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I. INTRODUCTION

Recent legal scholarship and medical literature pays great attention to financial conflicts of interest that arise in biomedical research. In brief, the source of funding for experiments or clinical trials may influence or appear to influence the direction and publication of such research. This influence may have detrimental impacts on scientific integrity and patient care.[1] The current policies that address the undue influence of financial conflicts of interest tend to focus on disclosure of funding from the private sector, which means that the conflict of interest may already exist. The current guidelines and regulations that govern conflicts of interest are inadequate because they do not fully address the harms caused by financial conflicts of interest. This article proposes a novel approach to implementing effective conflict of interest policies by analyzing the underlying behavior leading to conflicts of interest and proposing policy solutions that regulate behavior prior to the creation of an actual conflict of interest. In this way, the policy proposals attempt to incentivize behavior(s) that will not be unduly influenced by the funding source.

An overview of the financial landscape of biomedical research is critical to understanding the problems associated with financial conflicts of interest. The majority of basic biomedical research occurs in laboratories at universi-

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1. *See* Shira Lipton et al., *Conflicts of Interest in Academic Research: Policies, Processes, and Attitudes*, 11 ACCOUNTABILITY IN RES. 83, 94 (2004) ("[W]hen asked about the specific risks associated with financial ties between academe and industry, approximately three fourths of the respondents believed that there is an increased risk for bias in research design, analyses, and presentation of research results, and a heightened possibility of publication delay or suppression of results.").

ties.[2] Faculty, known as Principal Investigators ("PIs"), establish their own laboratories that may consist of personnel including post-doctoral researchers, graduate students working towards their PhDs, and laboratory research assistants. In general, PIs apply for grants from the government, and most often the National Institutes of Health ("NIH"), to fund the laboratory research.[3] In addition, PIs may apply to other federal agencies or state agencies for funding. PIs may also acquire funding from non-profit organizations such as the Howard Hughes Medical Institute. Finally, PIs may also be funded by the for-profit private sector. In general, however, reputational and financial considerations lead most PIs to apply for RO1 grants, which are funded through the NIH grant process.[4]

One of the reasons that public money is used to fund basic science is because a private market does not exist for such early stages of research where most experiments fail.[5] Despite the slow progress in science, scientists may learn from failed experiments, and of course, some experiments provide fruitful information. If a new pathway for cancer is discovered, or a new gene mutation is uncovered, these types of discoveries may become targets for drug discovery and treatment of disease. Once this occurs, a market for the private sector emerges and the pharmaceutical industry may want to invest in Research & Development ("R&D").[6] Despite the slow process of basic science, evidence suggests that there is a satisfactory rate of return to the economy from publicly funded research.[7]

The private sector plays an important role in bringing drugs and devices to patients. Private companies have two main goals: (1) the discovery, development and production of new drugs and devices and (2) making a prof-

2. Biomedical research is the use of science to understand disease. *See Definition of Biomedical Research*, THEFREEDICTIONARY.COM, http://www.thefreedictionary.com/biomedical+science (last visited June 29, 2011) ("the application of the principles of the natural sciences to medicine").

3. JOINT ECON. COMM., THE BENEFITS OF MEDICAL RESEARCH AND THE ROLE OF THE NIH (2000) *available at* http://www.faseb.org/portals/0/pdfs/opa/2008/nih_research_benefits.pdf.

4. *Types of Grant Programs*, NAT'L INSTS. HEALTH, http://grants.nih.gov/grants/funding/funding_program.htm (last updated Sept. 29, 2011).

5. *See e.g.*, Ian Cockburn & Rebecca Henderson, *Public-Private Interaction in Pharmaceutical Research*, 93 PROC. NAT'L ACAD. SCI. U.S. 12725, 12725 (1996); *see also* SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS, REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH AND SOCIETY 2 (2010) [hereinafter GENE PATENTS], *available at* http://oba.od.nih.gov/oba/sacghs/reports/SACGHSpatents_report_2010.pdf.

6. Jerome P. Kassirer, *Financial Conflict of Interest: An Unresolved Ethical Frontier*, 27 AM. J. L. & MED. 149, 152 (2001) ("Proponents of strong academic-industry relations argue that when public support of research is not forthcoming, and when profits are achievable, private industry will do a better job in developing useful products than academia.").

7. JOINT ECON. COMM., *supra* note 3, at 9.

it.[8] The first goal directly benefits the public. The second goal also benefits the public, but it carries a potential problem: a profit-seeking goal may dominate the scientific goal.[9] This problem creates distrust, damaging influences, and frankly, can promote bad science. High profile examples of this type of behavior include the reporting of only six months of data in a clinical trial that is designed to contain twelve months of data, incomplete reporting of data, and concealing clinical data that demonstrates that a treatment may be harmful.[10] When faculty obtains private funding, a public-private interaction may exist and PIs may have vested financial interest in the results of the research. Put differently, through the relationship with a private company, PIs may also have economic motives that blanket their main goal of contributing to science in an effort to better understand diseases. These issues exemplify the problems at the heart of a financial conflict of interest.

The public-private interaction has increased over the past thirty years. In 1980, Congress passed the Bayh-Dole Act, which allowed a university and the inventor to patent the new technology stemming from a PI's laboratory.[11] Prior to the Bayh-Dole Act, only the federal government could patent an invention developed through federally-funded research.[12] After the Bayh-Dole Act, once the university obtained the patent for an invention, the university could now license the technology to the private sector.[13] The Act significantly changed the relationship between the private and public sector, resulting in both positive and negative consequences. The Bayh-Dole Act

8. Catherine DeAngelis, *The Influence of Money on Medical Science*, 296 JAMA 996, 996 (2006); *see also*, SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST 1, 181 ("Public-interest science asks how knowledge can contribute to ameliorating social, technological, or environmental problems. Private-interest science asks how knowledge can produce a profitable product or defend a corporate client, whether or not it has social benefits and whether or not the product is distributed fairly and equitably.").

9. DeAngelis, *supra* note 8, at 996.

10. *Id.*; *but see*, Thomas P. Stossel, *Has the Hunt for Conflicts of Interest Gone Too Far?*, 336 BRIT. MED. J. 476, 476 (2008) ("All of these charges obscure the fact that only private companies bring new products to patients and that medical care has improved steadily and spectacularly because of them. Fraud and pathological bias could never have conferred these monumental achievements.").

11. Jesse A. Goldner, *Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach*, 28 J.L. MED. & ETHICS 379, 385 (2000); GENE PATENTS, *supra* note 5, at 28.

12. *See generally*, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1671-95 (1996) (describing the history of the government's policies).

13. Goldner, *supra* note 11, at 385; Eisenberg, *supra* note 12, at 1665, 1691 ("The agency response was to allow universities with approved technology transfer capabilities to retain title to patents and to grant exclusive licenses to industry under the terms of Institutional Patent Agreements ("IPAs").."); *see also* Kassirer, *supra* note 6, at 150; 35 U.S.C. §§ 200, 202 (2010).

permits universities to license patents directly to biotech companies. These licenses have two main advantages: (1) revenue for the university and (2) increase in the development of discoveries in basic science into potential treatments for disease.[14] Another advantage is that the PIs, who are probably most familiar with the patented discovery, are available for consultation by the licensee.[15] Conversely, one negative consequence is the development of changes in ethical norms in research.[16]

Over the past thirty years, since the passage of the Bayh-Dole Act, the public-private interaction has dramatically increased, not only through licensing but also through other funding activities in the basic and clinical sciences. The private sector may enter into agreements with universities in a number of ways. The private sector may license specific discoveries, fund clinical trials, enter into exclusive licensing agreements with the institution, or fund the laboratories of PIs.[17] Universities may even facilitate PIs to be founders of start-up companies. The start-up companies are based on a product from the PI's laboratory.[18] The university stands to make money from the start-up through licensing agreements or the university, itself, may hold equity in the start-up company.[19] Any of these types of agreements can create financial conflicts of interest if the research and academic integrity of the PI or the institution is diminished due to any undue influence of a profit-seeking motive.

The goal of any conflict of interest policy is to resolve or eliminate the profit-seeking goal from having an undue influence on the soundness of the science. In this way, an effective policy promotes the public goals and the private goals and eliminates the issue of when the profit-seeking motive distorts the science.

To date, most policies governing financial conflicts of interest center on disclosure. That is, PIs must disclose certain financial ties with the private sector to the university or the public funding source. The policy of disclosure, however, may be inadequate because the conflict may already exist. This article proposes a new approach to financial conflict of interest policies by altering the environment in which the agreements with the private

14. Eisenberg, *supra* note 12, at 1698-99 ("Like the government, universities are not in a position to develop new discoveries into commercial products, but need to attract commercial licensees to invest in further development. University-owned patent rights would facilitate this process in part by providing a source of exclusive rights to assure private firms that successful products would be profitable.").

15. *Id.* at 1700.

16. KRIMSKY, *supra* note 8, at 7.

17. *See, e.g., About CTT*, UNIVERSITY OF PENNSYLVANIA CENTER FOR TECHNOLOGY TRANSFER ,http://www.ctt.upenn.edu/about.html (last visited July 1, 2011).

18. *See, e.g., Upstart*, UNIVERSITY OF PENNSYLVANIA CENTER FOR TECHNOLOGY TRANSFER, http://www.ctt.upenn.edu/upstart.html (last visited July 1, 2011).

19. *See, e.g., id.*

sector are made.

Consider the following general scenario to understand the underlying behavior that may give rise to the susceptibility of influence from the private sector in the decision-making process. Assume an individual is experiencing work-related chronic stress and ask him to respond to a series of questions requiring him to make decisions. The responses will be referred to as "Behavior 1." Now, assume that individual is in a situation devoid of stress and ask him to respond to a series of questions requiring him to make decisions. The responses will be referred to as "Behavior 2."[20] Recent scholarship in behavioral ecology addresses the different behaviors that may result when an individual is placed in different environments.

A policy may seek to regulate the person demonstrating Behavior 1 and not Behavior 2. Or, the law may attempt to incentivize the person demonstrating Behavior 1 to change their behavior to that of Behavior 2. However, policymakers need to understand why an individual might exhibit both Behavior 1 and Behavior 2 depending on the circumstances of his environment. Under the above hypothetical, the environment, for example, exposure to chronic stress versus no stress, leads to different behaviors.

Behavioral ecology can be utilized and applied to identify and regulate financial conflicts of interest in academic settings.[21] The recognized problem is that a financial incentive can have an undue influence over faculty as they conduct and report their research. Without an understanding of why there is this problem of undue influence, it is difficult to craft an effective solution.

This article proposes that an analysis of behavior may be utilized to create an effective policy addressing financial conflicts of interest. Importantly, this article focuses on the academics that conduct basic science. Many of the issues faced by basic scientists are different than those faced by clinicians or institutions.[22] Academics conducting basic science face different pressures than clinicians and institutions, therefore their interests should be addressed separately in order to best craft a policy that addresses their unique positions.

To apply a behavioral approach to conflicts of interest, a comparison of academics in the behavioral ecology hypothetical described above can be

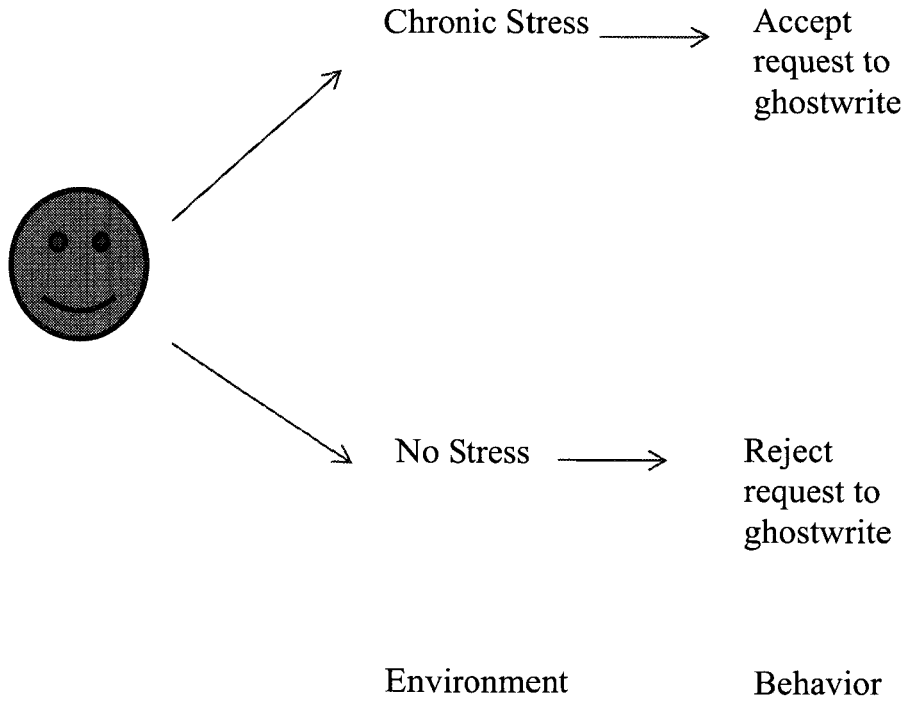
20. Owen D. Jones & Timothy H. Goldsmith, *Law and Behavioral Biology*, 105 COLUM. L. REV. 405, 501 (figure 3) (2005).

21. *See, e.g.*, Stephen G. Pauker & John B. Wong, *How Should Physicians Think?*, 304 JAMA 1233, 1234 (2010) ("Tools and perspectives from other fields can add perspective and provide solutions in medicine.").

22. *See, e.g.* Michael M.E. Jones et al., *Restoring Balance to Industry-Academia Relationships in an Era of Institutional Financial Conflicts of Interest*, 289 JAMA 741, 741-746 (2003) (addressing institutional financial conflicts of interest, but also lumping together discussion of conflict of interest policies for clinicians and researchers).

used. *See* Figure 1. PIs may exist in a state of chronic work-related stress. Academic scientists are under pressure to achieve results, support laboratory personnel and meet other obligations. This chronic stress may alter their decisions when faced with a situation that may pose a financial conflict of interest, such as ghostwriting an article, not reporting negative results, and spinning positive results.[23] If, however, these academic scientists are relieved, at least in part, from the chronic work-related stress, they may make different decisions. By understanding environmental differences and the impact on decision-making, policies concerning conflicts of interest may be designed to address and regulate the environment that creates the conflict of interest situation; that is, address the chronic work-related stresses that lead to poor decision-making.

Figure 1.[24]



23. This article focuses on financial conflicts of interest. Non-financial pressures exist as well; however, these are usually well managed by the scientific process and institutional policies. *See* David Korn, *Conflicts of Interest in Biomedical Research*, 285 JAMA 2234, 2234 (2000).

24. *See* Owen D. Jones & Timothy H. Goldsmith, *Law and Behavioral Biology*, 105 COLUM. L. REV. 405, 501 (figure 3) (2005).

An understanding of the background of the public-private interaction is critical to fully appreciate the rise of the financial conflicts of interest in biomedical science. Part II of this Article describes the rise of financial conflicts of interest and the types of harms that can occur in the absence of effective policy to regulate financial conflicts of interest.

Part III describes the current system addressing conflicts of interest, which relies mostly on disclosure. The policy of disclosure is inadequate and this section analyzes the deficiencies in the present system.

Part IV analyzes research in the social sciences and psychology and applies important developments in these areas to understand decisions that create financial conflicts of interest. Importantly, this section describes that the stress experienced by PIs may contribute to inappropriate responses to situations that contain a conflict. This part also includes a discussion of an empirical analysis of the results of a survey analyzing the responses of academic scientists to hypothetical situations in which a conflict of interest may arise. The results of this study can be utilized to assist in addressing areas in which a financial conflict of interest policy might be most beneficial.

Part V proposes policy recommendations to regulate financial conflicts of interest. The Article proposes a new approach that involves addressing issues in the environment in order to create an effective policy. Within the university, policy proposals include implementation of education programs, use of system-wide default rules, and changes to academic requirements. The creation of novel approaches to policy can be incentivized through federal grants that reward institutions for implementing effective strategies. Outside the institution, changes to intellectual property law may functionally alter the scientific environment.

II. CONFLICTS OF INTEREST

A conflict of interest is defined as "circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest."[25] Put simply, a conflict of interest poses a threat to the integrity of the research.[26]

Traditionally, the guiding motivations for PIs include: "faculty advancement, recognition by peers, the need to publish, to win research funding, and most importantly, to prove medicine's ability to assuage pain and

25. INST. OF MED. OF THE NAT'L ACADEMIES, CONFLICT OF INTEREST IN MED. RESEARCH, EDUCATION, AND PRACTICE 1, 6 (Bernard Lo & Marilyn J. Field eds., 2009). (2009).

26. S. Van McCrary, et al., *A National Survey of Policies on Disclosure of Conflicts of Interest in Biomedical Research*, 343 NEW ENG. J. MED. 1621, 1621 (2000); *see also* John E. Tyler III, *Advancing University Innovation: More Must be Expected-More Must be Done*, 10 MINN. J.L. SCI. & TECH. 143, 158 (2008-09) ("Critics argue that university-industry interactions compromise objectivity and that industry will try to unduly influence research topics, methods, results, and even the substantive reports themselves.").

suffering."[27] These are strong forces and have served to incentivize biomedical discovery and scientific advancement well.[28] That said, however, money is a motivator as well and the potential for money to conflict with the traditional motivations is real and should be addressed.[29]

Some argue that academic physicians and scientists will not be influenced by financial incentives because they are trained to be objective.[30] Further, the reputational scars that could result from being deemed non-objective might keep scientists from being unduly influenced. With this said, however, scientists are human and it is clear that they can be influenced by external factors, despite all of their training.[31] Academic science is a stressful endeavor. An appreciation of the stressful environment is critical to understanding how PIs may make a decision that creates a conflict of interest. Described below are examples of the environmental pressures experienced by PIs.

A. Pressures on PIs

PIs work under stressful conditions. Such stresses include funding, publishing, promotion, and recognition. Within each of these categories exist opportunities for decisions that may create potential financial conflicts of interest.

1. Funding

PIs must obtain funding in order to survive. Funding pays for salary, lab space, research, and other overhead costs. To obtain funding, PIs apply for grants and compete for research money in a competitive atmosphere. Although funding may be available through several sources, an RO1 grant from the NIH remains the gold-standard for funding.[32] The RO1 is one of the largest grants available to a PI.[33]

Over the years, the amount of money available through the RO1 grant program has stagnated.[34] Scientists worry that the amount of funding dedicated to RO1s will not increase and that money may be moved from the

27. Hamilton Moses & Joseph B. Martin, *Academic Relationships with Industry*, 285 JAMA 933, 935 (2001); *see also*, Korn, *supra* note 23, at 2234.

28. Moses & Martin, *supra* note 27, at 935.

29. *Cf.* Shira Lipton et al., *supra* note 1, 94.

30. Kassirer, *supra* note 6, at 153.

31. *Id.*

32. *US Health Bill Promises Changes for Biomedical Researchers*, 464 NATURE 479, 479 (2010) [hereinafter *Changes for Biomedical Researchers*] (quoting Mark Lively as stating that the RO1 is the "gold standard.").

33. *See* NIH Research Grant Program (RO1) (Feb. 2, 2011), http://grants.nih.gov/grants/funding/r01.htm.

34. *Changes for Biomedical Researchers*, *supra* note 32, at 479 (quoting Mark Lively as stating that "there has already been a long slide or stagnation in the funding" of RO1s.).

RO1 pool to other areas. This will lead to greater competition for funding because the amount of available money will decrease.

The recent and historic health-care bill contains provisions that impact biomedical research; by increasing funding for the translation of discoveries in basic science to the clinic.[35] The funding required to support these new provisions remains unclear, but some worry that it will cut into an already stretched NIH budget.[36]

Movement in this direction creates several situations that can increase work-related stress. First, PIs may now need to compete harder in an already competitive market for government funding. Second, a push for the translation of basic science into therapies may create pressures for PIs to try to get as many of their discoveries into clinical trials as soon as possible, which may not always be desirable due to inadequate understanding at the basic science level.

The pressure on PIs to fund research and pay laboratory personnel can create an environment ripe for financial conflicts of interest. With tightening federal and state budgets, PIs may turn to private sources for funding.[37] Funding by private sources, however, may come with attendant strings, such as control of study design, delay of publication, and restrictions on collaborations with other laboratories. The purpose of these restrictions may allow the private funding source to maintain control and privacy over studies to apply for patents or for other business-related reasons. These restrictions may have negative impacts on the advancement of science.

2. Publishing

Academics publish to communicate ideas. Publications are also important for career advancement. Scientific publications are peer-reviewed. The peer-review of manuscripts allows the scientific community to self-regulate and build consensus. That is, academics review each other's articles to determine what data is published. Once an article is peer-reviewed and accepted for publication, this signals that the PI's work is contributing to the scientific community.

35. *Changes for Biomedical Researchers*, *supra* note 32, at 479; Jocelyn Kaiser, *Health Bill Backs Evidence-Based Medicine, New Drug Studies*, 327 SCIENCE 1562 (2010).

36. *Changes for Biomedical Researchers*, *supra* note 32, at 479; Kaiser, *supra* note 35, at 1562.

37. In recognition of the rise of conflicts of interest, the new health-care bill addresses the financial conflicts of interest that may arise for physicians. The new health-care bill, however, does nothing to address the financial conflicts of interest that may arise with the basic scientists. *Changes for Biomedical Researchers*, *supra* note 32, at 479 ("Another provision in the bill will expose relationships between physician researchers and the medical industry."); Kaiser, *supra* note 35, at 1562; *see also*, *Physicians Payment Sunshine Act Guide*, PEW PRESCRIPTION PROJECT, http://www.prescriptionproject.org/sunshine_act (last visited July 21, 2011) (using links to describe problems with small gifts and legislation addressing this area).

a. Influence in the Publishing Landscape

The pressure to publish, however, may make PIs susceptible to industry publishing tactics when the PIs are involved in an industry-funded research project. Private companies may have a different motivation for publishing. For example, private companies may want to influence the direction of science in such a way that their profit-seeking motive is met. One way a private company may operate, for example, is to flood the literature with data in non-peer reviewed journals that may lead the science in a particular direction.[38] A study analyzed the conclusions of a number of review articles that reviewed the current literature on the effects, if any, of passive smoking.[39] This study found that approximately a third of the review articles concluded that passive smoking is not harmful.[40] The main correlation found in the articles that concluded that passive smoking is not harmful was that the authors were affiliated with the tobacco industry.[41] The study suggests that the private tobacco industry may be attempting to influence the dialogue on the effects of passive smoking by flooding the literature with statements that say as much.[42] The tobacco-industry tactics are discussed more fully below. A major problem with this is that the authors of these review articles, in large part, did not disclose their industry ties; thus, they did not explicitly appear to have financial motives.[43]

Another technique used by industry is to over-report or overstate favorable results.[44] A study comparing the results of new studies of cancer drugs revealed that studies funded by pharmaceutical companies were more likely to reach favorable qualitative results than studies funded by non-profit insti-

38. Kassirer, *supra* note 6, at 156 ("In analyses of review articles, new treatments were favored over traditional ones more frequently when the manufacturer of the new drug funded the research. Articles in symposiums sponsored by a single drug company were substantially more favorable to the drug than articles without company support.").

39. Richard Smith, *Conflicts of Interest: How Money Clouds Objectivity*, 99 J. OF THE ROYAL SOC'Y OF MED. 292, 293 (2006) (describing study).

40. *Id.* at 293 (describing study). Note: review articles are not peer-reviewed.

41. *Id.* (describing study).

42. *Id.* (describing study); *see also* Joanna K. Sax, *Protecting Scientific Integrity: The Commercial Speech Doctrine Applied to Industry Publications*, 37 AM. J. L. & MED. 203, 210-11 (2011) (see references therein).

43. Smith, *supra* note 39, at 293 (describing study). Another example of controlling the literature can be found where the pharmaceutical company is controlling the protocol to test for adverse effects. In a tort case, for example, the expert witness will not be allowed to testify if their method is not generally accepted by the scientific community. But, if the scientific community has a vested interest in the result, then this detracts from the ability of scientists to serve as expert witnesses.

44. Likewise, industry may underreport or suppress evidence. *Cf.* Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 AM. J. L. & MED. 119, 122 (2004).

tutions.[45] Likewise, studies funded by pharmaceutical companies were less likely to reach unfavorable conclusions regarding the cancer drug than studies funded by non-profit institutions.[46] A number of reasons may lead to these results. For example, pharmaceutical companies are unlikely to carry out full studies unless the preliminary data look promising.[47] Regardless, the bias of reporting positive or favorable qualitative results may flood the literature and influence the direction of science.[48]

In many ways the influence that a pharmaceutical company attempts to exert through scientific publications is similar to the activities of an interest group. As an analogy, the tobacco industry devoted an enormous amount of money and energy into attacking and attempting to undermine scientific data regarding the harmful effects of smoking.[49] To promote its agenda, the tobacco industry employed numerous strategies to suppress unfavorable research and promote its own conclusions.[50] One strategy employed was industry-sponsored research.[51] The tobacco industry funded research that was disseminated via symposiums, research publications, and industry-sponsored review articles.[52] For example, a study found that "[t]obacco industry-funded reviews were about ninety times as likely as reviews funded by any other source to conclude that passive smoking was not harmful."[53] The tobacco industry effectively flooded the market with tobacco-industry funded research to promote its own position. These activities were uncovered through litigation.[54] Investigation into the industry-sponsored tobacco literature revealed that lawyers and executives had a heavy hand in the design, dissemination and promotion of tobacco research.[55] An important

45. Mark Friedberg, et al., *Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology*, 282 JAMA 1453, 1455 (1999). Of note, the Friedberg study was funded by an unrestricted grant from Amgen, Inc. and Amgen had a contractual right to review and comment on the manuscript and abstract prior to publication.

46. *Id.* at 1455; *cf.* Wagner & Michaels, *supra* note 44, at 124 ("Evidence that parties with direct conflicts of interest can sometimes design and report results in ways that are favorable to their interests, rather than in ways that best represent the research, has been extensively documented.").

47. *See id.*

48. *Cf.* Wagner & Michaels, *supra* note 44, at 120 ("As long as sponsors control the research at some or all points in the research process, adverse results can be suppressed and the design and reporting of experiments can be biased in ways that produce results that support the sponsor's interests, rather than offer a disinterested examination of potential harms.").

49. Lisa A. Bero, *Tobacco Industry Manipulation of Research*, 120 PUB. HEALTH REPS. 200, 200-01 (2005); *see also*, Sax, *supra* note 42, at 210-11 (see references therein).

50. *Id.* at 201-05.

51. *Id.* at 201.

52. *Id.* at 202-03.

53. *Id.* at 203.

54. *Id.* at 201.

55. *Id.* at 206. Another example of this type of industry control is the story of understanding lead toxicity. KRIMSKY, *supra* note 8, at 190 ("Needleman realized that much of the research on lead toxicity was paid for and controlled by the industry 'who had a tight

lesson to learn here is that the private sector has a business motive and sometimes that business motive will conflict with what is best for the public.

Delay of publication is another problem. Often, industry may want a contractual provision with a PI that allows industry to delay publication of methods or results so that industry can keep results private until a patent application is on file.[56] Among the many problems with delaying publication is that it is diametrically opposed to the canon of sharing results among PIs. Sharing is essential to the advancement of science.[57] This is the antithesis of academic culture, where wide dissemination of research is encouraged to promote science, create collaborations, and stimulate scientific progress.

b. Ghostwriting

Ghostwriting, "a practice that, in its most extreme form, involves pharmaceutical companies designing and paying for studies or reviews, then seeking a guest author to be credited while the company goes unacknowledged,"[58] is a problem because ghostwritten papers tend to advocate positive conclusions, suggesting a bias, and are used to market drugs.[59] If a paper is authored by a pharmaceutical study promoting its own drugs, the experienced reader may view the results with skepticism because the reader knows that the pharmaceutical company has a vested financial interest in promoting the use of its drugs. If, however, a reader reviews the same article, but it is authored by an academic scientist, the reader will not have the same skepticism because the academic scientist carries a reputation for objectivity and should not have the same vested financial interest as the pharmaceutical company in promoting the use of any one drug.[60]

A PI may accept an offer to ghostwrite for a number of reasons. First, the pharmaceutical company may offer to pay the PI money. Second, the PI

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grip on what the public was permitted to know.' He decided he had to study the issues on its own terms without influence from the industry that profits from lead.").

56. Eyal Press & Jennifer Washburn, *The Kept University*, 285 ATLANTIC MONTHLY 39, 41 (2000) ("Today scientists who perform industry-sponsored research routinely sign agreements requiring them to keep both the methods and the results of their work secret for a certain period of time."); KRIMSKY, *supra* note 8, at 15, 37, 82 (providing an example of the contract containing a provision that no data can be published without written consent from the company).

57. KRIMSKY, *supra* note 8, at 83.

58. Nicola Jones, *Ghosts Still Present in the Medical Machine*, 461 NATURE 325, 325 (2009).

59. *Id.* ("[G]hostwritten papers tend to have more positive conclusions and can be used to market off-label uses of drugs.").

60. *See, e.g.*, Kassirer, *supra* note 6, at 156 (2001) (describing a researcher who was a ghostwriter on an article regarding obesity who admitted: "I think I've been pretty honest and uncorrupted by money. But who knows, maybe it's so insidious that I don't notice it.").

may need additional publications because the PI is facing a promotion and additional publications will help their chance of promotion. Third, it may be likely that the results of the study will be published in a high-impact journal, subsequently increasing the PI's reputation.

The problem is that ghostwriting does not promote the public good. An article promoting the use of a particular drug may receive increased press and increased use in the clinic because an academic PI authors an article containing favorable conclusions that are inaccurate.[61] The PI may not have been involved with the design study or analysis. Put simply, ghostwriting can have the unwanted effect of allowing industry to influence the trajectory of science,[62] thereby creating a bias.[63]

A recent study exposed the practice of pharmaceutical companies hiring public relations firms that specialize in producing, planning and tracking articles.[64] A pharmaceutical company can hire a public relations-type firm to institute strategic planning for publication and potentially influence the medical and scientific community. As part of the pharmaceutical company's strategic plans, they may fund academics, but this funding comes with strings, such as allowing the pharmaceutical company to prepare drafts, edit, delay publication, and prevent full access to data.[65] The PI's name may appear on the article as the author, but much of the work is controlled by the profit-seeking pharmaceutical company. The private sector can influence the trajectory of science by flooding the market and by spinning results.

In the late 1990s and early 2000s, some journal editors cracked down on the practice of ghostwriting.[66] The Journal of the American Medical Association ("JAMA"), for example, attempts to eliminate ghost authors by

61. *See* S. Rep. No. 112-11, at 48 (2011), *available at* http://www.gpo.gov/fdsys/pkg/CRPT-112srpt11/pdf/CRPT-112srpt11.pdf ("The researchers also reported that Merck hired a medical publishing company, Scientific Therapeutics Information, Inc., to draft manuscripts for the company's Vioxx studies and seek academic investigators to sign on as the primary author(s), even though the academic investigators may not be intimately familiar with the underlying data and/or relevant documentation. This is a practice known as ghostwriting. Information in scientific journals can have a significant impact on doctors' prescribing behavior and, in turn, on the taxpayer because Medicare and Medicaid pay billions of dollars for prescription drugs. Patients may be harmed if doctors are being misled to prescribe drugs that may not work or are unsafe.").

62. Sergio Sismondo, *Ghost Management: How Much of the Medical Literature is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 PLoS MED. 1429, 1429 (2007).

63. *Id.* at 1429.

64. *Id.* at 1430; *see also*, KRIMSKY, *supra* note 8, at 115 ("It works like this: Excerpta is contracted by a company to fine a distinguished academic scholar to agree to have his or her name placed on a commentary, editorial, review, or research article, which has been written by someone either from the company or someone selected by Excerpta.").

65. Sismondo, *supra* note 62, at 1430.

66. Jones, *supra* note 58, at 325.

requiring that "industry-affiliated papers must undergo an independent statistical review."[67] Other journals, however, do not explicitly address the problem of ghostwriting.[68] Some journals have adopted policies that require authors to disclose any potential financial conflicts of interest.[69] The practice of ghostwriting can be eliminated if PIs refuse offers from drug companies that request ghost-authorship.

Over time, the application of scientific rigor may ferret out some of the issues raised above. Scientists often attempt to replicate earlier experiments and if problems arise, previously published research may be exposed as not being able to be replicated.[70] It seems highly unlikely, however, that all publication bias can be exposed through this traditional mechanism; rather, other institutional remedies are needed. One way to do this is to create incentives to promote certain types of human behavior.

3. Promotion and Recognition

Other pressures on PIs include promotion and recognition. PIs undergo a review process every few years. As part of the review process, the faculty member's department will review a PI's publication record as well as other contributions to the medical community.[71] Leading up to a review, the PI will prepare a summary of his or her achievements. In addition, some reviews may require letters of recommendation from faculty outside the PI's institution.

Although the pressures of promotion and recognition can pose a non-financial conflict of interest with a PI's primary academic responsibilities; in general, academic policies and the academic culture effectively

67. Nicola Jones, *Spectre of Industry Bias*, 461 NATURE 325, 325 (2009); *see also* Catherine D. DeAngelis, et al., *Reporting Financial Conflict of Interest and Relationships Between Investigators and Research Sponsors*, 286 JAMA 89, 89 (2001). In addition to ghostwriting, JAMA has stringent publication rules to address conflicts of interest. *See* Phil B. Fontanarosa, et al., *Reporting Conflicts of Interest, Financial Aspects of Research, and Role of Sponsors in Funded Studies*, 294 JAMA 110, 110-111 (2005); Annette Flanagin, et al., *Update on* JAMA*'s Conflict of Interest Policy*, 296 JAMA 220-21 (2006).

68. Jones, *supra* note 58, at 325 ("[O]nly 4 of 26 journals she studied explicitly mention ghostwriting in their policies today.").

69. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Conflicts of Interest*, ICMJE, http://www.icmje.org/ethical_4conflicts.html (last visited Oct. 8, 2011).

70. *See* KRIMSKY, *supra* note 8, at 77.

71. Jesse A. Goldner, *Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach*, 28 J.L. MED. & ETHICS 379, 384 (2000); *see also* Donald S. Siegel, David Waldman, & Albert Link, *Assessing the Impact of Organizational Practices on the Relative Productivity of University Technology Transfer Offices: An Exploratory Study*, 32 RES. POL'Y 27, 43 (2003) ("The vast majority of interviewees also specifically commented on the fact that tenure and promotion decisions continued to be made almost strictly on the basis of publications and grants.").

manage these non-financial conflicts of interest.[72] Indeed, while these types of conflicts are acknowledged within academia, they do not receive much attention in the public because scientific processes and the scientific community itself do a good job of managing non-financial conflicts of interest.[73]

B. Founders and Equity Interest

The public-private interaction also occurs as a result of PIs founding their own companies to develop discoveries.[74] For example, in the mid-1990s a psychiatrist and his colleagues discovered a new way of treating psychotic depression by giving patients RU-486.[75] The psychiatrist conducted a clinical study and applied for a patent. When the pharmaceutical industry showed no interest in developing this treatment, the psychiatrist co-founded his own company to license his discovery.[76] It is possible that the psychiatrist may face a conflict of interest because the psychiatrist now stands to gain financially only if his discovery does well. If the psychiatrist is involved in additional clinical studies using his discovery, the psychiatrist has a financial interest in seeing that the trials obtain positive results. Any equity interest, where the value of that interest may depend on the outcome of a discovery, may then operate as a conflict of interest.[77]

Perhaps one of the most well-known financial conflict of interest examples is the case of Jesse Gelsinger at the University of Pennsylvania. Jesse, a volunteer in a clinical trial, died in a gene therapy trial. Both the lead investigator and the University of Pennsylvania owned equity in a company involved in the study.[78] After an investigation, the FDA concluded that Jesse's liver was not functioning at the minimum level in order to participate in the study in the first place.[79] In addition, the researchers failed to report severe side effects experienced by other subjects, which would have resulted in halting the study.[80] The literature on this subject suggests that

72. *See* Korn, *supra* note 23, at 2234.

73. *Id.*

74. Goldner, *supra* note 11, at 384. In fact, the university may even encourage the PI to found a start-up company. Kassirer, *supra* note 6, at 152 ("They point out that the several research and technology institutes that have encouraged their faculty to develop start-up companies have not only successfully retained superb faculty, but (according to them) have avoided potentially serious adverse consequences of these relationships.").

75. Jocelyn Kaiser, *Private Money, Public Disclosure,* 325 SCIENCE 28, July 3, 2009, at 28.

76. *Id.*

77. *See* Hamilton Moses III & Joseph B. Martin, *Academic Relationships with Industry,* 285 JAMA 933, 934 (2001).

78. Kaiser, *supra* note 75, at 29 ("[A] volunteer died in 1999 in a gene therapy trial in which the lead investigator and university had a financial interest[.]"); Goldner, *supra* note 11, at 379.

79. Goldner, *supra* note 11, at 379.

80. *Id.*

the potential financial gain by both the lead investigator and the University of Pennsylvania if the trial was successful may have clouded the judgment of those conducting the study.[81]

PIs may also obtain equity interests in companies because the companies want PIs to serve as consultants and on their boards, as the PIs are usually among the brightest scientists and they may be most familiar with the technology.[82] Again, due to the equity interest, the PIs have a financial interest in seeing that the company succeeds, which could cloud judgment.

C. Intellectual Property Law

Changes in intellectual property ("IP") law may contribute to some of the problems inherent to conflicts of interest. In 1980, the Supreme Court's decision in *Diamond v. Charkrabarty* provided that genetically modified bacteria are patentable.[83] This opened the door to allow the patenting of cell lines, genes, and other living organisms.[84] In essence, a new market was created for the biomedical enterprise. Of course, the Bayh-Dole Act was also passed in 1980, creating a perfect storm that considerably increased the commercialization of science.

It has been recognized that university patenting sharply increased after the passage of the Bayh-Dole Act.[85] It has also been questioned whether the taxpayers, who fund a large part of the research resulting in patents, are getting a good return on their investment, either financially or socially.[86]

IP policy is important in the public-private interaction. Patent protection is not available for discoveries that have been made public. For this reason, universities and the private sector may want PIs to refrain from publishing results of experiments until a patent application is filed. This interferes with collaborations among scientists, impedes research, and delays information from reaching the public. On the other hand, IP policy creates incentives for the private sector to invest in R&D and then reap the benefits of the exclusivity period granted by patent protection. Changes in IP law with respect to discoveries in the biomedical sciences, which is discussed in section V.F., may be needed to address the problems associated with the creation of conflicts of interest.

In sum, the combination of the pressures of academic success and the increased influence of the private sector on academic science creates a

81. *See also*, Kassirer, *supra* note 6, at 154 (describing that the "press has also ferreted out many financial conflicts of interest by physicians" including one related to a diabetes drug).

82. *Id.* at 152.

83. KRIMSKY, *supra* note 8, at 30; *see also* Diamond v. Charkrabarty, 447 U.S. 303 (1980).

84. KRIMSKY, *supra* note 8, at 30.

85. *Id.* at 32.

86. *Id.*

swamp for problems with conflicts of interest. The private money is important to fund academic research, but the influx of private money creates the potential for conflicts of interest. A policy is needed that recognizes and supports the use of private money in academic research, but creates appropriate incentives to minimize and potentially eliminate the creation of conflicts of interest.

III. THE PRESENT SYSTEM OF DISCLOSURE

A. Disclosure as the Current Process Used to Address Conflicts of Interest

The cornerstone of current policies aimed at controlling conflicts of interest is disclosure.[87] Mandated disclosure is an often-used first step towards regulation because it does not mandate specific outcomes and allows parties to retain freedom in transactions.[88] In addition, mandated disclosures only apply to parties that have entered into a transaction.[89]

The NIH proposed guidelines that would prohibit any relationship that might present a conflict after noting the increased public-private interaction created by the Bayh-Dole Act[90] and the potential for conflicts of interest that impact the integrity of scientific research.[91] These proposed guidelines were widely viewed as too restrictive.[92] In 1994, the Public Health Service and the National Science Foundation proposed revised guidelines that promulgated rules for PIs to report financial payments. These were adopted in 1995.[93] Under the rules enacted in 1995, academics must report to the funding agency any industry payments of $10,000 or more if the payments would reasonably appear to affect the research for which the PI is applying.[94] Grant applicants must also report equity holdings above five percent

87. *See* David B. Allison, Letter, *The Antidote to Bias in Research*, 326 SCIENCE 522, 522 (2009) (describing how some scientists question the value of disclosure policies); *see also* Daylian M. Cain & Allan S. Detsky, *Everyone's a Little Bit Biased (Even Physicians)*, 299 JAMA 2893, 2894-5 (2008) (describing experiments where disclosure had the opposite of the intended effect and how disclosure may not be the solution).

88. *See* Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, UNIVERSITY OF MICHIGAN LAW SCHOOL EMPIRICAL LEGAL STUDIES CENTER 23-4 (2010), *available at* http://law.bepress.com/umichlwps/empirical/art9/.

89. *See id.* at 24.

90. *See generally*, Eisenberg, *supra* note 12, at 1671-95 (describing the history of the current policy).

91. Van McCrary et al., *supra* note 26, at 1621.

92. *Id.* at 1621; *see also*, Korn, *supra* note 23, at 2235.

93. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. §§ 50.601-50.607 (2010).

94. Editorial, *Trust, but Verify*, 461 NATURE 315, 315 (2009) ("Under conflict-of-interest rules in place since 1995, extramural grant applicants must report industry payments of more than US$10,000 per year if those payments would 'reasonably appear to be affected by the research' for which NIH funding is sought."); Kaiser, *supra* note 75, at 29; *see also*

ownership in a company.[95] The home institution is charged, in its discretion, with managing or eliminating any financial conflict of interest and reporting back to the NIH.[96] In 2010, the NIH changed its guidelines so that grant applicants must disclose if they receive industry payments of $5,000 or more and if the PI holds any equity in a non-publicly traded company.[97]

Similar to the NIH, many universities mandate disclosure in their conflict of interest policies.[98] Some universities may have specific rules beyond disclosure. Harvard University, for example, recently enacted guidelines that doctors who serve on the board of directors for drug makers cannot be paid more than $5,000 per day.[99] Further, under these guidelines, doctors are not supposed to receive equity for their services.[100]

Recent investigations charged that many PIs and home institutions may be lax with respect to reporting requirements.[101] To address this, Senator Grassley (R-Iowa) proposed legislation to strengthen the reporting requirements.[102] The proposed legislation, however, only applies to clinical physicians, not to non-clinical scientists.[103]

B. Problems with Disclosure

The current policy of disclosure does not appear to work well. First, disclosure does not prevent PIs from entering into agreements where a con-

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Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 CFR §§ 50.604(c)(1).

95. *Trust, but Verify*, *supra* note 94, at 315; Kaiser, *supra* note 75, at 28; Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 CFR §§ 50.604(c)(1); Van McCrary et al., *supra* note 26, at 1621.

96. *Trust, but Verify*, *supra* note 94, at 315 (2009); Van McCrary, *et al.*, *supra* note 26, at 1621.

97. Jocelyn Kaiser, *Lowering the Boom on Financial Conflicts*, 328 SCIENCE 1065, 1091 (2010); Meredith Waldman, *NIH Set to Tighten Financial Rules for Researchers*, 465 NATURE 391, 407 (2010).

98. *See generally,* Mildred K. Cho, *et al.*, *Policies on Faculty Conflicts of Interest at US Universities*, 284 JAMA 2203, 2203-08 (2000).

99. Scott Hensley, *Harvard Hospitals Limit Industry Pay to Doctors*, NPR'S HEALTH BLOG (Jan. 4, 2010, 8:55 AM), http://www.npr.org/blogs/health/2010/01/harvard_hospitals_limit_indust.html. The author thanks a previous student for sending along this reference. *See also* Duff Wilson, *Harvard Teaching Hospitals Cap Outside Pay*, N.Y. TIMES, Jan. 2, 2010, at A1.

100. Hensley, *supra* note 99; Wilson, *supra* note 99.

101. *Trust, Trust, but Verify*, *supra* note 94, at 315 ("After much investigation, however, Grassley and his staff have alleged that some academic researchers have taken a relaxed approach to this reporting requirement, and that some institutions have been just as casual in monitoring their researchers."). *See generally*, Meredith Wadman, *The Senator's Sleuth*, 461 NATURE 330, 330-334 (2009).

102. *Trust, but Verify*, *supra* note 94, at 315.

103. *Id.* ("It's important to note that Grassley's Sunshine Act does not apply to non-physician scientists; he drafted it with medication-prescribing doctors in mind. Yet PhD scientists, too, play a vital part in many industry collaborations.").

flict of interest exists in the first place. Second, PIs may have difficulty understanding their home institution's policy regarding disclosure.[104] Third, disclosure does not address the underlying stressful environment that lends itself to decisions to enter into agreements where a conflict of interest may arise. Finally, disclosure is a limited policy solution.

Recent scholarship analyzes the problematic nature of mandated disclosure in a variety of settings, including mortgage lending, informed consent, drug labeling, and financial transactions.[105] In other fields, disclosure is supposed to create ability to make better informed decisions. The same idea may be applied to scientific publications, for example, where disclosure of a funding source allows the reader to assess the credibility of results. Internal disclosure within the university or to the NIH does not have the same objective as mandated disclosure in other fields. With this limitation, however, disclosure does not appear adequate to effectively manage conflicts of interest for reasons that are common to other industries and for reasons unique to biomedical research as well. Although mandated disclosure appears to be an easy information-sharing approach to regulation, it often does not effectively address the problems it is aimed at solving.[106] For these reasons, academic conflict of interest policies suffer from many of the same shortcomings of the use of mandated disclosures in other areas of the law; hence, policy recommendations and reform need to appropriately address financial conflicts of interest in the academic setting.

C. Problems with Creating an Effective Policy

Any policy recommendations must consider the process of biomedical research. An absence of understanding of the system can lead to remedies and policies that both undermine and damage the scientific process and any goal of translating basic scientific discoveries into actual medical treatment.[107] In addition, when crafting a policy, an understanding of how academic scientists respond to situations in which a conflict might arise is essential. To this end, my colleague and I conducted an empirical study of faculty responses to hypothetical situations in which a conflict of interest

104. *See, e.g.*, Shira Lipton et al., *supra* note 1, at 90.

105. *See generally,* Omri Ben-Shahar & Carl E. Schneider, *supra* note 88; *see also* Max H. Brazerman, *Behavioral Decision Research, Legislation, and Society: Three Cases*, 2 CAPITALISM & SOC'Y 1, 4 (2007) (describing how the SEC's policy of disclosure of conflicts of interest is ineffective).

106. *See* DAYLIAN M. CAIN, GEORGE LOWENSTEIN, AND DON A. MOORE, *Coming Clean by Playing Dirtier*, CONFLICTS OF INTEREST 104, at 104 (Don A. Moore, Daylian M. Cain, George Lowenstein & Max H. Bazerman eds., Cambridge University Press 2005) (discussing problems associated with disclosure of conflicts of interest).

107. Korn, *supra* note 23, at 2234 ("Absence of context can lead to proposed remedies that could damage both the scientific process and the translation of scientific discoveries into public health.").

may arise.[108] The results of this study are described in section IV.C. below.[109]

The university may face its own internal conflict when establishing any conflict of interest policies. On the one hand, any policy that restricts conflicts of interest may lead to less funding by the private sector.[110] Less money makes it harder to conduct research. On the other hand, publicity of conflicts of interest that lead to terrible results, such as the Jesse Gelsinger case, are not only tragic, but also poor public relations for the university and hurt the public trust of academic institutions.

In addition, if a conflict of interest exists, it can undermine the inherent culture of academic science, that is, the normative structure.[111] The academic culture is a free exchange of ideas, openness, pursuit of truth, and nature, not religion or culture, is the final word on the physical universe.[112] The pursuit of truth may be in jeopardy if industry money is devaluing the academic culture.

Academic PIs are immersed in the private industry. At leading research universities many PIs consult with industry, sit on boards, own equity, and are funded by private companies.[113] It makes sense that private companies want the best and the brightest scientists to provide advice and conduct research. The issue is whether this is good for scientific integrity and the public. The lack of clear policies within an institution combined with non-uniform policies across medical centers leads to confusion. Current policies appear to vary regarding disclosure, review, monitoring and management.[114] In sum, no consistent or effective policy exists to address financial conflicts of interest.

IV. BEHAVIORAL LAW AND ECONOMICS

Behavioral law and economics can be utilized to create an effective conflict of interest policy. Recent scholarship proposes the incorporation of behavioral decision-making into legal analysis.[115] In the conflict of interest

108. Joanna K. Sax & Neal Doran, *Evaluation of Academic Scientists' Responses to Situations that Pose a Conflict of Interest*, 12 CANCER BIOLOGY & THERAPY 4, 4-8 (2011).

109. *Id.*

110. Krimsky, *supra* note 8, at 47.

111. *Id.* at 73.

112. *Id.*

113. *See id.* at 111; *see also* Press & Washburn, *supra* note 56, at 47 ("The surprising twist, however, is that although university licensing offices are churning out patents, most of these offices are themselves barely breaking even.").

114. Cho et al., *supra* note 98, at 2207.

115. Owen D. Jones, *Time-Shifted Rationality and the Law of Law's Leverage: Behavioral Economics Meets Behavioral Biology*, 95 Nw. U. L. REV. 1141, 1142 (2001) ("'[B]ehavioral law and economics' (here "BLE") reflect[s] a new interdisciplinary approach that would incorporate into legal analysis important findings about irrationality from the field of cognitive psychology (and its cognates variously known as behavioral economics

arena, the application of principles from psychology and biology can help policymakers understand decision-making, which can provide powerful insight into creating effective policies.[116]

Policy incentivizes humans to behave in a socially desirable way.[117] In order to incentivize such behavior, one must first understand why humans behave the way they do and how they respond to different mechanisms.[118] This is often accomplished by either rewarding people for doing something socially or economically desirable, or extracting resources from people who do socially undesirable things.[119] A classic example of a policy that encourages a particular social behavior is the use of tax policy for charitable giving. The government encourages charitable giving by offering a tax deduction. Behavioral biology may help to explain *why* people will behave the way a policy model anticipates.[120]

A. Behavioral Biology and Economics

In essence, the law is about changing behavior.[121] For this reason, understanding human behavior seems to be an important part of any policy. The problem, however, is that a complete explanation of the gamut of human behavior does not exist.[122] This does not mean, however, that behavioral biology cannot serve as part of the research that contributes to policy decisions.[123]

Economics are often used to analyze or generate a policy decision. In conjunction with economic analyses, behavioral biology can be utilized to understand how to implement a policy to obtain a desired outcome. Behavioral biology may help to identify hidden policy conflicts, expose a poor policy for the desired outcome, or support a particular policy implementation.[124] At issue in the conflict of interest area, for example, could be a hid-

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and behavioral decision theory)."); *see also* Owen D. Jones, *Law, Emotions, and Behavioral Biology*, 39 JURIMETRICS J. 283, 284 (1999) (discussing that behavioral biology holds promise for legal thinkers); *see generally* Brazerman, *supra* note 104, at 1.

116. *See* Jones & Goldsmith, *supra* note 21, at 410 ("[E]volutionary insights into human decisionmaking processes can increase our understanding about people in ways useful to law and can also provide theoretical foundation for, and potential predictive power about, a variety of human behaviors – including, for example, economically irrational behavior.").

117. *See id.* at 414, 500.

118. *See id.* at 414.

119. *See id.* at 472.

120. *See id.* at 414.

121. *See id.* at 422.

122. *See id.*

123. Brazerman, *supra* note 105, at 14 ("The problem is that other social sciences have advanced to the extent that we now know of systematic patterns when we can adjust economic theory to make better predictions, yet decision-makers are not using this knowledge from other social sciences sufficiently.").

124. *See id.* at 14-15 (promoting use of social science in creating policy); *see also* Jones & Goldsmith, *supra* note 20, at 436 ("To the extent that behavioral biology can help uncover

den policy conflict where the Bayh-Dole Act encourages the public-private interaction yet fails to appropriately handle the financial conflicts of interest that arise from these relationships.

This Article proposes that an understanding of the environment and human behavior when faced with decisions that may create a conflict of interest is critical to any policy that governs conflicts of interest. The decision to enter into a funding agreement is a part of behavioral biology.[125] For example, emotions may strongly influence a decision.[126] In the conflict of interest arena, stress in the academic environment and a desire for recognition could impact the decision to enter into a particular agreement for funding.[127]

Some law and economic scholars are warming to the idea of considering behavioral biology as a component of policy analysis.[128] Other law and economics scholars criticize the application of behavioral biology to policy decision-making.[129]

Normatively, policymakers have a preference to bring about a certain behavior. Policymakers must consider how they want to affect a certain behavior and also how hard it will be to effect the specific change.[130] To do this, an understanding of the behavioral biology may lend assistance to determine both the 'how' and the 'how hard.'[131]

B. Human Responses to Situations

This article suggests approaches to conflicts of interest policies that allow funding opportunities by the private sector that do not create financial conflicts of interest. To do this, it is important to understand how people respond to decisions with attached financial incentives. For example, studies show that even a small amount of money may create conflict.[132] This

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hidden policy conflicts, it can also help to clarify and to quantify the actual tradeoffs involved in simultaneously pursuing two different legal goals that are in conflict.").

125. *See* Jones & Goldsmith, *supra* note 20, at 438 ("Yet another way to improve our understanding of human behavior is to improve our understanding of human decisionmaking.").

126. *See id.* ("A broader and more accurate view is that emotions and reasoning each effect the other.").

127. *See id.* at 449 ("Consider stress and its consequences. . . . In a different environment, however, where stress is caused through relatively long-lasting social interactions with members of the same species, relief becomes difficult.").

128. Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1471 (1998).

129. Richard Posner, *Rational Choice, Behavioral Economics, and the Law*, 50 STAN. L. REV. 1551, 1552 (1998).

130. *See* Jones & Goldsmith, *supra* note 20, at 470 (referring to tools and effort).

131. *See id.* at 471.

132. Troyen A. Brennan et al., *Health Industry Practices that Create Conflicts of Interest*, 295 JAMA 429, 430-31 (2006).

phenomenon may be explained in a famous psychology study conducted by Leon Festinger and Merrill Carlsmith in 1959.[133] In this study, subjects were asked to perform a series of boring tasks, such as turning pegs. The subjects were divided into three groups: control, one dollar, and twenty dollars. Subjects who just performed the tasks were then asked to tell the subjects who would next participate that they found the series of tasks to be interesting. For doing so, the original subjects were paid one dollar or twenty dollars, depending on their assigned group. [134] Those paid twenty dollars had no problem "lying" to the next subjects that the tasks were fun because they had a good reason, that is, they were paid twenty dollars.[135] Those paid one dollar, however, experienced what is termed "cognitive dissonance," which occurs when a person holds two thoughts that are psychologically inconsistent.[136] Here, the subjects knew the tasks were exceedingly boring, but they received one dollar to tell the next subject that the tasks were fun.[137] In this experiment, the one dollar group did tell the next subjects that the tasks were fun and they would justify their actions to themselves by thinking that tediousness is in the eye of the beholder.[138] This explains how the one dollar subjects brought together their inconsistent thoughts.[139]

The theory of cognitive dissonance may apply to PIs who face scenarios that give rise to financial conflicts of interest. That is, PIs may experience cognitive dissonance when faced with a decision to accept private money with strings attached. It may be that PIs can justify accepting private money, even though they may have to agree to delay publication or release the control of study design, because they need to financially support research and personnel. The rise of private money supporting research creates a problem where PIs may have psychologically inconsistent thoughts, and similar to the experiment described above, they may need to rationalize in the same way the subjects paid one dollar did.

Current conflict of interest policies do not consider human behavior in their regimes.[140] For example, the NIH's conflicts of interest guidelines state that financial investments or payments above a defined threshold must

133. SCOTT PLOUS, THE PSYCHOLOGY OF JUDGMENT AND DECISION MAKING 23-25 (Christopher Rogers & James R. Belser eds., McGraw-Hill, Inc. 1993) (describing study).

134. *Id.* at 23-25 (describing study).

135. *Id.* (describing study).

136. *Id.* (describing study and also discussing "self-perception" as an alternative theory).

137. *Id.* (describing study).

138. *Id.* (describing study).

139. *Id.* (describing study).

140. This may be, in part, because of the difficulties associated with testing for ethical decision-making. *See* Michael D. Mumford et al., *Validation of Ethical Decision Making Measures: Evidence for a New Set of Measures*, 16 ETHICS BEHAVIOR 319, 321 (2006).

be disclosed.[141] But, as the experiment by Festinger and Carlsmith demonstrates, even small payments can create cognitive dissonance.

All of this is to say that the current attempts to address conflicts of interest are inadequate because the policies do not address the constraints on human behavior, especially when experiencing chronic stress.[142] The atmosphere of academic research is stressful. As discussed above, PIs face stress regarding funding, publication, and promotion. One reason that PIs may enter into situations that pose a conflict of interest is that PIs are having to make decisions in a stressful environment.

Work stressors are broken down into different categories. First, a *stressor* is a characteristic of the environment that is objectively verifiable.[143] For example, the pressure to publish X-number of peer-reviewed articles every three years is a stressor. Second, *stress* is a subjective experience of the stressor.[144] For example, how a PI responds to the stressor of having to publish X-number of peer-reviewed articles every three years depends on the individual PI. Different PIs will experience the same stressor in different ways.[145] Third, the term *strain* is used to describe the outcome of the stress, for example, anxiety.[146] Finally, *chronic stressors* do not have a finite duration, rather they are repetitive in nature.[147] The demands of academic life, such as the need for recognition, concern for promotion, and the need for funding, place PIs in a chronically stressful environment. This environment may impact how PIs make decisions when faced with situations that create a conflict of interest.

For decades, scholars have studied the coping mechanisms employed in response to chronic stress.[148] While multiple theories exist, studies show that individuals who experience greater workplace stress have a reduction in their problem-solving capabilities.[149] Similar to other professions, PIs experience workplace stress. The reduction of available public funding through grants creates an environment where PIs need to look to the private sector to finance their research.[150] Moreover, the academic-private interaction is

141. Kaiser, *supra* note 97, at 1091; Wadman, *supra* note 97, at 407.

142. *See generally,* C. GAIL HEPBURN ET AL., COPING WITH CHRONIC STRESS 343-363 (Benjamin H. Gottlieb ed., Plenum Press 1997); *see also* DOLLY CHUGH ET AL., CONFLICTS OF INTEREST 91 (Moore, et al. eds., Cambridge U. Press 2005) (discussing decision-making).

143. HEPBURN ET AL., *supra* note 142, at 344.

144. *Id.*

145. *Id.*

146. *Id.*

147. *Id.* at 344-45 (providing career security as an example of a core chronic work stressor).

148. *Id.* at 352-53.

149. *Id.* at 353.

150. *See* Heidi Ledford, *Drug Buddies*, 474 NATURE 433, 433 (2011) ("Tightening federal budgets are also putting financial strains on academic labs, making industry collaborations more attractive.").

encouraged by federal policy. The limitations of public funding increased the pressures on PIs, because they are still expected to perform at better and better levels. It is also possible that some PIs may agree to terms with the private sector that they would not otherwise agree to, such as delaying publication in return for funding. In the minds of some PIs, delaying publication seems like a small price to pay for funding that supports research, salary, and overhead costs. And, on a limited basis, it may be a small price to pay, however industry's control over PIs is increasing and is threatening scientific integrity.

C. Empirical Study

To understand how academic scientists respond to hypothetical situations in which a conflict of interest may exist, a colleague and I conducted the following empirical study.[151] The faculty at five medical schools was requested to complete an anonymous on-line survey containing seven vignettes describing hypothetical situations in which a conflict of interest may arise.[152] The faculty was asked to respond to questions on a scale of 0-9, with 0 indicating the more appropriate response (i.e. least likely to enter into a conflict). The study hoped to address the following questions: (1) whether junior faculty may respond differently than senior faculty to questions posing a conflict of interest, suggesting that junior faculty may be less experienced or more susceptible to certain pressures; (2) whether faculty with primary research responsibilities respond differently than faculty with primary clinical responsibilities; and (3) whether responses from faculty in departments with higher amounts of federal grant money respond differently than faculty in departments with lower amounts of federal grant money.[153] To analyze the results, the seven vignettes were then separated into four overlapping categories: (1) conflicts with pharmaceutical companies; (2) reporting of data; (3) scientific versus profit motive; and (4) promotion.[154]

We used Tobit regression models to analyze whether the mean responses to each vignette category differed by academic rank (i.e. junior versus senior), academic sector (i.e. clinical versus research) and home department federal grant money per faculty member.[155] We found that senior faculty gave significantly lower (i.e. more appropriate) responses to each of the four categories of vignettes compared to junior faculty.[156] The amount

151. Sax & Doran, *supra* note 108, at 4-8. (Note, our empirical study did not test decision-making).

152. *Id.* at 5.

153. *Id.*

154. *Id.* at 5. A copy of the vignettes is available upon request from the author.

155. *Id.* at 5-6.

156. *Id.*

of departmental grant money per faculty member also impacted responses. Faculty from departments with more federal grant money responded significantly higher (i.e. less appropriate) to vignettes in the categories of pharmaceuticals, reporting of data and profit than faculty from departments with lower amounts of federal grant money.[157] Except in the profit vignettes, responses from faculty with primary research responsibilities were not significantly different from the response of faculty with primary clinical responsibilities. One reason for this result may be the failure of the survey to adequately tease out the research from the clinical faculty since many departments contain both types of faculty.[158] Interestingly, the faculty members' mean responses varied depending on vignette type.[159] For example, mean responses to vignettes concerning promotion were higher (i.e. less appropriate) than the mean responses to vignettes concerning pharmaceuticals. Our study is complementary to other studies that address the extent and type of financial relationships between industry and the academy.[160]

The results of the empirical study can be used to assist in developing an effective policy that manages financial conflicts of interest. The survey study begins to address an underlying problem that not all PIs respond in a uniform manner to questions posing potential conflicts of interest. For example, junior faculty responds differently than senior faculty. One reason for this could be that the *stressors* placed on junior faculty are different than senior faculty or that junior faculty responds differently to *stress* than senior faculty. This finding suggests that current 'one-size fits all' approaches to conflicts of interest policies may be inadequate. Instead, policy proposals should consider that different faculty experience varying pressures (or stressors) depending on experience, grant money, and primary responsibilities. To address these differences, universities might need to tailor training and education programs to these groups in order to bring everyone into compliance with a strong conflict of interest policy. In other words, education programs aimed at reducing the stress experienced by PIs – catered towards different phases of the PIs' career (e.g. junior versus senior) – may be beneficial. Recent studies suggest that training may be an effective tool to curb

157. *Id.*

158. *Id.* at 5-7.

159. *Id.* at 6.

160. *Id.* at 5, 7; *see generally* Eric G. Campbell et al., *Looking a Gift Horse in the Mouth: Corporate Gifts Supporting Life Sciences Research*, 279 JAMA 995 (1998) (examining the impact of research-related gifts from companies to scientists); *see generally* Eric G. Campbell et al., *Institutional Academic-Industry Relationships*, 298 JAMA 1779 (2007) (examining institutional academic-industry relationships); *see generally* Eric G. Campbell et al., *Financial Relationships Between Institutional Review Board Members and Industry*, 355 N. ENGL. J. MED. 2321 (2006) (studying the financial relationships between academic institutional review board members and industry).

decision-making in specific circumstances, and these studies may be utilized to determine whether such training programs are effective.[161]

Discussed below are approaches to implementing effective conflict of interest policies that consider the psychology scholarship and the results from our empirical study. In this vein, conflict of interest policies should consider that PIs experience a lot of stress, stress can cause inappropriate responses to situations in which conflicts may arise and any policy should consider how to incentivize PIs to respond appropriately either by creating a less-stressful environment or by helping PIs to understand how stress may impact their decision-making.

V. POLICY RECOMMENDATIONS THAT REQUIRE INSTITUTIONAL AND LEGAL ADJUSTMENTS

A new policy that considers how the environment of the PIs may impact how a PI approaches decision-making may be an effective way to address conflicts of interest. That is, the combination of the social sciences and economics can be used to create an effective policy. For example, the results from our survey demonstrate that seniority, sector, and dependency on grant money may be factors that impact how faculty respond to hypothetical situations in which a conflict of interest may arise.[162] It may be that the environment of a junior faculty member is different than the environment of a senior faculty member. Put differently, junior faculty may experience different stressors or experience stress differently than senior faculty. The current polices may not be effective because the policies do not consider the environment in which PIs live. Further, the Bayh-Dole Act encourages an environment that fosters the creation of conflicts of interest. To manage conflicts of interest, a policy must both consider the environment of PIs as well as the increased pressures they face to create and maintain interactions with the private sector.

Described below are a number of policy recommendations to address conflicts of interest that consider the environment of academic science and the pressure placed on PIs when they are faced with making decisions that could be influenced by the private sector. Importantly, the master policy would be the same for all PIs, but the roadmap to bringing all PIs into compliance with the policy may need to be different for faculty with varying needs. For example, different education or training programs may be needed for junior faculty than senior faculty. While all would be held to the same standard under the policy, different approaches may be needed to usher everyone under the umbrella of the policy.

161. *See generally* Michael D. Mumford et al., *A Sensemaking Approach to Ethics Training for Scientists: Preliminary Evidence of Training Effectiveness*, 18 ETHICS BEHAVIOR 315 (2008) (discussing the effectiveness of ethics training).

162. Sax & Doran, *supra* note 108, at 6-7.

A. Use of Default Rules

Perhaps the best way to contain the amount of influence that the private sector may exert over any academic research is for universities to collectively agree to a set of default rules for any contracts with the private sector.[163] The combination of default rules and the use of incentives can channel PIs into making decisions that minimize conflict of interests.[164]

For example, a default rule could be that the private sector cannot contract for a delay of publication with any PI. That is, a blanket prohibition against delay of the reporting of results. Another possible default rule could be that a PI must design and approve the experimental design of the study.[165] A series of default rules can be drafted that directly address known problems associated with the public-private interaction. These rules can be amended to respond to changes in the marketplace or to address as of yet unknown situations in which a conflict of interest may arise.

Default rules also have the advantage of taking the pressure off the PIs to negotiate with sophisticated private entities. PIs are scientifically trained and not necessarily business-savvy. For this reason, PIs should not be placed in positions in which they must negotiate with high-powered and self-interested private companies.

The only way that default rules can work, however, is if all medical schools agree to a set of rules. This is important because if Harvard applies a set of default rules, but Johns Hopkins does not, then industry will favor collaborations with PIs at Johns Hopkins. Conflicts of interest will continue to plague scientific integrity at those schools that do not adopt the default rules.[166]

B. Use of Technology Transfer Office

The technology transfer ("tech transfer") offices at universities may be the appropriate group to implement the default rules. Tech transfer offices are responsible for facilitating the patenting and licensing of patented discoveries developed at the university.[167] Universities introduce "technology-

163. *Cf.* Ben-Shahar & Schneider, *supra* note 88, at 65.

164. *See id.* (comparing disclosures and default rules).

165. *See, e.g., Sponsored Research Agreement*, University of Pennsylvania (May 1, 2004), http://www.upenn.edu/researchservices/pdfs/sponsres.pdf (this document does not address control of study design).

166. For additional ideas on default rules, *see* Joanna K. Sax, *Application of Default Rules to Address Financial Conflicts of Interest in Academic Medical Centers*, IND. L.J. SUPP. (forthcoming).

167. *See Glossary & Acronym List, Technology Transfer*, NAT'L INST. OF HEALTH, http://grants.nih.gov/grants/
glossary.htm (last visited Oct. 25, 2011) ("Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local Gov-

transfer offices to monitor, patent, and license potentially profitable discoveries of faculty."[168] However, no tech transfer office appears to be alike. That is, each university's tech transfer office has its own policies and procedures.[169] The problem is that there is no consistency as to how to address the public-private interaction. The good news is that each tech transfer office provides a laboratory to analyze and determine which policies work and which policies do not.

The general functions of a tech transfer office are as follows.[170] First, a PI discloses an invention to the tech transfer office.[171] The tech transfer office then evaluates whether the invention has a commercial use and whether to patent the technology.[172] If the tech-transfer office decides to apply for a patent and a patent is awarded, then the tech transfer office will market the invention to potential licensees.[173] Often, the PI will be involved in the marketing because they have the technical expertise to evaluate who will be a good licensee.[174] Once a potential licensee is found, the tech transfer office will negotiate a license agreement.[175] Following an initial licensing agreement, the tech transfer office will devote substantial resources to maintain and re-negotiate licensing agreements.[176] Start-up companies for PIs and sponsored research agreements often result directly from the licensing agreement.[177] This is a general overview and as is often the case, the details will be different across tech transfer offices. While the tech transfer office is in charge of licensing, it is unclear whether this department negotiates contracts between PIs and the private sector for other types of funding, such as follow-up research on a particular project. The PIs may be receiving private funding to continue research on a particular drug and this funding may be conditioned on certain provisions that contradict academic integrity, such as delay of publication.

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ernments.").

168. KRIMSKY, *supra* note 8, at 81.

169. *See* Tyler III, *supra* note 26, at 167 ("[M]any of the technology transfer offices that began to proliferate after Bayh-Dole seem to have emerged without adequate consideration about how the offices fit within and in service to the academic mission, the numerous intellectual property strategies available in addition to patenting and licensing, the financial and personnel resources necessary to operate such offices most effectively, and the Act's other purposes.").

170. Siegel et al., *supra* note 71, at 29.

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.* at 29.

176. *Id.* at 30.

177. *Id.* at 33; *see also* Kassirer, *supra* note 6, at 151 (" . . . [B]usinesses were 'spun off' by faculty at an increasing rate."); Of note, most schools do not make much money from the tech-transfer office. Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1385 (2006-07).

The New England Journal of Medicine (NEJM) published a study that analyzed the research institutions' in-house conflict of interest policies.[178] Just a sampling of the different university policies illuminates the variation among institutions. For example, some institutions require that PIs disclose financial relationships below that of the federal guidelines; others did not.[179] Some institutions require disclosure if the investigator believes that a possibility of a conflict may arise in the future; others did not.[180] Most institutions analyzed did not have an explicit or mandatory strategy to manage the initial disclosure.[181]

A different study of medical center conflict of interest policies was reported in JAMA.[182] Similar to the NEJM study, the authors found that each institution had varying policies. For example, nineteen percent of the policies examined by the authors of this study contained prohibitions or limits on activities related to research and teaching.[183] Of these, the activity that was most regulated was a faculty member having an equity interest in a company that sponsored their research.[184] This means that the majority of the medical center's policies failed to address potential conflicts of interest. Further, the study found that only twelve percent of policies limited the time that a PI could delay publication of results to allow review by a corporate sponsor or for the filing of a patent.[185] A delay of publication or presentation means that the data is not reaching the scientific community or the public. Depending on the circumstances, this may be harmful. For example, imagine if research regarding the H1N1 vaccine was not released due to a delay of publication or presentation related to a corporate sponsor.[186] This could have a devastating impact on the public.

The advantage of the tech transfer offices is that private companies will license the right to develop university-owned technology.[187] Prior to the Bayh-Dole Act, the Federal government owned the technologies derived from academic institutions and the private sector was relatively unwilling to

178. Van McCrary et al., *supra* note 26, at 1622. Noteworthy is that this study analyzed medical schools and other research institutions. This study found differences in conflicts of interest policies within medical schools as well as between medical schools and other research institutions.

179. *Id.*

180. *Id.* at 1623.

181. *Id.*

182. Cho et al., *supra* note 98, 2204.

183. *Id.* at 2206.

184. *Id.*

185. *Id.*

186. The H1N1 pandemic hit the world in 2009. *2009 H1N1 Flu ("Swine Flu") and You,* CDC, http://www.cdc.gov/
/h1n1flu/qa.htm (last visited Oct. 24, 2011).

187. Michael M.E. Johns et al., *Restoring Balance to Industry-Academia Relationships in an Era of Institutional Financial Conflicts of Interest*, 289 JAMA 741, 744 (2003).

license government-held patents.[188] The Bayh-Dole Act and the subsequent creation of tech transfer offices dramatically increased the abilities for private companies to obtain and develop new technologies.[189] Thus, the tech transfer office could be the central clearinghouse for all public-private interactions. This office can work closely with other university offices to implement effective conflict of interest policies.

C. Education

To many PIs, it may seem that the public-private interaction is at once both encouraged and discouraged. The problem lies in achieving a balance between incentivizing a productive public-private relationship and discouraging a harmful public-private result. One way to approach this difficulty is with education.

In a similar vein, one tactic used to reduce workplace stress is secondary-level preventative interventions that teach employees to recognize stressors in the workplace.[190] Under this approach, employees are trained to identify and cope with workplace stressors.[191] Studies have shown that cognitive-behavioral approaches to work-related stress may be effective.[192] This type of approach could be modified to address the chronic stress environment of the academic medical world.

In addition to the default rules, training or education programs may be employed to inform PIs about the academic-industry relationship and how to utilize this interaction in a way that promotes academic goals of objective and strong science.[193] Many PIs may be unfamiliar with strategies employed by industry that creates conflicts of interest. The results of our empirical study, for example, demonstrate that junior faculty responded less appropriately to situations in which a conflict of interest may arise when compared with senior faculty.[194] This is not surprising considering that junior faculty have less experience and may be under greater pressure to obtain funding. Thus, education programs aimed at graduate students, postdocs, and junior faculty that educates these groups about conflicts of inter-

188. *Id.* at 744.

189. *Id.*

190. HEPBURN ET AL, *supra* note 142, at 359.

191. *Id.* at 360.

192. *See* Jac J. L. van der Klink et al., *The Benefits of Interventions for Work-Related Stress*, 91 AM. J. OF PUB. HEALTH 270, 270, 274 (2001) (analyzing multiple studies).

193. Education is important in addition to default rules because the default rules may not address or eliminate all areas in which a conflict of interest may arise.

194. Sax & Doran, *supra* note 108, at 6; *see also see also* Pauker & Wong, *supra* note 21, at 1233-4 (describing how medical students cannot process information as effectively as experienced clinicians).

est may be helpful. In this way, junior faculty may be less likely to make a decision to enter into a relationship where a conflict of interest may arise.[195]

Senior faculty may also benefit from education. For example, senior faculty may be in a better position to be founders of start-up companies based on their academic research and may be more likely to serve as consultants or advisors to industry. Indeed, faculty is encouraged by the university to form start-up companies and enter into advisory or consulting roles.[196] But, PIs are scientists, not necessarily savvy business people, and additional education may be beneficial to inform senior faculty about situations in which a conflict of interest may arise. If PIs are educated as to when a conflict of interest may arise, they may be more likely to insist on limitations as to their involvement so as to minimize the risk of a conflict of interest.[197]

The need for education is also supported by evidence that faculty may not fully understand their institution's conflict of interest policies.[198] For example, many current conflict of interest policies require disclosure and then some sort of decision is made as to how to manage the conflict of interest.[199] Some faculty, however, may think that no research can be conducted if a conflict of interest exists.[200] This, however, is not a correct understanding, as universities may form committees to oversee studies in which a conflict of interest may exist. Some faculty view their institution's conflict of interest policy as an inhibitor to a PI's ability to collaborate with industry.[201] Other faculty view their institution's conflict of interest policy as a welcome effort towards creating a productive environment.[202]

In sum, there appears to be a disconnect between how PIs view conflicts of interest in general and how PIs view their institution's approach to managing conflicts of interest once they arise. An education program specifically designed to meet the needs of PIs may assist in lowering the number of situations in which a conflict of interest exists, which, in turn, may help to simplify the application of conflict of interest policies.

195. *Cf.*, Laura M. Brockway & Leo T. Furcht, *Conflicts of Interest in Biomedical Research – the FASEB Guidelines*, 20 FASEB J. 2435, 2436 (2006) (proposing guidelines for mentor-trainee relationships in academia-industry biomedical research); Mumford et al., *supra* note 139, at 340 (noting the effect of day-to-day work experiences on doctoral students' ethical decision making).

196. *See, e.g.*, Upstart, *supra* note 18.

197. *Cf.*, Brockway & Furcht, *supra* note 195, at 2436 (describing guiding principles for PIs); Mumford et al., *supra* note 139, at 339-40 (noting that training senior investigators on the responsible conduct of research may improve ethical decision making in researchers).

198. *See* Lipton et al., *supra* note 1, at 89-90.

199. *See id.* at 86-87.

200. *See id.* at 89-90.

201. *Id.* at 90-91.

202. *Id.* at 92.

D. Academic Requirements

Another way to avoid or manage conflicts of interest is to reduce or eliminate the work stressors.[203] For example, institutional changes in the requirements for review and promotion may alleviate some of the workplace stressors experienced by PIs.[204] Changing the institutional requirements, otherwise known as primary preventions, have shown to be effective in other circumstances.[205]

Changing academic requirements for review and promotion is not an easy task and it is likely that the universities would prefer that the PIs figure out how to handle chronic stress on their own.[206] However, studies show that changes in job design have beneficial effects on the employees.[207]

In general, scientific publications publish positive results. There may also be psychological reasons for the publication of positive results over negative results. For example, if a new drug is a better treatment than the standard treatment, then this suggests that the new drug is a departure from standard treatment.[208] That is a positive result that may help researchers, clinicians, and the public. Negative results, although not as "sexy" and maybe psychologically unattractive, also have the ability to teach researchers, clinicians and the public.

One change that could be considered is to allow unpublished negative results, if written-up, to be incorporated in reviews and promotions. When an experiment or a series of experiments fails, the scientific community and the public at large may never learn of these experiments. For example, a graduate student may spend years creating a transgenic mouse, but if the mouse has no phenotype, the result may never be published. One reason for this is because sometimes it is difficult to interpret and learn from negative results. A genetically modified mouse that does not show any developmental or health changes may or may not mean that the particular gene of interest is important. The peer-review of the negative results would occur within the department to determine the significance of the negative results. In many ways, it is the limitations on scientific experiments and discovery that may be the problem because we cannot yet test for certain characteristics.

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203. *Cf.*, HEPBURN ET AL., *supra* note 142, at 344, 360 (describing the effect on employees of reducing workplace stressors).

204. *Cf., id.*

205. *Id.*

206. *Id.* ("Unfortunately, the popularity of stress management programs suggests that organizations are more inclined to teach employees to cope with stress than to remove the sources of employee stress.").

207. *Id.*

208. *See* Tyler III, *supra* note 26, at 203-04 ("To some degree, game theorists and economists alike might persuasively contend that motivating disclosure is a matter of demonstrating that it is worthwhile and better than the next, best alternative, which might be nondisclosure, circumvention, or even departure.").

The consideration of solid science that yields negative results may soothe some of the stress associated with review and promotion. In this way, PIs may not feel the same level of chronic stress and they may, therefore, make different decisions.

E. Incentivizing Medical Centers to Implement Conflict of Interest Policies

To test and implement new ideas based on behavioral analysis, additional changes may be needed at the institutional level. The structural changes discussed above, including education, default rules, and academic requirements, can be encouraged through an incentive system. For example, medical centers that create innovative and effective ways to address financial conflicts of interest may be eligible for special funding opportunities through the NIH or NSF.[209] An external review committee can be utilized to evaluate and provide feedback.[210] Medical centers may also be eligible for special recognition or awards based on their programs. Through both financial and reputational incentives, the institutions stand to gain from effectively addressing financial conflicts of interest. This has the added benefit of allowing different medical centers to take different approaches to education, for example, and then study the effects of education over a five-year period. Effective programs can then serve as a model for other universities to adopt.

On the other end, sanctions can be used as a disincentive to certain behaviors. For example, if the NIH establishes an external review committee and this committee determines that a medical center is failing to implement policies to combat financial conflicts of interest, the medical center can first receive a written sanction. If the medical center fails to respond and improve its program, then the NIH can consider suspending research privileges or funding.[211] One problem with this approach, however, is that it may have the unwanted effect of punishing innocent PIs because they would experience collateral damage and be affected by a suspension of privileges or funding. Another possibility is for the university, itself, to utilize internal sanctions as a mechanism to deter PIs from entering into situations that create a conflict of interest.[212]

F. Changes to Intellectual Property Law

Another way to change the academic environment is to address whether current IP law is properly suited to advance science in academic settings.

209. *Cf.*, Sandra Titus & Xavier Bosch, *Tie Funding to Research Integrity*, 466 NATURE 436, 437 (July 22, 2010) (promoting good research practices through an incentive system).

210. *Id.*

211. *Id.*

212. *See* Tom R. Tyler, *Managing Conflicts of Interest with Organizations,* CONFLICTS OF INTEREST 13, 17 (Moore, Cain, Lowenstein & Bazerman eds., 2005).

IP law is an external pressure that impacts how the private sector interacts with academia. Universities and the private sector may be encouraged to patent discoveries for economic motives. These economic motives may conflict with non-financial responsibilities of PIs who conduct research with public money. A reflection upon the past thirty years of the public-private interaction may provide valuable insight into the adjustment of IP law to balance ways to incentivize innovation without causing harm to the public.

Ass'n for Molecular Pathology, et al. v. USPTO, et al., known as the Myriad case, is illustrative of the problem created when economic motives may conflict with the public's access to medical treatment. This case involved technology that was created through a private-academic relationship. In brief, in the Myriad case, Plaintiffs complained that Myriad's patents on the breast cancer genes, isolated BRCA1/2, created a problem whereby researchers could not conduct clinical research on these genes and patients did not have access to genetic screening.[213] One reason, for example, that patients did not have access to genetic screening was that Myriad might not have accepted their insurance.[214] The University of Utah Research Foundation was named as a defendant because it had ownership interest in each of the patents at issue in the case.[215] The history of the discoveries that led to the patent applications for BRCA1/2 straddled several years. Suffice it to say, both public and private money was used and several collaborations between the private sector and universities were involved in the discoveries that led to the patents at issue.[216] Since being granted the patents, Myriad vigorously defended its patent rights by sending cease and desist letters to multiple academic medical institutions who were testing its patients for mutations in the BRACA1/2 genes.[217] Plaintiffs argued that Myriad's patents hindered patient access to tests, interfered with research in this area and impacted patient care.[218] Myriad disagreed.[219] The trial court did not resolve the questions of fact argued by each side; instead, the court held the patents invalid because isolated genes are not patentable as a matter of law. That is, the BRCA1/2 genes are a product of nature and therefore not patentable.[220] On appeal, the Court of Appeals for the Federal Circuit overturned the trial court's decision, 2-1.[221]

213. Ass'n for Molecular Pathology, et al. v. USPTO, et al., 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

214. *Id.* at 375.

215. *Id.* at 376-77.

216. *Id.* at 378.

217. *Id.* at 379.

218. *Id.* at 380-81.

219. *Id.* at 381.

220. *Id.* at 381.

221. Andrew Pollack, *Ruling Upholds Gene Patent in Cancer Test*, N.Y. TIMES, July 29,

The BRCA1/2 gene patents arose from the public-private interaction; however, once the patents were granted, it appears that the exclusivity arguably caused harm to the public, which is a separate policy issue from whether or not the court correctly applied the facts to the Patent Act. While it is understandable that some sort of exclusive period or reward is needed to incentivize the research and development of new medical technologies; any policy must balance this with the needs of the public to receive access to medical therapy as well as allow for the academic community to continue research. Others have proposed exemptions from infringement or other solutions.[222]

The ability to patent genes may also impact innovation.[223] For example, it may be difficult to create diagnostic tests for particular diseases due to fear of infringement.[224] In many ways the greatest impact is felt in the private sector because it is the biotechnology industry that is the market for diagnostic tests. But, the weight of the patent world will also be felt in academics, particularly in the clinic. For example, clinicians at major medical centers experienced difficulty in testing new diagnostic methods for breast cancer because they received cease and desist letters from Myriad.[225]

It is unclear how to resolve the issues raised by IP law. On the one hand, universities and the private sector want the exclusivity period on discoveries. On the other hand, it may be difficult to arrange licensing agreements on many types of patents, such as gene patents, for a small company to profitably design and market a new type of test.[226] This has the effect of deterring innovation. That is, if it seems too difficult to obtain licenses, a new company may decide not to invent a new test. Or, if a new company thinks that it may face intense litigation, even if no patent is infringed, that can deter the formation or funding of a new company. One way to resolve some of the issues raised, for example by gene patents, is to say that DNA (including human engineered DNA or cDNA) cannot be patented.[227]

It is unclear whether the incentives created by IP law are really necessary in the academic world. PIs are motivated by concerns such as advancement in understanding, treating disease, and improve reputations.[228] That is, PIs will pursue scientific advancement even in the absence of IP

2011, http://www.nytimes.com/2011/07/30/business/gene-patent-in-cancer-test-upheld-by-appeals-panel.html?_r=1.

222. GENE PATENTS, *supra* note 5, at 44-46.

223. *See* Colin Macilwain, *Pharmaceutical Industry Must Take its Medicine*, 470 NATURE 141, 141 (2011).

224. Sam Kean, *The Human Genome (Patent) Project*, 331 SCIENCE 530, 530-31 (2011).

225. Ass'n for Molecular Pathology, et al. v. USPTO, et al., 669 F. Supp. 2d 365, 378-79 (S.D.N.Y. 2009).

226. Kean, *supra* note 224, at 530-31.

227. USPTO, 669 F. Supp. 2d at 380. Note that the Court of Appeals for the Federal Circuit overruled the trial court, 2-1. Pollack, supra note 221.

228. GENE PATENTS, *supra* note 5, at 20-22.

protection.[229] It may be however, that patent protection contributes to private sector investment.[230]

In sum, intellectual property laws have cascading effects on academics and biotechnology. It may be that the current intellectual property laws are not well-suited for biomedical discovery and innovation. Changes in IP law may have the added benefit of changing the environment of academic scientists.

G. Industry

Industry has an interest in maintaining the integrity of academic scientists.[231] Industry seeks academics to conduct science and publish articles for a number of reasons including: (1) academics are often the best and brightest, (2) academics have the highest reputation for objectivity, and (3) public trust in academics is generally high. If the reputation and credibility of academic institutions and PIs are harmed, collaborations between the private sector and academic centers are tarnished. For this reason, industry should be receptive to institutional and legal changes that effectively curb financial conflicts of interest by properly managing the public-private interaction.

VI. CONCLUSION

A new model is needed to address financial conflicts of interest. The use of disclosure as the cornerstone to manage conflicts of interest is only a band-aid on a much larger problem. In- depth analysis, empirical data, and application of social science and psychology are needed to effectively create a policy to manage conflicts of interest created by the public-private interaction. In this way, the benefits of the public-private interaction can thrive, while the negative consequences can be avoided.

This Article proposes that changes to the internal and external environments of PIs can change how PIs make decisions in situations in which conflicts of interest may arise. While structural changes are much more difficult to accomplish than implementing a policy of disclosure, time has shown that disclosure is an ineffective way to address conflicts of interest. For this reason, new approaches that alter the environment will prove useful in addressing this important area of concern.

229. *Id.* at 20-21.

230. *Id.* at 23-25.

231. I thank my colleague, Ed Dauer, for raising this important point.