization of neoliberalism as a core set of values around which society is structured. Where the recognition of authorship provides a means of ensuring the individual contributions made by researchers to a piece of research are properly accounted for, the imposition of a contract research model alongside the growing commercial pressures imposed on the research process by industry has ultimately seen the role and associated responsibilities of the researcher become externalized from the actual knowledge they produce. Instead, the relationship between researcher and their research becomes framed explicitly in terms of the production of a commodity whose ultimate purpose is to be sold. As a result, the primary responsibilities of researchers no longer are expressed in

¹⁸⁵ Tobenna D. Anekwe, “Profits and Plagiarism: The Case of Medical Ghostwriting,” *Bioethics* 24, no. 6 (2010): 267.

terms of the research they conduct, but instead can be articulated as part of their individual entrepreneurial character as ideal neoliberal subjects seeking to translate research findings into future funding opportunities. The result is that the underlying relationship on which much of the literature is focused can no longer be expressed in terms of the researcher and their research, but must instead take on a form that is no different than any other exchange of commodities. As a result, individual contributions to the production of medical knowledge are no longer for the express purpose of obtaining wider social recognition in keeping with more traditional conceptions of authorship, but are instead framed in terms of a producing a product that comes to possess a direct monetary value, subject to private individual ownership, and produced for the ultimate goal of market exchange.

Another common focus found within the literature focuses on the potential use of legal mechanisms as a means to address conflicts of interest. While the specific application of these legal arguments may vary, each shares a common focus in that they view conflicts of interest or the behavior they produce at odds with established legal frameworks. One potential recommendation offered by Stern and Lemmens outlines treating the products of pharmaceutical marketing strategies, particularly those involving the use of ghostwriting as fraud that causes substantive harm to readers. By handling such issues within the dedicated legal context offered by the Racketeer Influenced and Corrupt Organizations Act, the reduced institutional capacity at the academic level to

penalize offenders no longer presents a serious obstacle.¹⁸⁶ However, despite this added enforcement mechanism, the existing track record of legal recourse for even the most well-known cases has failed to produce lasting systemic change within the industry. Even with the monetary costs associated with legal fees and potential settlements seemingly continuing to rise, the added earnings capacity made possible through an explicit focus on marketing and the utilization of ghostwritten research continues to surpass the direct costs for individual firms associated with the occasional legal challenge. Furthermore, this reliance on the imposition of monetary penalties to produce corrective actions does little to challenge the underlying commercial focus that has come to dominate modern medical research. Rather, with the most recent legal cases limited to monetary settlements, the use of existing legal structures as a means of addressing conflicts of interest effectively reaffirms the industries' predominant focus on fiscal performance by allowing prospective legal actions to be readily accounted for simply as a potential cost of doing business. As such, while a legal recourse may offer a viable option to address issues on a product-by-product basis, existing legal structures lack sufficient scope to combat the problems associated with conflicts of interest across the industry as a whole in order to facilitate lasting systemic change.

Other arguments also maintain an emphasis on the role of the researcher but go beyond strictly examining authorship requirements as their central focus. A significant

¹⁸⁶ For an overview of potential legal action to address these issues including the use of the False Claims Act and potential liability under Anti-kickback statutes in the United States see Simon Stern and Trudo Lemmens, "Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles," *PLoS Medicine* 8, no. 8 (2010): 1-5; Xavier Bosch, Bijan Esfandiari, and Leemon McHenry, "Challenging Medical Ghostwriting in US Courts," *PLoS Medicine* 9, no.1 (2012): 1-4; Paul E. Kalb and Kristin Graham Koehler, "Legal Issues in Scientific Research," *JAMA* 287, no. 1 (2002): 85-91.

portion of the literature also examines the obligation of authors to voluntarily disclose potential conflicts of interest. According to Avanzas et al., disclosing conflicts of interest is a standard practice for many journals and serves to place the obligation for addressing conflicts of interest on individual authors and not on editorial staff.¹⁸⁷ While authors may possess the most accurate knowledge about their own potential conflicts of interest, relying on authors to voluntarily disclose these conflicts is highly problematic due to the potential for individual authors to profit and benefit directly from non-disclosure.

Implementing policies to require the voluntary disclosure of conflicts of interest is further complicated by the varied standards and interpretations as to what effectively constitutes a conflict. Producing a concise definition of what a conflict of interest entails is an entirely subjective process that varies from researcher to researcher. In a study conducted by Keune et al. the declared conflicts of interests offered by individual researchers were examined. Their findings indicate that out of 3,122 reported disclosures made on the behalf of 480 individuals that 195 distinct terms including the most common declarations involving consulting arrangements, speaker honorariums, and research grants were utilized to disclose potential conflicts of interest.¹⁸⁸ While there may exist on some level a broad understanding of what generally constitutes a conflict of interest, the presence of 195 distinct terms used to describe such conflicts presents a significant area of ambiguity for not only individual researchers questioning whether or not to declare a potential conflict but also readers who have to parse out the level of influence identified

¹⁸⁷ Pablo Avanzas, et al., "Ethical Considerations in the Publication of Scientific Articles," *Revista española de cardiología* 64, no. 5 (2011): 428.

¹⁸⁸ Jason D. Keune et al., "Taking Disclosure Seriously: Disclosing Financial Conflicts of Interest at the American College of Surgeons," *Journal fo the American College of Surgeons* 212, no. 2 (2011): 220.

by each of these respective statements. Keune et al. pickup on this fact and were able to narrow the range of statements to a system of fifteen categories with which to classify these disclosures. Their findings speak to not only establishing a snapshot of the types of conflicts of interest that are present in medical science but also serve to indirectly illustrate the subjective nature of disclosure.

It is this inherently subjective nature of disclosure that results in varying interpretations on behalf of researchers as to what actually is considered a conflict of interest needing to be disclosed. Through this inherent subjectivity, the process of disclosure, in the absence of more precise definitions, comes to reflect the individual attitudes of researchers as to types of relationships and actions that may be seen as potentially worrisome to scientific practice. However, with the increasingly commercial outlook of modern medicine, the involvement of industry has become increasingly normalized resulting in the increased potential for researchers to simply disregard the impact of such relationships. It is this ability for the actions and relationships at the heart of conflicts of interest to become seen as so natural and expected within the research process that the judgments of individual researchers may no longer present a sufficient safeguard when coupled with disclosure to address these issues. Despite this significant issue, Keune et al. fail to question the researcher centered focus of voluntary disclosure with respect to both the conflicting roles and responsibilities facing researchers and how the relationships that they produce in turn shape their subjective understanding of the root conflicts that exist within modern medical science.

In addition to focusing on the role of the researcher in facilitating the disclosure of conflicts of interest, journal editors are also subject to extensive scrutiny in the literature.

Given the negative perception of ghostwriting within medical research, it is not uncommon to find journals vis-à-vis their editors readily defending their own publications and working vehemently to clarify existing disclosure policies. Editorial comments on behalf of journal editors seek to demonstrate that journals are actively involved in addressing conflicts of interest often citing their concerns with such practices alongside suggested improvements that can be made to their own editorial practices.¹⁸⁹ However, despite this active engagement with conflicts of interest and recognition of issues such as ghostwriting, editorial commentaries stay trapped within a focus on the individual researcher as the necessary facilitators of disclosure. As such, despite the attempt, editors often remain blind to the realities facing medical research and fail to appreciate the extent to which the reorganization of the research process to function in an explicit marketing capacity and practices such as ghostwriting and other conflicts of interest have become more pronounced as a result of the growing involvement of the pharmaceutical industry in all phases of the research process. As a result, while their analysis recognizes the problem it ultimately offers little beyond calls to strengthen and clarify existing policy approaches in order to present the appearance of proactive engagement on behalf of individual journals. In other words, while editors are consciously aware of the issues presented by ghostwriting and other conflicts of interest, their approach to the problem only provides minor reforms as opposed to the significant systemic revolution that is necessary.

¹⁸⁹ For one example of these types of editorial comments see Clifford J. Rosen, “Conflict of Interest: Explicit Rules!” *Journal of Clinical Densitometry* 2, no. 3 (1999): 209-10; Camilleri, Dubnansky, and Rustgi, “Conflicts of Interest,” 841-47.

However, this is not to say that all existing literature on ghostwriting and medical conflicts of interest is focused entirely on the role of the individual. While the focus for many studies rests on framing conflicts of interest as a problem best addressed by individual researchers, many studies have chosen the changing role of medical research as the focal point of discussion. Such studies explore a number of different areas involving knowledge production within the pharmaceutical industry. Among such studies, the most noticeable and heavily studied area of this trend concerns the shift of medical research out of the academy and into the private contract based organizations discussed earlier in this chapter. This trend has resulted not only in the alignment of scientific research with the commercial goals of industry, but more fundamentally has altered social perceptions concerning the creation of scientific knowledge. Offering a general look at how science, and with it knowledge has been fundamentally altered as it has transitioned from the public to private sphere, Krimsky explores this transition and how it directly impacts the changing ethos of science allowing secrecy and privatization to replace openness and community as key values that had previously defined scientific research.¹⁹⁰ To illustrate this change, Krimsky draws on a number of case studies from different areas of science emphasizing how the approach to conflicts of interest has become focused on attempts to manage them “rather than ‘avoiding’ or ‘preventing’” them to begin with.¹⁹¹ While Krimsky provides an analysis that transcends individual researchers and begins exploring how conflicts of interest intersect with a broader societal conception of science through its distinct ethos, he fails to connect this change

¹⁹⁰ Krimsky, 2003, *Science in the Private Interest*, 7.

¹⁹¹ *Ibid.*, 9.

within science to the important ideological shifts that have occurred since the 1980s with the emergence of neoliberalism. With ideology serving as a means of influencing the way in which society envisions and interacts with a number of social and institutional processes it seems remiss to not extend this understanding to the field of medical science. In particular, with Krinsky offering a means of understanding more broad shifts occurring within societies understanding of science and how it comes to be organized, there remains a distinct oversight in his failure to connect these changes to the emergence and resulting entrenchment of neoliberalism as the dominant ideological framework within society.

With the existing literature on medical conflicts of interest, in particular the nature of ghostwriting focused largely on the individual impact such issues have for researchers, there is a pronounced deficiency in accounting for the structural and ideological shifts that have occurred within medical science. While many authors agree that ghostwriting and conflicts of interest pose a serious challenge to modern medicine, the approaches offered by much of the literature to address these problems fails to appreciate the connection between two separate areas of focus. Where much of the literature recognizes the importance attributed to the role of individual authors, editors, and prestigious academics, there is an obvious gap concerning the impact of how ideology influences the very ethos of science as characterized by the push towards the greater commercialization and marketing of research findings.

To this end, what is necessary to fully understand the problem posed by conflicts of interest and specific practices such as ghostwriting in the context of modern medical research is to bridge the gap that exists between recognizing the role of individual

researchers and corresponding function exerted by neoliberal ideology in shaping the individual roles and institutional processes governing the research process. Doing so presents a new means of understanding the manner in which the relationships of individual researchers are shaped by a wider set of ideological precepts that has enabled a transformative change within both the institutions and processes guiding medical research. It is this link that is missing from the existing literature and can be filled through a more critical examination of the existing policy measures enacted by medical journals to address conflicts of interest by utilizing the theoretical framework advanced in Chapter 2. Drawing on this perspective it is possible to more fully understand and account for the formative role of neoliberal ideology and the systemic exploitation of conflicts of interest made possible through the use of ghostwritten research and KOLs in order to facilitate the use of medical research as an explicit form of marketing to advance the commercial interests of the pharmaceutical industry.

5 Chapter: Methodological Considerations

With conflicts of interest attracting renewed attention in light of the ability for medical research to function in an explicit marketing capacity, there have been significant efforts put forth by medical journals to revise their own editorial policies to provide updated standards detailing what are deemed to be the acceptable roles and responsibilities that accompany industry involvement in the research process. Many of these updated standards center on offering more precise definitions pertaining to central issues problematized through the utilization of industry funded marketing campaigns and the rise of corporate ghostwriting. As a result, medical journals have gone through extensive efforts to develop more rigid standards with respect to key areas including ensuring the proper attribution of authorship, instituting provisions to better allow individual researchers to identify conflicts of interest, and efforts to curtail potential misuses of medical publications. The result of this continued evolution of conflict of interest policies has enabled medical journals to assume a progressive stance on new corporate strategies such as ghostwriting through the implementation of proactive policy measures to address the spread of corporate influence in medical research while serving as focal point in the ongoing contestation surrounding the normative and social frameworks that guide medical research.

This chapter therefore seeks to build on the contextual foundations offered throughout the preceding chapters concerning the structural transformation of medical research by developing the necessary methodological processes to guide the subsequent analysis of the conflict of interest policies utilized by six leading medical journals and related policy recommendations offered by two influential organizations. The first

section of this chapter serves to offer an explanation as to why medical journal conflict of interest policies represent an ideal case study with which to examine the ongoing changes and contestations occurring within medical research. Given the extensive number of medical publications and the limited focus of this project, the next section of this chapter serves to develop an explicit rationale with which to guide the selection of journals to include as part of the analysis. With this rationale serving to directly frame the scope of the inquiry and develop a list of eligible journals, the final section of the chapter will detail the necessary methodological processes to employ qualitative content analysis as a means of developing the necessary questions and categories to structure the subsequent analysis. This chapter will conclude with the development of a set of categories and related questions derived from the existing conflict of interest policies of each journal and organization that form the necessary components to guide the resultant analysis.

5.1 Medical Journals as an Ideal Case Study

As illustrated in previous chapters, medical journals have come to assume an integral function in satisfying the commercial marketing objectives that exist at the core of the pharmaceutical industries' business model. Regardless of the direct economic value journal publications have come to possess as a result of ties to the marketing efforts of industry, medical journals retain important social and communicative functions within modern medicine. Serving as the primary means of conveying the evolving standards of clinical practice, medical journals and the editorial policies they enact occupy a unique position concerning ongoing efforts to address the problems and potential challenges posed by conflicts of interest. With journals serving as the principle means of informing physicians about new standards and practices, the editorial policies they employ represent

the most direct means in which policy is able to influence the content reaching physicians. As a result, such policies serve as an ideal focal point for any case study wishing to analyze the impact associated with conflicts of interest by examining firsthand the intentions and objectives put forth by key agents in the communication of medical knowledge.

With medical journals revisiting their own editorial policies concerning conflicts of interest, existing iterations of these policies can be viewed as the direct evolutionary by-product to the structural developments identified within the previous chapter that have enabled research to function in an explicit marketing capacity. As such, current journal policies do not represent a strictly idealized response to conflicts of interest, but rather are rooted in the firsthand challenges faced by individual journals and their tacit acknowledgement concerning the influence of industry and its impact on the objectivity of medical research. Therefore, it is in the vested interest of individual medical journals that the outcomes and apparent efficacy of their own editorial policies are seen to be reliable methods to address conflicts of interest in order to sustain a journal's reputation and continue to attract high quality manuscript submissions. Thus, it is the reliance of journals on the success of their own policies that instills an important sense of authenticity and analytical validity to this particular case study by recognizing that journals themselves not only actively guide the formation of policy, but serve as the direct beneficiaries of these policies as well.

This ability of medical journals to guide the development of their own conflict of interest policies is a direct by-product of the editorial process intrinsic to the nature of publishing. With medical journals serving as the principle means of informing and

educating physicians about new and relevant clinical findings, the editorial bodies and the policies that guide their operation effectively shape their communicative function. To this end, while journals may serve as a readily accessible archive of medical knowledge for physicians, it is ultimately the editors who serve as gatekeepers deciding which articles are ultimately published. Editors therefore possess a unique social function afforded by their position to directly influence the information reaching physicians not only through decisions made regarding the perceived scientific merit of prospective publications, but also through the formation of policy measures that dictate the principles and processes on which articles are judged suitable for publication. This ability of journals vis-à-vis their editors and related policy implements to have a direct and selective role regarding which articles see print enables medical journals to enact and enforce explicit policies concerning how each respective journal wishes to handle potential conflicts of interest.

In effect, the publication requirements established through the respective policies and editorial function of medical journals come to act as an institutional filter for the archives of medical knowledge. Medical journals are therefore able to implement and utilize conflict of interest policies as a means of ascribing necessary conditions and requirements that prospective articles must successfully satisfy if they are to be published. Such requirements therefore come to serve as a potential obstacle to the pharmaceutical industries' successful utilization of medical research as a marketing tool. The ability for medical journals to dictate such conditions through their respective editorial functions enables policies such as those governing conflicts of interest to serve not only as a direct means of regulating the involvement of industry within medical

research, but more importantly offer an explicit reflection of the existing ethos of science and its accompanying normative structure. Such policies echo the underlying normative structure that constitutes the ethos of science by characterizing the extent to which particular actions and relationships are deemed acceptable for research to be acknowledged as part of the published record of medical knowledge. Thus it is through the act of social acceptance that accompanies the publication of a prospective article that specific norms are able to be recognized and embraced by the scientific community while others are explicitly sanctioned through the imposition of direct policy measures designed to regulate or curtail their existence.

Conflict of interest policies can therefore be seen not only as a reflection of a particular ethos of science, but also as a means of shaping its continued development by rewarding particular relationships and actions through publication and exposure consistent with its normative structure while regulating and obstructing potentially antagonistic ideals through direct policy proscriptions. Thus, it is this potential to either reward or regulate the involvement of industry that affords the editorial capacities of medical journals and the conflict of interest policies they rely upon to represent a focal point in the ongoing contestation surrounding the normative dimensions of utilizing medical research in a marketing capacity. It is from this potential for contestation arising from the institutional function held by medical journals and the social function of their editors to selectively screen articles based on an established set of criteria that represents an ideal focal point for any substantive analysis that seeks to examine how existing responses to the issues raised by conflicts of interest within modern medicine intersect

with wider negotiations concerning the accepted normative structure of the ethos of science itself.

The ability of conflict of interest policies to serve as a means of focusing an analysis is ultimately contingent on the continued ability for medical journals to act as the primary means of disseminating medical knowledge. It is the underlying importance of this ability to inform and educate physicians about particular treatment options that sustains the social and cultural importance of medical journals while allowing them to retain their commercial appeal as active targets for the marketing strategies employed by the pharmaceutical industry. Thus, it is by virtue of being the ideal subjects of pharmaceutical marketing strategies that ensures medical journals remain immersed at the heart of issues related to conflicts of interest. This resulting proximity and direct experience with conflicts of interest allows the specific policies enacted by individual journals to serve as a strategic point to concentrate any substantive analysis wishing to examine the interplay between conflicts of interest and medical science. With medical journals continuing to be directly impacted by conflicts of interest and forced to act under their editorial responsibilities, it makes logical sense to incorporate the specific policies utilized by individual journals in any analysis wishing to examine how these issues relate to the broader structural transformations that have taken place within medical research and the resulting impact this has on the normative dimension of medical science. As such, medical journal conflict of interest policies offer a strategic, readily accessible, and vibrant array of textual data that when analyzed within the appropriate methodological bounds can offer profound insights into the dynamics governing the relationships between conflicts of interest, medical science, and the pharmaceutical industry.

5.2 Refining the Scope of the Analysis – Identifying Key Journals

With medical journal conflict of interest policies presenting an ideal case study with which to examine both the institutional reactions to the growing prevalence of research functioning in a marketing capacity and the normative shifts within the ethos of science brought about by such practices, the necessary first step before undertaking any substantive analysis involves clearly establishing the criteria employed to frame the scope of the analysis. Given the extensive volume of medical publications it is simply not feasible to examine the specific policies enacted by each individual journal. Rather, the capacity to produce a meaningful analysis of conflict of interest policies requires developing an explicit rationale with which to guide the selection of a set of key journals whose own policies can be seen to function as a representative sample of recent trends and potential future developments concerning conflict of interest policies and their subsequent impact in shaping the ethos of science.

With such a rationale serving as the principle means of justifying the inclusion of specific journals in the final analysis, it is of paramount importance to ensure that the factors informing journal selection are well supported by accompanying research and documentation so as to quell potential concerns regarding oversights or potential bias in the selection process. To this end, the specific rationale used to guide journal selection centers on two key elements: the perceived sociocultural prestige of various journals derived from their statistically calculated impact factors and subsequent commercial appeal to publication planning strategies; and a recognition as to an institutional configuration that emphasizes the role of key policy makers such as the International Committee of Medical Journal Editors (ICMJE) whose members have a pronounced

influence over the ongoing development of conflict of interest policies. To this end, by utilizing these criteria as the means of developing an explicit rationale to guide journal selection, the journals and organizations included as part of the analysis can be seen to provide not only a representative sample of existing conflict of interest policies but also offers the distinct advantage of examining the functions of key policy makers to yield insights into the future evolution of conflict of interest policy development.

Perhaps the most commonly accepted means of developing a consistent approach to ranking the perceived impact and prestige of medical journals lies with the socially accepted, mathematically derived impact factor.¹⁹² Offering a direct quantitative measure for ranking journals, calculating a journal's impact factor requires "2 elements: the numerator, which is the number of citations in the current year to items published in the previous 2 years, and the denominator, which is the number of substantive articles and reviews published in the same 2 years."¹⁹³ Impact factors therefore represent an explicit metric with which to evaluate the perceived influence of a journal based on the relative "frequency with which the 'average article' in a journal has been cited in a particular year or period."¹⁹⁴ The importance of citation rates is recognized by Callahan, Wears, and Weber who conclude that elements such as a journals' impact factor offered a more

¹⁹² It is important to note that impact factors are used here as a means of assessing the prestige of individual journals and in no way offer a means of evaluating the comparative quality of the research presented in each journal. In fact, impact factors offer a highly problematic assessment of the quality of research and often overlook significant issues in their calculations. For more information on some of these issues see Per O. Seglen, "Why the impact factor of journals should not be used for evaluating research," *BMJ* 314, no. 15 (1997): 498-502.

¹⁹³ While Garfield only mentions the calculations required for a 2 year impact factor, it is common to also calculate a 5 year impact factor in order to provide a more generalized metric of perceived impact of a journal. This is achieved simply by adjusting the range of years from 2 to 5. See Eugene Garfield, "The History and Meaning of the Journal Impact Factor," *JAMA* 295, no. 1 (2006): 90.

¹⁹⁴ Eugene Garfield, "The Thomson Reuters Impact Factor," Thomson Reuters, accessed March 4, 2014, <http://wokinfo.com/essays/impact-factor>.

accurate means of predicting citation rates than fundamental elements of the study itself such as the specific methodology or comparative quality of the research presented.¹⁹⁵

Impact factors therefore represent a viable means of developing a systematic approach to evaluate the perceived influence of a journal by virtue of the average citation rates of their respective articles and corresponding ability to shape the collective consciousness of the scientific community.

The ability of citation rates and journal impact factors to serve as a means of evaluating the potential influence of a journal is tied to their ability to enhance the exposure of a publication and have its claims continually revisited by the scientific community through subsequent citations. With each citation serving as the means to perpetuate the claims of the original article, the scientific community is able to become increasingly familiar with heavily cited papers allowing them to become recognized as the authoritative position on particular issues. Each recurring citation therefore serves to not only expand the authority of a particular paper and its associated claims, but also enhance its influence beyond the scope which was garnered during its initial publication allowing the claims it presents to reach a larger audience than those familiar solely with the original paper. As a result, heavily cited papers become positioned within the scientific consciousness as the key focal points around which future research and understanding is based. This allows the claims advanced by heavily cited articles to more readily become common knowledge within the scientific community as evidenced by the “most cited 15% of articles account[ing] for 50% of the citations, and the most cited 50%

¹⁹⁵ Michael Callaham, Robert L. Wears, and Ellen Weber, “Journal Prestige, Publication Bias, and Other Characteristics Associated With Citation of Published Studies in Peer-Reviewed Journals,” *JAMA* 287, no. 21 (2002): 2849.

of articles account[ing] for 90% of the citations.”¹⁹⁶ Thus, this ability of heavily cited papers to shape subsequent understandings of medical science serves as a direct means with which to guide the future direction of scientific publishing and by doing so influence the particular understandings adopted by individual researchers.

In other words, the citation rates of frequently referenced articles position the scientific claims advanced by these papers in such a way that they possess a greater ability to influence the collective consciousness of the scientific community, a function that has become of paramount importance to the realization of the commercial marketing objectives of the pharmaceutical industry. Further to this point, with Healy and Cattell noting a pronounced difference in the relative citation rates and corresponding impact factor of publishing journals between articles compiled through publication planning strategies and independently produced studies,¹⁹⁷ utilizing these metrics as a means to inform journal selection would seemingly facilitate the analysis of journal policies that are more likely to be active targets of the commercial marketing strategies of the pharmaceutical industry. It is this ability of high impact journals to represent the ideal targets of publication planning strategies that lends further credence to the use of impact factors and citation rates as a means of evaluating the prestige of journals and their respective publications. Impact factors thus not only represent a means of evaluating the prestige of key journals but also provide an indirect measure of their commercial desirability to publication planning strategies based on their ability to influence the collective consciousness and understanding of the wider scientific community.

¹⁹⁶ Seglen, “Why the impact factor,” 499.

¹⁹⁷ Healy and Cattell, “Interface between authorship.”

The use of impact factors as a means of informing journal selection therefore offers an initial criterion with which to begin constructing a list of eligible journals to include as part of the later analysis. Utilizing impact factors calculated between 2001 and 2012 published annually as part of the Journal Citation Reports by Thomson Reuters and focusing solely on the category recognizing general medical journals given their comprehensive focus,¹⁹⁸ the rankings for individual journals when sorted by impact factor produce relatively consistent results throughout this period. As shown in Table 4, the top six journals exhibit little variation within their respective rankings throughout the last decade with the most pronounced changes occurring in 2005 with the initial publication of PLoS Medicine effectively replacing the Annual Review of Medicine in these rankings.

Table 4: Journal Impact Factors and Associations

Journal Name	Journal Citation Reports Impact Factor Ranking											
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
NEW ENGLAND JOURNAL OF MEDICINE ¹²	1	1	1	1	1	1	1	1	1	1	1	1
LANCET ¹²	2	2	2	2	2	2	2	3	2	2	2	2
JAMA - JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION ¹²	3	3	3	3	3	3	3	2	3	3	3	3
ANNALS OF INTERNAL MEDICINE ¹²	4	4	4	4	4	4	4	4	4	4	4	6
PLOS MEDICINE ²	**	**	**	**	7	5	6	6	6	5	5	5
BRITISH MEDICAL JOURNAL (BMJ) ¹²	7	6	6	7	6	7	7	5	5	6	6	4

1: Full ICMJE Member Journal

2: World Association of Medical Editors (WAME) Member Journal

** : PLoS Medicine did not begin publishing until 2004 hence there are no impact factors for 2001-2004.

Source: 2001-2012 Journal Citation Reports® Science Edition. Thomson Reuters, 2013.

¹⁹⁸ Journal Citation Reports are broken into a number of different categories with different respective requirements for inclusion. The examined journals all belong to the ‘Medicine – General & Internal’ category. For a more specific explanation as journal requirements and scope of this category see “Scope Notes 2012 – Science Citation Index,” Thomson Reuters, accessed March 4, 2014, http://ip-science.thomsonreuters.com/mjl/scope/scope_scie/.

Thus, given the relative stability of the rankings throughout this period, including the six journals that have consistently demonstrated the highest impact factors offers an ideal starting point given both their influential status and commercial desirability as targets for pharmaceutical marketing strategies.

In addition to these journals consistently yielding the highest impact factors for their respective category, each of the listed journals with the exception of PLoS Medicine occupies an important institutional function by serving to guide the ongoing development of conflict of interest policies adopted by other journals as full members of the ICMJE. While no formalized regulatory body exists to govern the editorial policies adopted by individual journals, the development of the Uniform Manuscript Requirements by the ICMJE has come to represent an informal standard for conflict of interest policies. With over 1,300 journals claiming to follow the ICMJE guidelines to some degree,¹⁹⁹ including a little over half of the fifty top general medical journals ranked by impact factors in 2011,²⁰⁰ the institutional importance of the ICMJE as a means of influencing the development of conflict of interest policies cannot be understated.

Therefore, in order to account for the institutional importance of the ICMJE it becomes necessary to look beyond solely examining the stated policies of its member journals. With the real potential for variance between the policies enacted by member journals and stated ICMJE standards, it is necessary to also include an explicit mention of

¹⁹⁹ These numbers are based solely off of requests by journals to be listed by the ICMJE and thus may not include all journals following the ICMJE guidelines. For a full list of the 1400 journals who have requested to be listed as following the ICMJE recommendations see “Journals Following the ICMJE Recommendations,” ICMJE, accessed March 4, 2014, <http://www.icmje.org/journals.html>.

²⁰⁰ Based on the 2011 Journal Citation Reports for the Medicine – General & Internal Category, 28 of the 50 highest impact factor journals are either members of the ICMJE, or follow to some degree the recommendations put out by the ICMJE.

the ICMJE guidelines in any analysis given their central importance and resulting influence in guiding policy development for non-member journals who integrate these recommendations into their own approach to conflicts of interest. As such, the inclusion of the ICMJE recommendations can help to develop a more robust and representative case study by offering an alternate means of examining journals that normally would be excluded from the final analysis due to their comparatively lower impact factors. Approaching the ICMJE as a set of policies separate from those employed by its own member journals therefore makes apparent not only the potential for variance between each set of policies, but also offers a viable substitute for the large number of journals who draw on the ICMJE recommendations as the primary means to inform and develop their own conflict of interest policies. It is therefore necessary for any substantive analysis of medical journal conflict of interest policies to incorporate in some manner the standards proposed by the ICMJE given their ability to influence the ongoing development of the conflict of interest policies throughout a significant portion of the medical literature.

Despite the institutional importance of the ICMJE as a means of guiding conflict of interest policy development, membership in the organization is restricted to a total of eleven journals with new members being admitted at the sole discretion of existing members. It is this highly selective approach to membership that has raised concerns that the ICMJE is “too small, self-serving, and exclusive” and fails to recognize the global demand for assistance in developing and improving medical journal editorial standards

and practices.²⁰¹ To this end, it is prudent to also consider a second set of alternate policies centering on the guidelines and recommendations regarding conflicts of interest put out by the World Association of Medical Editors (WAME). Functioning as an additional pseudo-regulatory association focused on improving the editorial standards and practices of medical journals,²⁰² WAME was founded with the goal of providing a more accessible and globally aware alternative to the ICMJE. This emphasis on accessibility is readily apparent given the significant differences in membership between each organization. Whereas the ICMJE employs a highly selective approach to membership, WAME instead advocates for a far more open approach as evidenced by the 718 editors of medical journals who are listed as current members including a significant overlap in membership between high impact journals.²⁰³

Another key area of difference between the ICMJE and WAME involves the significantly different approach utilized to develop guidelines concerning the best editorial practices and policy approaches to handle conflicts of interest. Despite both the ICMJE and WAME utilizing a select editorial group to produce their respective guidelines, WAME employs a far more organic means of identifying particular issues and areas that are seen to require a clarifying policy statement. Reflecting the more open and democratic basis for membership, WAME policies originate through member comments

²⁰¹ Bruce P. Squires and Suzanne W. Fletcher, "The World Association of Medical Editors (WAME): Thriving in Its First Decade," *Science Editor* 28, no. 1 (2005): 13.

²⁰² "About WAME," World Association of Medical Editors, last modified June 24, 2011, <http://www.wame.org/about>.

²⁰³ Each of the top six ranking journals by impact factor claim membership in WAME including the five which are also ICMJE member journals. For a full list of WAME member journals see "Journals Whose Editors Belong to WAME," World Association of Medical Editors, accessed March 4, 2014, <http://www.wame.org/services.htm/web-sites-of-journals-whose-editors-belong-to-wame/>.

and discussions occurring on a general listserv that are then translated into more formal policy statements.²⁰⁴ As such, despite each organization operating under a similar mandate, the inclusion of WAME as an added perspective on conflicts of interest offers a means with which to directly compare and contrast the policies and recommendations proposed by the ICMJE. Thus, the analytical value of including WAME rests in the ability of the organization to address criticisms leveled at the exclusivity of the ICMJE by drawing on a more open and representative standard for membership alongside a more organic and democratic means of generating policy recommendations than the processes employed by the ICMJE.

An additional factor that helps lend further analytical strength to the selected sample emerges as a result of use of journal impact factors to guide the selection of key journals. While many high impact journals have published extensive criticisms regarding the negative impacts associated with conflicts of interest, one journal in particular has gone beyond what is typically expected and by doing so has had a profound impact in shaping the very debate surrounding conflicts of interest. In this regard, while the inclusion of PLoS Medicine is already warranted based on its impact factor alone, its own involvement pertaining to conflicts of interest introduces arguably one of the more critical publication records of industry involvement in medical research with a particular emphasis on the use of ghostwriting as a marketing tool. This critical stance stems from their direct involvement in the successful action to make public legal documents relating to the use of ghostwriting by Wyeth in relation to hormone replacement therapies. The

²⁰⁴ Squires and Fletcher, "The World Association of Medical Editors," 14.

action initiated on the behalf of PLoS Medicine represents one of the few instances where a journal has assumed a direct role beyond their capacity as a publisher to actively engage in the debate concerning not only the practice of ghostwriting but also related issues concerning conflicts of interest.²⁰⁵ Pursuing this legal recourse sets PLoS Medicine apart from other journals by actively engaging in a course of action that has direct consequences in shaping the debate surrounding conflicts of interest beyond the more passive involvement assumed by other journals that is limited to traditional expectations accompanying their publishing and editorial capacities. As a result, it is by virtue of their direct involvement in pursuing legal action against the pharmaceutical industry that PLoS Medicine not only effectively reaffirms their own critical stance towards conflicts of interest and the involvement of industry in the research process, but does so in a way that enables them to be an active participant in shaping the very debate beyond solely their role as a publisher.

By drawing on these criteria to derive an underlying rationale to frame the scope of the analysis, the conflict of interest policies of the following six journals and two organizations will be examined in greater detail utilizing the methodological approach outlined in the following section:

- New England Journal of Medicine
- The Lancet
- Journal of the American Medical Association
- Annals of Internal Medicine
- PLoS Medicine
- British Medical Journal
- International Committee of Medical Journal Editors

²⁰⁵ For more extensive information about the details of the legal action see “Wyeth Ghostwriting Archive,” *PLoS Medicine*, accessed March 4, 2014, <http://www.plosmedicine.org/static/ghostwriting>.

- World Association of Medical Editors

5.3 Operationalizing Qualitative Content Analysis

Recognizing the analytical potential afforded by medical journal conflict of interest policies as a means of understanding the interplay between the commercial interests of industry and medical science requires adopting a methodological approach capable of formulating a structured and systematic means of coordinating both the collection of data and guiding its subsequent analysis. With the conceptual purpose of methodology being to describe the underlying logics of the research process²⁰⁶ and providing the necessary set of guidelines and processes with which to conduct research, it is of paramount importance to ensure that the selected methodology properly compliments both the data and its intended uses. To this end, this section seeks to outline the application of qualitative content analysis as it pertains to an examination of medical journal conflict of interest policies.

Qualitative content analysis provides the necessary means and methods to conduct “a systematic reading of a body of texts, images, and symbolic matter”²⁰⁷ with the express purpose of “making replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use.”²⁰⁸ Successfully realizing the potential of qualitative content analysis to construct new analytical meanings rests on the recognition as to the centrality of context and its ability to not only ascribe meanings to particular texts but also define the conceptual frameworks that account for how these same texts

²⁰⁶ Klaus Krippendorff, *Content Analysis: An Introduction to its Methodology*, 2nd ed. (Thousand Oaks, California: Sage Publications, 2004), xxi.

²⁰⁷ *Ibid.*, 3.

²⁰⁸ *Ibid.*, 18.

come to be understood and evaluated. To this end, in order for qualitative content analysis to successfully produce new analytical meanings it is necessary to situate the original text in an alternate context allowing for the elaboration of a unique theoretical framework and accompanying array of concepts and meanings with which to re-examine and challenge the established meanings found in the original text. In order to achieve this, it is necessary to first look beyond “the physicality of texts – for example, to how people [...] use these texts, what the texts tell them, [and] the conceptions and actions the texts encourage”²⁰⁹ in order to be able to begin “resolving [textual] data into its constituent components, [and] to reveal its characteristic elements and structure.”²¹⁰ It is through the purposeful deconstruction of the original text to reveal its underlying structure that presents a means of identifying the key themes, concepts, and categories with which to articulate the dimensions of a particular context imposed by the researcher. Successfully realizing the analytical potential of this new context requires more than simply articulating its dimensions through the identification of these key themes, concepts, and categories. What is also needed is the simultaneous development of a theoretical framework and corresponding set of analytical tools capable of devising new ways of understanding these issues such that they offer an alternative account to the established meanings embodied in the original text. Therefore, it is necessary when imposing a particular context to draw on these key themes, concepts, and categories not only as a means of defining the boundaries and limitations of the analysis, but also as a check to ensure that the theoretical and analytical capacity of the context prescribed by

²⁰⁹ Ibid., 23.

²¹⁰ Ian Dey, *Qualitative Data Analysis: A User-Friendly Guide for Social Scientists* (London and New York: Routledge, 1993), 31.

the researcher possesses the necessary capacity and breadth to explicitly challenge the embodied meanings and understandings of an established text.

Applying qualitative content analysis to explore medical journal conflict of interest policies requires taking this set of relatively abstract processes and applying them in a more procedural and structured manner. In this regard, the development of a more structured approach to qualitative content analysis is perhaps best conveyed by Forman and Damschroder who envision a process consisting of three sequential phases involving the immersion, reduction, and interpretation of texts in order to “create new knowledge from raw, unordered data.”²¹¹ It is by drawing on these three phases as the means of describing the methodological principles associated with qualitative content analysis that it becomes possible to envision a more structured and systematic approach to examining medical journal conflict of interest policies. Relying solely on these three phases as the means of describing the processes associated with qualitative content analysis however can be seen to offer at best a general account regarding how to navigate the research process. It is also necessary is to provide a more detailed account as to how each of these three phases can be employed throughout a rigorous examination of medical journal conflict of interest policies in order to facilitate the development of new analytical meanings.

²¹¹ Jane Forman and Laura Damschroder, “Qualitative Content Analysis,” in *Empirical Methods for Bioethics: A Primer*, eds. Liva Jacoby and Laura A. Siminoff, (Oxford: Elsevier, 2008), 46. Other authors utilize similar albeit functionally equivalent categories to describe the process of qualitative content analysis. For example, Pope, Ziebland and Mays utilize five categories consisting of familiarisation, identifying a thematic framework, indexing, charting, and lastly mapping and interpretation while Dey utilizes six categories: description, contexts, intentions, process, classification, making connections. Despite each author relying on different categories, each ultimately recognizes the same underlying purpose of content analysis that can be consolidated to the more basic categories of immersion, reduction, and interpretation. See Catherine Pope, Sue Ziebland, Nicholas Mays, “Qualitative research in health care: Analysing qualitative data,” *BMJ* 320 (2000): 114-16; Dey, *Qualitative Data Analysis*, 31-56.

Immersion provides an initial means of allowing the researcher to not only familiarize themselves with the working intricacies of the texts they wish to examine, but to also develop the requisite aptitude needed to identify and extract recurring meanings and key thematic elements from this data.²¹² The first element of the immersive phase of qualitative content analysis begins at the earliest stages of the research process by engaging in a comprehensive review of the existing literature focused on conflicts of interest and ghostwriting. With this literature review serving as the principle means of developing the necessary foundation and background knowledge to understand the operational dynamics of the pharmaceutical industry, it also presents an indirect means of identifying the central issues surrounding conflicts of interest that are likely to be represented in the respective policies of the examined journals and organizations. Some of the more prominent themes identified throughout this initial review included but was not limited to topics relating to: the role of and proper attribution of authorship;²¹³ developing standards to recognize contributions that did not satisfy the criteria for authorship;²¹⁴ the various financial dimensions of conflicts of interest;²¹⁵ the role and purpose of disclosure as an approach to address conflicts of interest;²¹⁶ perceived

²¹² Pope, Ziebland, and Mays, "Qualitative research in health care," 116.

²¹³ Jackie M. Street et al., "Credit where credit is due? Regulation, research integrity and the attribution of authorship in the health sciences," *Social Science & Medicine* 70 (2010): 1458-65; Charlton, "Figureheads, ghost-writers," 475-80; Flanagan et al., "Prevalence of articles," 222-224; Wislar et al. "Honorary and ghost authorship," 1-7.

²¹⁴ Liesegang et al., "How to ensure our readers' trust," 337-340; Elizabeth Wager, "Authors, Ghosts, Damned Lies, and Statisticians," *PloS Medicine* 4, no. 1 (2007): 5-6.

²¹⁵ Catherine D. DeAngelis, Phil B. Fontanarosa, and Annette Flanagan, "Reporting Financial Conflicts of Interest and Relationships Between Investigators and Research Sponsors," *JAMA* 286, no. 1 (2001): 89-91; Sheldon Krimsky and L.S. Rothenberg, "Financial Interest and Its Disclosure in Scientific Publications," *JAMA* 280, no. 3 (1998): 225-26; Keune et al., "Taking Disclosure Seriously," 215-24.

²¹⁶ Rebecca M. Minter et al., "Ethical Management of Conflict of Interest: Proposed Standards for Academic Surgical Societies," *Journal of the American College of Surgeons* 213, no. 5 (2011): 677-82;

limitations of disclosure as a policy mechanism;²¹⁷ and potential penalties and enforcement measures regarding conflicts of interest and scientific misconduct.²¹⁸ While this list of categories in no way represents the full range of issues related to conflicts of interest and ghostwriting, the central importance afforded to each of these issues within the literature would seemingly imply that each issue is likely to be well recognized by the respective policies of each of the journals and organizations included in the final analysis. As such, by drawing on this literature review as the means of constructing an initial set of primary thematic categories related to conflicts of interest, it is possible to engage in a more directed means of evaluating the actual policies themselves.

After developing this set of primary themes identified through a substantive review of literature focused on conflicts of interest and ghostwriting, the next step of the immersive phase of qualitative content analysis is to shift the focus to examine the actual texts themselves. In this particular case, the texts consist of the stated conflict of interest policies of the six journals and two organizations identified earlier in this chapter. Given the electronic nature of modern publishing, the individual conflict of interest policies employed by each respective medical journal and organization have become readily accessible through their respective websites. As such, the process of gathering relevant

Joseph S. Alpert, "Doctors and the drug industry: How can we handle potential conflicts of interest?" *The American Journal Of Medicine* 118, no. 2 (2005): 99-100; Camilleri, Dubnansky, and Rustgi, "Conflicts of Interest," 841-47; Karine Morin et al., "Managing Conflicts of Interest in the Conduct of Clinical Trials," *JAMA* 287, no. 1 (2002): 78-84.

²¹⁷ David Korn, "Conflicts of Interest in Biomedical Research," *JAMA* 184, no. 17 (2000): 2234-37; Daylian M. Cain, George Loewenstein, and Don A. Moore, "The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest," *Journal of Legal Studies* 34 (2005): 1-25.

²¹⁸ Stern and Lemmens, "Legal remedies," 1-5; Kalb and Koehler, "Legal Issues in Scientific Research 85-91; David M. Studdert, Michelle M. Mello, Troyen A. Brennan, "Financial Conflict of Interest in Physicians' Relationships with the Pharmaceutical Industry – Self-Regulation in the Shadow of Federal Prosecution," *NEJM* 351, no. 18 (2004): 1891-1900.

policy information concerning conflicts of interest entailed a thorough examination of the respective websites for each journal and organization with a particular emphasis on the sections of each respective website focused on the instructions provided for authors concerning manuscript submission, stated editorial policies, and when noted those policies stating they explicitly involved conflicts of interest. In situations where the policies set out by individual journals or organizations provided additional content in the form of editorials, other published articles, or other means of clarifying their policies, these documents were included and evaluated in the same manner as the stated policies provided they had been made available by the journal or organization as a direct part of their respective conflict of interest policies. With this process culminating in the collection of an aggregate set of textual data concerning the respective policies and procedures involving conflicts of interest for each journal and organization, further parsing was necessary in order to identify and extract the central thematic elements found in the policies themselves.

Deriving meaningful insights from this aggregate collection of textual data concerning conflict of interest policies began in a similar, albeit more focused manner to that of the initial literature review. Drawing on the sense of familiarity with the topic and corresponding list of primary themes present in the literature, a review of each journals' and organizations' respective conflict of interest policies was conducted to not only ensure each of these already identified themes was present but to also further supplement this list with issues and themes presented by the policies themselves. As such, this review not only confirmed the prevailing attitudes present in the literature with respect to the already established primary themes, but was able to also identify a number of more

specific secondary issues often focused on more procedural issues pertaining to the application of the policies themselves. Examples of these secondary issues included: the explicit definitions of what constitutes a conflict of interest; the degree of recognition afforded to both financial and non-financial conflicts of interest; defining concepts such as authorship and contributorship and the means of communicating this information to readers; addressing factors such as industry sponsorship, publication planning, independent statistical analyses, and the contributions made by medical writers; the specifics as to what information needs to be disclosed when there is a conflict of interest; how conflict of interest disclosures are collected and communicated to the reader; when does disclosure take place and what impact it has on the publication process; the uniform application of conflict of interest policies across different types of articles; what enforcement mechanisms exist and how do they operate in the event conflict of interest policies are violated. Yet again, while this is in no way a complete list of the issues found within each set of policies; these issues represent either the more common themes present within the examined set of policies or when applicable a unique approach enacted by a single journal that based on its departure from other policies warranted inclusion and further examination.

Identifying these secondary issues entailed reviewing the complete set of policies and explicitly seeking themes and issues that had not previously been raised during the initial literature review. Added clarification was also sought regarding the practical dimensions of each of the issues identified during the literature review and subsequent examination of the policies themselves. The purpose of this clarification was primarily to elicit greater detail as to the dimensions and scope of each theme and issue, but also to

develop a better sense as to practical applications of each set of policies. Identifying which themes and issues required greater clarity and supplementary information was determined by the presence of any direct mention in the respective policies of one or more journals or organizations to the issue or theme itself. Additionally, any mention in the respective policies that was able to provide added clarity or detail as to a specific issue or theme was also noted and included. In other words, the results of this process involved the purposeful collection of any and all information that may be deemed relevant to the central issues and themes of the policies themselves. No information was excluded unless it exhibited no direct relevancy to conflicts of interest or ghostwriting. The end result of this process was the identification of the key themes and issues present in either the established body of literature or the individual policies of the journals themselves. This information was then presented in the form of a question alongside the specific area(s) of each journals' and organizations' respective policy that was able to either offer an answer to the question being posed or any potentially relevant information concerning that particular theme or issue.

With the immersive phase of qualitative content analysis generating an aggregate set of the key themes and issues identified from both a review of the relevant literature as well as an in-depth examination of the actual policies employed by the examined journals and organizations, the next step of qualitative content analysis involves approaching this data through the concerted process of reduction. Where immersion serves as the means of guiding the collection of relevant information to inform the analysis, the reductive phase takes this collected data and is able to better identify and organize the recurring thematic elements into new, manageable analytical categories or codes that are better

capable of supporting both the research questions and contextual framework identified by the researcher.²¹⁹ Reduction offers a means of taking the existing totality of data gained through immersion and distil it in a manner that “strip[s] away unnecessary detail and delineate[s] more clearly the central characteristics of data”²²⁰ in such a way that the resulting categories are able to explicitly reflect the contextual framework imposed by the researcher. In this way, reduction offers the necessary means of developing a more unified and coherent set of analytical “categories [that] may be derived inductively—that is, obtained gradually from the data—or used deductively, either at the beginning or part way through the analysis as a way of approaching the data”²²¹ to produce a more cogent and directed analysis capable of addressing the underlying research question.

With reduction serving as the means to develop a set of more manageable and meaningful analytical categories to inform the subsequent interpretation of the data, the first step of the reductive phase involved an examination of the aggregate list of textual data generated through immersion. Seeking to identify the overarching thematic elements from this range of topics, the result of this examination is the clear elaboration of three primary categories concerning issues related to authorship, contributorship, and the use of disclosure as a means of addressing conflicts of interest. With the practice of ghostwriting directly challenging the established notions of scientific authorship and the resulting emergence of contributorship as a means of recognizing the actions of medical writers and other non-authorial functions, each of these themes is prominently represented in both the literature and respective conflict of interest policies. As such,

²¹⁹ Forman and Damschroder, “Qualitative Content Analysis,” 48.

²²⁰ Dey, *Qualitative Data Analysis*, 40.

²²¹ Pope, Ziebland, and Mays, “Qualitative research in health care,” 114.

their prominence alone warrants recognition as part of two distinct categories. Similar reasoning extends to the inclusion of a separate category for issues related to disclosure. Given its prominence as the principle approach to address conflicts of interest for each of the examined journals and organizations, the relevancy of disclosure to understanding the respective conflict of interest policies cannot be understated.

In addition to incorporating these primary themes, two more general categories were also necessary to operationalize and identify the specific definitions and general attitudes presented by each journal and organization with respect to conflicts of interest. As such, individual categories concerning both the primary policy mechanism and general attitudes of each journal and organization, alongside the specific definitions used to determine what constitutes a conflict of interest were established in order to convey these relevant details. It was also necessary to include a final category to account for the implicit variation that exists between the policies of each individual journal and organization in order for potential differences in the specific approaches used to address conflicts of interest to be examined. While not specifically informed by the literature or specific policies, the recognition and inclusion of difference as an individual category provides a critical means of identifying specific points of contestation within the individual policies of each set of journals and organizations.

After identifying these six primary categories, each of the remaining themes and concepts identified during the initial literature review and subsequent examination of the actual conflict of interest policies were organized in a complimentary fashion such that each was able to provide added clarity and content concerning a more specific issue related to the primary theme. Organizing the remaining themes, concepts, and categories

in this manner ensured that the specific details and content each offered remained an important part of the analysis but in a way that did not distract from the research questions being presented. Recognizing these remaining themes as related sub-categories within the analysis is possible due to the fact that their analytical contribution rests in their descriptive qualities more so than their potential theoretical and contextual importance. The end result of organizing the remaining themes and categories in this manner was a condensed list consisting of a series of six primary questions accompanied by a varying number of related sub-questions that was organized in the following form:

1. How are conflicts of interest defined by each journal?
 - a. Does this definition include both financial and non-financial conflicts of interest? Is one emphasized above the other?
 - b. What is the stated timeframe for what constitutes a conflict of interest?
2. What is the role and purpose attributed to authorship within each journal and who qualifies for this?
 - a. How is authorship defined by the journal?
 - b. What actions and roles qualify to be recognized as authorship?
3. How are contributions that do not qualify for authorship recognized by each journal?
 - a. How is contributorship defined by the journal and what actions qualify for it?
 - b. How are such contributions communicated to the reader?
 - c. What actions and roles qualify to be recognized as contributorship?
4. What are the primary policy mechanisms and attitudes concerning conflicts of interest for each individual journal and organization?
5. What does disclosure of conflicts of interest entail?
 - a. What information is required to be disclosed?
 - b. How and when is this information collected?
 - c. Does the disclosure of a conflict of interest have any impact on decisions to publish an article?
 - d. How is the information regarding disclosed conflicts of interest communicated to readers? Is it readily accessible?
 - e. Is disclosure required for situations where no apparent conflicts of interest exist?
6. Are there any apparent differences in how each journal applies their own conflict of interest policies or specific requirements that distinguishes them from those of other journals?

- a. Are the stated conflict of interest policies applied uniformly to all types of articles?
- b. Does the journal have any unique requirements that may not be found in the policies of other journals?

Drawing on this list of primary themes and related sub-questions presents a range of issues around which to structure a more in-depth discussion and theoretical analysis capable of satisfying the final phase of qualitative content analysis. This final phase entails first engaging in a substantive discussion as to the findings offered by each set of policies that provides the basis to inform a more theoretically informed analysis drawing on the framework outlined in Chapter 1. It is through this more theoretical engagement that develops the necessary range of conceptual meanings and analytical tools capable of implementing a novel context with which to understand, evaluate, and challenge the range of established meanings that have come to be associated with specific conflict of interest policies employed by the examined journals and organizations. Combining the key themes and issues identified and strengthened throughout the immersive and reductive phases of qualitative content analysis with an accompanying context derived from a unique theoretical understanding it becomes possible to begin the interpretative phase allowing each of the included texts to be examined in such a way so as to begin deriving new meanings and methods of understanding their underlying significance.

5.4 Outlining the Results

Before it is possible to engage in any substantive discussion or theoretical examination of the examined policies, it is necessary to first summarize how each journal and organization is able to satisfy the primary and secondary questions posed to guide the analysis. To this end, the most straightforward manner to accomplish this task involves

constructing a series of tables providing direct references to the relevant sections of each journal and organizations' respective conflict of interest policies capable of addressing the question being posed. In situations where the individual policies either do not provide a direct answer to the question being posed or additional information is necessary, a descriptive account is instead offered to either outline the implied meaning offered by each journal and organization or to provide supplementary information concerning the stated question.

With the policies of each journal and organization being the primary object of analysis, the resulting data extracted from each set of policies is best organized by journal so as to provide a more accurate and complete picture concerning how each of the specific primary and secondary questions contribute to understanding the entirety of the journals approach to address conflicts of interest. The complete results of this process are available unabridged at the end of the thesis in the included Appendices with Table 5 providing a concise summary of the primary questions guiding the analysis.

With the primary themes of each journal and organization's respective conflict of interest policies clearly outlined, it now becomes possible to use this raw textual data as the foundation on which to structure a more in-depth analytical discussion and theoretical evaluation necessary to explore the inherent similarities and points of departure between policies in order to assess their respective efficacy in addressing conflicts of interest.

Table 5: Summary of Results

	ICMJE	NEJM	The Lancet	JAMA
How are COIs defined?	The range of financial or personal relationships that inappropriately influence or bias actions.	Uses same definition as the ICMJE.	Uses same definition as the ICMJE.	Uses same definition as the ICMJE.
What is the role and purpose of authorship?	Involves substantive contribution and the ability to take responsibility for at least one component of the work. Establishes ICMJE standard for authorship.	Authorship implies accountability and independence with respect to the production of content for a manuscript. Uses ICMJE definition for authorship.	Implies that the purpose of authorship is to bestow a sense of accountability and ownership over the results being presented. Uses ICMJE definition for authorship.	Authors take public responsibility for specific elements of the manuscript with one or more taking responsibility for the work as a whole. Uses ICMJE definition for authorship.
How are contributions not recognized by authorship recognized?	Contributors that fail to qualify for authorship are listed in an acknowledgements section.	Contributions that do not qualify for authorship are listed in an appendix.	Recognizes contributorship. Requires that the actions of both authors and contributors be documented at the end of the manuscript in the acknowledgements section.	Contributorship listed in acknowledgements section at end of manuscript.
What is the primary policy mechanism used to address conflicts of interest?	Disclosure to readers of any financial or personal relationships that may be deemed a COI.	Disclosure to readers of the financial associations of authors using the standard form provided by the ICMJE.	Full disclosure of any actual or potential COI to editors that are then published as part of the article using their own form to document each authors contributions.	Complete disclosure for all potential COI using the form provided by the ICMJE.
What information is required to be disclosed?	All financial and personal relationships that may be deemed a conflict of interest must be included in standard ICMJE disclosure form. Authors must also describe the role of the study sponsor.	Any associations on behalf of the author or their family with commercial entities that supported the work or may have an interest in the work. Nonfinancial associations relevant to the manuscript. The entirety of this information will be posted online with a summary appearing in the article.	Authors must disclose any financial or personal relationship with other people or organizations that may influence their work. This information is made available at the end of the article.	Authors must disclose all relevant financial interests, activities, relationships and affiliations regardless of their value. This information is listed in the acknowledgement section at the end of the article before the references.
Are there any apparent differences in how each journal applies their own conflict of interest policies or specific requirements that distinguishes them from those of other journals?	Applied uniformly. ICMJE standards act as the baseline to evaluate other policies given their position of institutional importance.	Authors of review articles and editorials previously were expected to have no relevant financial relationships. Now are expected to have no significant relationships over \$10,000. Also notes that contractual terms must not limit rights to examine data independently or impede the decision to submit manuscript for publication.	Comments, Seminars, Reviews, and Series will not be published if author has COI within last 3 years. Also requires that authors confirm they have full access to all data and have made the decision to publish.	Policy applies to all types of articles. Industry sponsored studies previously required independent analysis of the underlying data but this has since been dropped as a requirement.

	Annals of Int. Medicine	PLOS Medicine	BMJ	WAME
How are COIs defined?	Uses same definition as the ICMJE with slightly different language to produce the same meaning.	Anything that could be perceived to or actually interferes with the full and objective presentation, peer review, editorial decision-making, or publication of an article.	Framed in terms of a primary interest (such as patients health) being influenced by a secondary interest (such as financial gain).	Exists when an individual's private interests may appear to impact their scientific responsibilities. In effect frames COI in terms of a divergence between an individual's private interests and their public responsibilities.
What is the role and purpose of authorship?	Authorship implies accountability for the intellectual content of the manuscript. Uses ICMJE definition for authorship.	Authors take public responsibility for their respective portions of the content they produce. Uses ICMJE definition for authorship.	Emphasis on ICMJE standards of authorship as a means of recognizing important contributions to the research.	Emphasis on ICMJE standards of authorship but recognizes some added flexibility not offered by the ICMJE. Proposes that authorship should be determined early on in the research process to avoid potential problems.
How are contributions not recognized by authorship recognized?	Contributions that do not qualify for authorship are listed in the Acknowledgements section along with a brief description of each contributors actions.	Contributions that do not qualify for authorship are recognized as contributors and listed in the Acknowledgements.	Utilizes the concept of contributorship to account for those who do not satisfy the conditions for authorship. This information is listed at the end of the article with details pertaining to planning, conducting, and reporting the research.	Encourages adoption of contributorship with recognition of these actions in the form of a statement appearing in the manuscript such that their involvement in the manuscript is made transparent..
What is the primary policy mechanism used to address conflicts of interest?	Disclosure of academic affiliation and initial summary of all financial relationships that could be viewed as a potential COI when a manuscript is submitted followed by the standard form provided by the ICMJE.	Emphasis on promoting transparency for readers through the disclosure of all relevant competing interests.	Disclosure of any competing interest held by author to readers so that they can evaluate their impact. Specifically states that BMJ is not trying to eliminate COI. For research papers, this information is obtained using the standard form provided by the ICMJE.	COI do not imply wrongdoing but they need to be appropriately managed. Managing them in this manner depends on disclosure given the inability to monitor or investigate whether COI are present.
What information is required to be disclosed?	Authors must explicitly state whether COIs exist in the form of academic, financial, institutional, or personal relationships. The entirety of this information is made available online when an article is published.	Authors must declare all financial competing interest along with any non-financial competing interest of both a personal and professional nature. This information will appear at the front of the manuscript in a dedicated section for Competing Interests, any information concerning study funding will appear in a financial disclosure section.	Three types of information is necessary concerning associations with commercial entities providing support for work or having an interest in the area of the work and non-financial associations that may be relevant or seen to be relevant. The manner in which this information is made available to the reader depends on the type of article with research articles relying on the standard ICMJE disclosure form to gather the information that will then appear in the manuscript.	Recognizes that there is no accepted standard as to the degree to which a potential COI may impact the judgment of an individual researcher. Instead recognizes need for individual journals to provide as precise requirements as possible while also recognizing the need to explicitly acknowledge the source of funding and any resulting involvement in collection, or analysis of data, or reporting of results.
Are there any apparent differences in how each journal applies their own conflict of interest policies or specific requirements that distinguishes them from those of other journals?	Avoids publishing editorials, reviews, or guidelines by authors with direct COI but evaluates this on case-by-case basis. Requires authors confirm they had access to all study data.	Policy applies to all types of articles. Specifically recognizes the involvement of medical writers and industry funding as explicit elements of stated policies and provides information concerning this. Also recognizes the need to ensure that all data pertaining to a study is made readily available to interested parties.	Varying requirements depending on type of article with most extensive being required for those presenting original research. Articles concerning presenting either an Analysis or Methods simply require a statement explaining potential COIs on behalf of author. Explicitly recognizes industry funding with GPP2 guidelines providing guidance on how to properly report the involvement of medical writers. BMJ has also undertaken a commitment to make available all relevant data from studies on request.	Explicitly recognizes ghostwriting and provides a working definition of the practice. Recognizes that ghostwriting goes beyond individual authors and identifies the involvement of marketing, communications, and medical education companies who must be part of the approach to address ghostwriting.

6 Chapter: Constructing a Novel Understanding of Conflict of Interest

Policies

We reject also the presumption that the pursuit of profit along with the progress of science and medicine is inherently in conflict. In fact, in our experience the marketplace accurately reflects the public's hopes and expectations for science, and is a powerful guardian of behavior. It has little tolerance for shoddy performance or misapplied energies. It is a powerful mechanism for progress, for which no apologies are needed.

Helen Davies,
Senior V.P, Quintiles Transnational Corp.
Talk Delivered at the Institute of Medicine
April 21, 2001.²²²

Each of the proceeding chapters have served to outline the necessary contextual and methodological processes with which to identify and elaborate the key thematic elements that will serve to inform a more rigorous analysis of medical journal conflict of interest policies. It is at this point that it becomes crucial to revisit the theoretical framework outlined in Chapter 1 as a means of advancing a deeper understanding capable of evaluating the wider implications and meanings attached to these policies. It is through this purposeful reintroduction of theory as a means of developing the necessary conceptual tools to promote a novel means of understanding the themes and categories developed during qualitative content analysis that yields the potential to construct new

²²²Helen Davies, "The Role of the Private sector in Protecting Human Research Subjects: A CRO perspective," talk delivered to the Institute of Medicine and originally available at http://www.acrohealth.org/policy/pdfs/testimony_82101.pdf quoted in Mirowski and Van Horn, "The Contract Research Organization," 507. While the original PDF file accessed by Mirowski and Van Horn is no longer available directly through Acrohealth, it is possible to access an archived copy of the page that contains the contents of the original talk at https://web.archive.org/web/20041110235805/http://www.acrohealth.org/policy/testimony_082101.asp.

philosophical meanings from existing social phenomena encapsulated within medical journal conflict of interest policies.

With theory serving to provide the means of developing a proper contextual framework with which to formulate new analytical meanings, this chapter seeks to accomplish two key tasks. The first of which involves discussing the respective conflict of interest policies enacted by each journal and organization in greater detail so as to provide a thorough and descriptive account as to how each set of policies addresses the key thematic issues identified in the previous chapter. Thus, while this first task serves principally as a means of communicating the salient elements of each journal's respective conflict of interest policies, it also enables a comparative analysis of each set of policies by implicitly identifying points of agreement and any key differences that exist within each distinct approach. The second and arguably more important task this chapter seeks to accomplish is to elaborate new ways of understanding and evaluating conflict of interest policies by engaging in a rigorous theoretical analysis that seeks to problematize existing accounts that have become embedded within social consciousness and have thus far remained unquestioned.

Instituting the theoretical framework discussed in Chapter 1 as a means of cultivating the necessary concepts with which to achieve this secondary goal, the analysis presented in this chapter serves to outline how existing conflict of interest policies present an insufficient means of addressing the structural transformation of medical research and instead facilitate the further entrenchment of a neoliberal ethos of science. It is through the appropriation of a set theoretical context and its accompanying conceptual framework then that this chapter seeks to not only outline the key themes of

each journal's respective conflict of interest policies, but to use this information to summarily evaluate the efficacy and potential held by such policies to address transformative changes occurring within the both social and institutional processes guiding medical research and within the generalized ethos of science itself.

6.1 Defining Conflicts of Interest

Utilizing explicit policy measures to establish codified guidelines to address conflicts of interest has become a common feature of medical publishing and willingly accepted as a necessary procedural safeguard to preserve the objectivity of medical research. As a result of the acceptance of conflict of interest policies, there exists a certain degree of harmonization between the approaches of individual journals particularly with respect to some of the most pressing issues concerning conflicts of interest. While such commonalities offer an important means of identifying many of the recurring challenges faced by medical journals, the application of such policies is far from homogenous. Rather, in contrast to these commonalities there exist subtle and important variations within each journal and organizations' approach to conflicts of interest, often concerning detailed and specific elements unique to each set of policies that can be easily overlooked when examined independently. Presenting a comparative review of the respective policies utilized by six top ranking medical journals and two highly influential organizations serves to incorporate not only the shared commonalities present in each set of policies, but also the purposeful inclusion of the underlying differences and variations between them as well.

Providing an informative discussion as to the specific content of each of the journals and organizations respective conflict of interest policies must first begin by

defining what particular relationships and actions are deemed to actually constitute a conflict of interest. In this regard, the general definition regarding conflicts of interest offered by the ICMJE forms the basis for many of the respective definitions employed by each of the other journals and organization. A conflict of interest according to the ICMJE:

exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that *inappropriately influence (bias) his or her actions* (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from being negligible to having great potential for influencing judgment. Not all relationships represent true conflict of interest.²²³

It is this characterization of conflicts of interest to be the product of an ability to influence a resulting action that is found in each of the explicit definitions offered by the examined journals and organizations.²²⁴ While the degree of influence recognized as a conflict varies based on the individual journal, four clear standards are present ranging from a very specific “inappropriate influence” found in both the New England Journal of Medicine (NEJM) and the Lancet,²²⁵ more relaxed standards that “could influence” or “may be influenced” in both the Journal of the American Medical Association (JAMA)

²²³ “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Consideration in the Conduct and Reporting of Research: Conflicts of Interest,” International Committee of Medical Journal Editors, accessed February 15, 2013, http://www.icmje.org/ethical_4conflicts.html. (Emphasis Added).

²²⁴ The full definitions as to what constitutes a conflict of interest for each journal and organization as per their respective policies are available in the included Appendices located at the end of this thesis.

²²⁵ “Uniform Requirements for Manuscripts,” ICMJE, reprinted in Frank Davidoff et al., “Sponsorship, Authorship, and Accountability,” *New England Journal of Medicine* 345, no. 11 (2001): 826-27; “Statements, permissions, and signatures – Declaration of interests,” the Lancet, accessed February 15, 2013, <http://www.thelancet.com/lancet-information-for-authors/statements-permissions-signatures#conflicts-of-interest>.

and British Medical Journal (BMJ),²²⁶ a middle ground to each of these in the Annals of Internal Medicine and WAME concerning actions that may “unduly influence,”²²⁷ and lastly the adoption of entirely different yet functionally similar language by PLoS Medicine referring to interference rather than influence.²²⁸

While the definitions offered by each journal and organization recognize varying degrees of influence, each maintains that conflicts of interest center on the ability for a particular form of influence to hinder or sway the actions or responsibilities of either the author or researcher (or their institution). In the case of the ICMJE, NEJM, Lancet, JAMA, and the Annals of Internal Medicine, this influence is framed explicitly in terms of its potential to introduce bias to the actions of an author or researcher that is then reflected in the final research or publication. Adding to this understanding, the Annals of Internal Medicine further recognizes the potential for influence to impact the responsibilities of an author throughout the publication process. This recognition is also shared by WAME who offer an interpretation concerning a “divergence between an individual’s private interests [...] and his or her responsibilities to scientific and publishing activities”²²⁹ and PLoS Medicine who present a more thorough account of the impact of influence on publishing by recognizing the responsibility of authors to present

²²⁶ “JAMA Instructions For Authors – Conflicts of Interest and Financial Disclosures,” Journal of the American Medical Association, accessed February 15, 2013, <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx#ConflictsofInterestandFinancialDisclosures>; “Declaration of competing interests,” BMJ, accessed February 15, 2013, <http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/declaration-competing-interests>.

²²⁷ “Conflict of Interest in Peer-Reviewed Medical Journals,” World Association of Medical Editors, accessed February 15, 2013, <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>; “Information for Authors – Authorship Issues,” Annals of Internal Medicine, accessed February 15, 2013, <http://annals.org/public/authorsinfo.aspx#authorship-issues>;

²²⁸ “PLOS Editorial and Publishing Policies – Competing Interests,” PLoS Medicine, accessed February 15, 2013, <http://www.plosmedicine.org/static/policies#competing>.

²²⁹ WAME, “Conflict of Interest.”

a “full and objective presentation”²³⁰ of their research. The most general interpretation however is offered by BMJ whose definition simply accounts for the presence of a “secondary interest (such as financial gain or personal rivalry)” capable of influencing the author or researcher. While some commonalities exist concerning the way influence is understood among each of the examined journals and organizations, it is important to note that not all forms of influence are deemed to necessarily entail a conflict of interest as explicitly noted by the ICMJE, NEJM, and the Annals of Internal Medicine. With each adopting almost identical language concerning the negligible impact certain relationships have on the research process, it is important to recognize that despite the central importance afforded to influence in defining conflicts of interest for each of these journals, it alone does not automatically represent a “true conflict of interest” resulting in further determining factors being necessary.

Although there may exist some ambiguity as to the extent of influence that is seen to warrant a true conflict of interest, identifying the particular relationships and actions deemed impactful enough to influence the research process and the knowledge it generates often requires more explicit recognition than is possible by framing conflicts of interest solely in terms of influence. As such, each of the examined journals and organizations also draw on more precise methods for defining the particular actions and relationships that may result in a conflict of interest. These methods entail dividing potentially conflicting actions and relationships into two key categories: financial and non-financial conflicts of interest. The more prominent of these categories concerns the

²³⁰ PLoS Medicine, “PLOS Editorial Policies.”

relationships and actions related to the array of financial incentives that come to directly influence the conduct and actions of researchers. As noted by the ICMJE, these “[f]inancial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself.”²³¹ Accompanying this emphasis on financial incentives is the corresponding potential for relationships and actions of a non-financial nature to also generate conflicts of interest. Some examples offered by the Lancet, BMJ, and PLoS Medicine include “personal relationships, academic competition, or intellectual passion,”²³² unpaid roles, memberships, and advisory positions in various organizations such as charities or professional groups,²³³ as well involvement in lobbying activities or personal convictions that may hinder the objective presentation of research findings.²³⁴ While these non-financial conflicts lack the readily identifiable characteristics of their financial counterparts and are therefore more difficult to appraise their potential impact, they nonetheless present a significant obstacle to the objective presentation of medical research. However, it is the relative ease with which financial incentives can be identified and the formative influence such relationships offer that has allowed their role to be emphasized within the conflict of interest policies of the examined journals and organizations.

²³¹ ICMJE, “Uniform Requirements for Manuscripts.”

²³² The Lancet, “Statements, permissions, and signatures.”

²³³ “BMJ Group policy on declaration of interests,” BMJ, accessed February 15, 2013, http://www.bmj.com/sites/default/files/BMJ_Group_policy_on_declaration_of_interests.pdf.

²³⁴ PLoS Medicine, “PLOS Editorial Policies.”

One example of this emphasis on financial conflicts of interest is reflected in the standardized form prepared by the ICMJE²³⁵ and required as part of the conflict of interest policies employed by the NEJM, JAMA, the Annals of Internal Medicine, and BMJ for authors to disclose potential conflicts of interest. With the ICMJE disclosure form offering a standardized means of gathering the requisite information related to conflicts of interest, the primary focus of both the form and its accompanying instructions focus principally on financial activities and incentives related to both the work being submitted and any relevant activities of the author beyond the work itself. Other non-financial activities and incentives are then simply amalgamated into a broad category focused on ‘Other Relationships’ with comparatively little guidance offered as to the specific requirements and reasoning behind the inclusion of certain relationships and actions in this particular category. A similar albeit less pronounced emphasis on financial conflicts of interest is also found in the modified disclosure form utilized by the Lancet wherein the examples utilized to demonstrate conflicts of interest directly reflect those provided by the ICMJE concerning financial conflicts of interest with the sole difference being the addition of explicit mentions of both patent applications and travel grants.²³⁶ By drawing on the same examples as the ICMJE, the Lancet effectively places a greater

²³⁵ The original analysis examined a previous version of the ICMJE Standard Disclosure form available through JAMA at http://jama.jamanetwork.com/data/ifora-forms/icmje_author_form.pdf. The ICMJE has since updated this form to include a standalone section on conflicts of interest related to Intellectual Property concerning ownership and royalties originating from patents and copyrights. In addition to this update, significant changes to the section concerning disclosing conflicts related to the submitted work were also made. These changes now require the submitting author to manually add every financial relationship and categorize it as either a Grant, Personal Fees, Non-Financial Support, Other. The previous version of the form required the author to remove categories that did not apply while also offering a “No” option concerning funding of a particular type. The updated version of the ICMJE disclosure form is available here http://www.icmje.org/coi_disclosure.pdf.

²³⁶ The Lancet, “Author statements form,” accessed February 15, 2013, <http://download.thelancet.com/flatcontentassets/authors/tl-author-signatures.pdf>.

emphasis on these financial incentives than those relationships and actions that may not directly involve a financial dimension.

While each of these journals emphasizes financial conflicts of interest as part of their required disclosure forms, this is not to say that they do not also recognize the influence afforded by non-financial relationships and actions. To the contrary, each of the examined journals does recognize to varying degrees non-financial conflicts of interest, however this recognition is often afforded a less prominent role than similar conflicts of a financial nature. Perhaps the most balanced approach to handling each of these types of conflicts of interest is employed by PLoS Medicine whose own policies provide arguably the most extensive explanation as to the particular relationships and actions that define not only financial conflicts of interest, but also those which yield non-financial conflicts of both a professional and personal nature. In this way, while there remains a strong emphasis on financial conflicts of interest within the policies enacted by PLoS Medicine, this presents less of an issue than other journals given the comparative emphasis on non-financial conflicts allowing them to be treated in a similar manner to their financial counterparts.

In addition to clarifying the particular relationships and actions deemed to constitute a conflict of interest, it is also necessary to establish a definitive timeframe as to when these same relationships are deemed impactful to the research process. In this regard, the conflict of interest policies of the examined journals and organization recognize two key periods where potential conflicts of interest must be disclosed. The first timeframe is that related to “the work itself, from the initial conception and

planning”²³⁷ to the point at which the work is submitted to a journal for consideration. Recognizing this period is relatively straightforward given the potential of conflicts of interest to directly influence the research process as it takes place and the resulting knowledge it generates. As such, this is one of the few areas within each of the respective conflict of interest policies where a clear consensus exists between each of the examined journals and organizations without any subtle distinctions as found in other areas of their policies. The second timeframe however is far more subjective as it concerns the period of time before the research process actually begins allowing the influence exerted by conflicts of interest to be more ambiguous and indirect. In spite of this added degree of ambiguity there still exists a relative consensus among each of the examined journals and organizations as to necessary timeframe before research begins where disclosure of potential conflicts of interest is required. Each of the examined journals as well as the ICMJE requires that authors and researchers disclose potential conflicts of interest during the three years prior to the initial inception of a research project with only PLoS Medicine surpassing this standard by instead mandating disclosure for a period of five years. While WAME offers no explicit recommendations as to a specific timeframe, their own policies do stress the importance of determining a precise period before the research process begins where authors must disclose relationships and actions that may be perceived as potential conflicts of interest but leaves the determination of the exact timeframe up to individual journals.²³⁸

²³⁷ “ICMJE Form for Disclosure of Potential Conflicts of Interest,” ICMJE, accessed February 15, 2013, http://www.icmje.org/coi_disclosure.pdf.

²³⁸ WAME, “Conflict of Interest.”

6.2 Bifurcating Recognition – Issues of Authorship and Contributorship

After outlining the specific criteria utilized by each journal and organization to define conflicts of interest, the next prominent issue that must be addressed involves clarifying the accepted standards concerning the attribution of authorship and the related capacity to recognize contributions to the research process from non-authorial parties. Given that the primary role and purpose of authorship is to provide a means of recognizing the contributions made by individuals to the research process and by doing so instill a sense of accountability concerning the information being presented,²³⁹ the importance of authorship in facilitating the objective presentation of scientific research cannot be understated. With each of the examined journals and organizations relying on the authors of a prospective publication to personally disclose potential conflicts of interest, ensuring adherence to stated conflict of interest policies requires clearly delineating the specific roles and responsibilities that qualify for authorship. Therefore, it is this reliance on disclosure that represents one of the primary reasons why it is necessary to consider the individual authorship policies of each of the examined journals alongside those directly related to conflicts of interest. Lacking a purposeful means of clarifying who qualifies for authorship entails that an author centric policy mechanism such as disclosure can in no way offer an effective solution to address the challenges posed by conflicts of interest. Further to this point, with the rise of industry funded ghostwriting campaigns directly challenging established notions of authorship, clarifying the accepted standards employed by medical journals is even more crucial in order to

²³⁹ WAME Editorial Policy Committee, “Policy Statements – Authorship,” World Association of Medical Editors, accessed February 15, 2013, <http://www.wame.org/resources/policies#authorship>.

recognize the substantive contributions made to the research process by other parties such as medical writers and statisticians. As a result, it is necessary to also account for and explain how each journal and organization handles the rise of the related concept of contributorship in any assessment of issues related to either authorship or conflicts of interest in their respective policies.

The definition of authorship employed by each of the examined journals is derived from the guidelines and recommendations put out by the ICMJE. These guidelines stipulate that authors must satisfy each of three separate criteria in their entirety to be recognized as an author and receive appropriate credit in the byline of the final published article. Authorship according to the ICMJE:

should be based on 1) substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.²⁴⁰

It is these three specific criteria that form not only the basis of the ICMJE's own definition of authorship, but also the corresponding definition that has been accepted and integrated in its entirety by the respective policies of each of the examined journals.

Utilizing the definition of authorship advanced by the ICMJE allows each of the examined journals to enforce strict guidelines as to the particular contributions that each researcher must make in order to qualify for authorship. However, this highly selective approach may fail to adequately recognize important contributions made by other actors

²⁴⁰ "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship," International Committee of Medical Journal Editors, accessed February 15, 2013, http://www.icmje.org/ethical_1author.html.

including the services provided by medical writers, statisticians, and those actively involved in collecting the underlying data itself. While each of these functions has a direct and meaningful impact on the final results produced by the research process, assessed independently none of these contributions would be sufficient to satisfy the established criteria for authorship imposed by the ICMJE.

Perhaps the most glaring oversight involving the definition of authorship employed by the ICMJE concerns an inability to acknowledge the use of medical writers to draft and develop published manuscripts as part of the established standards of authorship. It is this inability to recognize the growing involvement of medical writers that is of particular importance given that the commercial value of ghostwriting relies heavily on concealing their involvement so as to purposefully downplay potential conflicts of interest that may accompany the involvement of industry in the research process. By relying on the established standards of authorship set out by the ICMJE, existing conflict of interest policies can be seen to further reinforce the hidden nature of ghostwriting by failing to explicitly recognize the substantial intellectual contributions made by medical writers to the production of a final manuscript as sufficient to be recognized in terms of authorship. This failure by the ICMJE standards lies in stark contrast to the guidelines adopted by WAME whose own standards require only that authors have “made substantial intellectual contributions to the study on which the article is based”²⁴¹ while also explicitly calling attention to failures in recognizing the contributions made by medical writers to the production of published manuscripts.

²⁴¹ WAME Editorial Policy Committee, “Policy Statements – Authorship.”

Although the authorship standards employed by the ICMJE and adopted by each of the examined journals fail to offer an explicit means of recognizing the significant contributions made by actors such as medical writers and statisticians, each of the examined conflict of interest policies have come to utilize alternate methods to account for substantial contributions that fail to satisfy established standards for authorship. These methods entail utilizing a secondary classification of contributorship for those actions that are deemed important enough to impact the research process that they warrant recognition yet fail to satisfy the established criteria set out by the ICMJE for authorship. While no formalized definition of contributorship is offered by any of the examined journals beyond simply recognizing the need to acknowledge those who have made ‘substantial contributions,’ the most practical understanding is that offered by the ICMJE who imply that contributorship is characterized by any combination of actions that would normally satisfy at least one criterion of the ICMJE’s standards for authorship yet fails to satisfy all three as required by authorship.²⁴² As such, despite the fact that each of the examined journals relies extensively on contributorship to address an apparent gap in the capacity of existing authorship standards to fully recognize important contributions to the research process, the concept remains relatively poorly defined. Despite this limitation, drawing on the implied meaning of contributorship offered by the ICMJE would seemingly present not only a viable understanding as to how the concept is recognized by each individual journal, but to do so in a way that remains consistent with their established standards of authorship.

²⁴² ICMJE, “Uniform Requirements: Authorship and Contributorship.”

The role of contributorship can therefore be seen to offer a supplementary method of recognizing those actions that cannot be captured solely within existing authorship standards. By augmenting existing authorship standards to include the added dimension of contributorship it becomes possible to account for the actions of a wider range of actors including but not limited to medical writers and statisticians as well as properly identifying those individuals who handle specific tasks within the research process such as data collection and analysis, handling administrative functions,²⁴³ and securing research funding.²⁴⁴ In this way, the inclusion of contributorship within conflict of interest policies can be seen to offer a complimentary means of addressing the issues associated with the inherent rigidity found in established authorship standards by including an additional set of more flexible criteria to identify and acknowledge the contributions made by actors not recognized as authors by the ICMJE.

In addition to utilizing this more flexible criteria with which to differentiate contributorship from authorship, the manner in which each is communicated to the reader is also markedly different. Where authorship traditionally invokes acknowledgement in the form of a prominent note in the byline of a published manuscript, recognition of contributorship is instead far more subdued with each of the examined journals relying on the provision of a separate ‘Acknowledgements’ or ‘Contributors’ section at the end of the text whose sole purpose is to provide the requisite means of properly attributing non-authorial contributions. Given that the implied definition of contributorship is derived

²⁴³ “JAMA Instructions for Authors - Editorial Policies for Authors,” Journal of the American Medical Association, accessed February 15, 2013, <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx#EditorialPoliciesforAuthors>.

²⁴⁴ “PLOS Editorial and Publishing Policies – Author Status,” PLoS Medicine, accessed February 15, 2013, <http://www.plosmedicine.org/static/policies#author>.

from the authorship standards offered by the ICMJE, there is little if any substantive difference between the underlying actions performed by authors and contributors. Rather, the primary difference is based simply on the number of criteria with authors needing to satisfy additional criteria in order to assume ownership of the research and be held socially accountable for the results being presented. Therefore, by acknowledging contributorship through a the use of a specific ‘Acknowledgements’ section at the end of a manuscript as opposed to the byline mention afforded to authorship, the existing approach utilized by each of the examined journals can be seen to reinforce the perceived superiority of authorship by effectively downplaying what remain by definition substantial contributions to the research process by individual contributors. Resultantly, this approach to acknowledge contributorship fails to properly recognize the significance of contributions made by actors who fail to satisfy the established criteria for authorship allowing contributorship to function as a means of downplaying the perceived impact and involvement of particular actors such as medical writers whose actions by definition entail a substantial contribution to the production of medical knowledge.

Drawing on the flexible nature of contributorship to supplement established authorship standards has allowed medical journals a greater capacity to recognize the growing prevalence of contributions that extend beyond the roles and actions attributed solely to individuals involved in the research process. Consequently, the inclusion of contributorship has provided the necessary means for journals to recognize those contributions made by or on the behalf of institutional and industry actors. In this regard, by utilizing the more flexible nature of contributorship to account for actions made on behalf of institutions or industry, medical journals have the opportunity to use

contributorship as a means of clearly delineating the source of funding for medical research while also calling attention to how the research process itself can be shaped to influence the production of medical knowledge. Despite this potential, the extent to which contributorship has been utilized to explore the sources of funding within medical research exhibits significant variation between each of the examined journals with many remaining focused predominantly on documenting the source of funding rather than actually characterizing the issues associated with particular forms of funding.

For instance, in the policies of both JAMA and the NEJM while an explicit need for authors to account for the role of study sponsors exists, the weight and subsequent value of this information takes a less prominent role than other journals given its placement in the Acknowledgements section at the end of the published manuscript. By contrast, both the Annals of Internal Medicine and the Lancet who also require an explicit recognition as to the role of industry funding, instead choose a more prominent means of recognizing the impact of research funding by requiring authors include a description as to the involvement of industry directly in the Methods sections of the article.

Approaching industry sponsorship in this manner allows authors to expressly illustrate the impact of sponsorship in terms of its ability to shape key elements of the study itself and represents perhaps the most comprehensive approach employed by the examined journals. Lastly, both BMJ and PLoS Medicine also explicitly recognize the need to account for the role of industry sponsorship but instead of offering their own recommendations choose to rely on a series of predominantly industry written publication

guidelines produced by the International Society for Medical Publication Professionals²⁴⁵ that simply reaffirm the need to incorporate some form of acknowledgement regarding industry sponsorship in the final publication without providing more direct guidance.²⁴⁶ In the case of PLoS Medicine, this acknowledgement is included at the beginning of the article online and on the front page of a printed manuscript whereas BMJ instead relies on similar placement as both the NEJM and JAMA where the acknowledgement of industry funding appears at the end of the article. As such, while the guidelines utilized by both BMJ and PLoS Medicine offer nothing new in terms of recommendations concerning how best to acknowledge the presence of industry funding, the referenced guidelines do represent the only instance where any of the examined conflict of interest policies explicitly recognize the use of publication planning strategies by industry.

While present, the scope of this recognition falls well short of appreciating the structural significance and impact of publication plans in favorably shaping the research process in accordance with the commercial marketing objectives of industry instead framing their use in terms of providing support for authors to ensure the effective and timely publication of scientific results.²⁴⁷ As a result, while the guidelines referenced by PLoS Medicine and BMJ offer the only unequivocal mention of publication planning, they fail to offer any substantive recommendations regarding their significant structural

²⁴⁵ The International Society for Medical Publication Professionals is a professional organization representing medical writers and publication planning professionals and offering a code of conduct regarding established standards and practices for this part of the industry. It is also important to note that they are heavily reliant on industry funding to sustain their operations. For more information about the organization and its policies see "ISMPP Home," accessed February 15, 2013, <http://www.ismpp.org/>.

²⁴⁶ Chris Graf et al., "Good publication practice for communicating company sponsored medical research: the GPP2 guidelines," *BMJ* 339, published November 30, 2009, <http://www.bmj.com/content/339/bmj.b4330>.

²⁴⁷ Ibid.

influence over the research process and instead focus solely on reiterating the need to properly acknowledge individual contributions made by all parties involved in the research process.

Issues of authorship and contributorship retain a central focus in the conflict of interest policies of each of the examined journals and organizations. While the existing approach to address these issues may be at times problematic, medical journals have come to rely on clearly accrediting authorship in order to facilitate the proactive disclosure of conflicts of interest that may impact the production of medical knowledge. However, given the author centric nature of disclosure the success of conflict of interest policies ultimately depends on the adherence of individual authors to willingly disclose their own potential conflicts of interest while also identifying the respective contributions of those contributors who fail to receive authorship credit. In this way, the preeminent focus on disclosure as the principle policy mechanism for each of the respective journal and organizations requires that information concerning not only how conflicts of interest are defined but also the specific roles and actions that warrant disclosure be made readily available to prospective authors. Only after this information is made available that it then becomes possible to compare the logistical requirements utilized by each of the examined journals to collect and make available the relevant information pertaining to the disclosures made by individual authors concerning their respective conflicts of interest.

6.3 Encapsulating Disclosure as a Policy Mechanism

The next prominent issue to discuss entails examining the specific ways in which each of the examined journals and organizations have organized their respective conflict of interest policies to address the particular actions and relationships that may be

construed to unduly influence the conduct of researchers and skew the presentation of medical research. In the case of each of the examined journals and organizations, a relatively uniform approach is presented whereby each respective set of policies is structured in such a way that their primary emphasis rests on promoting a greater sense transparency concerning how the research process operates by utilizing targeted policy mechanisms designed to provide a more thorough account of the relationships and actions that may come to influence the conduct of individual researchers. It is thought that by encouraging a more transparent understanding of the relationships and interests held by individual researchers involved in the research process that medical journals would possess a sufficient means of managing the negative impact associated with any underlying conflict of interest that could appear in a published manuscript. Transparency in this regard can be seen to center on the ability of journals and organizations to make available relevant information concerning the relationships and interests of individual researchers that may be construed as a conflict of interest and have this information form the basis on which to evaluate these potential conflicts. As such, it is this underlying emphasis on transparency and corresponding need to make available information concerning potential conflicts of interest that has allowed each of the examined journals and organizations to develop explicit policy measures requiring that each prospective authors proactively disclose any relationship or interest that may appear to influence their actions or conduct throughout the entirety of the research process. The use of disclosure has become the prominent method with which to address conflicts of interest and has come to serve as the central policy mechanism for each of the examined journals and organizations given its ability to collect relevant information that readers can then use to

evaluate the extent to which certain relationships and interests may impact either the research process or actions of individual researchers. With each of the examined journals and organizations adopting disclosure as the cornerstone of their respective conflict of interest policies, its consistent use has come to actively reinforce the belief that the impact associated with conflicts of interest over both researchers and the research process can be suitably managed through the implementation of an appropriate set of policy measures emphasizing transparency.

Disclosure is seen to offer medical journals an explicit and readily codified means with which to gather pertinent information that can be used to gauge the extent to which certain relationships and interests are able to influence the research process and resultant actions of individual researchers. In the case of each of the examined journals and organizations, the relationships and actions that must be disclosed focus largely on those of a financial nature given the high likelihood that any resulting benefits will be accrued directly by the author(s). However, the emphasis on disclosure also recognizes the need for authors to identify relationships that supersede their own direct financial interests and may be perceived as beneficial for other actors, including those conflicts of a personal nature or those relationships that actively involve industry. To this end, perhaps the most succinct account of these requirements is set out in an editorial published in the NEJM by the editors of the ICMJE member journals which clearly states that authors are required to disclose any “associations with commercial entities that provided support for the work [...] their associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript [...] any similar financial associations involving their spouse or their children under 18 years of age [and lastly] nonfinancial

associations that may be relevant to the submitted manuscript.”²⁴⁸ In this regard, disclosure requires that authors must identify any relationship regardless if it is of a financial or personal nature that may appear to influence or provide some form of incentive concerning an individual’s conduct during the research process or with respect to an authors’ presentation of research findings. Further to this point, each of the examined journals with the exception of the NEJM and Annals of Internal Medicine also mandate disclosure for those situations where authors do not possess a potential conflict of interest. In situations where no declared conflicts of interest exist, each of these journals instead require that authors make explicit declarations reaffirming this fact effectively disclosing an absence of potential conflicts. The use of this so-called form of negative disclosure ensures that in all eventualities prospective authors are required to make some form of declaration concerning their potential conflicts of interest even if the purpose of such declaration is to simply confirm that potential conflicts do not exist.

In addition to the type of information disclosed by each author, the point in time that disclosure occurs is also an important element to consider given the perceived relevancy of using such information as the basis of editorial decisions regarding publishing. Each of the examined journals requires that relevant information concerning the potentially conflicting personal and financial relationships of authors be collected prior to a manuscript being accepted for publication. For most, this collection process occurs at the point in time when a manuscript is initially submitted for consideration, and involves authors completing an electronic disclosure form fully documenting any

²⁴⁸ Jeffrey M. Drazen et al. “Uniform Format for Disclosure of Competing Interest in ICMJE Journals,” *NEJM* 361,no. 19 (2009): 1896.

relationships or interests that may be perceived as a potential conflict of interest. The most common version of this form is the one produced by the ICMJE and utilized by the NEJM, JAMA,²⁴⁹ BMJ, and the Annals of Internal Medicine that offers authors a readily personalized yet structured means of identifying potentially conflicting relationships and interests. While both the Annals of Internal Medicine and NEJM initially require only a summary of each author's relationships and interests, a more detailed account utilizing this form is ultimately required at a later point in the publication process. The Lancet also makes use of an electronic disclosure form to identify potential conflicts of interest that is functionally equivalent to that offered by the ICMJE but allows a more open ended interpretation pertaining to how authors identify potential conflicts.²⁵⁰ Opting to instead contact each author via email to obtain the requisite information concerning any potential conflicts, PLoS Medicine is the sole journal that does not actively rely on the use of a standardized form to collect information from authors concerning potential conflicts of interest.²⁵¹ Consequently, while some minor variation exists concerning the logistics of collecting information disclosed by authors regarding their potentially conflicting

²⁴⁹ While *JAMA* does make use of the ICMJE disclosure form, they also utilize a supplementary form to verify eligibility for authorship in accordance to ICMJE standards. In addition to validating eligibility for authorship according to ICMJE standards, this form also provides a direct reminder to authors that they must also complete the ICMJE disclosure form.

²⁵⁰ The disclosure form offered by the ICMJE is far more structured than that offered by *The Lancet*. By listing a number of financial incentives such as grants or honorariums by default on the form, authors are forced to identify each as being either relevant to either themselves, their institutions, or not at all while also listing the particular name of the entity involved in a particular relationship and any further comments that are necessary. The form is also setup in such a way that should an author have multiple relationships of the same kind — for instance an author received payment for reviewing a manuscript from two different companies — each is recognized independently from one another. By comparison, the disclosure form utilized by *The Lancet* while requiring essentially the same information instead simply provides a text box to account for the role of the funding source, any conflicts of interest that may be relevant, and the contributions made by the author. The form itself provides little guidance to the author as to what each statement needs to include beyond a list of examples that may be relevant and only requires the authors signature confirming that the provided information is both complete and correct.

²⁵¹ PLoS Medicine, “Editorial Policies – Competing Interests.”

relationships and interests, it is clearly evident that each journal makes a concerted effort to gather relevant information from authors at the beginning of the publication process while clearly indicating that such information functions as an important element of each of the examined journals respective conflict of interest policies.

One possible explanation as to the importance of the information obtained through disclosure focuses on the opportunity it grants medical journals and their editors to gauge the extent to which certain relationships and interests can be interpreted to truly represent a conflict of interest and by doing so clearly denote those actions which are deemed acceptable to accompany a prospective publication. Drawing on the information provided by authors at the time a manuscript is submitted, disclosure provides journal editors the opportunity and ability to selectively screen prospective manuscripts and purposefully exclude those whose potential conflicts are deemed severe enough that they may be compromise the research findings being presented. Despite this opportunity, the conflict of interest policies employed by the majority of the examined journals with the sole exception of PLoS Medicine fail to specifically prohibit a manuscript with conflicts of interest from progressing onto further stages of the publication process such as peer review. As such, despite efforts to obtain information pertaining to each authors' conflicts of interest during the initial submission of a manuscript, the information obtained through disclosure comes to serve little practical purpose in terms of informing the editorial decisions made by these journals. Rather the value of disclosure for these journals rests on the ability to reaffirm the belief that conflicts appearing in published manuscripts can be suitably managed through the implementation of an appropriate set of policy measures emphasizing an underlying sense of transparency provided by

disclosure. It is this underlying emphasis on transparency that comes to shape how each of the examined journals and organizations make use of the information concerning an author's potential conflicts of interest gathered through disclosure.

Through the use of disclosure as a central component of their respective conflict of interest policies, each of the examined journals and organizations have been able to retain a prominent focus on promoting a sense of transparency concerning how the research process operates and resulting actions undertaken on the behalf of parties who hold a vested interest in its outcomes. The sense of transparency achieved by utilizing information garnered from authors to compose a standardized disclosure statement allows medical journals to make available to readers a short summary outlining the potentially conflicting relationships and interests declared by each author that can then be included as part of a published manuscript. Additionally, these disclosure statements are often accompanied by a supplementary set of acknowledgements for those individuals who fail to satisfy the established criteria for authorship allowing the actions of these so-called contributors to also be recognized in some form in the published manuscript. It is through the act of disclosing this information — first by the author and subsequently by the journal — that offers what has become an effective means with which to exculpate those articles containing what are deemed less impactful conflicts by presenting what is portrayed as useful tool to help “the reader to understand the relationships between the authors and various commercial entities that may have an interest in the information

reported in the published article.”²⁵² It is through this implied ability of disclosure to enlighten readers as to the myriad of interests that may influence the research being presented that seemingly provides journals with the necessary means of facilitating a more transparent understanding as to how conflicts of interest may impact the research process.

Utilizing the information obtained through disclosure in this manner, each of the examined journals have been able to utilize an author’s declared conflicts in such a way that they no longer present an impediment to the publication of a manuscript. Rather, such conflicts and their accompanying disclosure statements are depicted in such a way that they are seen to provide an added value to readers by succinctly conveying information that is deemed necessary to properly evaluate how an author’s disclosed relationships and interests may ultimately impact the claims being presented in a manuscript. With the information obtained through disclosure providing readers a better understanding as to how an author’s declared conflicts of interest may impact the research being presented, each of the examined journals are able to satisfy their underlying commitment to transparency by offering readers what are seen as the necessary tools to not only better understand the contributions made by individual researchers to the research process, but do so in a way that recognizes the potential impact an authors’ disclosed conflicts may have on the research being presented. Consequently, it is this implied ability of disclosure to function in an educative capacity for readers that not only reinforces the shared commitment of the examined journals to

²⁵² Drazen et al., “Uniform Format for Disclosure,” 1896; “Editorial Policies – Financial Associations/Conflict of Interest,” New England Journal of Medicine, accessed February 15, 2013, <http://www.nejm.org/page/about-nejm/editorial-policies>.

promoting transparency, but also strongly reaffirms the belief that any impact associated with conflicts of interest can be suitably managed through the implementation of an appropriate set of policy measures requiring authors proactively disclose any and all potential conflicts of interest.²⁵³

6.4 Accounting for Variance

While the discussion thus far has been framed in such a way as to purposefully accentuate a number of key themes related to conflicts of interest including issues related to authorship, contributorship, and the use of disclosure, any substantive analysis would be seriously remiss to exclude the fact that many of the examined journals also require prospective authors satisfy a number of additional conditions outside of those directly stated in their conflict of interest policies. Recognizing each of these added conditions is of paramount importance given their ability to signify more rigorous standards and by doing so identify perceived deficiencies in the policies of other journals. Furthermore, while it is important to consider these additional specificities and their ability to ascertain key points of difference between the policies of individual journals, recognizing any internal discontinuity in how each journal applies their own conflict of interest policies also warrants significant consideration. Incorporating these internal discontinuities offers a way in which to identify the most pressing issues faced by each of the examined journals whereby the most stringent requirements are reserved for those issues deemed of

²⁵³ Despite its intended use to address conflicts of interest, the use of disclosure can present a number of unintended and potentially problematic issues. For further detail regarding some of these issues see George Loewenstein, Sunita Sah, and Daylian M. Cain, “The Unintended Consequences of Conflict of Interest of Disclosure,” *JAMA* 307, no. 7 (2012):669-70; Nicholas B. King and Jay S. Kaufman, “More Author Disclosure: Solution or Absolution?” *Epidemiology* 273, no. 6 (2012): 777-79; Gabriel K. Silverman et al., “Failure to discount for conflict of interest when evaluating medical literature: a randomised trial of physicians,” *Journal of Medical Ethics* 36 (2010): 265-70.

greatest importance to the individual journal. Thus, it is through the addition of this inherently comparative examination of the policies of each journal and the differences in how they are applied that provides a necessary dimension not present when examining only the core elements of each set of policies.

The first theme addressed by these added requirements concerns the need for authors to have full and unrestricted access to data related to the study they are wishing to publish. With concerns over industry sponsored studies withholding relevant information necessary to evaluate potential adverse reactions or therapeutic efficacy, many journals have placed a renewed focus on ensuring that the information made available to authors represents all aspects of a study and is not simply used to portray a specific product in a positive light. As a result, the *Lancet* and *Annals of Internal Medicine* have both incorporated explicit language reaffirming the need for authors to have full and unrestricted access to trial data as part of their respective editorial policies in an effort to ensure that the claims made in subsequent publications provide an accurate representation of the underlying data. This requirement is taken one step further by *BMJ* whose recent push towards a more open-access style of publishing now mandates that access to trial data extend beyond authors whereby upon request all relevant trial data is to be made available and subsequently stored in a digital repository that is readily accessible to any interested party.²⁵⁴ With *PLoS Medicine* sharing a similar commitment concerning the availability of data,²⁵⁵ the issue of access has become a central concern given the

²⁵⁴ Fiona Godlee and Trish Groves, "The New *BMJ* policy on sharing data from drug and device trials," *BMJ* 345, published November 20, 2012, <http://www.bmj.com/content/345/bmj.e7888>.

²⁵⁵ "PLOS Editorial and Publishing Policies – Sharing of Data, Materials, and Software," *PLoS Medicine*, accessed February 15, 2013, <http://www.plosmedicine.org/static/policies#sharing>.

perceived inability of traditional publishing safeguards such as peer review to ensure the proper scrutiny of published results.²⁵⁶ The NEJM also maintains a strong emphasis on ensuring authors have access to all relevant data but do so in a less direct manner than the aforementioned journals. Rather than directly calling for authors to receive unfettered access to trial data, the NEJM instead incorporates language that reaffirms the journals commitment through their stated opposition to contractual terms and obligations that deny authors and other actors involved in a study the ability to analyze study data independently from the sponsor. While the inclusion of provisions focused on ensuring authors receive full access to trial data are relatively recent additions to the policies of their respective journals, there appears to be a growing consensus on the need to ensure that published manuscripts alone are no longer a sufficient means of validating scientific claims and that access to the underlying data has become a necessary component of the modern research process.

Further to this recent effort to ensure that authors have unrestricted access to trial data is a related move by some journals to ensure that the decision to publish research is made solely by individual authors and not done simply to appease the wishes of another party. In similar fashion to the need for authors to independently evaluate trial data, the decision to publish research in itself has become another avenue where commercial influence can have a detrimental role on the findings being presented. With systematic efforts undertaken by the pharmaceutical industry to carefully dictate how products are positioned in the medical literature, the need to ensure that publishing decisions are based

²⁵⁶ This sentiment is echoed by the *BMJ* editorial explaining their shift towards a more open access emphasis of publishing. See Godlee and Groves, “The New *BMJ* policy,” 1.

on an author's own evaluation as to the clinical value offered by a manuscript and not constrained by the financial motivations of industry. Consequently, this has led the NEJM, the Lancet, and Annals of Internal Medicine to each individually integrate language emphasizing the need for authors to exercise total independence concerning the final decision to submit a manuscript for publication into their respective editorial policies.

Perhaps the most unique requirement however was until recently found in the editorial policies of JAMA. While other journals have recognized the need for authors to have full access to trial data, this requirement was taken one step further by JAMA whereby data supporting all industry sponsored studies was required to undergo further independent examination "by an independent statistician at an academic institution [who] must be a faculty member at a medical school or academic medical center, or an employee of a government research institute, that has oversight over the person conducting the analysis and that is independent of the commercial sponsor."²⁵⁷ By requiring this further analysis, JAMA was able to ensure that the data used to support the research findings of any industry sponsored study were evaluated by at least one party who could be seen as being free of direct commercial influence and thus help to reduce the likelihood of a potential conflict of interest on behalf of the examiner. While the need for industry sponsored studies to be independently evaluated offered JAMA a unique

²⁵⁷ This requirement has since been dropped from *JAMA's* editorial policies and no longer appears as part of the online instructions provided for authors. For an archive of the original page outlining this specific policy please see "JAMA Instructions for Authors – Data Access and Responsibility," Journal of the American Medical Association, accessed February 15, 2013, <http://web.archive.org/web/20130529031553/http://jama.jamanetwork.com/public/instructionsForAuthors.aspx>, originally accessed at <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx>.

opportunity to implement a novel approach to address conflicts of interests at the editorial level, this requirement has since been withdrawn allowing all studies regardless of their source of funding to be considered for publication even if their underlying analysis is conducted solely by parties who possess direct financial ties to industry. The stated rationale given for this shift in policy was that the need for independent evaluation of trial data was:

developed during a time when several high-profile trials had evidence of problems with data integrity, inappropriately conducted statistical analyses, and incomplete reporting of major findings. Over time some of these policies have been modified and strengthened but have been perceived by some in academia and industry as creating barriers to publication of important trial results. Moreover, over the past 2 years, our experience has been that the conduct of additional analyses by independent academic biostatisticians generally did not result in meaningful changes in the study results.²⁵⁸

The explanation offered by JAMA makes it readily apparent that the benefits associated with the need to independently evaluate trial data are readily overshadowed by the need to ensure the expedient publication of research findings. Thusly it is through the purposeful abdication of this need for industry funded trials to be independently evaluated that the remaining elements of JAMA's conflict of interest policy have come to further reflect key elements of the policies of the other examined journals further reinforcing a certain degree of homogeneity between the respective policies.

A final unique requirement concerns the explicit recognition offered by some journals concerning the contributions offered by either medical writers or their ghostly

²⁵⁸ Howard Bauchner, "Editorial Policies for Clinical Trials and the Continued Changes in Medical Journalism," *JAMA* 310, no. 2 (2013): 149.

counterparts. With only PLoS Medicine and WAME actively incorporating any direct mention as to the contributions made by either ghostwriters or medical writers, the use of such parties within medical research remains obscured by the common utilization of more broadly defined categories of contributorship that offer the remaining journals a flexible means of ensuring that such roles are acknowledged albeit in a way that lacks the precision and certainty afforded by a more direct emphasis in the journals stated editorial policies. Recognizing the role of medical writers in PLoS Medicine should come as no surprise given the journals lengthy publication record that has been highly critical of the use of ghostwriters in medical research. Despite this however, PLoS Medicine offers little in the way of their own substantive policy beyond requiring that the involvement of medical writers must be declared instead relying on the established guidelines provided by the European Medical Writers Association for a more detailed examination of the practice.²⁵⁹ WAME however offers a more substantial recommendation concerning ghostwriting in the form of a dedicated policy statement on the matter. Providing proactive suggestions for curtailing the practice, the guidelines offered by WAME serve to offer journals a more structured approach to not only identify ghostwriting but also present a viable starting point to begin conceptualizing practical solutions to address the practice as well.²⁶⁰

Stemming from this initial discussion of the key themes present in each journals' respective conflict of interest policies, the reintroduction of the theoretical framework

²⁵⁹ "PLOS Medicine Guidelines for Authors – Author Status," PLoS Medicine, accessed February 15, 2013, <http://www.plosmedicine.org/static/guidelines#status>.

²⁶⁰ WAME Editorial Policy Committee, "Policy Statements – Ghost Writing Initiated by Commercial Companies," World Association of Medical Editors, accessed February 15, 2013, <http://www.wame.org/resources/policies#ghost>.

introduced earlier in Chapter 2 offers the means of developing new conceptual understandings necessary to explain and understand how existing approaches to conflicts of interest reliant on practices such as disclosure and particular notions concerning authorship and contributorship come to reflect a particular normative understanding of science. It is through the reintroduction of theory at this critical juncture that the necessary conceptual framework to generate new ways of understanding these core themes is made possible. Through the development of new conceptual understandings it becomes possible to purposefully re-evaluate how the existing array of policy measures encapsulated in each of the examined journals conflict of interest policies comes to reinforce a particular understanding of science defined by neoliberal ideology and by doing so reaffirm the associated normative structure that accompanies it.

6.5 Characterizing Neoliberal Science as Common Sense

With the pertinent elements of each journal's respective conflict of interest policies clearly established, analyzing the significance and efficacy of these policies requires revisiting the theoretical framework introduced at the beginning of this thesis. The reintroduction of theory provides the necessary conceptual tools with which to examine how the policies of each of the examined journals seek to not only address the problems posed by conflicts of interest, but more importantly assess how such policies help illustrate the underlying ethos of science and the accompanying social processes that drive medical research. With the underlying research question framed in such a way so as to evaluate the impact of medical journal conflict of interest policies in shaping the ethos of science itself, it is necessary to begin any substantive analysis by first clearly outlining the dominant normative structure that defines the current ethos of science. Only

with these parameters clearly established does it then become possible to evaluate the efficacy of the individual policies in addressing not only the issues posed by conflicts of interest, but also their subsequent influence in contesting the entrenchment of a particular form of common sense that has come to define a neoliberal ethos of science.

Applying a theoretical framework informed by Gramsci to develop new understandings concerning conflicts of interest must begin by first identifying the dominant normative framework that not only shapes the production of medical knowledge but also how society understands and interacts with science itself. For Gramsci, the ability to articulate this normative framework draws on the particular philosophical currents that can be expressed as common sense and can be seen to constitute and perpetuate a particular hegemonic viewpoint. With hegemony assessed not only in terms of its ability to alter the respective understandings of individuals but to also perpetuate these ideas by harnessing the productive capacity of key social institutions, the emergence of a dominant ethos of science consistent with the ideals of neoliberalism becomes readily apparent through the need for medical research to increasingly satisfy the pharmaceutical industries' impetus on marketing and promotion. As a result of the structural reorganization of pharmaceutical research discussed in Chapter 4, a decidedly neoliberal conception of science has been able to emerge not only as the dominant conception of science driving medical research, but also that which can be readily expressed in terms of common sense. Reliant on the functional importance of key social institutions such as CROs and RCTs to facilitate the favorable dissemination of medical knowledge, the emergence of neoliberal science has allowed these institutions to internalize a normative structure consistent with central tenets of neoliberalism. In this

way, the current ethos of science and its accompanying normative structure can be expressed in terms consistent with Gramsci's conception of common sense allowing both the image of medical science and its accompanying social institutions to articulate two key values consistent with a neoliberal conception of science.

The first of such values espoused by the current neoliberal ethos of science concerns the structural reorganization of medical research to reinforce and prioritize market exchange as a core premise in the production and dissemination of medical knowledge. Market exchange in this manner represents a distinct shift in the processes that come to drive the research process such that economic incentives come to form the basis on which individual actions are undertaken and evaluated when producing new forms of medical knowledge. This exists in contrast to the more traditional vision of science postulated by Merton whereby the predominant goal of science is the pursuit of certifiable knowledge assessed in more holistic terms rather than a process of discovery focused solely on realizing potential economic value. Accounting for this shift involves recognizing two distinct factors that have come to influence how the research process prioritizes economic value and the related processes of market exchange as the primary means of shaping the decisions impacting both the creation of medical knowledge and guiding the research process.

Acknowledging the centrality of market exchange involves recognizing that medical knowledge has become indistinguishable from any other commodity given the increasing pressures to satisfy the marketing objectives set out by industry. Through this process of commodification, the end goal of the research process comes to be expressed in terms capable of satisfying the underlying logics of market exchange by prioritizing

those discoveries that can be readily translated into a tangible product that can then be bought or sold. Success therefore comes to be framed predominantly in terms of the particular actions capable of realizing the potential economic value held by medical knowledge allowing alternative methods of assessing value to be overlooked. As a result, the research process comes to prioritize specific forms of medical knowledge capable of satisfying this economic means of assessing value and by doing so actively reaffirm the need for medical knowledge to satisfy the principles of market exchange. In other words, the existing structural configuration of medical research comes to prioritize the development of medical knowledge deemed valuable by a predetermined set of economic incentives. It is by assessing value in strictly economic terms that reaffirms not only the treatment of medical knowledge as a commodity governed by the principles of market exchange, but more importantly serves to validate a key value consistent with a neoliberal conception of science.

Building on this is a related need to recognize a second key value stemming from the dominant organizational form governing medical research. With CROs now serving as the prevailing organizational model for conducting medical research, not only does the actual knowledge being produced come to be assessed in economic terms but similar methods of assessment extend to the research process as well. Successful research comes to be framed not only in terms of the knowledge it produces, but also based on the ability for each phase of the research process to strictly adhere to established budgets and deadlines. Further compounding these pressures is the temporary nature of contract research whereby the ability of individual CROs to secure future contracts is dependent not only on the quality of research they produce but more importantly on their ability to

satisfy the economic imperatives set out by industry. In the same way that the value of medical knowledge is assessed by its ability to conform to established economic metrics, a similar method of assessment can be readily extended to the research process itself with those parties unable to satisfy specific criteria excluded from future research opportunities. Thus the entirety of the research process and the knowledge it generates comes to reflect an underlying focus on economic incentives by slowly discarding the forms of knowledge and organizational processes that are deemed inconsequential through a strictly commercial determination of value. The end result is the creation of a product and a research process readily suited for market exchange in accordance with neoliberalism.

The ascendance of CROs as the dominant means of conducting medical research has also allowed private institutions to increasingly control what has historically been held in the public domain. The most direct example of this process concerns the diminishing role held by public institutions such as universities within the research process. With medical research increasingly relying on the participation of private CROs to satisfy a wider range of services within the research process alongside growing pressures for university faculty to commercialize their individual discoveries, the remaining role for public institutions within the research process has been dramatically scaled back with their remaining social function increasingly defined by the cultural prestige derived from these institutions. It is through this shift in the research process from a publicly oriented mandate to that which emphasizes the role of the private sector that reaffirms another core value consistent with neoliberalism. Justified by a belief in the inherent efficiencies afforded through the empowerment of markets and the reduced

regulatory burden available to private institutions, this shift is seen to represent not only the ideal conditions for the production of medical knowledge, but also a set of guiding principles that come to impact how the research process itself is organized and how society comes to envision the ideal operation of science as well.

The integration of each of these key values helps to perpetuate a decidedly neoliberal conception of science within the social institutions that serve to define the form of new medical knowledge and the processes used in its creation. Consequently, it is the ability for these specific values to shape the research process itself that has allowed neoliberal science to emerge as the dominant normative framework governing the current structural configuration of medical research and allow it to be articulated in terms resembling the consensual dynamics central to Gramsci's conception of hegemony. With the realization of hegemony premised on the tacit acceptance of particular ideological currents, the restructuring of medical research to accentuate a normative structure consistent with a neoliberal conception of science and the corresponding ability of key social institutions such as CROs to internalize a related set of values has served to develop the necessary level of consent to allow neoliberal science to be accepted as the dominant normative framework governing medical research and be expressed in terms of a common sense way of understanding medical science.

Consequently, it is the pervasive and transformative power of neoliberal science in shaping the very ethos of science itself that must ultimately come to form the basis for evaluating any potential response posed to address the impact of this shift within medical research. Thus the reaction by medical journals in the form of specific policy measures to address the inherent problems posed by conflicts of interest arising out of this

decidedly neoliberal form of science must be evaluated in terms of their ability to challenge the same ideological entrenchment that has helped the values consistent with a neoliberal conception of science become accepted as common sense in medical research. It is therefore necessary when assessing the efficacy of the policy response presented by medical journals to address conflicts of interest to focus on the ability of existing conflict of interest policies to address the transformative influence neoliberalism on key social institutions by actively engaging with its ideological and normative dimensions in order to challenge the further entrenchment of neoliberal science as common sense.

6.6 Gramsci and Ghostwriting – Constructing a Theoretical Account of Disclosure

Despite an inherent degree of variance in the policies enacted by each of the examined journals and organizations, there exists an established consensus concerning what is deemed to be the ideal approach to address conflicts of interest. In the case of each of the examined journals and organizations the central focus remains on utilizing disclosure as the primary element of each policy given the belief that by identifying potential conflicts of interest it becomes possible to minimize and ultimately mitigate their resulting impact. While the unanimous use of disclosure helps to create the appearance of an effective solution to the problems presented by conflicts of interest, the core premise of disclosure ultimately relies on embracing a core premise of neoliberalism by relying on the empowerment of individual subjects. It is through this empowerment of individual subjects that allows neoliberal ideology to define the optimal parameters of social interaction whereby decisions are seen to reflect the actions of rational individuals seeking to maximize their own self-interests while correspondingly assuming the associated burden of any risks tied to these same decisions.

The practice of disclosure reaffirms this same focus on empowering individual subjects. By having each of the examined policies focus on ensuring that individual authors report potential conflicts, existing conflict of interest policies and the measures of their success have come to be framed in terms of the actions and relationships of individual authors while ignoring the substantive impact of such conflicts on the research itself. While detailed information about each authors' personal conflicts must inevitably be secured from the authors directly, it is how the information made available through disclosure is used that ultimately matters. As per the stated policies for the majority of the examined journals, it is simply enough that authors have disclosed their potential conflicts in order for a submitted manuscript to still be considered for publication. With only the Lancet, NEJM,²⁶¹ and PLoS Medicine directly stating that potential conflicts of interest may serve to exclude a submitted manuscript from publication, each of the journals' respective policies remain more concerned with ensuring that submitted manuscripts are accompanied by the appropriate disclosure statements documenting an authors' potentially conflicting relationships and actions than taking a more proactive editorial stance seeking to evaluate the potential impact such conflicts have on the actual research itself. The absence of an institutional response on the behalf of the examined journals is perhaps best embodied by the actual policies of BMJ that clearly identifies the core focus of their conflict of interest policy:

²⁶¹ This policy applies only for editorials and review articles. Any manuscript that is presenting original research and may have potential conflicts of interest can still be published.

We are not aiming to eradicate such interests; they are almost inevitable. We will not reject your article simply because you have a conflict of interest, but we want you to make a declaration on whether or not you have competing interests.²⁶²

While this may be the most extreme example taken from the included policies, it clearly demonstrates that despite their editorial function, the examined journals remain focused more on framing conflicts of interest in terms of the actions of individual authors rather than addressing the systemic impact of the actual conflicts themselves. In this way, conflict of interest policies and the resulting measures of their success have come to be framed explicitly in terms of the relationships and interests held by individual authors effectively neglecting the importance of other key factors such as the organizational structure of the research process itself and corresponding role of ideology in helping to define the specific contexts and associated impact conflicts of interest have on the research being presented. It is by framing conflicts of interest in terms of the actions and relationships of individual authors that helps exemplify the subtle influence neoliberal science has in shaping the individual policy responses enacted by each of the examined journals. Adopting this focus on the actions of individual authors rather than attempting to address the impact of conflicts themselves, the examined journals reassert the very neoliberal logics such policies should be attempting to address. The resulting focus on individual authors serves to further legitimize the underlying ideological components of neoliberal science whereby the range of available solutions is artificially curtailed to include only those that actively focus on and can be expressed in terms of the actions of

²⁶² “Declaration of competing interests,” BMJ, accessed February 15, 2013, <http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/declaration-competing-interests>.

individual subjects. In the case of each of the examined policies, the extent of a journal's action is limited to securing voluntary disclosure information from individual authors despite the capacity to establish and implement more rigorous standards given their respective editorial functions. It is this capacity for the veiled ideological components of neoliberal science to constrain the actions of journals that demonstrates one aspect of the transformative power of common sense in shaping the range of potential policies deemed to be available to address the problems associated with conflicts of interest.

In addition to the author-centric focus found in existing conflict of interest policies, the abdication of each of the examined journals from taking a more proactive role to evaluate the impact of potential conflicts allows the onus of this task to be placed directly on the reader. Relying on the use of disclosure statements to communicate what is deemed to be pertinent information obtained from authors concerning potential conflicts; medical journals have come to internalize the belief that disclosure serves an educative function capable of allowing individual readers to make the appropriate evaluative judgements concerning the extent to which a potential conflict may impact the research being presented when provided with relevant information. In addition to bearing the responsibility for evaluating conflicts of interest, readers also assume the associated risks that may result from failing to recognize or appreciate the extent of a potential conflict. However, the commonly accepted practice of relying on readers to judge the impact of a potential conflict is severely problematic given the complex and often layered nature of influence exerted by the pharmaceutical industry over each phase of the research process. With the power of marketing strategies such as ghostwriting and the corporate construction of medical knowledge focused not only on crafting a specific

message, but doing so in a way that appears to be the product of good scientific practice, even under ideal circumstances as Anekwe points out where a “ghostwritten article declares its author’s conflicts of interest, the reader cannot know exactly what part of the article was biased [...] and when companies take the extra step of hiding negative results or deliberately biasing experiments, bias detection becomes impossible.”²⁶³ Thus even in ideal situations with full disclosure, it is highly unlikely that even the most astute reader will be able to accurately determine the impact specific conflicts have on the research being presented without also having access to more detailed information about the involvement of industry or by replicating the study itself in order to validate the results being presented. This problem is further compounded given the variable technical knowledge of individual readers whereby highly specialized research findings may require a more in-depth understanding of the subject material in order to identify how the declared conflicts of an author may impact the research being presented. However, perhaps the most problematic issue faced by readers is the situation raised by Matheson whereby:

Ironically, ‘conflict of interest’ statements may provide an opportunity for subterfuge, since authors or speakers frequently list all their commercial affiliations, not only the salient ones, obscuring the truth about who is paying for a specific article and implying balance because the author appears to be representing different interests.²⁶⁴

Thus, it is this potential for disclosure to work too well by identifying not only the relationships and actions that influence the presentation of the research at hand, but also

²⁶³ Anekwe, “Profits and Plagiarism,” 271.

²⁶⁴ Matheson, “Corporate Science,” 369.

those that are either not relevant or have no significant impact. The potential for disclosure to identify the relationships and actions of authors that have no direct impact on the research being presented severely strains the capacity of individuals to form accurate assessments of a potential conflict resulting in their true significance either being overlooked entirely or woefully underappreciated.

This inability of disclosure to identify only those relationships and actions that impact the research being presented speaks to a serious limitation within the existing requirements set out by the examined journal and organizations. With variable requirements as to the specific elements that warrant disclosure, the image presented by existing conflict of interest policies for each of the examined journals and organizations as to what constitutes a meaningful conflict is far from homogenous. To this end, the way in which potential conflicts are ultimately articulated by authors may rely on subjective interpretations as to the requirements set out by each individual journal and organization. As such, the specific way in which disclosure statements classify potential conflicts can vary not only from author to author, but also from journal to journal making it even more difficult for readers to clearly identify the manner in which particular relationships and actions can influence the research they are evaluating. One such example of this issue is raised by Ngai et al. whereby the acknowledgement of “industry support” in a manuscript can take on a numerous meanings ranging from comparatively straightforward provision of financial support to more extensive involvement whereby “a company conducted a study, hired a professional writer, and then merely attached another

scientist's name to the paper.”²⁶⁵ Thus it is through an intrinsic degree of ambiguity that readers are presented with another serious obstacle when attempting to ascertain how a particular conflict of interest comes to influence the presentation of research.

It is the continuing reliance on individual readers to evaluate the perceived impact of conflicts of interest that reinforces the primacy of neoliberal ideology as the principle means of informing the conflict of interest policies of each of the examined journals and organizations. Despite serious limitations concerning the ability of readers to accurately evaluate the impact associated with conflicts of interest based on disclosure statements alone, the continued reliance on readers to perform this very function demonstrates how pervasive neoliberal science has become in shaping the very parameters that come to inform policy decisions. The lasting commitment to reaffirm rational individualism in the form of reader empowerment allows existing conflict of interest policies to be structured in such a manner that they further reinforce common sense by acting to internalize a set of ideological and normative imperatives consistent with neoliberal science while discounting the potential of alternative solutions.

With the conflict of interest policies of each of the examined journals focused on ensuring individual readers are able to form evaluative judgements concerning the impact of a potential conflict; any remaining role held by the journals themselves is dramatically scaled back. As a result, the remaining role of journals comes to be focused predominantly on ensuring that information disclosed by authors is made available to readers. However, this seemingly minor function represents an important secondary

²⁶⁵ Stephanie Ngai et al., “Haunted Manuscripts: Ghost Authorship in the Medical Literature,” *Accountability in Research* 12, no. 2 (2005): 109.

issue within the neoliberal emphasis on individualism. While neoliberalism promotes the empowerment of individual actors, this process occurs as part of a broader shift whereby the capacity of social and institutional settings is severely undercut by the ideological and structural impetus that serves to elevate individual actions over those possessing a more communal nature. As such, conflict of interest policies come to not only prioritize the decisions made by individual readers, but to do so in a way that rules out the potential contributions made by journals themselves symbolizing a characteristic shift from more public and communal structures to those of a private and individual nature. While journals may not technically satisfy the traditional definition of public institutions given their largely private character, their editorial function does represent a more communal means of addressing conflicts of interest than relying solely on the judgements of individual readers. Despite this, the reliance of existing conflict of interest policies on the evaluative judgements offered by individual readers clearly demonstrates the ability for existing policy measures to articulate key normative values consistent with a decidedly neoliberal conception of science.

In addition to existing conflict of interest policies being structured in such a way so as to readily internalize a normative framework consistent with neoliberalism, the way in which conflicts of interest themselves have come to be understood is also subject to these same ideological pressures. With existing conflict of interest policies readily incorporating the neoliberal emphasis on rational individualism, the further entrenchment of neoliberal science has seen the very concept of what constitutes a conflict of interest readily internalize the importance of competition. The most pronounced example of this shift occurs within the stated policies of the ICMJE whereby “[f]or the purposes of

disclosure, the term “competing interest” should be considered synonymous with conflict of interest.”²⁶⁶ While on the surface this statement may appear to be relatively innocuous, properly contextualized it represents an important juncture concerning how the issues associated with conflicts of interest come to be addressed. By equating the terminology of conflict and competition not only does the ICMJE recognize the importance of yet another key normative value consistent with neoliberalism, but more importantly alters the very manner in which conflicts of interest come to be understood.

Invoking the more traditional terminology denoting a ‘conflict’ of interest implies a more oppositional meaning characterized by the presence of multiple inherently incompatible motivations. This is not the case for a ‘competition’ of interest. Rather, embracing the competition terminology instead presents a meaning that recognizes the ability for multiple potentially congruent motivations to be present with a single one rising to prominence without necessarily discounting other options. It is this fundamental difference that allows ‘conflicts’ of interest to present a more prescriptive normative perception concerning the range of motivations that are deemed to be acceptable and those that are not. This situation is much less clear when utilizing the competition terminology relying instead on imperfect market logics as the means to determine the particular dynamics and social acceptance of the underlying relationships held by researchers. Despite this clear distinction in both the meaning and significance of the terminology employed to describe the multitude of relationships that permeate the research process, what would initially appear to be a relatively banal point raises an

²⁶⁶ “ICMJE Conflict-of-Interest Form: Glossary of Terms,” International Committee of Medical Journal Editors, accessed February 15, 2013, http://www.icmje.org/coi_glossary.pdf.

important issue particularly when situated within the context of neoliberal science. With one of the most direct manners for influencing individual philosophy as required for the construction of common sense being the ability to alter the very meanings and understandings afforded to key terms and their accompanying definitions, the functional equivalence afforded to competitions of interest is of particular importance. Altering the underlying meanings and accompanying definitions of these key terms allows them to be expressed in terms supporting the normative and ideological dimensions of a particular philosophical point of view allowing the shift in language from ‘conflicts’ to ‘competitions’ of interest to represent a critical juncture in the further entrenchment of neoliberal science as common sense. While the extent of this shift within established conflict of interest policies to adopt new terminology to describe competition of interests may currently be isolated to the ICMJE, the relative position and influence afforded to the organization in guiding future policy directions allows even a subtle shift such as this to reflect ongoing developments within the particular normative and ideological frameworks that exist as common sense.

The prominent focus afforded to disclosure and resulting empowerment of individual actors by each of the examined journals and organizations to address conflicts of interest has done little to challenge the emergence of neoliberal science as common sense. Rather than providing a viable means of contesting the entrenchment of neoliberal ideology, the existing range of policies the journals responsible for their implementation have come to rely on a core normative values consistent with neoliberalism to serve as central elements to guide their respective approach to address conflicts of interest. By embracing neoliberal ideology and its accompanying normative framework, the

respective conflict of interest policies of each of the examined journals and organizations have thus far been unable to surpass their author-centric focus and promote more progressive structural reforms impacting key social institutions within the research process such as CROs. Rather, it is the underlying reliance on a set of normative values consistent with neoliberal science that enables existing conflict of interest policies and the journals and organizations responsible for their implementation to facilitate the further entrenchment of neoliberal science as common sense by accepting the very normative framework and ideological principles as defining elements of their respective policies. It is through this act of acceptance and subsequent acquiescence on the behalf of each of the examined journals and organizations that demonstrates not only an inability for existing conflict of interest policies to promote more progressive structural reforms impacting key social institutions involved in medical research, but to characterize the further entrenchment of neoliberal science as the increasingly accepted method of organizing and conducting medical research.

The policies enacted by each of the examined journals and organizations can therefore be seen as providing an ineffective response to the problems presented by conflicts of interest for medical research and instead serve to further solidify neoliberal science as common sense. With the policies of the examined journals and organizations failing to raise the necessary level of critical self-consciousness required for the elaboration of good sense necessary to contest common sense as laid out by Gramsci, each set of policies instead comes to be structured in such a way so as to reflect the already dominant normative structure and ideological principles of neoliberal science. Thus, while the emergence of conflict of interest policies has been in direct response to

the problems posed by the intensification of marketing and promotional efforts by the pharmaceutical industry, the effectiveness of this response has been conditioned and ultimately curtailed by the very structural and ideological frameworks that have allowed such practices to become thoroughly integrated in the modern research process. In this way, existing conflict of interest policies come to draw on the very norms and ideological components that they intend to address instead utilizing these for the foundation of the very solutions that they are seen to offer.

6.7 Key-Opinion Leaders as Gramscian Intellectuals

In a similar fashion to the inability of existing conflict of interest policies to present a viable means of contesting the construction of neoliberal science as common sense, such policies also fail to adequately address the ability of KOLs to act as the surrogate authors of ghostwritten manuscripts and provide the appearance of objectivity and independence for medical knowledge produced through publication planning strategies. Rather, it is the appearance of objectivity afforded by the prominent social position and prestige of KOLs that serves to further reinforce a decidedly neoliberal conception of science and its corresponding normative structure. Given the key social function held by KOLs and their subsequent importance to the marketing and promotional strategies employed by the pharmaceutical industry, it is possible to conceptualize and explore their role utilizing the concept of the traditional intellectual offered by Gramsci.

While Gramsci is predominantly focused on the impact and emergence of organic intellectuals as one of the necessary components for the realization of counter-hegemonies, analyzing the function of KOLs within the pharmaceutical industry involves

recognizing the important contributions made by traditional intellectuals in facilitating the construction of common sense. Assuming the form and function of traditional intellectuals as noted by Gramsci, KOLs are actively utilized by the pharmaceutical industry as a means of manufacturing the necessary level of consent to reinforce a particular normative framework consistent with a neoliberal conception of science. As Gramsci notes, the formation of consent achieved by traditional intellectuals hinges on their “prestige (and subsequent confidence)”²⁶⁷ alongside their perceived autonomy and accompanying politico-social functions.²⁶⁸ With the selection of KOLs drawing on these same criteria, with academic affiliation being among the most prominent factors, the pharmaceutical industry is able to target not only well respected and highly influential academic subjects to aid in the dissemination of favourable medical knowledge, but do so in a way that allows KOLs to not only maintain but also internalize a sense of independence and autonomy in the research they present.

By drawing on their academic affiliation, KOLs are able to preserve the appearance of autonomy while allowing industry to downplay the extent to which they are able to directly influence the research process. Research therefore comes to reflect the merits of individual KOLs and their accompanying prestige rather than the potential risks stemming from the extensive involvement of industry. This enables KOLs to assume the ahistorical quality identified by Gramsci and consistent with traditional intellectuals such that their actions come to be evaluated not in terms of the dominant

²⁶⁷ Gramsci, *Selections from the Prison Notebooks*, 12.

²⁶⁸ Gramsci, *Selections from the Prison Notebooks*, 14.

normative framework governing science, but instead based on the sense of autonomy and independence afforded by their occupational attachment to specific social positions.

The social importance of traditional intellectuals as recognized by Gramsci stems from their ability to lend a sense of legitimacy and independence to the particular social forces they come to indirectly support through the prestige and influence afforded by their respective social positions. In the case of medical research, ensuring the support of KOLs is of paramount importance given the need for publication planning strategies to enlist ‘authors’ capable of masking the extent of corporate involvement in ghostwriting. It is this sense of ahistorical independence and autonomy afforded to KOLs through their academic affiliation and individual prestige that places them at a crucial nexus in shaping how medical knowledge comes to be disseminated to the wider public. With the basic goal of marketing and promotion being the targeted dissemination of medical knowledge supporting a particular commercial goal, the selection of KOLs based on their highly influential social positions bestows upon them a formative influence in shaping not only the accepted body of medical knowledge, but also the underlying ethos of science itself by serving as representative figures of what is deemed to be acceptable scientific conduct within the wider community. In this way, the social function of KOLs possesses the necessary capacity to influence the ethos of science based on their individual ability to reaffirm what is deemed to be acceptable scientific conduct based on the particular actions they undertake. Serving as active participants in ghostwriting and publication planning strategies, KOLs come to lend their tacit support for the particular ideological and normative frameworks that drive these activities while retaining the perceived appearance of autonomy and independence from these same actions.

Consequently, evaluating the efficacy of existing conflict of interest policies comes to depend on recognizing not only the critical importance of KOLs and their ability to function in the capacity of traditional intellectuals but perhaps more importantly the potential to contest the sense of legitimacy they bestow upon the marketing and promotional efforts of the pharmaceutical industry. In the case of ghostwriting, challenging this sense of legitimacy is inherently tied not only to the ability of KOLs to assume the authorial responsibilities that accompany a published manuscript but also the way in which their disclosed conflicts of interest are ultimately handled by each journal.

The ability for existing conflict of interest policies to effectively address the power held by KOLs is directly dependent on handling questions pertaining to issues of authorship and the way in which the contributions of ghostwriters are recognized within published manuscripts. In similar fashion to the use of disclosure forming a core component of the examined conflict of interest policies, the manner in which authorship is defined and attributed remains relatively consistent across each of the examined journals with the definition offered by the ICMJE and noted earlier serving as the accepted standard. Based on this definition, the standards for authorship are quite rigid with potential authors needing to satisfy multiple different elements in order to ensure that their actions have truly made a substantial contribution to the preparation of the final manuscript.

However, the rise of practices such as ghostwriting and the reliance on KOLs to assume authorship of published manuscripts has served to challenge the limits of the accepted standards for authorship within medical research. With ghostwriting ultimately dependent on its ghostly character to escape public scrutiny and mask the involvement of

industry, the intrinsic sense of rigidity within the authorship standards proposed by the ICMJE can be readily exploited to mask the actions of ghostwriters as noted by Matheson. Given the need for authors to satisfy each of three distinct criteria, it is possible to effectively downplay the significant contributions made by ghostwriters and other actors to the final manuscript by purposefully failing to satisfy but a single criterion of the ICMJE standards.²⁶⁹ Similarly, these same standards can also function in the opposite manner allowing KOLs to satisfy the criteria set out by the ICMJE to obtain authorship despite having a less substantive role in the production of the final manuscript than other actors who fail to qualify for authorship. Thus the attribution of authorship particularly when confronted with challenges such as ghostwriting and publication planning is by no means as clearly structured as the definition offered by the ICMJE would entail. Despite the implementation of a rigid set of standards by the ICMJE, ensuring the proper attribution of all parties involved in the production of a final manuscript requires greater capacity to recognize a wider range of actions than those simply defined by authorship alone. As a result, each of the examined journals have also come to rely on a supplementary classification to ensure those who fail to satisfy the established criteria for authorship yet whose contributions have a significant impact on the final manuscript are properly recognized.

The inability of authorship alone to recognize the growing range of parties involved in the production of a final manuscript has resulted in the need for the ICMJE to consider a second more broadly defined classification known as contributorship. While

²⁶⁹ For a more detailed explanation of how this can occur see Alastair Matheson, “How Industry Uses the ICMJE Guidelines to Manipulate Authorship – And How They Should Be Revised,” *PLoS Medicine* 8, no. 8 (2011): 1-5.

the requirements for authorship within the ICMJE are strictly defined, contributorship presents a much more lax set of standards with a significant number of journals including the ICMJE offering no explicit definition for the specific actions and roles that actually qualify. Rather, the standards for contributorship instead come to be implied within the policies of many journals and function as a catchall for the range of actions that can be seen to add to the final manuscript yet fail to satisfy the ICMJE's established requirements for authorship. However, while contributorship provides a means of recognizing a greater range of actions than authorship alone, it does so by enforcing an explicit distinction between authorship and contributorship. It is this distinction that ultimately comes to further exemplify the very elements of social prestige that KOLs utilize to derive their economic value and important social function in legitimizing the marketing and promotional efforts of the pharmaceutical industry.

With the addition of contributorship providing a means of recognizing actions such as ghostwriting that cannot be captured by authorship alone, the manner in which it has been implemented by the examined journals does little to challenge the underlying prestige and social influence held by KOLs. Although the addition of contributorship has allowed journals to directly acknowledge the involvement of ghostwriters and allow their contributions to no longer be masked in secrecy, it is the continued fixation on behalf of each of the examined journals pertaining to the pre-eminence of authorship that has allowed KOLs to retain the very elements of prestige and traditional authority that come to define their social function. It is this preeminent focus in recognizing the specific elements of social prestige and authority afforded by authorship that become readily apparent in how each of the examined journals actively handles not only the physical

placement of information related to both authorship and contributorship, but also the subsequent information that is required from each of these distinct roles.

In keeping with traditional forms of recognition, each of the examined journals relies on the byline of a published manuscript to communicate to readers those parties who satisfy the requirements set out for authorship. While alone this is nothing out of the ordinary, it is common practice for many journals to also include the corresponding institutional affiliations alongside any personal or professional titles for each of the listed authors either in the byline or within close proximity and often on the first page of the manuscript. The inclusion of this information serves to connect listed authors with positions of traditional prestige and authority often originating from the same academic affiliations that receive prominent attention from the journals themselves. In contrast to authorship, the recognition of contributorship focuses instead on named individuals, their funding sources, and the specific function they held in the production of the manuscript with each journal except for JAMA making no mention of any criteria related to the individual contributors institutional or professional affiliations.

Furthermore, the manner in which contributorship is communicated to the reader also receives comparatively less attention than that utilized by authorship. With each of the examined journals making explicit mention in their respective policies that information pertaining to the involvement of contributors is to appear at the end of the manuscript, many journals choose to include this as part of a separate acknowledgements section that is accompanied by each authors disclosed conflicts of interest. Thus it is through the prominent placement of elements of traditional prestige, authority, and status originating from an authors' academic affiliation or professional titles that come to take

on a greater sense of importance than other relevant information pertaining to the contributions of other actors that would seemingly have a far more pronounced impact on the research being presented.

Similar issues are also readily apparent in how each of the examined journals handles information obtained from authors pertaining to their disclosed conflicts of interest. In much the same manner as information pertaining to contributorship is vital for readers to evaluate the research being presented, the information obtained through disclosure is often placed inconspicuously at the end of the manuscript where it can be easily overlooked by readers, simply ignored after the article has been read, or taken into consideration only after the reader has already formed an initial judgement concerning the research findings being presented. One exception to this practice is offered by PLoS Medicine which includes separate sections detailing both funding and disclosed conflicts of interest on the first page of the published article where it is readily available for readers to review prior to engaging with the research being presented. The other exception concerns both the Annals of Internal Medicine and NEJM who do not provide any direct conflict of interest information in the article itself. Rather, both journals include links for the reader to directly download the electronic disclosure forms submitted by authors themselves. However, while this practice arguably provides the greatest amount of information, it is highly problematic and represents a worrying trend concerning the availability of information pertaining to conflicts of interest. With journal reprints providing the pharmaceutical industry a highly targeted method of disseminating favourable medical knowledge while also bolstering the financial bottom lines of journals

themselves,²⁷⁰ the lack of disclosure information made available in these physical reprints requires that physicians go out of their way to actually obtain information concerning conflicts of interest when evaluating new research.

With disclosure operating on the premise that when provided with the proper information readers are able to properly evaluate the impact of conflicts of interest, it follows that information about these same conflicts should be readily available prior to engaging with the actual article. While there is nothing stopping readers from reviewing disclosure information before beginning to read the actual article, its placement at the end of the manuscript within the majority of the examined journals presents a potential hindrance from this actually occurring. Furthermore, the placement of this information is also subject to the same appeal to traditional authority derived from each author's institutional affiliation and personal or professional titles. Thus, for most of the examined journals, personal and institutional prestige come to be afforded a more prominent focus within the published article than information that is necessary to evaluate the potential impact associated with conflicts of interest disclosed by authors.

It is this underlying appeal to prestige and traditional authority on behalf of the examined journals that allows KOLs to not only retain the necessary elements of traditional authority and influence central to their social function but to do so in a way that remains unchallenged by existing conflict of interest policies. While such policies rightly recognize that authorship remains an important component of both the research and resulting publishing processes, it is necessary to clarify exactly what the role and

²⁷⁰ Andrea Lundh et al., "Conflicts of Interest at Medical Journals: The Influence of Industry-Supported Randomised Trials on Journal Impact Factors and Revenue – Cohort Study," *PLoS Medicine* 7, no. 10 (2010): 1-7.

purpose of authorship truly is. With an increasingly varied set of actors, relationships, and sources of influence involved in the production of medical knowledge, the use of contributorship can only do so much so long as it remains subordinate to the more socially recognized and strategically important function of authorship. With many of the actors recognized as contributors now having a greater combined impact over the production of medical knowledge than those recognized as authors, it is necessary to revisit the manner in which contributorship is recognized by medical journals particularly when situated alongside the use of KOLs by the pharmaceutical industry.

As long as the prestige afforded to authorship continues to supplant the importance of adequately recognizing contributorship it will continue to be possible for KOLs to leverage their own social influence and the appeal of traditional authority to effectively divert attention from the actions of the pharmaceutical industry even when such actions are readily acknowledged through the provision of contributorship in the final manuscript. Successfully challenging the ability of KOLs to legitimize the marketing and promotional efforts of the pharmaceutical industry depends not simply on expanding the annals of contributorship to account for a growing range of activities such as ghostwriting, but to ensure that such activities are properly recognized for the impact they truly have on the research process. By incorporating an explicit recognition as to the extent to which activities such as ghostwriting are able to influence the production of medical knowledge it is possible to demonstrate that contrary to the sense of independence and legitimacy they project, the actions of KOLs are anything but autonomous and instead reflect the commercial interests of the pharmaceutical industry and a set of related norms consistent with a neoliberal conception of science. With only

WAME providing a substantive policy statement on the issue of ghostwriting and both the Annals of Internal Medicine and PLoS Medicine making only a brief reference to the term itself, the remaining journals instead choose to frame the issue in terms of how to best recognize what has come to be portrayed as the legitimate contributions offered by medical writers to the dissemination of medical knowledge.

A more pronounced effort is needed on behalf of each of the examined journals to purposefully call attention to the extent to which ghostwriting has impacted the production of medical knowledge in order for medical journals by virtue of their own social position to not only contest the established social function of KOLs, but to foster the development of a caste of organic KOLs functioning in an intellectual capacity extolled by Gramsci. By either seeking to integrate existing KOLs or by elevating their own KOLs into the future development of more progressive policy mechanisms, medical journals possess the necessary capacity to develop new ways of conceptualizing and organizing not only the research process but the accompanying normative structure and ideological framework that accompanies it and by doing so effectively challenge the further entrenchment of neoliberal science as common sense.

7 Chapter: Envisioning an Alternative Ethos of Science

The principle focus of modern medical research is no longer seen to be tied to the pursuit of therapeutic innovation but instead can be readily characterized by efforts seeking to realize specific marketing and promotional strategies pursuant to the commercial interests of industry. Central to these goals has been the ability for medical knowledge itself to function in an explicit marketing capacity. As a result, the research process has come to be organized in a manner capable of supporting these commercial objectives by systematically leveraging conflicts of interest through the rise to commercially oriented publication planning strategies reliant on ghostwriting and the accompanying social prestige and influence afforded by KOLs as a means of producing favourable and seemingly unbiased medical knowledge. The restructuring of medical research to achieve these commercial objectives has resulted in the increasing prevalence of conflicts of interest throughout the research process and in published medical literature. This has in turn brought about a renewed focus to understand not only the substantive impact such conflicts have on the evolution of clinical practice, but also fostered an ongoing policy discussion concerning how best to approach the intensification of marketing and promotional efforts within medical research and the issues that accompany the presence of conflicts of interest.

With medical journals providing a critical social function with respect to the dissemination of medical knowledge, the ongoing debate concerning how to best address conflicts of interest has often been framed directly in terms of the ability of journals themselves to proactively implement effective policy measures. A thorough analysis of

the respective policies enacted by high impact medical journals reveals that the use of disclosure has become an accepted and predominant method for addressing conflicts of interest and is seen to contribute to a more transparent understanding as to the role of the pharmaceutical industry within the research process. It is from this sense of transparency garnered through the information obtained from authors' disclosures that medical journals have come to rely exclusively on the ability of individual readers to evaluate the extent to which particular conflicts come to influence the research itself. Additionally, medical journals have also made pronounced efforts to provide viable means of recognizing the expanding set of roles and responsibilities within the research process that can no longer be captured solely by traditional conceptions of authorship.

These efforts have been necessary to combat the seemingly secret and hidden nature of ghostwriting and have augmented existing authorship standards to include a second and complimentary category of contributorship. While the inclusion of contributorship has allowed the often-substantial role of ghostwriters to be recognized in published manuscripts, this recognition remains overshadowed by the continued social prominence afforded to authorship. As a result, conflict of interest policies have come to reflect the sense of social superiority intoned by authorship resulting in a clear oversight to appreciate the manner in which the distinction between authorship and contributorship aids the success of the pharmaceutical industries marketing and promotional efforts through the use of KOLs. Privileging authorship in this manner downplays the actions of contributors by emphasizing the academic and institutional affiliations of KOLs allowing them to sustain the elements of institutional prestige and authority that underpins their

economic value within the marketing and promotional strategies of the pharmaceutical industry.

It is in light of the profound changes occurring within medical research that the impact associated with the rise of marketing and promotion goes well beyond simply a novel set of organizational processes that have come to define the research process. Rather, the ongoing transformation within medical research to satisfy the commercial marketing objectives of industry represents a more subtle and pervasive shift within the underlying ideological and normative values that define the ethos of science itself. This shift can be readily characterized by adoption of a decidedly neoliberal conception of science whereby social institutions at the heart of the research process and resulting policy response come to be structured in such a way so as to reflect a set of normative values and ideological principles consistent with neoliberalism. It is the extent of this normative shift within medical science that has largely been overlooked by conventional accounts concerning the impact of conflicts of interest and related rise of marketing and promotion within the pharmaceutical industry. Where existing approaches rightfully recognize the problematic nature of marketing and promotion and the related intensification of conflicts of interest, what remains absent is the elaboration of theoretical and conceptual tools capable of appreciating the manner in which particular ideological and cultural forms have dramatically altered the way in which society not only understands science but also interacts with it. As a result, it is the introduction of a theoretical framework rooted in Merton and informed by Gramsci that offers the necessary capacity to elaborate on these deficiencies by presenting a more robust understanding of not only the issues inherent to the increasingly commercial focus of

modern medicine but also the resulting policy response enacted by individual medical journals.

Drawing on key theoretical concepts advanced by Gramsci including the formative power of common sense and an understanding as to the importance of intellectuals and social institutions in shaping public consciousness, the rise of medical marketing and the resulting policy response to conflicts of interest can be readily understood in terms that recognize the importance of ideology and are able to articulate how such forces come to shape the approach undertaken by individual medical journals. Recognizing that the structural reorganization of the research process that has accompanied the rise of marketing and promotional efforts has been premised on more than economic efficiency, key events such as the emergence of CROs come to signify formative events in shaping the underlying normative structure of science itself. Allowing the research process to operate in a manner supporting a decidedly neoliberal conception of science, such events help to lend credence to Gramsci's emphasis on social institutions as a means of reflecting the dominant ideological and cultural practices of a given period. With the restructuring of medical research to rely on CROs representing a pivotal moment for the entrenchment of neoliberal science, it is the formative ability of neoliberal science to shape individual conflict of interest policies that allows it to be expressed in terms of common sense. Amidst growing attention to conflict of interest policies in light of the growing challenges posed by the rise of medical marketing, neoliberal science has come to favourably shape the parameters of conflict of interest policies to reflect the very normative principles and ideological precepts that such policies seemingly wish to address. It is this formative capacity of neoliberal science

expressed through key values to influence the respective policy decisions of the examined journals and organizations that demonstrates the inadequacy of existing approaches to address not only the inherent problems posed by conflicts of interest, but also the underlying problem concerning the extent of industry influence over the production and dissemination of medical knowledge.

Recognizing the ability of neoliberal science to define the parameters of conflict of interest policies provides a means with which to directly challenge a number of key assumptions and beliefs held sacrosanct by these existing policy approaches. Among these, perhaps the most important dimension concerns the consistent reliance on disclosure and rampant focus on individualism that form authoritative components of established conflict of interest policies. It is the central focus afforded to these defining elements that clearly elucidates the formative power of neoliberalism and its subtle and pervasive acceptance as common sense. Responding to the inherent challenges raised by the use of medical knowledge in a marketing capacity, conflict of interest policies have come to be defined and shaped by the very ideological processes and structural dynamics that necessitate their very existence. The resulting juxtaposition between the formative influences exhibited by neoliberal science and the resulting policy frameworks enacted by individual journals offers a testament as to the theoretical validity of utilizing the concepts offered by Gramsci to understand and untangle the complexities arising from the interplay between neoliberalism, medical research, and a social understanding of science itself. It is by virtue of questioning these foundational precepts that it becomes possible to identify an alternative set of issues that have thus far remained absent from the existing conflict of interest policies employed by medical journals. Invoking a critical

focus in keeping with Gramsci's conception of good sense to challenge the range of accepted and embedded social conceptions found within existing approaches to address conflicts of interest presents a means of not only identifying the failures and shortcomings that exist within the current iterations of policy but to do so in a way that helps account for these issues by fostering much needed critical discussion capable of invoking further action.

It is this need for critical discussion as to the limits of existing conflicts of interest policies and resulting call for action that raises the most direct opportunity for further research and scholarship in this area of study. While the focus on medical journals and their respective conflict of interest policies presented an opportune research subject by virtue of their social function pertaining to the dissemination of medical knowledge and readily accessible policy positions, successfully challenging the entrenchment of neoliberal science as common sense requires recognizing the extent to which the examined journals and organizations themselves as social institutions are subjected to the same financial pressures and ideological commitments that confront both the pharmaceutical industry and society as a whole. It is this dimension of the analysis that presents the next logical step for further study particularly when situated alongside the inherent revolutionary tendencies of Gramsci's thought as to the necessary elaboration of an organic intellectual stratum capable of championing emerging forms of consciousness capable of contesting the entrenchment of common sense.

It is by virtue of their prominent role in the dissemination of medical knowledge that medical journals present perhaps the most obvious and direct means of elaborating the critical thought in keeping with Gramsci's conception of good sense. With journals

able to take a direct role in shaping the approach to conflicts of interest via their respective editorial capacities, they possess the theoretical capacity to serve as the organic intellectuals characterized by Gramsci and promote an alternative normative and ideological vision of medical science. A key example of this ability for journals to function in the capacity of organic intellectuals is offered by the independent French medical journal *Prescrire* whose approach to both publishing and conflicts of interest radically differs from that of the examined journals. While there is a shared conviction that the editorial staffs of all journals must remain free from potential conflicts of interest, this stance is further intensified by *Prescrire* whose adamant insistence on operating without any conflicts of interest extends to an explicit effort to remain financially independent in order to avoid potential issues induced through a financial reliance on industry.²⁷¹ With many journals dependent on revenue sources linked directly to the marketing interests of the pharmaceutical industry including selling journal reprints or the sale of advertising space, the insistence on remaining financially independent affords *Prescrire* the advantage of not relying on external sources of revenue when implementing either their own conflict of interest policies or adopting a more critical editorial stance towards industry. Thus, it is through this financial independence that *Prescrire* is able to implement more aggressive conflict of interest policies without the risk of alienating the very revenue streams that are necessary to remain operational.

Further to this point, *Prescrire* is able to employ a novel publishing process that is unique from other journals. Where many medical journals rely primarily on submissions

²⁷¹ For more details as to the extent of this independence see “Non merci: *Prescrire* = no conflicts of interest,” *Prescrire*, accessed March 4, 2014 <http://english.prescrire.org/en/82/173/0/0/About.aspx>.

evaluated through editorial and peer review processes to fill their pages, *Prescrite* sidesteps traditional conceptions of authorship by relying on the editors themselves to produce the majority of content for publication.²⁷² This departure from more traditional publishing methods is important for two reasons: firstly, by relying primarily on their own editors to produce content, *Prescrite* is better able to ensure that manuscripts are free from conflicts of interest through firsthand knowledge of the specific relationships held by their editorial staff; and second, given the collaborative process of developing journal content, the attribution of authorship is instead leveled on the journal as a whole rather than utilizing more traditional means of recognizing individual authors.²⁷³ Each of these departures from more traditional methods of publishing allow *Prescrite* to offer an important alternative perspective as to how best to handle conflicts of interest from the relatively homogenous approach found in more mainstream journals. These departures from mainstream publishing practices and the steadfast focus on remaining independent of conflicts of interest allows *Prescrite* to present one of the truly radical alternatives to the established publishing practices demonstrated by journals included as part of this analysis. It is by virtue of these unique practices that allow *Prescrite* to offer a potential starting point with which to begin formulating potential alternatives to the range of existing policy measures that draw on the normative and ideological principles of neoliberal science as constituent components of their approach to conflicts of interest.

²⁷² While *Prescrite* does occasionally solicit articles to be written by known experts in their particular fields, such instances are far from the established norm. Rather, the bulk of publications offered by *Prescrite* are produced solely by their editorial staff with authorship attributed as such. For a more in-depth explanation as to how this process functions see “How a review in *Prescrite* is produced,” *Prescrite*, June 2008: 1-4, <http://english.prescrite.org/Docu/Archive/docus/HowReviewsProduced.pdf>.

²⁷³ *Prescrite*, “How a Review is Produced,” 3.

However, despite this obvious potential, the formative influence of common sense presents a significant obstacle to realizing the potential offered by Prescrire, and makes embracing what is a unique and significant departure from the standard approach to address conflicts of interest a daunting and arduous task. It is this attestation as to the deeply rooted nature of common sense that firmly exemplifies the innate difficulty in contesting it.

With the existing range of policy options available to journals curtailed by their reliance on a normative structure and ideological framework consistent with neoliberal science, existing conflict of interest policies represent an inadequate means of addressing the problems posed for medical research by conflicts of interest. What is necessary for journals themselves to implement truly effective conflict of interest policies depends on their ability to function in an organic capacity to help elaborate and organize solutions that serve to not only contest the coercive nature of neoliberal science as common sense but do so in a way that presents an effective means of ensuring that medical knowledge reflects therapeutic and clinical needs of patients and physicians rather than that of the commercial marketing objectives of industry.

Appendices: Conflict of Interest and Authorship Policies of the Examined Journals and Organizations

Appendix A International Committee of Medical Journal Editors (ICMJE)

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from being negligible to having great potential for influencing judgment. Not all relationships represent true conflict of interest. On the other hand, the potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgement. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.²
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.¹
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • Financial COIs are listed first and noted as being the "most easily identifiable" and "most likely to undermine the credibility of the journal."* • Non-financial COIs are listed at the end and do not provide specific examples as is done for financial COIs.*
What is the stated timeframe for what constitutes a COI?	<p>The work under consideration for publication.</p> <ul style="list-style-type: none"> • This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present.³ <p>Relevant financial activities outside the submitted work.</p> <ul style="list-style-type: none"> • Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work.³
Issues of Authorship	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. (1). An authors must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors' ability and integrity.¹ • Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.¹
How is authorship defined?	<ul style="list-style-type: none"> • Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.¹ • All persons designated as authors should qualify for authorship, and all those who qualify should be listed.¹

What actions and roles qualify for authorship?	<ul style="list-style-type: none"> • No specific examples are provided. Authorship defined by the three criteria set out by the ICMJE.*
Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section.¹
How is contributorship defined?	<ul style="list-style-type: none"> • No explicit definition is offered. ICMJE guidelines imply that all contributors who do not meet the criteria for authorship should be recognized as contributors.*
How are such contributions communicated to the reader?	<ul style="list-style-type: none"> • Contributions listed in an acknowledgements section.*
What actions and roles qualify for contributorship?	<ul style="list-style-type: none"> • Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support. Editors should ask corresponding authors to declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. If such assistance was available, the authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article.¹ • Groups of persons who have contributed materially to the paper but whose contributions but do not justify authorship may be listed under such headings as "clinical investigators" or "participating investigators," and their function or contribution should be described - for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients."¹
Detailing Disclosure	
What is the primary policy mechanism used to address conflicts of interest?	<ul style="list-style-type: none"> • When authors submit a manuscript, whether an article or a letter, they are responsible for disclosing all financial and personal relationships that might bias their work.²
What information is required to be disclosed?	<ul style="list-style-type: none"> • All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest.² • You should disclose interactions with any entity that could be considered broadly relevant to the work.³ • Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research.³

	<ul style="list-style-type: none"> • For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed.³
How and when is this information collected?	<ul style="list-style-type: none"> • The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically [...] Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information.³
Does this information have any impact on decisions to publish an article?	<ul style="list-style-type: none"> • Editors may use information disclosed in conflict-of-interest and financial-interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.²
How is this information communicated to the reader?	<ul style="list-style-type: none"> • To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist. Authors should do so in the manuscript on a conflict-of-interest notification page that follows the title page, providing additional detail, if necessary, in a cover letter that accompanies the manuscript.² • Editors also need to decide whether to publish information disclosed by authors about potential conflicts. If doubt exists, it is best to error on the side of publication.²
Is it readily accessible to the reader?	<ul style="list-style-type: none"> • To prevent potential conflicts of interest from being overlooked or misplaced, this information needs to be part of the manuscript. The ICMJE has developed a uniform disclosure form for use by ICMJE member journals. Other journals are welcome to adopt this form. Individual journals may differ in where they include this information, and some journals do not send information on conflicts of interest to reviewers.⁴
How are situations where no apparent conflicts of interest handled?	<ul style="list-style-type: none"> • The ICMJE Disclosure form requires authors who do not have any conflicts of interest to explicitly reaffirm this fact by selecting No for each of the listed examples.*
Is there an explicit recognition of industry funding?	<ul style="list-style-type: none"> • Increasingly, individual studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.² • Researchers should not enter into agreements that interfere with their access to all of the data and their ability to analyze them independently, and to prepare and publish manuscripts. Authors should describe the role of the study sponsor, if any, in study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases. Some journals, therefore, choose to include information in the Methods section about the sponsor's involvement.²

Accounting for Variance and Difference

<p>Are the stated conflict of interest policies applied uniformly to all types of articles?</p>	<ul style="list-style-type: none"> • ICMJE recommendations do not change based on type of article.*
<p>Does the journal have any unique requirements that may not be found in the policies of other journals?</p>	<ul style="list-style-type: none"> • The ICMJE offers a baseline with which to evaluate and compare the policies of the other included journals and organizations.*

Sources:

1: “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship,” ICMJE, accessed February 15, 2013, http://www.icmje.org/ethical_1author.html.

2: “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Consideration in the Conduct and Reporting of Research: Conflicts of Interest,” ICMJE, accessed February 15, 2013, http://www.icmje.org/ethical_4conflicts.html.

3: “ICMJE Form for Disclosure of Potential Conflicts of Interest,” ICMJE, accessed February 15, 2013, http://www.icmje.org/coi_disclosure.pdf.

4: “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Manuscript Preparation and Submission: Preparing a Manuscript for Submission to a Biomedical Journal,” International Committee of Medical Journal Editors, accessed February 15, 2013, http://icmje.org/manuscript_1prepare.html.

*: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

Appendix B New England Journal of Medicine (NEJM)

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions. The potential of such relationships to create bias varies from negligible to extremely great; the existence of such relationships does not necessarily represent true conflict of interest, therefore. (Relationships that do not bias judgment are sometimes known as dual commitments, competing interests, or competing loyalties).
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Adopts standard definition presented by the ICMJE Main emphasis is on financial COIs with lesser recognition of non-financial COI in the form of personal relationships. No clarification as to types of relationships*
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • Using same definition as the ICMJE therefore will have the same focus as the ICMJE.*
What is the stated timeframe for what constitutes a COI?	<ul style="list-style-type: none"> • We consider interactions that occur within two years before the publication date of an article to be pertinent. Information about financial relationships below the de minimis level but relevant to the article will be disclosed in the Journal.⁴ <u>ICMJE Form for Disclosure of Potential Conflicts of Interest:</u> <u>The work under consideration for publication.</u> • This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present.⁷ <u>Relevant financial activities outside the submitted work.</u> • Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work.⁷
Issues of Authorship	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • Prior to publication, we require authors to document their role by signing the following statement: "I, the undersigned, certify that I accept responsibility for the content of this article. I helped write this manuscript, and agree with the decisions about it. I meet the definition of an author as stated by the International Committee of Medical Journal Editors, and I have seen and approved the final manuscript. Neither the article nor any essential part of it, including tables or figures, will be published elsewhere before appearing in the Journal."⁸ • Authorship means both accountability and independence. A submitted manuscript is the intellectual property of its authors, not the study sponsor. We will not review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication.²
How is authorship defined?	<ul style="list-style-type: none"> • As stated in the ICMJE Recommendations, credit for authorship requires (a) substantial contributions to the conception and design; or the acquisition, analysis, or interpretation of the data, (b) the drafting of the article or critical revision for important intellectual content, (c) final approval of the version to be published, and (d) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved. Each author must sign a statement attesting that he or she fulfills the authorship criteria of the ICMJE Recommendations. At least one person's name must accompany a group name (e.g., Thelma J. Smith, for the Boston Porphyria Group). As part of the submission process, authors must indicate whether any writing assistance other than copy editing was provided.⁶

	<ul style="list-style-type: none"> • It is the responsibility of every person listed as the author of an article published in the Journal to have contributed in a meaningful and identifiable way to the design, performance, analysis, and reporting of the work.¹
What actions and roles qualify for authorship?	<ul style="list-style-type: none"> • As in the past, our policy is that all persons listed as authors must meet the ICMJE requirements for authorship. In keeping with the tradition of scientific trust, we do not ask that the specific contributions of individual authors be reported to us. It is instead the duty of the corresponding author to ensure that each of the authors listed meets the necessary criteria; before an article is published, we will require a written statement from the corresponding author to this effect.¹
Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • The names of persons who have contributed substantially to a study but who do not fulfill the criteria for authorship will be listed in an appendix.¹
How is contributorship defined?	<ul style="list-style-type: none"> • No explicit definition is offered. Only mention is for those who have "contributed substantially to a study. Given that the NEJM emphasizes ICMJE guidelines, it is implied that all contributors who do not meet the criteria for authorship should be recognized as contributors.*
How are such contributions communicated to the reader?	<ul style="list-style-type: none"> • The names of persons who have contributed substantially to a study but who do not fulfill the criteria for authorship will be listed in an appendix.¹
What actions and roles qualify for contributorship?	<ul style="list-style-type: none"> • As part of the submission process, authors must indicate whether any writing assistance other than copy editing was provided.⁶
Detailing Disclosure	
What is the primary policy mechanism used to address conflicts of interest?	<ul style="list-style-type: none"> • Disclosure of financial associations of authors of articles published in biomedical journals has become common practice. The information provided in these disclosures helps the reader to understand the relationships between the authors and various commercial entities that may have an interest in the information reported in the published article.³ • Our purpose in publishing financial- disclosure statements is to inform readers of the existence of financial relationships that, in our judgment, are pertinent to the article, and to affirm that we had access to this information during our deliberations.⁴
What information is required to be disclosed?	<ul style="list-style-type: none"> • As part of the reporting requirements, we will routinely require authors to disclose details of their own and the sponsor's role in the study.² • We ask authors to disclose four types of information. First, their associations with commercial entities that provided support for the work reported in the submitted manuscript (the time frame for disclosure in this section of the form is the life span of the work being reported). Second, their associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript (the time frame for disclosure in this section is the 36 months before submission of the manuscript). Third, any similar financial associations involving their spouse or their children under 18 years of age. Fourth, nonfinancial associations that may be relevant to the submitted manuscript.³

<p>How and when is this information collected?</p>	<ul style="list-style-type: none"> • Authors of original research articles are not required to submit a formal Financial Disclosure Form at the time of submission. We will request it later, if necessary. However, we do request that you note major conflicts of interest in your cover letter or in the Source of Funding text box. • All authors of review articles are required to submit our Disclosure Form. • With this editorial, which is being published simultaneously in all International Committee of Medical Journal Editors (ICMJE) journals, we introduce a new disclosure form that has been adopted by all journals that are members of the ICMJE. We encourage other journals to adopt this reporting format, and we are placing the form in the public domain.³ • During the editorial process, we ask authors for details of their financial relationships with biomedical companies, such as consulting fees, service on advisory boards, ownership of equity (or options thereon), patent royalties, honorariums for lectures, fees for expert testimony, and research grants.⁴ • We realize this disclosure form requires authors to report a great deal of information about their relationships with entities that could be viewed as having interests that compete with the research being reported. With this in mind, some journals may ask for all these details at the time of initial manuscript submission, whereas other journals may ask for much less information at submission and require completion of the detailed form later in the editorial process.³
<p>Does this information have any impact on decisions to publish an article?</p>	<ul style="list-style-type: none"> • Authors of research articles should disclose at the time of revision any financial arrangement they may have with a company whose product is pertinent to the submitted manuscript or with a company making a competing product. Such information will be held in confidence while the paper is under review and will not influence the editorial decision, but if the article is accepted for publication, a disclosure statement will appear with the article.⁶ • Because the essence of reviews and editorials is selection and interpretation of the literature, the Journal expects that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article.⁶
<p>How is this information communicated to the reader?</p>	<ul style="list-style-type: none"> • At present, many journals ask authors to report such relationships by completing a form with information about their financial associations. The journals then either post the complete information online or create a summary of the information and publish it with the article in question.³
<p>Is it readily accessible to the reader?</p>	<ul style="list-style-type: none"> • With regard to Original Articles and Special Articles, we will continue to follow the policy that was restated at that time. In such articles, we disclose the sponsorship of the studies and relevant financial information about the authors.⁴
<p>How are situations where no apparent conflicts of interest handled?</p>	<ul style="list-style-type: none"> • In a statement in such articles, we report all relevant financial relationships; if an author has reported no relevant financial relationships, there is no statement.⁴
<p>Is there an explicit recognition of industry funding?</p>	<ul style="list-style-type: none"> • For all research articles we publish, NEJM lists study sponsorship and all relevant financial information as disclosed by the authors. The disclosure forms of all authors are available online with the full text of each article. Additional information about the contributions of authors may also appear in the Methods section of research articles.⁸
<p>Accounting for Variance and Difference</p>	
<p>Does the journal have any unique requirements that may not be found in the policies of other journals?</p>	<ul style="list-style-type: none"> • A separate policy applies to Review Articles and editorials, which comment on published articles but do not present new research. NEJM expects that authors of such articles not have any significant financial interest in any biomedical company relevant to the topics and products discussed in the article. When a prospective author does have financial ties to disclose, the editors decide whether they are relevant to the topic and whether they are de minimus.⁸

	<ul style="list-style-type: none"> • More than a decade ago, the editors became concerned about the possible influence of commercial associations on viewpoints and opinions expressed in the Journal. The policy is laid out in Information for Authors: Because the essence of reviews and editorials is selection and interpretation of the literature, the Journal expects that authors of such articles will not have any financial interest in a company (or its competitor) that makes a product discussed in the article.⁴ • We have concluded that our ability to provide comprehensive, up-to-date information, especially on recent advances in therapeutics, has been constrained.⁴ <p>Therefore, beginning with this issue of the Journal, we have modified the statement in Information for Authors to read as follows:</p> <ul style="list-style-type: none"> • Because the essence of reviews and editorials is selection and interpretation of the literature, the Journal expects that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article.⁴ • The addition of the word “significant” acknowledges that not all financial associations are the same. Some, such as the receipt of honorariums for occasional educational lectures sponsored by biomedical companies, may be appropriately viewed as minor and unlikely to influence an author’s judgment. Others, such as ownership of substantial equity in a company, are of greater concern. It is our intent to focus on the financial relationships that, in our judgment, could produce bias, or the perception of bias, in an article.⁴ • The key provision of the definition sets an upper limit on the annual sum that a person may receive before a relationship is automatically considered significant (the limit, currently \$10,000, is referred to as the de minimis level). We also regard as a significant interest any holding in which the potential for profits is not limited, such as stock, stock options, and patent positions.⁴ • With respect to research grants, our policy will continue to require that authors of review articles and editorials, through their institutions, not have major research support or a major proportion of their funding from relevant companies.⁴
<p>Are there any unique requirements that may be important as part of a comparison with other policies?</p>	<ul style="list-style-type: none"> • As editors, we strongly oppose contractual agreements that deny investigators the right to examine the data independently or to submit a manuscript for publication without first obtaining the consent of the sponsor.² • When the sponsor employs some of the authors, these authors' contributions and perspective should be reflected in the final paper as are those of the other authors, but the sponsor must impose no impediment, direct or indirect, on the publication of the study's full results, including data perceived to be detrimental to the product.² • With these modifications in policy, we can prevent financial interests from infringing on the editorial content of the Journal, while at the same time acknowledging that some level of interaction between academia and industry may facilitate the dissemination of scientific knowledge and its application to patient care.⁴

Sources:

- 1: Jeffrey M. Drazen and Gregory D. Curfman, "On Authors and Contributors," *NEJM* 347, no. 1 (2002): 55.
 - 2: Frank Davidoff et al. "Sponsorship, Authorship, and Accountability," *NEJM* 345, no. 11 (2001): 825-26.
 - 3: Jeffrey M. Drazen et al., "Uniform Format for Disclosure of Competing Interests in ICMJE Journals," *NEJM* 361, no. 19 (2009): 1896-97.
 - 4: Jeffrey M. Drazen and Gregory D. Curfman, "Financial Associations of Authors," *NEJM* 346, no. 24 (2002): 1901-2.
 - 5: Robert S. Schwartz et al., "Full Disclosure and the Funding of Biomedical Research," *NEJM* 358, no. 17 (2008): 1850-51.
 - 6: "Author Center: New Manuscripts," *NEJM*, accessed February 15, 2013, <http://www.nejm.org/page/author-center/manuscript-submission>.
 - 7: "ICMJE Form for Disclosure of Potential Conflicts of Interest," ICMJE, accessed February 15, 2013, <http://www.nejm.org/userimages/ContentEditor/1277392443758/ICMJEDisclosureForm0521101RE.pdf>. This is the standardized disclosure form utilized by the ICMJE and is simply being hosted directly by the *NEJM*. The contents of this form are identical to those found in Appendix A reference 3 which is instead hosted directly by the ICMJE.
 - 8: "About *NEJM*: Editorial Policies," *NEJM*, accessed February 15, 2013, www.nejm.org/page/about-nejm/editorial-policies.
- *: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

Appendix C The Lancet

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • A conflicts of interest exists if authors or their institutions have financial or personal relationships with other people or organisations that could inappropriately influence (bias) their actions. Financial relationships are easily identifiable, but conflicts can also occur because of personal relationships, academic competition, or intellectual passion.³ • For any journal, a conflict of interest exists when an author, reviewer, or editor has ties to activities that could inappropriately influence judgment. Conflicts of interest can affect the individual or be relevant to the individual's institution; they can be personal, professional, or financial; and they can be actual (do influence judgment) or potential (could affect judgment).¹ • Financial conflicts of interest that are not exclusions to commissioning or considering spontaneously submitted items, but must be declared in the published paper, are: consultancies, honoraria, speakers' fees; research funding or funding for equipment or drugs; travel or accommodation payments; or expert testimony fees. We have not introduced a financial cut-off such as US\$10000 because we do not accept that there is a universally agreed sum of money that if exceeded will result in bias.²
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Mentions both financial and non-financial conflicts of interest.*
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • Mentions both types. Begins with Financial COIs and mentions they are easily identifiable and then introduces non-financial and provides far more detailed examples about what constitutes them.*
What is the stated timeframe for what constitutes a COI?	<ul style="list-style-type: none"> • Examples of financial conflicts include employment, consultancies, stock ownership, honoraria, paid expert testimony, patents or patent applications, and travel grants, all within 3 years of beginning the work submitted.³ • For Comment, Seminars, Reviews, and Series, The Lancet will not publish if an author, within the past 3 years, and with a relevant company or competitor, has any stocks or shares, equity, a contract of employment, or a named position on a company board; or has been asked by any organisation other than The Lancet to write, be named on, or to submit the paper.³
Issues of Authorship	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • Manuscripts must be solely the work of the author(s) stated, must not have been previously published elsewhere, and must not be under consideration by another journal.³ • It is implied that authorship bestows a sense of accountability and ownership over the results being presented.*
How is authorship defined?	<ul style="list-style-type: none"> • A specific definition is not provided as to what constitutes authorship. Given that the Lancet directly states they largely follow ICMJE guidelines it is implied that they also use ICMJE standards for authorship.* • The Lancet is a signatory journal to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, issued by the International Committee for Medical Journal Editors (ICMJE)³ • As a signatory journal to the Uniform requirements for manuscripts submitted to biomedical journals, and following publication of a joint statement by members of the International Committee of Medical Journal Editors (ICMJE), the principles for our management of conflicts of interest for original research largely follow ICMJE guidelines.²

What actions and roles qualify for authorship?	<p><u>The Lancet's Author Statements Form:</u></p> <ul style="list-style-type: none"> • Please insert here the contribution each author made to the manuscript—eg, literature search, figures, study design, data collection, data analysis, data interpretation, writing etc. If all authors contributed equally, please state this.⁴
Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • Clearly notes that in addition to authorship there is a second classification of contributorship that makes some degree of individual contribution to the text itself.*
How is contributorship defined?	<ul style="list-style-type: none"> • Does not provide a specific definition simply states that things such as the source of funding, the role of medical writers and editors need to be recognized in the Acknowledgements section at the end of the text.*
How are such contributions communicated to the reader?	<ul style="list-style-type: none"> • We ask all authors, and all contributors (including medical writers and editors), to specify their individual contributions at the end of the text.³
What actions and roles qualify for contributorship?	<ul style="list-style-type: none"> • If a medical writer or editor was involved in the creation of your manuscript, we need a signed statement from the corresponding author to include their name and information about funding of this person.³ • This information should be added to the Acknowledgments and/or Contributors section.³ • We require signed statements from any medical writers or editors declaring that they have given permission to be named as an author, as a contributor, or in the Acknowledgments section.³ • Please disclose any funding sources and their role, if any, in the writing of the manuscript or the decision to submit it for publication. Examples of involvement include: data collection, analysis, or interpretation; trial design; patient recruitment; or any aspect pertinent to the study. Please also comment whether you have been paid to write this article by a pharmaceutical company or other agency.⁴
Detailing Disclosure	
What is the primary policy mechanism used to address conflicts of interest?	<ul style="list-style-type: none"> • A conflict can be actual or potential, and full disclosure to the Editor is the safest course. Failure to disclose conflicts might lead to publication of a statement in our Department of Error or even to retraction. All submissions to <i>The Lancet</i> must include disclosure of all relationships that could be viewed as presenting a potential conflict of interest.³ • What we can do is publish what we judge to be conflicts for authors or their institutions that readers should know about because they affect how the results may be perceived. We can also promote debate about conflicts of interest, especially where our policy may have failed to highlight important conflicts for readers.¹ • Conflicts of interest (or competing interests as they are also called) are ubiquitous. Editors, authors, and reviewers of manuscripts in <i>The Lancet</i> all have conflicting interests that can lead to bias in what we publish. What we can do, though, is reduce the potential for bias by having systems for managing conflicts of interest in the journal.²
What information is required to be disclosed?	<ul style="list-style-type: none"> • At the end of the text, under a subheading “Conflicts of interest”, all authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of financial conflicts include employment, consultancies, stock ownership, honoraria, paid expert testimony, patents or patent applications, and travel grants, all within 3 years of beginning the work submitted.³ • All sources of funding should be declared as an acknowledgment at the end of the text.³

How and when is this information collected?	<ul style="list-style-type: none"> All authors are required to provide a signed statement of their conflicts of interest as part of the author statement form.³
Does this information have any impact on decisions to publish an article?	<ul style="list-style-type: none"> The extent of conflicts described by authors has contributed to our decision to reject original research in several instances²
How is this information communicated to the reader?	<ul style="list-style-type: none"> For original research, from the beginning of 2002, we have included details of the role of the funding source and detailed conflict of interest statements for individual authors in print.² <p><u>Conflict of interest statement (published at end of text) includes:</u></p> <ul style="list-style-type: none"> Any financial arrangement (employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications, travel grants) that could bias your submitted work¹ Any personal relationship with other people or organisations that could bias your submitted work¹ Statement that you had full access to all data¹ Statement that you took final responsibility for decision to submit¹
Is it readily accessible to the reader?	<ul style="list-style-type: none"> At the end of the text, under a subheading “Conflicts of interest”, all authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work.³
How are situations where no apparent conflicts of interest handled?	<ul style="list-style-type: none"> If there are no conflicts of interest, authors should state that.³
Is there an explicit recognition of industry funding?	<ul style="list-style-type: none"> At the end of the Methods section, under a subheading “Role of the funding source”, authors must describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication.³ If there is no Methods section, the role of the funding source should be stated as an acknowledgment. If the funding source had no such involvement, the authors should so state.³ What more can The Lancet do to minimise the influences conflicts of interest can have on the research record? We, in conjunction with ICMJE, could insist that the data are analysed independently of the funding source, at least for industry-sponsored studies. We should ask authors to state that their study is as specified in the protocol (or if not, why not). And we could even ask for the paper to be written by the authors as stated, or to ensure that those who wrote the paper are listed as authors.¹
Accounting for Variance and Difference	
Are the stated conflict of interest policies applied uniformly to all types of articles?	<ul style="list-style-type: none"> For Comment, Seminars, Reviews, and Series, The Lancet will not publish if an author, within the past 3 years, and with a relevant company or competitor, has any stocks or shares, equity, a contract of employment, or a named position on a company board; or has been asked by any organisation other than The Lancet to write, be named on, or to submit the paper.³
Does the journal have any unique requirements that may not be found in the policies of other journals?	<ul style="list-style-type: none"> The corresponding author should confirm that he or she had full access to all the data in the study and had final responsibility for the decision to submit for publication.³ We do not expect readers to have to work out whether a review is biased, and would rather risk rejecting the occasional objectively balanced paper than ask readers to invest their time deciding for themselves.²

Sources:

- 1: Astrid James and Richard Horton, "The Lancet's policy on conflicts of interest," *The Lancet* 361, no. 9351(2003): 8-9.
 - 2: Astrid James et al., "The Lancet's policy on conflicts of interest — 2004," *The Lancet* 363, no. 9402 (2004): 2-3.
 - 3: "Information for Authors," The Lancet, accessed February 15, 2013, <http://download.thelancet.com/flatcontentassets/authors/lancet-information-for-authors.pdf>.
 - 4: "Author statements," The Lancet, accessed February 15, 2013, <http://download.thelancet.com/flatcontentassets/authors/tl-author-signatures.pdf>.
- *: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

Appendix D Journal of the American Medical Association (JAMA)

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • A conflict of interest may exist when an author (or the author’s institution or employer) has financial or personal relationships or affiliations that could influence (or bias) the author’s decisions, work, or manuscript. All authors are required to complete and submit the ICMJE Form for Disclosure of Potential Conflicts of Interest. Note: This form will be requested after a manuscript has been submitted. In this form, authors will disclose all potential conflicts of interest, including relevant financial interests, activities, relationships, and affiliations (other than those affiliations listed in the title page of the manuscript)¹
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Both financial and personal relationships are mentioned.*
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • No apparent emphasis on either type. Neither includes added examples or explanations.*
What is the stated timeframe for what constitutes a COI?	<ul style="list-style-type: none"> • Any potential conflicts of interest “involving the work under consideration for publication” (during the time involving the work, from initial conception and planning to present)¹ • Any “relevant financial activities outside the submitted work” (over the 3 years prior to submission)¹ • Any “other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing” what is written in the submitted work (based on all relationships that were present during the 3 years prior to submission).¹
Issues of Authorship	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.²
How is authorship defined?	<ul style="list-style-type: none"> • Per the guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit should be based only on (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met.²
What actions and roles qualify for authorship?	<ul style="list-style-type: none"> • No explicit roles stated as part of the ICMJE definition for authorship. Any person who meets all of these criteria warrants authorship status.*
Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • Listed in the Acknowledgements section at the end of the manuscript.*

How is contributorship defined?	<ul style="list-style-type: none"> All other persons who have made substantial contributions to the work reported in this manuscript (eg, data collection, analysis, or writing or editing assistance) but who do not fulfill the authorship criteria should be named with their specific contributions and affiliations in an Acknowledgment in the manuscript.²
How are such contributions communicated to the reader?	<ul style="list-style-type: none"> The “Acknowledgment section” is the general term for the list of contributions, disclosures, credits, and other information included at the end of the text of a manuscript but before the references. The Acknowledgment section includes authors’ contributions; information on author access to data; disclosure of potential conflicts of interest, including financial interests, activities, relationships, and affiliations; sources of funding and support; an explanation of the role of sponsor(s); information on independent statistical analysis (if required); names, degrees, and affiliations of participants in a large study or other group; any important disclaimers; information on previous presentation of the information reported in the manuscript; listing of supplemental material; and the contributions, names, degrees, affiliations, and indication if compensation has been received for all persons who have made substantial contributions to the work but who are not authors.¹
What actions and roles qualify for contributorship?	<ul style="list-style-type: none"> Recognizes data collection, analysis, writing or editing assistance.*
Detailing Disclosure	
What is the primary policy mechanism used to address conflicts of interest?	<ul style="list-style-type: none"> Although editors are willing to discuss disclosure of specific conflicts of interest with authors, JAMA’s policy is one of complete disclosure of all potential conflicts of interest, including relevant financial interests, activities, relationships, and affiliations (other than those affiliations listed in the title page of the manuscript). The policy requiring disclosure of conflicts of interest applies for all manuscript submissions, including letters to the editor.¹
What information is required to be disclosed?	<ul style="list-style-type: none"> Authors are expected to provide detailed information about all relevant financial interests, activities, and relationships as stipulated in the ICMJE Form for Disclosure of Potential Conflicts of Interest including, but not limited to, employment, affiliation, grants or funding, consultancies, honoraria or payment, speakers’ bureaus, stock ownership or options, expert testimony, royalties, donation of medical equipment, or patents planned, pending, or issued. Although many universities and other institutions have established policies and thresholds for reporting financial interests and other conflicts of interest, JAMA requires complete disclosure of all relevant financial relationships and potential financial conflicts of interest, regardless of amount or value. For example, authors of a manuscript about hypertension should report all financial relationships they have with all manufacturers of products used in the management of hypertension, not only those relationships with companies whose specific products are mentioned in the manuscript. If authors are uncertain about what constitutes a relevant financial interest or relationship, they should contact the editorial office.¹
How and when is this information collected?	<ul style="list-style-type: none"> All authors are required to complete and submit the ICMJE Form for Disclosure of Potential Conflicts of Interest.² After manuscript submission, all authors of papers under consideration for publication will be sent an Authorship Form to complete and submit.³

<p>Does this information have any impact on decisions to publish an article?</p>	<ul style="list-style-type: none"> For all accepted manuscripts, the corresponding author will have been asked to confirm that each coauthor's disclosures of conflicts of interest and relevant financial interests, activities, relationships, and affiliations and declarations of no such interests are accurate, up-to-date, and consistent with the disclosures reported in the Acknowledgment section of the manuscript because this information will be published in the Acknowledgment section of the article. Decisions about whether such information provided by authors should be published, and thereby disclosed to readers, are usually straightforward.¹
<p>How is this information communicated to the reader?</p>	<ul style="list-style-type: none"> The "Acknowledgment section" is the general term for the list of contributions, disclosures, credits, and other information included at the end of the text of a manuscript but before the references. The Acknowledgment section includes authors' contributions; information on author access to data; disclosure of potential conflicts of interest, including financial interests, activities, relationships, and affiliations; sources of funding and support; an explanation of the role of sponsor(s); information on independent statistical analysis (if required); names, degrees, and affiliations of participants in a large study or other group; any important disclaimers; information on previous presentation of the information reported in the manuscript; listing of supplemental material; and the contributions, names, degrees, affiliations, and indication if compensation has been received for all persons who have made substantial contributions to the work but who are not authors.⁴
<p>Is it readily accessible to the reader?</p>	<ul style="list-style-type: none"> Information about disclosed conflicts of interests are included at the end of the text in an Acknowledgements section.*
<p>How are situations where no apparent conflicts of interest handled?</p>	<ul style="list-style-type: none"> Authors <i>without</i> conflicts of interest, including relevant financial interests, activities, relationships, and affiliations, should indicate such in the ICMJE form and include a statement of no such interests in the Acknowledgment section of the manuscript. Failure to include this information in the manuscript may delay evaluation and review of the manuscript. Authors should err on the side of full disclosure and should contact the editorial office if they have questions or concerns.¹
<p>Is there an explicit recognition of industry funding?</p>	<ul style="list-style-type: none"> All financial and material support for the research and the work should be clearly and completely identified in an Acknowledgment section of the manuscript. The specific role of the funding organization or sponsor in each of the following should be specified: "design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication."⁵
<p>Accounting for Variance and Difference</p>	
<p>Are the stated conflict of interest policies applied uniformly to all types of articles?</p>	<ul style="list-style-type: none"> The policy requiring disclosure of conflicts of interest applies for all manuscript submissions, including letters to the editor. If an author's disclosure of potential conflicts of interest is determined to be inaccurate or incomplete after publication, a correction will be published to rectify the original published disclosure statement, and additional action may be taken as necessary.¹
<p>Does the journal have any unique requirements that may not be found in the policies of other journals?</p>	<ul style="list-style-type: none"> For industry-sponsored studies, an analysis of the data (based on the entire raw data set and evaluation of the study protocol, and prespecified plan for data analysis) must be conducted by an independent statistician at an academic institution, rather than by statisticians employed by the sponsor or by a commercial contract research organization. The independent biostatistician must be a faculty member at a medical school or academic medical center, or an employee of a government research institute, that has oversight over the person conducting the analysis and that is independent of

	<p>the commercial sponsor. Details of this independent statistical analysis, the name and institutional affiliation of the independent statistician, and whether compensation or funding was received for conducting the analyses should be reported in the Acknowledgement section of the manuscript.**</p> <ul style="list-style-type: none"> • These policies - which included a requirement for independent statistical analysis by an academic biostatistician for industry sponsored and industry-analyzed studies - were developed during a time when several high-profile trials had evidence of problems with data integrity, inappropriately conducted statistical analyses, and incomplete reporting of major findings. Over time some of these policies have been modified and strengthened but have been perceived by some in academia and industry as creating barriers to publication of important trial results. Moreover, over the past 2 years, our experience has been that the conduct of additional analyses by independent academic biostatisticians generally did not result in meaningful changes in the study results.⁶ • Accordingly, we are once again modifying one of the policies. JAMA will evaluate and consider for publication clinical trials that are analyzed by statisticians employed by or contracted by the study sponsor, without requiring independent statistical analysis by an academic biostatistician.⁶
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Sources:

1: "JAMA Instructions for Authors – Conflicts of Interest and Financial Disclosures," JAMA, accessed February 15, 2013, <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx#ConflictsOfInterestandFinancialDisclosures>.

2: "JAMA Instructions for Authors – Authorship Criteria and Contributions and Authorship Form," JAMA, accessed February 15, 2013, <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx#AuthorshipCriteriaandContributionsandAuthorshipForm>.

3: "JAMA Instructions for Authors – Manuscript Submission," JAMA, accessed February 15, 2013, <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx#ManuscriptSubmission>.

4: "JAMA Instructions for Authors – Acknowledgement Section," JAMA, accessed February 15, 2013, <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx#AcknowledgmentSection>.

5: "JAMA Instructions for Authors – Funding/Support and Role of Sponsor," JAMA, accessed February 15, 2013, <http://jama.jamanetwork.com/public/instructionsForAuthors.aspx#FundingSupportandRoleofSponsor>.

6: Howard Bauchner, "Editorial Policies for Clinical Trials and the Continued Changes in Medical Journalism," *JAMA* 310, no. 2 (2013): 149-50.

*: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

** : During the initial data collection and analysis JAMA required that the raw data for all industry funded studies be reviewed by an independent statistician. This requirement has since been dropped and no longer appears online as part of their stated conflict of interest policies. For an archived version of this policy see <http://web.archive.org/web/20130529031553/http://jama.jamanetwork.com/public/instructionsForAuthors.aspx>.

Appendix E The Annals of Internal Medicine

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • Conflict of interest exists when an author, editor, or peer reviewer has a competing interest that could unduly influence (or be perceived to do so) his or her responsibilities in the publication process. The potential for an author's conflict of interest exists when he or she (or the author's institution or employer) has personal or financial relationships that could influence (bias) his or her actions. These relationships vary from those with negligible potential to influence judgment to those with great potential to influence judgment. Not all relationships represent true conflict of interest. Conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment.¹
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Recognizes both financial and non-financial COI.*
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • Neither type of COI is emphasized.*
What is the stated timeframe for what constitutes a COI?	<ul style="list-style-type: none"> • While the Annals does not provide a specific timeframe. One is provided by the American College of Physicians who publish the Annals. Also since the Annals utilizes the ICMJE disclosure form it would follow that the same timeframe given the ICMJE also applies here.* • These relationships are often, but not always, financial. ACP requires disclosures of these relationships over the past 3 years.²
Issues of Authorship	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • Authorship implies accountability. Listed authors must have contributed directly to the intellectual content of the paper, and the corresponding author should list the specific contributions of all authors in the appropriate section of the Authors' Form.¹
How is authorship defined?	<p>Authors should meet all of the following criteria, thereby allowing persons named as authors to accept public responsibility for the content of the paper.</p> <ol style="list-style-type: none"> 1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND 2) Drafting the work or revising it critically for important intellectual content; AND 3) Final approval of the version to be published; AND 4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.¹
What actions and roles qualify for authorship?	<ul style="list-style-type: none"> • Medical writers and industry employees can be legitimate contributors, and their roles, affiliations, and potential conflicts of interest should be described when submitting manuscripts writers should be acknowledged on the byline or in the Acknowledgments section in accord with the degree to which they contributed to the work reported in the manuscript. The editors consider failure to acknowledge these contributors ghostwriting, which is contrary to Annals' editorial policy.¹ • Otherwise, all contributions that meet the ICMJE criteria are credited with authorship.*

Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • Holding positions of administrative leadership, contributing patients to a study, and collecting and preparing the data for analysis, however important to the research, are not, by themselves, criteria for authorship. The manuscript should note people who made substantial, direct contributions to the work but did not meet the criteria for authorship in the Acknowledgments section, and should provide a brief description of their contributions.¹
How is contributorship defined?	<ul style="list-style-type: none"> • No explicit definition offered, references all contributions that do not satisfy the criteria for authorship.*
How are such contributions communicated to the reader?	<ul style="list-style-type: none"> • We advise authors to arrange components of manuscripts in the following order (see below for further instructions): title page, abstract, text, acknowledgements (if any), references, tables in numerical sequence, figure legends, figures in numerical sequence, and appendices (if any).¹ • Acknowledge only persons who have contributed to the scientific content or provided technical support. Authors should obtain written permission from anyone they wish to list in the Acknowledgments section. The corresponding author must also affirm that he or she has listed everyone who contributed significantly to the work in the Acknowledgments.¹ • The manuscript should note people who made substantial, direct contributions to the work but did not meet the criteria for authorship in the Acknowledgments section, and should provide a brief description of their contributions.¹
What actions and roles qualify for contributorship?	<ul style="list-style-type: none"> • Positions of administrative leadership, contributing patients to a study, collecting or preparing data for analysis, Medical writers and industry employees are all recognized as being important contributors.* • Anyone who has made contributions to the scientific conduct or provided technical support.*
Detailing Disclosure	
What is the primary policy mechanism used to address conflicts of interest?	<ul style="list-style-type: none"> • Authors, editors, and peer reviewers must disclose their primary academic and institutional affiliations and all financial relationships that could be viewed as presenting a potential conflict of interest.¹ • For faculty, authors, and anyone in a position to control or influence the content of an educational activity, disclosure is the principal mechanism for determining conflict of interest and minimizing bias or the effect of bias in the College's education programs and publications. Faculty, authors, and anyone in a position to control or influence the content or who is involved in the planning or execution of an educational activity must disclose conflicts of interest and potential conflicts of interest.²
What information is required to be disclosed?	<ul style="list-style-type: none"> • These include, but are not limited to, any financial relationship that involves conditions or tests or treatments discussed in the manuscript and alternatives to the tests or treatments for those conditions. If persons are uncertain, they should err on the side of full disclosure.¹ • Authors, editors, and peer reviewers must state explicitly whether potential conflicts do or do not exist. Academic, financial, institutional, and personal relationships (such as employment, consultancies, close colleague or family ties, honoraria for advice or public speaking, service on advisory boards or medical education companies, stock ownership or options, paid expert testimony, grants or patents received or pending, and royalties) are potential conflicts of interest that could undermine the credibility of the journal, the authors, and science itself.¹

<p>How and when is this information collected?</p>	<ul style="list-style-type: none"> • All authors of papers accepted for publication must electronically sign a form affirming that they have met the criteria for authorship, have agreed to be authors, and are aware of the terms of publication. We request that authors complete these forms when we suggest revisions to manuscripts. We do not require them when manuscripts are initially submitted.¹ • At the time of manuscript submission, Annals of Internal Medicine requires corresponding authors to summarize all authors' conflict of interest disclosures. (We also require conflict of interest disclosures from members of panels that help formulate consensus or guideline recommendations, even if those contributors are not named authors on the consensus or guideline statement.) We provide the summary information collated by the corresponding author to editors and peer reviewers. If editors later invite the authors to revise a manuscript after peer review, we ask each author, including the corresponding author, to complete his or her own International Committee of Medical Journal Editors (ICMJE) Conflict of Interest Disclosure Statement. Information about this form, which all ICMJE member journals have adopted, is available at www.ICMJE.org. At the time of manuscript acceptance, we ask authors to confirm and update, if necessary, their online disclosure statements. At the time of publication, the completed disclosure statements become available for readers to view on www.annals.org.¹
<p>Does this information have any impact on decisions to publish an article?</p>	<ul style="list-style-type: none"> • As part of the initial submission process, we also ask the corresponding author to attest that the authors had access to all the study data, take responsibility for the accuracy of the analysis, and had authority over manuscript preparation and the decision to submit the manuscript for publication. We do not consider an article unless the corresponding author makes this attestation on behalf of the authors.¹
<p>How is this information communicated to the reader?</p>	<ul style="list-style-type: none"> • Annals publishes author's conflict of interest disclosures and discloses editor's financial and academic relationships.¹ • At the time of publication, the completed disclosure statements become available for readers to view on www.annals.org.¹
<p>Is it readily accessible to the reader?</p>	<ul style="list-style-type: none"> • Contributions made by those who fail to satisfy authorship criteria are listed in an acknowledgements section.*
<p>How are situations where no apparent conflicts of interest handled?</p>	<ul style="list-style-type: none"> • Nothing explicitly stated in journal policies.*
<p>Is there an explicit recognition of industry funding?</p>	<ul style="list-style-type: none"> • For all studies, include a statement at the end of the Methods section describing the role of the funding source for the study. If the study had no external funding source or if the funding source had no role in the study, state so explicitly.¹
<p>Accounting for Variance and Difference</p>	
<p>Are the stated conflict of interest policies applied uniformly to all types of articles?</p>	<ul style="list-style-type: none"> • Disclosure of these relationships is essential not only for original research articles but also for editorials, letters, commentary, and review articles.¹ • Annals avoids publishing editorials, reviews, and guidelines authored by individuals with potential financial conflicts of interest but considers each such manuscript on a case-by-case basis.¹

<p>Does the journal have any unique requirements that may not be found in the policies of other journals?</p>	<ul style="list-style-type: none"> • As part of the initial submission process, we also ask the corresponding author to attest that the authors had access to all the study data, take responsibility for the accuracy of the analysis, and had authority over manuscript preparation and the decision to submit the manuscript for publication. We do not consider an article unless the corresponding author makes this attestation on behalf of the authors.¹
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Sources:

1: “Information for Authors – Authorship Issues,” *Annals of Internal Medicine*, accessed February 15, 2013, <http://annals.org/public/authorsinfo.aspx#authorship-issues>.

2: “ACP Conflict of Interest: Policy and Procedures,” *American College of Physicians*, accessed February 15, 2013, http://www.acponline.org/about_acp/who_we_are/cid_policy.htm.

*: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

**: Requirements for all categories of articles largely conform to the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” developed by the International Committee of Medical Journal Editors (ICMJE).

Appendix F PLoS Medicine

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • PLoS defines a competing interest as anything that interferes with, or could reasonably be perceived as interfering with, the full and objective presentation, peer review, editorial decision-making, or publication of research or non-research articles submitted to one of the journals. Competing interests can be financial or non-financial, professional, or personal. Competing interests can arise in relationship to an organization or another person. See below for definitions and examples of various competing interests.²
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Recognizes both financial and non-financial conflicts of interest. Also includes categories for professional and personal conflicts of interest.*
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • No explicit emphasis offered by the definition.*
What is the stated timeframe for what constitutes a COI?	<ul style="list-style-type: none"> • As a guide, any competing interest that arose within the five years either before or after the commencement of the research described, or within five years of the article being written, or within five years of events described in the article, should be declared. However, interests outside this time-frame might also be relevant; if so, they should also be declared so that their relevance can be judged by the journal editorial team.²
Issues of Authorship	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.¹
How is authorship defined?	<ul style="list-style-type: none"> • All PLoS journals base their criteria for authorship on those outlined in the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals, which are excerpted below. • Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.³ • All persons designated as authors should qualify for authorship, and all those who qualify should be listed.³
What actions and roles qualify for authorship?	<ul style="list-style-type: none"> • No specific roles explicitly specified.*
Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • The contributions of all authors must be described. Contributions that fall short of authorship should be mentioned in the Acknowledgments section of the paper.³
How is contributorship defined?	<ul style="list-style-type: none"> • No explicit definition is offered. ICMJE guidelines imply that all contributors who do not meet the criteria for authorship should be recognized as contributors.*

How are such contributions communicated to the reader?	<ul style="list-style-type: none"> • People who contributed to the work, but do not fit the criteria for authors should be listed in the Acknowledgments, along with their contributions. You must also ensure that anyone named in the acknowledgments agrees to being so named.¹
What actions and roles qualify for contributorship?	<ul style="list-style-type: none"> • Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.¹
Detailing Disclosure	
What is the primary policy mechanism used to address conflicts of interest?	<ul style="list-style-type: none"> • PLoS is committed to ensuring that research is as free from bias as possible and is seen to be so. It is increasingly recognized that everyone — authors, authors' employers (e.g., an academic institution, government department, commercial company, or other), sponsors of the work, reviewers, editors, and publishers — has competing interests of some sort. It is difficult for individual readers to assess objectively whether competing interests could have biased the presentation of, peer review of, or decision to publish a given work. Transparency of competing interests allows readers to better evaluate the possibility of such bias. Journals and their editors must take all competing interests into account during the review process and ensure that any relevant ones are declared in the published article. PLoS journals therefore have the following three requirements: <ol style="list-style-type: none"> 1) Authors must declare all relevant competing interests for consideration during the review process. 2) Editors (professional or academic, paid or unpaid) and reviewers must declare their own competing interests and if necessary disqualify themselves from involvement in the assessment of a paper. 3) Anyone who comments on or rates published papers in any PLoS journal must declare their competing interests at the time of posting their comments and/or rating.² • Everyone involved in authorship, funding, review, and editorial decision-making of submitted articles, or who wishes to comment on or rate published articles, must declare any and all relevant competing interests.²
What information is required to be disclosed?	<ul style="list-style-type: none"> • Authors must declare all relevant competing interests for consideration during the review process.² • Financial competing interests include but are not limited to: ownership of stocks or shares; paid employment or consultancy; board membership; patent applications (pending or actual), including individual applications or those belonging to the institution to which the authors are affiliated and from which the authors may benefit; research grants (from any source, restricted or unrestricted); travel grants and honoraria for speaking or participation at meetings; gifts.² • Non-financial competing interests include but are not limited to: <ol style="list-style-type: none"> 1) Professional: acting as an expert witness; membership in a government or other advisory board; relationship (paid or unpaid) with organizations and funding bodies including nongovernmental organizations, research institutions, or charities; membership of lobbying or advocacy organizations; writing or consulting for an educational company. 2) Personal: personal relationships (i.e. friend, spouse, family member, current or previous mentor, adversary) with individuals involved in the submission or evaluation of a paper, such as authors, reviewers, editors, or members of the editorial board of a PLoS journal; personal convictions (political, religious, ideological, or other) related to a paper's topic that might interfere with an unbiased publication process (at the stage of authorship, peer review, editorial decision-making, or publication).²

How and when is this information collected?	<ul style="list-style-type: none"> • All authors will be contacted by email at submission to ensure that they are aware of and approve the submission of the manuscript, its content, and its authorship.³ • Failure to declare competing interests at submission, or when an article is commissioned, can result in immediate rejection of the paper.³
Does this information have any impact on decisions to publish an article?	<ul style="list-style-type: none"> • No decision is made to publish any paper submitted to a PLoS journal until a competing interests statement has been submitted for all authors.³ • The editors of a PLoS journal might decide not to publish a paper if they believe the competing interests declared by the authors or funders might have compromised the objectivity or validity of the research, analyses, or interpretations in the paper. PLoS editors will not publish a commissioned or any other non-research article if they are aware of a competing interest that, in their judgment, could introduce bias or a reasonable perception of bias. PLoS editors do not consult reviewers who have competing interests that, in the editors' judgment, could interfere with unbiased review. Failure to declare competing interests at submission, or when an article is commissioned, can result in immediate rejection of the paper. If a competing interest comes to light after publication, PLoS journal will issue a formal correction to or retraction of the whole paper, as appropriate.³
How is this information communicated to the reader?	<p>Separate sections for each of the following: acknowledgements (contributors); financial disclosure (funding statement); authors contributions (to list what each author did); competing interests (for author COIs)*</p> <p><u>Acknowledgments</u></p> <ul style="list-style-type: none"> • People who contributed to the work, but do not fit the criteria for authors should be listed in the Acknowledgments, along with their contributions. You must also ensure that anyone named in the acknowledgments agrees to being so named.¹ • Details of the funding sources that have supported the work should be confined to the funding statement. Do not include them in the Acknowledgments.¹ <p><u>Financial Disclosure</u></p> <ul style="list-style-type: none"> • This section should describe sources of funding that have supported the work. Please include relevant grant numbers and the URL of any funder's Web site. Please also include this sentence: "The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript." If this statement is not correct, you must describe the role of any sponsors or funders, and amend the aforementioned sentence as needed.¹ <p><u>Author Contributions</u></p> <ul style="list-style-type: none"> • All authors on a paper will be contacted separately to provide information about their contribution and competing interests into our system. This information will be pulled into the article file on acceptance.¹ <p><u>Competing Interests</u></p> <ul style="list-style-type: none"> • This section should list specific competing interests associated with any of the authors. If authors declare that no competing interests exist, we will print a statement to this effect.¹
Is it readily accessible to the reader?	<ul style="list-style-type: none"> • Each of the above items are stated within the text. Financial Disclosure and Competing Interests appear at the front of the manuscript while Author Contributions and Acknowledgements appear at the end.*
How are situations where no apparent conflicts of interest handled?	<ul style="list-style-type: none"> • If authors declare that no competing interests exist, we will print a statement to this effect.¹

<p>Is there an explicit recognition of industry funding?</p>	<ul style="list-style-type: none"> • Details of the funding sources that have supported the work should be confined to the funding statement. Do not include them in the Acknowledgments.¹ • This section should describe sources of funding that have supported the work. Please include relevant grant numbers and the URL of any funder's Web site. Please also include this sentence: "The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript." If this statement is not correct, you must describe the role of any sponsors or funders, and amend the aforementioned sentence as needed.¹ • In addition, we require that the role of all funding sources in the work be described, and authors are required to state explicitly whether the funder was involved in the study design; collection, analysis and interpretation of data; writing of the paper; and/or decision to submit for publication (read more about our Financial Disclosure policy).² • Studies Sponsored by Specific Funders - Pharmaceutical companies. We support GPP2 Good Publication Practice for Communicating Company-Sponsored Medical Research.³
<p>Accounting for Variance and Difference</p>	
<p>Are the stated conflict of interest policies applied uniformly to all types of articles?</p>	<ul style="list-style-type: none"> • Policies are applied uniformly for all types of articles.*
<p>Does the journal have any unique requirements that may not be found in the policies of other journals?</p>	<ul style="list-style-type: none"> • The involvement of any professional medical writer in the publication process must be declared. We encourage authors to consult the European Medical Writers' Association Guidelines on the role of medical writers. • Authors are expected to be aware of, and comply with, best practice in publication ethics specifically with regard to authorship (for example avoidance of ghost or guest authorship)³ • PLoS is committed to ensuring the availability of data and materials that underpin any articles published in PLoS journals. PLoS's ideal is to make all data relevant to a given article and all readily replaceable materials immediately available without restrictions (while not compromising confidentiality in the context of human-subject research).⁴ • For studies sponsored by the Pharmaceutical industry, PLoS medicine supports the GPP2 Good Publication Practice for Communicating Company-Sponsored Medical Research guidelines. No further information is provided as to what this support entails.*

Sources:

1: "PLOS Medicine Guidelines for Authors," PLoS Medicine, accessed February 15, 2013, <http://www.plosmedicine.org/static/guidelines>.

2: "PLOS Editorial and Publishing Policies – Competing Interests," PLoS Medicine, accessed February 15, 2013, <http://www.plosmedicine.org/static/policies#competing>.

3: "PLOS Editorial and Publishing Policies – Author Status," PLoS Medicine, accessed February 15, 2013, <http://www.plosmedicine.org/static/policies#author>.

4: "PLOS Editorial and Publishing Policies – Sharing of Data, Materials, and Software," PLoS Medicine, accessed February 15, 2013, <http://www.plosmedicine.org/static/policies#sharing>.

*: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

Appendix G British Medical Journal (BMJ)

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • A competing interest—often called a conflict of interest—exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise for the authors of a <i>BMJ</i> article when they have a financial interest that may influence, probably without their knowing, their interpretation of their results or those of others.⁵
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Recognizes both financial and personal conflicts of interest. Framed in terms of primary versus secondary interest.*
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • Both are mentioned but later part of definition focuses on financial conflicts of interest.*
What is the stated timeframe for what constitutes a COI?	<ol style="list-style-type: none"> 1. Associations with commercial entities that provided support for the work reported in the submitted manuscript (the timeframe for disclosure in this section of the form is the life span of the work being reported). 2. Associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript (in the three years before submission of the manuscript). 3. Non-financial associations that may be relevant or seen as relevant to the submitted manuscript.⁵
Issues of Authorship	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • Emphasis on ICMJE standards and ability for authorship to recognize important contributions to the research.*
How is authorship defined?	<p>The uniform requirements for manuscripts submitted to medical journals state that authorship credit should be based only on substantial contribution to:</p> <ul style="list-style-type: none"> • conception and design, or analysis and interpretation of data • drafting the article or revising it critically for important intellectual content • and final approval of the version to be published. <p>All these conditions must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship.</p> <p>We want authors to assure us that all authors included on a paper fulfil the criteria of authorship. In addition we want assurance that there is no one else who fulfils the criteria but has not been included as an author.⁶</p>
What actions and roles qualify for authorship?	<ul style="list-style-type: none"> • No specific roles mentioned, all who satisfy the ICMJE criteria should be recognized as authors.*
Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • Contributorship status exists for those who do not satisfy authorship criteria.*

<p>How is contributorship defined?</p>	<ul style="list-style-type: none"> • We believe that the definition of authorship, produced by the International Committee of Medical Journal Editors (or Vancouver Group), has some serious flaws. • The current definition of authorship does not make clear who has contributed what to the published study, nor does it clarify who is responsible for the overall content. It also excludes those whose sole but often large contribution has been to collect data.⁶ • We now list contributors in two ways. Firstly, we publish a list of authors' names at the beginning of the paper and, secondly, we list contributors (some of whom may not be included as authors) at the end of the paper, giving details of who did what in planning, conducting, and reporting the work. • One or more of these contributors are listed as guarantors of the paper. The guarantor accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.⁶
<p>How are such contributions communicated to the reader?</p>	<ul style="list-style-type: none"> • We now list contributors in two ways. Firstly, we publish a list of authors' names at the beginning of the paper and, secondly, we list contributors (some of whom may not be included as authors) at the end of the paper, giving details of who did what in planning, conducting, and reporting the work.⁶
<p>What actions and roles qualify for contributorship?</p>	<ul style="list-style-type: none"> • Contributorship and guarantorship are concepts that were applied first to original research papers, and are sometimes hard to define for other articles. Each contributorship statement should make clear who has contributed what to the planning, conduct, and reporting of the work described in the article, and should identify one, or occasionally more, contributor(s) as being responsible for the overall content as guarantor(s). For BMJ articles that do not report original research such as editorials, clinical reviews, and education and debate please state who had the idea for the article, who performed the literature search, who wrote the article, and who is the guarantor (the contributor who accepts full responsibility for the finished article, had access to any data, and controlled the decision to publish). For non-research articles that include case reports such as lessons of the week, drug points, and interactive case reports, please also state who identified and/or managed the case(s).⁶
<p>Detailing Disclosure</p>	
<p>What is the primary policy mechanism used to address conflicts of interest?</p>	<ul style="list-style-type: none"> • We believe that, to make the best decision on how to deal with an article, we should know about any competing interests that authors may have, and that if we publish the article readers should know about them too. We are not aiming to eradicate such interests; they are almost inevitable. We will not reject your article simply because you have a conflict of interest, but we want you to make a declaration on whether or not you have competing interests. (We also ask our staff and reviewers to declare any competing interests.)⁵
<p>What information is required to be disclosed?</p>	<p>The form asks authors to disclose three types of information:</p> <ol style="list-style-type: none"> 1. Associations with commercial entities that provided support for the work reported in the submitted manuscript (the timeframe for disclosure in this section of the form is the life span of the work being reported). 2. Associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript (in the three years before submission of the manuscript). 3. Non-financial associations that may be relevant or seen as relevant to the submitted manuscript.⁵

<p>How and when is this information collected?</p>	<ul style="list-style-type: none"> • A declaration of interests for all authors must be received before an article can be reviewed and accepted for publication. It should take one of two forms, depending on what type of article you are submitting. • From July 2010, the BMJ (along with other journals that are members of the International Committee of Medical Journal Editors) has asked authors of research papers to use a revised version of the ICMJE’s unified disclosure form.⁵
<p>Does this information have any impact on decisions to publish an article?</p>	<ul style="list-style-type: none"> • We are not aiming to eradicate such interests; they are almost inevitable. We will not reject your article simply because you have a conflict of interest, but we want you to make a declaration on whether or not you have competing interests. (We also ask our staff and reviewers to declare any competing interests.)⁵
<p>How is this information communicated to the reader?</p>	<p>BMJ Requires the following to be listed in the manuscript for all Research articles:*</p> <ul style="list-style-type: none"> • A competing interest declaration. This should be composed after each author has filled in the International Committee of Medical Journal Editors' Unified Competing Interest form and the corresponding author should keep the completed forms in case they are required later. Please then add to the manuscript a statement in the following format: “All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) [initials of relevant authors] have support from [name of company] for the submitted work; (2) [initials of relevant authors] have [no or specified] relationships with [name of companies] that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have [specified] financial relationships that may be relevant to the submitted work; and (4) [initials of relevant authors] have no [or specified] non-financial interests that may be relevant to the submitted work.” • details of contributors - giving their names and specific roles - and the name of the guarantor(s) for the study • a statement giving the details of all sources of funding for the study • a statement of the independence of researchers from funders • a statement that all authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis • a transparency declaration: a statement that the lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.² <p>BMJ Requires the following for Analysis Articles:*</p> <ul style="list-style-type: none"> • CONTRIBUTORS and SOURCES: We ask for a 100-150 word supplementary paragraph (excluded from word count) to explain the article’s provenance. It should include the relevant experience and expertise of each author, his or her contribution to the paper, and the sources of information used to prepare it. One author must be nominated as the guarantor of the article. • CONFLICTS OF INTEREST: All authors should read our competing interests policy and include the appropriate declaration in their manuscript. Where a competing interest exists that might disqualify an author from contributing, it is wise to discuss it with a BMJ editor before writing the article.³

	<p>BMJ Requires the following for Methods Articles:*</p> <ul style="list-style-type: none"> • a statement of sources and selection criteria: as well as the standard statements of funding, competing interests, and contributorship, please provide at the end of the paper a 100-150 word paragraph (excluded from word count) explaining the paper's provenance. This should include the relevant experience/expertise of the authors and the sources of information used to prepare the paper. It should also give details of each author's role in producing the article and name one as guarantor.⁴
Is it readily accessible to the reader?	<ul style="list-style-type: none"> • Information is listed in the manuscript. The specific information made available depends on the type of article.*
How are situations where no apparent conflicts of interest handled?	<p><u>No competing interests:</u></p> <ul style="list-style-type: none"> • All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work."⁵
Is there an explicit recognition of industry funding?	<ul style="list-style-type: none"> • If you are submitting an original article reporting an industry-sponsored clinical trial, postmarketing study, or other observational study please follow the guidelines on Good Publication Practice (GPP2) and on properly reporting the role of professional medical writers.²
Accounting for Variance and Difference	
Are the stated conflict of interest policies applied uniformly to all types of articles?	<ul style="list-style-type: none"> • Varying requirements for different types of articles with the most extensive set being for those articles presenting original research. Articles concerned with either Analysis or Methods require only a statement explaining any conflicts of interest and contributions made by each author.*
Does the journal have any unique requirements that may not be found in the policies of other journals?	<ul style="list-style-type: none"> • Please ensure that anything you submit to the BMJ conforms to the uniform requirements for manuscripts submitted to biomedical journals, drawn up by the International Committee of Medical Journal Editors (ICMJE).¹ • From January 2013, trials of drugs and medical devices will be considered for publication only if the authors commit to making the relevant anonymised patient level data available on reasonable request (see editorial). This policy applies to any research article that reports the main endpoints of a randomised controlled trial of one or more drugs or medical devices in current use, whether or not the trial was funded by industry. • "Relevant data" encompasses all anonymised data on individual patients on which the analysis, results, and conclusions reported in the paper are based.²

Sources:

- 1: "Article Requirements," BMJ, accessed February 15, 2013, <http://www.bmj.com/about-bmj/resources-authors/article-submission/article-requirements>.
- 2: "Research," BMJ, accessed February 15, 2013, <http://www.bmj.com/about-bmj/resources-authors/article-types/research>.
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*: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

Appendix H World Association of Medical Editors (WAME)

Defining Conflicts of Interest	
How are COIs defined?	<ul style="list-style-type: none"> • Conflict of interest (COI) exists when there is a divergence between an individual’s private interests (competing interests) and his or her responsibilities to scientific and publishing activities such that a reasonable observer might wonder if the individual’s behavior or judgment was motivated by considerations of his or her competing interests. • In the context of medical publishing, COI exists when a participant in the publication process (author, peer reviewer, or editor) has a competing interest that could unduly influence (or be reasonably seen to do so) his or her responsibilities in the publication process. Among those responsibilities are academic honesty, unbiased conduct and reporting of research, and integrity of decisions or judgments. The publication process includes the submission of manuscripts, peer review, editorial decisions, and communication between authors, reviewers and editors.¹
Recognition of both financial and non-financial COI?	<ul style="list-style-type: none"> • Rather than utilizing financial and non-financial conflicts in the definition, instead offers a distinction between individual private interests and public responsibilities.*
Which type is emphasized in this definition?	<ul style="list-style-type: none"> • Definition and accompanying examples do not specifically emphasize any particular type of conflict.* • Many kinds of competing interests are possible. Journals often have policies for managing financial COI, mostly based on the untested assumption that financial ties have an especially powerful influence over publication decisions and may not be apparent unless they are made explicit. However, other competing interests can be just as damaging, and just as hidden to most participants, and so must also be managed. The following are examples of competing interests; they do not include all possibilities and they may coexist. • Financial ties. This conflict is present when a participant in the publication process has received or expects to receive money (or other financial benefits such as patents or stocks), gifts, or services that may influence work related to a specific publication. • Academic commitments. Participants in the publications process may have strong beliefs (“intellectual passion”) that commit them to a particular explanation, method, or idea. • Personal relationships. Personal relationships with family, friends, enemies, competitors, or colleagues can pose COIs. • Political or religious beliefs. Strong commitment to a particular political view (e.g., political position, agenda, or party) or having a strong religious conviction may pose a COI for a given publication if those political or religious issues are affirmed or challenged in the publication. • Institutional affiliations. A COI exists when a participant in the publication process is directly affiliated with an institution that on the face of it may have a position or an interest in a publication.¹
What is the stated timeframe for what constitutes a COI?	<ul style="list-style-type: none"> • Journals should publish all COI (or their absence) reported by authors that are relevant to the manuscript being considered. In addition to financial COI, policies for authors should be extended to other types of competing interests that might affect (or be seen to affect) the conduct or reporting of the work. Journals should disclose all COIs that they themselves thought were important during the review process.¹

Detailing Disclosure	
What is the role and purpose of authorship?	<ul style="list-style-type: none"> • Authorship implies a significant intellectual contribution to the work, some role in writing the manuscript and reviewing the final draft of the manuscript, but authorship roles can vary. Who will be an author, and in what sequence, should be determined by the participants early in the research process, to avoid disputes and misunderstandings which can delay or prevent publication of a paper.³
How is authorship defined?	<ul style="list-style-type: none"> • Everyone who has made substantial intellectual contributions to the study on which the article is based (for example, to the research question, design, analysis, interpretation, and written description) should be an author. It is dishonest to omit mention of someone who has participated in writing the manuscript (“ghost authorship”) and unfair to omit investigator who have had important engagement with other aspects of the work.²
What actions and roles qualify for authorship?	<ul style="list-style-type: none"> • Simply refers to authors as those who have made a substantial intellectual contribution to the research.*
Accounting for Contributorship	
How are contributions not recognized by authorship recognized?	<ul style="list-style-type: none"> • Many journals publish the names and contributions of everyone who has participated in the work (“contributors”). Not all contributors necessarily qualify for authorship. The nature of each contributors’ participation can be made transparent by a statement, published with the article, of their names and contributions and WAME encourages this practice.²
How is contributorship defined?	<ul style="list-style-type: none"> • No explicit definition of contributorship is provided.*
How are such contributions communicated to the reader?	<ul style="list-style-type: none"> • Many journals publish the names and contributions of everyone who has participated in the work (“contributors”). Not all contributors necessarily qualify for authorship. The nature of each contributors’ participation can be made transparent by a statement, published with the article, of their names and contributions and WAME encourages this practice.²
What actions and roles qualify for contributorship?	<ul style="list-style-type: none"> • Performing technical services, translating text, identifying patients for study, supplying materials, and providing funding or administrative oversight over facilities where the work was done are not, in themselves, sufficient for authorship, although these contributions may be acknowledged in the manuscript.²
Detailing Disclosure	
What is the primary policy mechanism used to address conflicts of interest?	<ul style="list-style-type: none"> • Everyone has COIs of some sort. Having a competing interest does not, in itself, imply wrongdoing. However, it constitutes a problem when competing interests could unduly influence (or be reasonably seen to do so) one’s responsibilities in the publication process. If COI is not managed effectively, it can cause authors, reviewers, and editors to make decisions that, consciously or unconsciously, tend to serve their competing interests at the expense of their responsibilities in the publication process, thereby distorting the scientific enterprise. This consequence of COI is especially dangerous when it is not immediately apparent to others. In addition, the appearance of COI, even where none actually exists, can also erode trust in a journal by damaging its reputation and credibility. • Managing COI depends on disclosure because it is not possible to routinely monitor or investigate whether competing interests are present. Disclosure is about the facts that might bear on COI; assertions of integrity are not, in themselves, helpful.¹

What information is required to be disclosed?	<ul style="list-style-type: none"> • No generally accepted standard, nor evidence-based consensus, exists for precisely defining the degree of financial COI or the timeframe that creates a substantial risk of bias or damage to the journal's reputation. Judgments may be affected by many factors including, in the case of financial COI, the amount of money, goods, or services exchanged, how recently they were received and whether they are expected in the future, as well as the services provided in return. To guide authors in this decision, journals should publish their own standards for financial COI, including its standards on expiry on COI (e.g., only declare COI within last five years), as precisely as possible. • Declarations should require authors to explicitly state funding sources and whether the organization that funded the research participated in the collection and analyses of data and interpretation and reporting of results.¹
How and when is this information collected?	<ul style="list-style-type: none"> • All declarations about COI should be requested in writing as a condition of reviewing a manuscript and asked in such a way that authors will have a high likelihood of reporting their COIs related to the manuscript.¹
Does this information have any impact on decisions to publish an article?	<ul style="list-style-type: none"> • Which COIs will result in a manuscript not being considered further? Journals must be transparent about COI situations that, if present, will result in a manuscript not being considered further. Some journals have made it explicit that they will exclude authors from writing narrative (not systematic) reviews of topics in which they have a competing financial interest, on the grounds that it is more difficult for readers to detect bias in reviews than reports of original research, where methods are made more explicit. Some journals may apply internal editorial rules about which COI situations are not acceptable but these may not be explicit to those involved in the publication process; a journal COI policy needs to articulate the journal's position.¹
How is this information communicated to the reader?	<ul style="list-style-type: none"> • Journals should publish all relevant COI disclosures with the publication.¹
Is it readily accessible to the reader?	<ul style="list-style-type: none"> • No specific guidance or recommendations are offered as to how to communicate this information to the reader.*
How are situations where no apparent conflicts of interest handled?	<ul style="list-style-type: none"> • Journals should publish all COI (or their absence) reported by authors that are relevant to the manuscript being considered.¹
Is there an explicit recognition of industry funding?	<ul style="list-style-type: none"> • Commercial sources of funding, by companies that sell drugs and medical devices, are generally seen as the most concerning, perhaps because of many well-publicized examples of bias related to ties to industry. Examples of financial ties to industry include payment for research, ownership of stock and stock options, as well as honoraria for advice or public speaking, consultation, service on advisory boards or medical education companies, and receipt of patents or patents pending. Also included are having a research or clinical position that is funded by companies that sell drugs or devices.¹
Accounting for Variance and Difference	
Are the stated conflict of interest policies applied uniformly to all types of articles?	<ul style="list-style-type: none"> • No distinction between different types of articles within stated conflict of interest guidelines.*

<p>Does the journal have any unique requirements that may not be found in the policies of other journals?</p>	<ul style="list-style-type: none"> • Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself. WAME considers ghost authorship dishonest and unacceptable. Ghost authors generally work on behalf of companies, or agents acting for those companies, with a commercial interest in the topic, and this compounds the problem. For example, a writer employed by a commercial company may prepare an article, then invite an expert in the field to submit the work, perhaps with minor revisions, under his or her own name. The submitting author may be paid, directly or indirectly, for this service. In other circumstances, investigators may pay a professional writer to help them prepare their article but not mention this assistance, gaining credit for writing they have not done. Although editors seek to avoid publication of ghost written articles, these articles are often very difficult to detect. • However, responsibility for ghost written manuscripts goes beyond individual authors. Other parties, including companies—such as marketing, communications, and medical education companies who are paid to assist pharmaceutical and medical device companies in disseminating favorable messages about their products—may initiate the sequence of events for which the author is the final and most easily identified participant. These other participants are also responsible for ghost written manuscripts and addressing their roles should be part of the solution.²
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Sources:

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 - 3: WAME Editorial Policy Committee, “Publication Ethics Policies for Medical Journals – Authorship,” WAME, accessed February 15, 2013, <http://www.wame.org/resources/publication-ethics-policies-for-medical-journals#authorship>.
- *: Authors paraphrases for situations where the specific question was not directly addressed by the examined policies resulting in any Implied or explicit meaning being listed instead.

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