

# DRUGS & MONEY: THE IMPACT OF INDUSTRY “DONATED” MONEY ON PUBLIC RESEARCH AND THE NEED FOR STRICTER CONFLICT OF INTEREST STANDARDS

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## I. INTRODUCTION

### A. SOURCES OF RESEARCH FUNDING

In a time when pharmaceutical companies are constantly overwhelming the public with television advertisements touting the latest miracle cure for depression, sleeplessness, or allergies, it is easy to understand why little thought is given to the research being conducted by public research institutes and universities. Although the private sector spends significantly more money on research and development (“R&D”) than is spent by the government on public research (federally funded research institutes, other non-profits, and universities), the importance of publicly funded research should not be undervalued; while pharmaceutical companies tend to focus on producing profitable products, publicly funded research has the freedom to focus on less basic biomedical research, unfettered by the obligations that may be imposed by industry. Private and public research facilities both play key roles in medical research conducted in the United States; however, when the two overlap, it can undermine the benefits provided by their being distinct entities.

Federal funding of research and development, which expanded dramatically during Bill Clinton’s presidency, has failed to continue to grow throughout George W. Bush’s presidency, and has decreased since the terrorist attacks of September 11, 2001.<sup>1</sup> In 2006, funding for all R&D programs failed to keep up with inflation; despite a \$2.2 billion budget increase, funding<sup>2</sup> actually fell two percent, after adjusting for inflation.<sup>3</sup> Furthermore, federal funding of *medical* research has decreased

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<sup>1</sup> Brandon Shackelford, National Science Foundation, Directorate for Social, Behavioral, and Economic Sciences, U.S. R&D Project to Have Grown Marginally in 2003, INFOBRIEF, NSF 04-307 (Feb. 2004), available at <http://www.nsf.gov/statistics/infbrief/nsf04307.pdf>.

<sup>2</sup> For funding in all R&D programs except defense weapons development and human space exploration.

<sup>3</sup> American Association for the Advancement of Science, R&D Budget and Policy Program, *Congress Finishes FY 2006 Appropriations, Caps a Disappointing Year for R&D Funding*, Jan. 6, 2006, available at <http://www.aaas.org/spp/rd/fy06.htm>.

dramatically, while federal research expenditures are channeled into defense weapons development and other R&D fields.<sup>4</sup> In fact, ninety-seven percent of the 2006 budget increase went to two R&D fields: defense weapons development and human space exploration.<sup>5</sup>

The National Institutes of Health (“NIH”) is the premiere source of federal funding for biomedical research, with a budget of \$26.4 billion in 2003;<sup>6</sup> after the NIH, the next largest sources of federal funding for biomedical research are the Department of Defense (\$1.2 billion), the Department of Agriculture (\$0.5 billion), the National Science Foundation (\$0.5 billion), and the Department of Energy (\$0.4 billion).<sup>7</sup> NIH saw its budget double between 1998 and 2003, only to be greeted in 2006 by its first budget cut in thirty-six years.<sup>8</sup> According to a report prepared by the Democratic staff of the Committee of Appropriations for the U.S. House of Representatives,<sup>9</sup> NIH used to provide annual increases in the amount of the research grants they distributed to account for the increasing costs of medical research over time. This policy, which helped publicly funded researchers keep up with the increasing costs of conducting their research, was primarily discontinued in 2006, and looks to be completely abandoned in 2007 due to a shortage of funds.<sup>10</sup> The end of this program comes at the same time as an overall decrease in the number and percentage of grant applications funded by NIH each year. At the end of 2003, NIH funded roughly thirty percent of applications for grants that it received; this number dropped to twenty-two percent in 2005 and is projected to fall to nineteen percent in 2006.<sup>11</sup> This drop in the percentage of grant applications funded is not simply a result of more requests for funding; the actual number of grants funded each year has also dropped.<sup>12</sup> After the total number of grants funded by NIH peaked in 2004,<sup>13</sup> the number has dropped in each of the following years, with the number of grants funded in 2007 projected to be 1570 fewer than in 2004.<sup>14</sup> The cuts to the NIH budget will affect not only the ability of public researchers to conduct basic research, but also the number of clinical trials that can be conducted.<sup>15</sup> Clinical trials are of paramount importance to the medical research field. Success in laboratory testing does not always accurately translate into success in practice; clinical trials are therefore a necessary element of medical research, serving to determine whether the new drug or medical treatment will be a success or a failure.<sup>16</sup>

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<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> Hamilton Moses, III, E. Ray Dorsey, David H. M. Matheson & Samuel O. Thier, *Financial Anatomy of Biomedical Research*, 294 J. AM. MED. ASS'N 1333, 1335 (2005).

<sup>7</sup> *See id.*

<sup>8</sup> *See* American Association for the Advancement of Science, *supra* note 3.

<sup>9</sup> U.S. House of Representatives, Committee on Appropriations – Democratic Staff, *President Bush and House Republicans Undermine Life Saving Health Research*, Sept. 12, 2006 (on file with author).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

## B. EFFECT OF BUDGET CUTS ON ACADEMIC MEDICAL RESEARCH

The effect of the budget cuts is pronounced. Under a bill that has already passed through its committee, a number of prominent healthcare research institutes would receive significant budget cuts for 2007.<sup>17</sup> When adjusted for inflation, the National Cancer Institute would have 4.1% less funding than in 2006 and an incredible 10.2% less funding than in 2003.<sup>18</sup> The National Heart, Lung, and Blood Institute would see a similar decrease in funding of 4.0% from 2006, and 9.9% from 2003,<sup>19</sup> while the National Institute of Neurological Disorders and Stroke would receive 4.0% less funding than it did in 2006, and 9.2% less than in 2003.<sup>20</sup> Such institutes play a key role in society: they research medical conditions that do not have the lucrative potential to attract the attention of industry. When federal funding is cut for important research, public researchers are forced to look elsewhere for sources of financing or else risk decreasing or even eliminating research. Dr. Steven Burakoff, the director of New York University's ("NYU") Cancer Institute, notes that most medical institutions, including NYU, have been forced to reduce the size of their laboratories in response to the decreased funding.<sup>21</sup>

While pharmaceutical companies have contributed money to public research facilities for at least fifteen years, the need for such funds has increased in direct correlation to the decrease in federal funding.<sup>22</sup> As publicly funded researchers struggle to finance their laboratories, the monies offered by pharmaceutical companies have become an integral and essential part of overall funding strategies. Herbert Pardes, the president and CEO of New York-Presbyterian Hospital, notes that the decrease in federal funding has forced research hospitals to look elsewhere for funding, stating that, "we try to come up with every conceivable approach to dealing with it, whether that's more philanthropy, partnerships with biotech companies, partnerships with more private sector companies, and more efficiencies."<sup>23</sup>

## C. NOTE OVERVIEW

This Note will discuss the range of alternative sources of industry funding for public research institutes, and the various conflict of interest issues that they raise. The purpose of this Note is to examine the ramifications of recent cuts in federal funding of medical research, with the ultimate goal of highlighting the problems that public researchers are facing and the effect that those problems could have on the health of the American public. Section II is a general overview of the sources of private funding currently available to public researchers. This section also briefly

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> Jill Gardiner, *Hospitals Grapple with Slowdown in Federal Funding*, NEW YORK SUN, Sept. 18, 2006, available at <http://nysun.com/pf.php?id=39829&v=4092331021>,

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

discusses the conflicts of interest that the various funding sources can cause for the researchers and their research institutions. These conflicts are further analyzed in Section III, with a discussion of the current framework set up by the NIH and other governmental regulatory agencies, as well as the framework set up by individual academic journals to avoid potential conflicts, and also to make public any appearance of conflicts in an effort to fully inform readers of scientific papers of potential biases of the authors. Section IV discusses the ways in which Congress can affect a positive change in the public research sector by changing the current regulatory framework to minimize the impact that industry financing has on research produced, and the analysis of such research, by academic researchers with financial ties to industry.

## II. TYPES OF FINANCIAL SUPPORT FROM INDUSTRY AND THEIR EFFECT ON RESEARCHERS

### A. “DONATIONS” FROM INDUSTRY: PURE GIFTS OR COVERT BRIBES?

While on the surface, the monetary “donations” given by pharmaceutical companies to public research facilities seem like beneficent contributions to poorly-funded organizations. However, the donations rarely come without strings—whether implicit or explicit—attached.<sup>24</sup> Rather than being given in the form of a direct cash contribution, the financial support may be given as an in-kind donation of research equipment or biomaterials.<sup>25</sup> Other donations come earmarked as support for student workers or to fund the researcher’s trip to conferences.<sup>26</sup> While these types of contributions appear to be pure gifts without any direct benefit to the donor company, this is generally not the case.

In an article published in the *Journal of the American Medical Association* (“JAMA”) by Eric G. Campbell, Karen Seashore Louis, and David Blumenthal, the authors wrote that “recipients frequently think that donors place restrictions and expect returns” from research-related gifts.<sup>27</sup> The authors found that despite the pure gift-like appearance of the financial contributions, most researchers felt that the contributions came with expectations on the part of the contributor—but the researchers varied in types of expectations they felt the companies held.<sup>28</sup> Sixty-three percent of the researchers felt that the donors wanted acknowledgement in their publications,<sup>29</sup> while thirty-two percent felt that the donor wanted pre-publication review rights to articles generated by the researchers’ use of the gifts.<sup>30</sup> Finally, thirty percent of the researchers believed that the company expected their lab to test their products,<sup>31</sup> and nineteen percent stated that

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<sup>24</sup> Eric G. Campbell, Karen Seashore Louis & David Blumenthal, *Looking a Gift Horse in the Mouth: Corporate Gifts Supporting Life Sciences Research*, 279 J. AM. MED. ASS’N 995, 995 (1998).

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 997.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

the donor expected to be able to patent any results from the gift-supported research.<sup>32</sup> It is important to note that these numbers reflect the assumptions of the researchers—not the actual expectations of the donors. However, the assumptions of those accepting the gifts are relevant to this analysis, as it is their assumptions that affect and guide the behavior of the researchers.

The high percentages of researchers believing that the gifts they accept indebted them to industry inspires the obvious question: why do the researchers accept the gifts? Campbell, et al., found that sixty-six percent of the researchers who received such gifts stated that the gifts were either “essential,” “very important,” or “important” to their research.<sup>33</sup> Researchers seem to be correct in their assessment of the importance of the gifts. Campbell, et al., showed that researchers who received gifts were “significantly more commercially productive than non-recipients.”<sup>34</sup> The authors state that the results remained the same when controlled for variables such as academic rank and the number of publications in peer-reviewed journals in the last three years,<sup>35</sup> which would suggest that the donations are among the causes of increased commercial productivity rather than indicators that the donations are only going to already successful researchers.<sup>36</sup>

## B. BINDING CONTRACTS

While the donations described above do not come with explicit strings attached, it is becoming more and more common for researchers and the non-profit institutes or universities that they work for to enter into binding contracts with pharmaceutical companies. Such contracts often make explicit what was seen as implicit when the companies made “donations” to the researchers and their institutions. In 1993, the University of California, Berkeley entered into a twenty-five million dollar agreement with Swiss drug company, Novartis, that would provide approximately one-third of the university’s budget for Berkeley’s Department of Plant and Microbial Biology over a five-year period.<sup>37</sup> At the time this deal was brokered, such large scale public-private arrangements were rare; the support of individual faculty by industry was estimated to be around two billion dollars in 1993, but the funding of an entire department was unheard of.<sup>38</sup> The agreement was met with some opposition by members of the university; the Students for Responsible Research criticized the agreement as having a “narrow focus on profit-oriented and controversial biotechnological research.”<sup>39</sup> Certain features of the agreement caused more concern than others, most notably the fact that two Novartis representatives would be on the five person committee that decided how the funds would be allocated each

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<sup>32</sup> *Id.*

<sup>33</sup> *Id.* (stating that 13% of recipients said the gifts were “essential,” 22% said they were “very important,” and 31% said they were “important” to the progress of their research).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 998.

<sup>37</sup> Vicky Elliot, *Who Calls the Tune?*, THE UNESCO COURIER, Nov. 2001.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

year.<sup>40</sup> The agreement proved beneficial to Novartis; the company optioned the rights to seven patent applications, four of which were from projects funded in part by the agreement, and three which were funded solely by it.<sup>41</sup>

Since the Berkeley-Novartis agreement, such agreements have become much more common. The Center for Science in the Public Interest's Integrity in Science project maintains a comprehensive database of industry partnerships with the research community.<sup>42</sup> The database reads like a list of who's who in the world of medical research; non-profit groups in the database range from the Asthma and Allergy Foundation of America to the American Diabetes Association to the La Jolla-based The Scripps Research Institute ("TSRI").<sup>43</sup> The list of universities with ties to industry is even more astonishing; Harvard, Stanford, and Princeton are joined by the University of California, Los Angeles and Berkeley, and dozens of other premiere medical research facilities.<sup>44</sup>

While a number of these institutes and universities are on the receiving end of "donations," a number of the research institutes and universities engage in financial agreements similar to that established by Berkeley and Novartis in 1993. According to the Integrity in Science database, in 2006, TSRI brokered an agreement whereby Pfizer would contribute \$100 million to TSRI over a five-year period of time, in exchange for first rights to almost half the intellectual property generated as a result of the funding.<sup>45</sup> This was not the first large scale agreement between TSRI and industry. TSRI and Novartis already had a long-term agreement in which Novartis contributes financially to TSRI in exchange for the first rights to certain licensing options.<sup>46</sup>

Massachusetts Institute of Technology ("MIT") has a long-term agreement with Merck & Co., which gives Merck "certain patent and technology license rights to developments resulting from the Merck-supported collaborations in exchange for funding up to \$15 million over [an] initial five-year period, with an option to extend these collaborations to ten years."<sup>47</sup> In addition, the agreement created a MIT-Merck Fellowship Program, whereby Merck & Co. supported eighteen Merck Scholars: eight graduate students in engineering, physical science, and mathematics, and ten post-doctoral biological science scholars.<sup>48</sup>

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<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> Center for Science in the Public Interest, *Integrity in Science*, available at <http://cspinet.org/integrity/about.html> (last visited Mar. 8, 2008).

<sup>43</sup> Center for Science in the Public Interest, *Integrity in Science: Non-Profit Organizations Receiving Corporate Funding*, available at <http://cspinet.org/integrity/nonprofits/index.html> (last visited Mar. 8, 2008).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* (citing Bruce Lieberman, *Pfizer to Pay Scripps for Licensing Option*, SAN DIEGO UNION-TRIBUNE, Nov. 30, 2006, at A1).

<sup>46</sup> *Id.* (citing Scripps' I.R.S. 990 for fiscal year 2003).

<sup>47</sup> *Id.* (citing Press Release, Mass. Inst. Of Tech., *Merck, MIT Announce 5-Year, \$15 Million Collaboration* (Mar. 19, 1997), available at <http://web.mit.edu/newsoffice/nr/1997/43449.html>).

<sup>48</sup> *Id.*

There is no question that binding contracts between industry and researchers have some positive aspects; the companies provide much needed funding for research that often has important implications for public health. However, the conflicts of interest that arise when non-profit research institutions and universities enter into binding agreements with industry may outweigh the benefits that such agreements provide. The negative effects of these agreements will be discussed along with the negative effects of all forms of industry-research collaborations in the following sections.

### C. POTENTIAL EFFECT ON RESEARCHERS AND THE PUBLIC

There appears to be no question that donations from industry have a positive effect on the ability of researchers to conduct and publish their research.<sup>49</sup> However, it is also clear that the researchers who are receiving the donations feel indebted to the donors,<sup>50</sup> and that this indebtedness affects the public at large. The indebtedness manifests itself in different ways, as discussed previously, and runs the gamut from relatively benign to creating a clear conflict; some researchers feel that they are expected to cite the company as the source of funding in a publication,<sup>51</sup> while others feel that they are expected to give pre-publication review rights to the donors.<sup>52</sup> Each of these expectations has different ramifications that can affect the independent nature of research.

It would be difficult to argue that thanking a large drug company in a publication for its donation of equipment or biomaterials would create a problematic conflict of interest. If, however, the donation was of expensive equipment or scarce biomaterials, the donation could result in increased feelings of indebtedness. While the expression of gratitude may result in the company garnering goodwill and a positive reputation among researchers, this is unlikely to have any real effect on the health or welfare of the public. However, the other expectations raise more serious concerns.

Thirty-two percent of researchers believe that their industry donors expect pre-publication review rights.<sup>53</sup> By acting on the expectation that the donor-company wants pre-publication review rights and giving the donor-company the ability to review articles published by the researcher's lab, the researcher is risking the imposition of the company's interests on the researcher's independence. If the company does not like the outcome of the research they could delay or prevent its publication, or encourage the researcher to be selective in the results that he seeks to make public. By having such influence over researchers, the donor-company essentially subverts the independence of the researchers. Rather than being able to publish the full and complete result of the research, the publishing researcher is constrained by the demands of the drug company. Additionally, by giving pre-publication review to the donor-company, the

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<sup>49</sup> Campbell et al., *supra* note 24, at 997.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

researcher risks delays to his publication, which can have severe effects on future research.<sup>54</sup> A recent study found that delays of over six months from the time research could first be published to when it actually was published were associated with industry-supported research.<sup>55</sup> Such delays in publication may prove to be detrimental to the progress of the researcher's work, especially when the research is in a rapidly developing field.<sup>56</sup> The risk of a delay to a researcher's work would give the researcher even more incentive to prepare a manuscript that is most likely to meet the desires of the donor-company; the inclusion of the "undesirable" data might lead to a protracted period of negotiation between the two parties as to exactly what should be published and would only further delay the work.

Thirty percent of the researchers who received donations believed that the company expected the lab to test their products.<sup>57</sup> This creates two possible problems: first, by testing the products created by the company, valuable time and energy is expended testing the company's products that would otherwise be spent on the lab's independent research; second, and perhaps more problematic, the researcher and his employees may be inclined to design the experiments or to analyze the results in the way most favorable to the company, or even skew the results in the company's favor, in order to assure their donations will continue.<sup>58</sup>

Dr. William H. Pelham, a professor of psychology at State University of New York at Buffalo, and director of the University's Center for Children and Families, receives funding from both NIH and pharmaceutical companies to study treatments for attention-deficit hyperactivity disorder.<sup>59</sup> He cites problems that he has encountered in his dealings with industry, including being "pressured ... to change the text in three journal articles, both to minimize the contribution of psychosocial treatments to the studies' outcomes and to put a positive spin on drug effects."<sup>60</sup> In an article published in 2000 in the *New England Journal of Medicine*, author Thomas Bodenheimer stated that there is considerable evidence that shows that medical researchers who have ties to drug companies are more likely to report results favorable to the companies than researchers without such ties.<sup>61</sup> While the suggestion that researchers may skew their interpretation of their research to appease the donor-company attributes a measure of bad faith to the researchers, it is an important consideration. Financing can be scarce and highly competitive, and retaining access to the deep pockets of a pharmaceutical company could mean years of financial support. Although she acknowledges that some researchers are asked to proactively alter

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<sup>54</sup> *Id.* at 999.

<sup>55</sup> *Id.* (citing David Blumenthal, Eric G. Campbell, Melissa S. Anderson, Nancyanne Causino & Karen Seashore Louis, *Withholding Research Results in Academic Life Science: Evidence From a National Survey of Faculty*, 277 J. AM. MED. ASS'N 1224, 1224 (1997)).

<sup>56</sup> Campbell et al., *supra* note 24, at 997.

<sup>57</sup> *Id.*

<sup>58</sup> Tory DeAngelis, *Does Industry Funding Deserve a Bad Rap?*, 34 AM. PSYCHOL. ASS'N 28, JUL.-AUG.2003, available at <http://www.apa.org/monitor/julaug03/industry.html>.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> Thomas Bodenheimer, *Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539, 1543 (2000).



research results, Marcia Angell, MD is more concerned with the less obvious forms of result ‘misinterpretation’: “What is at issue is not whether researchers can be ‘bought,’ in the sense of a quid pro quo. It is that close and remunerative collaboration with a company naturally creates goodwill on the part of the researchers and the hope that the largesse will continue.”<sup>62</sup> Even if the researcher and his employees did not intentionally or in bad faith misinterpret the results of the research, the aggressive independence that is so important in medical research would not be present, and negative aspects of the company’s products may go unnoticed or untested.

Whether the misinterpretation is intentional or subconscious on the part of the researchers, it still has a potential negative effect on the public at large. The primary reason that drugs go through independent testing prior to being placed in the marketplace is to protect would-be consumers.<sup>63</sup> Before the FDA will allow a new drug to be distributed in the marketplace, the company producing the drug must demonstrate the drug’s efficacy and its safety—while independent corroboration may not be required, it certainly enhances the company’s claim that their drug should be sanctioned by the FDA. The private company that discovers, produces, and markets a new drug has a vested interest in its profitability, which is jeopardized by focusing on the potential ill effects on the public. As a result, independent testing makes sure that there are no dangerous effects, but also corroborates the marketing company’s claims as to the drug’s efficacy and quality. If the “independent” lab that is conducting the testing of the drug is also receiving financial aid from the company, the independence of the research is undermined. If the relationship between the researcher and the company is not disclosed to the FDA, the possible misinterpretation of results by the researcher may go unnoticed, with potentially negative effects to consumers of the drug.

Nineteen percent of researchers who took donations from industry believe that the donor company expected to get all patent rights to discoveries by the researcher.<sup>64</sup> While this may cause the researcher problems with the research institute he works for (the university or institute may want to retain the patents on certain drugs or negotiate an actual contract with the donor company),<sup>65</sup> it also creates a conflict with the purpose of public research institutes. The conflicts that arise when a researcher assumes that the donor company wants patent rights to the work are similar to those that result when the researcher and the company have entered into a binding contract that guarantees the company certain licensing or patent rights. The commercialization of research that defines private industry often conflicts with the more academic pursuits of public research institutes and universities. While industry has a financial motivation behind its research, academics have a “tradition of free inquiry

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<sup>62</sup> Marcia Angell, *Is Academic Medicine for Sale?*, 342 *NEW ENG. J. MED.* 1516, 1518 (2000).

<sup>63</sup> U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *available at* <http://www.fda.gov/cder> (last visited Mar. 21, 2007).

<sup>64</sup> Campbell et al., *supra* note 24, at 997.

<sup>65</sup> *Id.* at 999.

and free exchange of ideas, ‘united in the shared purpose to create knowledge, to critique existing knowledge, and to disseminate knowledge.’”<sup>66</sup>

A statement issued by the Harvard University Faculty of Medicine emphasized the “intellectual principles and purposes and the freedom of inquiry” that characterizes non-industry research.<sup>67</sup> The statement affirms the importance of free communication among researchers and students, and highlights the special importance of free communication and free rights to publication of research by students.<sup>68</sup> This freedom is often hindered or halted completely by industry claiming patent rights to research done in the laboratory.<sup>69</sup> However, just as it is essential to academics and students to have a free exchange of ideas, it is essential to industry that their potentially patentable research results be protected from becoming public.

This conflict of interest—between a researcher’s responsibilities to the company that is partially funding his work and the general purpose of his work as a medical researcher—can have ramifications not only for the researcher but for the public at large. By being tied to industry through his funding, the researcher often cuts himself off from the open exchange of ideas that characterizes academic research. The privacy concerns of the donor-company prevent the researcher from discussing his work, or his results, with others and will often delay publication of his work. This ultimately affects the researcher’s ability to advance in his work—without colleagues to critique and constructively criticize his work, the researcher is often unable to see problems with his work or his results and this may stunt the ability of the researcher to discover other avenues of research that could stem from his work.

### III. CURRENT REGULATORY FRAMEWORK

#### A. BAYH-DOLE ACT

The primary federal legislative act that controls funding of public researchers is the 1980 Bayh-Dole Act (officially, the University and Small Business Patent Procedures Act).<sup>70</sup> Prior to 1980, the government retained the rights to any discoveries made by researchers funded by public monies.<sup>71</sup> Spurred by the frustration of public interest organizations and universities that desired the ability to profit from the research conducted by their employees, Senators Birch Bayh of Indiana and Robert Dole of

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<sup>66</sup> Columbia University, Responsible Conduct Research, *Conflicts of Interest*, available at [http://ccnmtl.columbia.edu/projects/rcr/rcr\\_conflicts/foundation/index.html](http://ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/foundation/index.html) (last visited Mar. 8, 2008) (citing American Society of Gene Therapy policy/position statement, *Policy of the American Society of Gene Therapy on Financial Conflict of Interest in Clinical Research*, Apr. 5, 2000, available at <http://www.asgt.org>).

<sup>67</sup> Harvard University, Faculty of Medicine Statement on Research Sponsored by Industry, Jan. 1996, available at <http://www.hms.harvard.edu/integrity/industry.html>.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> The Bayh-Dole Act is codified in 35 U.S.C. § 200–212, and is implemented by 37 C.F.R. 401.

<sup>71</sup> Colorado State University Research Foundation, *What is Bayh-Dole and why is it important to Technology Transfer?*, available at [http://www.csurf.org/eneews/bayhdole\\_403.html](http://www.csurf.org/eneews/bayhdole_403.html).

Kansas sponsored the Act.<sup>72</sup> The main impact of the Bayh-Dole Act was that it allowed academic researchers to actively market their research by either getting patents granted on behalf of their parent institution or selling the patent rights to private interests.<sup>73</sup> This invigorated the research industry from all sides; academic institutions were infused with funds from the sale of patent rights and from the profits of patents of which they retained ownership.<sup>74</sup> Academic researchers found that they had more money for their research; previously supported primarily by federal grants, the researchers found a new source of funding in the form of contracts with industry eager to purchase the rights to patents from the researchers. Industry was positively affected by the enactment of Bayh-Dole as well; previously constrained from approaching academic researchers about buying their work, the industry found itself able to buy control patents produced by others rather than its own researchers.

Although Bayh-Dole had a number of positive financial impacts on research, it also brought with it a host of problems that had not previously been faced. Before Bayh-Dole, the financial conflicts-of-interest described previously were not a concern because industry and academic research rotated on separate axes with distinct financial controls and motivations. With Bayh-Dole, the two began to overlap, creating the host of conflicts that divergent financial motivations generate. In response to these conflicts, Congress has enacted regulations that attempt to address the conflict-of-interest issues that Bayh-Dole creates, while minimizing the effect the controls have on the positive results of the Act.<sup>75</sup> These regulations are implemented and imposed by the governmental agencies that fund and oversee the funding of research, most importantly the NIH. Finally, academic journals have changed their own policies in an attempt to address the issue and maintain the integrity and credibility of their publications.

## B. FEDERAL CONFLICT OF INTEREST REGULATIONS

### 1. *Overview*

The federal government has enacted one primary regulation that purports to manage conflict-of-interest problems in federally funded research. The regulation, Responsibility of Applicants for Promoting Objectivity in Research for which PHS<sup>76</sup> Funding is Sought (the "Applicants' Regulation") (codified as 42 C.F.R. 50(f)), establishes requirements that must be followed by the NIH in choosing what requests for grants to fund.<sup>77</sup>

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<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> PHS stands for Public Health Services.

<sup>77</sup> National Institutes of Health, *Reminder of Financial Conflict of Interest Requirements for All NIH-Supported Institutions*, Dec. 6, 2004, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-013.html>.

The stated purpose of the Applicants' Regulation is to promote objectivity in research by "establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator."<sup>78</sup> The regulation requires that each institution (defined as any "domestic or foreign, public or private, entity or organization")<sup>79</sup> that applies for PHS grants must maintain its own "appropriate written, enforced policy on conflict of interest"<sup>80</sup> that complies with the requirements of the regulation, and that the institution must make sure that all of its Investigators (defined as the "principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding")<sup>81</sup> are aware of the policy, the Investigator's responsibilities under the policy, and the Applicants' Regulation in general.<sup>82</sup> In order to ensure that the Institute's policy is not a hollow one, the Applicant's Regulation also requires that the Institute establish "adequate enforcement mechanisms and provide for sanctions where appropriate."<sup>83</sup>

In addition to maintaining an official policy on conflicts of interest, the Institution is also required to designate an individual or individuals (the "designated reviewer") within the Institution to review financial disclosures prepared by each Investigator who participates, or plans to participate, in PHS-funded research.<sup>84</sup> The Institution must also require that, prior to submitting a grant application to PHS, each Investigator submit a listing to the Institute's designated reviewer of his or her known "Significant Financial Interests" (defined as "anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights)),<sup>85</sup> and any Significant Financial Interests of the Investigator's spouse and dependent children<sup>86</sup> that "would reasonably appear to be affected by the research for which PHS funding is sought,"<sup>87</sup> and Significant Financial Interests "in entities whose financial interests would reasonably appear to be affected by the research."<sup>88</sup> The Applicants' Regulation requires that this reporting be updated throughout the period of the grant, either annually or as new reportable interests are established.<sup>89</sup> It is the job of the designated reviewer to review all financial disclosures to determine "whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate

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<sup>78</sup> 42 C.F.R. § 50.601 (2008).

<sup>79</sup> § 50.603.

<sup>80</sup> § 50.604(a).

<sup>81</sup> § 50.603.

<sup>82</sup> § 50.604.

<sup>83</sup> § 50.604(f).

<sup>84</sup> § 50.604(b).

<sup>85</sup> § 50.603.

<sup>86</sup> § 50.604(c)(1).

<sup>87</sup> § 50.604(c)(1)(i).

<sup>88</sup> § 50.604(c)(1)(ii).

<sup>89</sup> § 50.604(c)(2).

such conflict of interest.”<sup>90</sup> The Applicant’s Regulation defines a conflict of interest as a situation where the designated reviewer “reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.”<sup>91</sup>

The Applicants’ Regulation suggests six ways that an Institute can manage conflicts of interest: “public disclosure of significant financial interests,”<sup>92</sup> “monitoring of research by independent reviewers,”<sup>93</sup> “modification of the research plan,”<sup>94</sup> “disqualification from participation in all or a portion of the research funded by the PHS,”<sup>95</sup> “divestiture of significant financial interest,”<sup>96</sup> and “severance of relationships that create actual or potential conflicts.”<sup>97</sup> The regulation fails to offer suggestions for what corrective action should be taken by an Institute if it discovers that one of its researchers has failed to comply with the disclosure requirements or with the action taken by the Institute to minimize or eliminate a conflict. However, the regulation does require that the Institute “promptly notify the PHS Awarding Component of the corrective action taken or to be taken” in the event a researcher fails to comply.<sup>98</sup> The regulation leaves it to the PHS Awarding Component to determine what course of action will be taken from their end.<sup>99</sup>

The Institution is also required to maintain records of the financial disclosures, as well as all actions taken in response to those disclosures, for a minimum of three years from the date the Institute submits its final expenditures report to the funding agency.<sup>100</sup> In order to keep the funding agency adequately advised about conflicts of interest, the Applicant’s Regulation requires that before the Institute can spend any of the funds from the agency, the Institute must first report to PHS the existence of any conflict of interest found by the Institute, and the actions taken to minimize or eliminate the conflict.<sup>101</sup> The regulation, however, specifically does not require that the Institute tell PHS the nature of the interest or other details; it is simply required to report the existence of the interest.<sup>102</sup> Any conflicts of interest that are discovered after the money has been spent are required to be reported to PHS within sixty days of its discovery, and must be “managed, reduced, or eliminated” within that same sixty days.<sup>103</sup>

In addition to the broad requirements for the Institutes that receive funding from PHS agencies, the Applicants’ Regulation specifically allows the Department of Health and Human Services (“HHS”) to inquire at any

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<sup>90</sup> § 50.605(a).

<sup>91</sup> *Id.*

<sup>92</sup> § 50.605(a)(1).

<sup>93</sup> § 50.605(a)(2).

<sup>94</sup> § 50.605(a)(3).

<sup>95</sup> § 50.605(a)(4).

<sup>96</sup> § 50.605(a)(5).

<sup>97</sup> § 50.605(a)(6).

<sup>98</sup> § 50.606(a).

<sup>99</sup> *Id.*

<sup>100</sup> § 50.604(e).

<sup>101</sup> § 50.604(g)(2).

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

time into the Institute's "procedures and actions regarding conflicting financial interests in PHS-funded research."<sup>104</sup> The regulation gives HHS the authority to conduct a review of all the records relevant to compliance with the conflict of interest standards.<sup>105</sup> Once HHS has conducted its review, it is then up to the individual granting agency to decide whether a conflict calls for further corrective action or whether suspension of funding is needed until the problem can be completely resolved.<sup>106</sup> The regulation has a special provision for failure to disclose or properly manage a conflict that relates to a project to "evaluate the safety or effectiveness of a drug, medical device, or treatment."<sup>107</sup> Any Investigators involved in such a situation are required by the Institute to disclose the conflict of interest during every public presentation of the results of the research.<sup>108</sup>

## 2. *Are Institutions Complying with the Regulation?*

The NIH has established a program that is meant to determine compliance with the Applicants' Regulation.<sup>109</sup> The Targeted Site Review program was designed to determine whether (i) "grantee institutions are fully and correctly implementing the FCOI ["financial conflict of interest"] regulation,"<sup>110</sup> and whether (ii) "reporting requirements are being met."<sup>111</sup> In 2006, eighteen targeted site reviews were commissioned by the NIH division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, Office of Extramural Research.<sup>112</sup> The eighteen reviews represented four billion dollars of funding, approximately twenty-five percent of the NIH grant budget.<sup>113</sup>

The targeted site reviews found no instances of "intentional noncompliance."<sup>114</sup> Rather, the report issued by NIH claims that the reviewed institutions "implemented the Federal regulation thoughtfully and with diligence."<sup>115</sup> The most common compliance issues that the reviewers found centered around the definition of "Investigator" and also around institutional reporting requirements.<sup>116</sup>

Some institutions defined "Investigator" too narrowly.<sup>117</sup> When "Investigator" is limited by the Institution to the principal investigator, there is a higher chance that a significant financial conflict of interest will go unreported.<sup>118</sup> According to the NIH report, Institutions need to define

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<sup>104</sup> § 50.606(b).

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> § 50.606(c).

<sup>108</sup> *Id.*

<sup>109</sup> See National Institutes of Health, *Targeted Site Reviews on Financial Conflict of Interest Observations*, Feb. 14, 2007, available at [http://grants.nih.gov/grants/policy/coi/TSR\\_Observations\\_2-14-2007.doc](http://grants.nih.gov/grants/policy/coi/TSR_Observations_2-14-2007.doc).

<sup>110</sup> *Id.* at 1.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.* at 2.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

the term more broadly to include all lab workers involved in the research (e.g. technicians, lab assistants, students, etc.) so as to assure that any potential conflicts are recognized.<sup>119</sup>

The reviewers also found that some Institutions encountered problems when new Investigators entered a project after the initial expenditure of funds.<sup>120</sup> The reviewers found that the problem was centered around education of Investigators;<sup>121</sup> when they were better educated about the reporting requirements, there was a higher likelihood that Investigators joining a project later would take the initiative of reporting any financial conflicts of interest.<sup>122</sup>

The report also stated that they found other compliance issues, including: 1) Institutions that had no "provision for sub-recipient monitoring to ensure that identified conflicts are reported through the prime grantee to NIH;"<sup>123</sup> 2) Institutions that failed to have consistent reporting processes in place;<sup>124</sup> 3) grant applications that were submitted before the Institution finished collecting reports of significant financial interests from Investigators;<sup>125</sup> and 4) the expenditure of grant funds prior to the reporting of identified financial conflicts to NIH.<sup>126</sup>

While the NIH claims that their program found that Institutions were substantially complying with the Applicants' Regulation, their report seems to state otherwise; the report lists a number of problems that they found at the Institutions that *volunteered* to be reviewed. Despite the fact that the Applicants' Regulation is very broad in that it allows the Institutions much leeway to form their own conflict of interest policies, the NIH still found that some Institutions failed to maintain a consistent reporting process.<sup>127</sup> It is difficult to thoroughly analyze the compliance of NIH-funded institutions from this report, as it lacked numerical data, making it impossible to note how many of the eighteen Institutions reviewed failed to meet each requirement of the regulation. Rather, we are left weighing the agency's statement that the reviewed Institutions were substantially complying with the regulation against the list of the problems they found, which seem to show that there is a significant problem with compliance.

### C. JOURNALISTIC INTEGRITY: ACADEMIC JOURNALS EMPLOY STRICTER STANDARDS

In an effort to protect their academic integrity in the face of growing ties between medical research and industry, a number of leading medical research journals have created strict conflict of interest standards for their authors, editors, and reviewers. Unsatisfied with the methods employed by

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<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

the federal government, these journals have established disclosure standards that force contributors to disclose not only to the journal, but also to the journal's readership, the details of their financial conflicts of interest, not just the presence of such an interest.

The New England Journal of Medicine ("NEJM") requires that a financial disclosure statement be included with each published article. The disclosure must make clear who designed the study, who analyzed the data, who vouches for the accuracy and authenticity of the data and the analysis of the data, and who wrote the paper.<sup>128</sup> In addition to specifying everyone involved in the research and writing of the paper, the NEJM requires that the financial disclosure statement describe the relationship that each of those people has or had with any companies that "make products relevant to the paper."<sup>129</sup> The NEJM not only requires that this information be provided to the journal, it also requires that it be included in a disclosure footnote within the printed paper.<sup>130</sup> This requirement allows the journal's readership to analyze the conflict for themselves, rather than being forced to rely on the determination of the journal that there were no significant financial conflicts of interest.

JAMA has a similarly stringent conflict disclosure policy. When submitting a paper to the journal for publication consideration each author must include a full disclosure in the Acknowledgements section at the end of the paper.<sup>131</sup> This disclosure must include any past or present financial interest, conflict, or relationship.<sup>132</sup> Additionally, JAMA requires its prospective authors to disclose any interests that might arise in the foreseeable future.<sup>133</sup> While the federal regulations only require the disclosure of conflicts that exceed a minimum financial threshold, JAMA requires complete disclosure of any financial interest, no matter how small or seemingly inconsequential.<sup>134</sup> However, JAMA specifically excludes the ownership of shares of a mutual fund that owns shares in a pharmaceutical company among its other publicly traded companies.<sup>135</sup> As is the policy of the NEJM, when JAMA chooses to publish a paper or editorial, the disclosure is published alongside the written work allowing the journal's readers to analyze the conflicts for themselves.<sup>136</sup> JAMA's disclosure policy extends to everything published in their journal—from scholarly articles to letters to the editor and book reviews.<sup>137</sup>

Science, a world renowned weekly scientific journal, has instituted a policy similar to that employed by the NEJM and JAMA. The editors of Science have issued a Statement on Real or Perceived Conflicts of Interest

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<sup>128</sup> New England Journal of Medicine, *Author Center: How to Prepare Your Financial Disclosure Statement*, available at <http://authors.nejm.org/Misc/disclos.asp> (last visited Mar. 8, 2008).

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> Annette Flanagan, Phil B. Fontanarosa & Catherine D. DeAngelis, *Update on JAMA's Conflict of Interest Policy*, 296 J. AM. MED. ASS'N 220, 220 (2006).

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*



for Authors on its website, which states that the journal has a responsibility to its readers “to provide in its pages clear and unbiased scientific results and analyses.”<sup>138</sup> To accomplish that goal, Science requires that all authors disclose all of their affiliations, funding sources, and financial holdings that might raise a suggestion of bias.<sup>139</sup>

Prior to 2001, Nature, another weekly scientific journal, did not require any sort of disclosure by its contributors.<sup>140</sup> However, the journal’s editors recognized that evidence suggested that “publication practices in biomedical research have been influenced by the commercial interests of authors”<sup>141</sup> and that there was a growing concern among researchers about the “possible undermining of the integrity of scientific research by increasing commercial links and consequent influences.”<sup>142</sup> Nature now requires authors to disclose all “competing financial interests,”<sup>143</sup> which it defines as an interest that, through its “potential influence on behaviour or content or from perception of such potential influences, could undermine the objectivity, integrity or perceived value of a publication.”<sup>144</sup> While Nature will accept and publish an article when its author refuses to make a financial disclosure, the journal will publish the fact that the author refused full disclosure.<sup>145</sup> Scientific and medical journals differ in the thresholds that they set for financial disclosure; the federal regulations set that threshold at ten thousand dollars, while some publications require the disclosure of *any* financial interest, however small. Nature takes a unique approach; rather than setting a financial threshold, the editors of the journal state that authors should disclose any financial interest that, if left undisclosed, “could embarrass [the author] were they to become publicly known after [the author’s] work is published.”<sup>146</sup>

It is clear that the leading medical and scientific journals have taken strong steps towards exposing potential conflicts of interest to their readership. The standards set by the leading journals differ immensely from the less restrictive standards set by the federal government,<sup>147</sup> which nonetheless funds a large portion of the contributions to the journals. However, these journals represent only a small sector of the scientific research being conducted and being funded, at least partially, by federal tax dollars. The question then, is whether the federal government should create stricter conflict of interest standards to monitor the usage of the monies distributed by its agencies. By establishing regulations that mirror the standards used by the NEJM, JAMA, Science, and Nature, the agencies that

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<sup>138</sup> American Association for the Advancement of Science, *Statement on Real or Perceived Conflicts of Interest for Authors*, available at <http://www.sciencemag.org/feature/contribinfo/prep/coi.pdf> (last visited Mar. 8, 2008).

<sup>139</sup> *Id.*

<sup>140</sup> Nature, *Competing Financial Interests*, available at [http://www.nature.com/authors/editorial\\_policies/competing.html](http://www.nature.com/authors/editorial_policies/competing.html) (last visited Mar. 8, 2008).

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> See *supra* text accompanying notes 77–106.

dispense the sought-after funds will be better able to serve their constituents—the American taxpayers.<sup>148</sup>

#### IV. RECOMMENDATIONS

##### A. OVERVIEW

In an ideal world, funding for all research would be unlimited, and we would not need to concern ourselves with the influence of industry on academic medical research. However, even when the budget for medical research was not as minimal as it is presently, federal funding always has been, and likely always will be, limited, encouraging the use of private funds by academic researchers.<sup>149</sup> To ban federally-funded researchers from taking supplementary financing from industry would be absurd; monetary and other forms of support from industry have become necessary to fund the day-to-day operations of many academic researchers and without that support, the body of research produced each year would decline significantly. However, the current regulatory framework fails to properly protect the public from the inevitable conflicts of interest that arise when industry and academic research overlap. It is therefore necessary for Congress to reform or supplement the Applicants' Regulation to make the federal standards stricter, and to create a uniform conflict of interest policy that must be met or exceeded by all Institutions and Investigators applying for federal funds.

There are two primary issues that need to be addressed by Congress in the creation of the new uniform federal conflict of interest policy. First, it is of paramount importance that PHS and the specific funding agencies have complete and accurate information about actual and potential conflicts of interest. Second, it is vital not only that the conflicts of interest be fully disclosed to the funding agency, but also that they be prevented from affecting the research and analysis of the Investigator and the Institution as a whole. It is important for the federal government to alter its regulatory scheme to affect a change in the way financial contacts with industry impact both the receiving Institution and individual Investigators.

##### B. UNIFORM FEDERAL CONFLICT OF INTEREST POLICY

The current Applicants' Regulation delegates the responsibility for constructing conflict of interest policies and for ensuring that Investigators comply with the policies to each individual Institution that receives federal funding.<sup>150</sup> This results in a myriad of different policies ostensibly seeking the same result: minimization of potential conflicts of interest. This means that the federal funding agencies must rely on the administrators in each individual Institution to develop an adequate conflict of interest policy. In the event that a funding agency needs to evaluate an Investigator's

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<sup>148</sup> See *infra* pp. 28–35.

<sup>149</sup> See *supra* text accompanying notes 2–24.

<sup>150</sup> See *supra* text accompanying note 79.

compliance with his Institute's policy, the agency needs to first understand and analyze the policy itself. By having a uniform policy that is followed by all Institutions and Investigators applying for federal funds, the federal government will make it easier for funding agencies to analyze compliance, as they will be familiar with the policy's requirements and procedures. Site reviews like those conducted by the NIH<sup>151</sup> would be easier to conduct if there was a uniform policy in place that the agency could use to gauge compliance. Additionally, a uniform policy would make it easier to compare the compliance of one Institution to that of another, as the policy they follow would be the same.

A uniform federal policy would do more than serve an administrative function; it would work to encourage better compliance through competition. By enacting a uniform federal policy that each Institution and Investigator must follow, we would lessen the chance that there will be discrepancies in the way conflicts are managed among Institutions vying for the same financing. Institutions that are unable to minimize their policy requirements in an effort to make it easier for Investigators to get federal funding would be forced to minimize the existence of potential conflicts, as the application process would be easier the less conflicts there were to disclose or mitigate. When Institutions are allowed to create their own policies, there is a somewhat perverse incentive for them to minimize their policy requirements, so as to make the process easier for its Investigators to comply with, which would, in turn, make the application for federal funds easier.

Finally, and perhaps most importantly, a uniform federal conflict of interest policy may serve to increase the quality of the conflict prevention and mitigation efforts of the Institutions and individual Investigators. The Targeted Site Reviews conducted by the NIH show that there are interpretation problems and discrepancies between Institutions and Investigators. By having an explicitly enunciated policy rather than the broad guidelines that are currently in effect, funding agencies would have more assurance that conflicts are being accurately disclosed and mitigated. By allowing each Institution to craft its own conflict of interest policy, the federal government is leaving vast amounts of room for variation in interpretation. Because the current regulation allows Institutions to "manage" conflicts that arise, and to simply notify the funding agency of their successful management,<sup>152</sup> this system does nothing to assure the funding agencies that the conflicts are being managed in a way that they would deem appropriate for the specific conflict. By creating a uniform federal conflict of interest policy, with detailed instructions for managing types of conflicts and potential conflicts, and with a requirement that each Institution detail to the funding agency how the conflicts were managed, the agencies could have a measure of security that the conflicts are being controlled and managed in a way that is acceptable to them. A clearly set standard for disclosure and management that must be complied with by all applicants for federal funding will increase the level of both disclosure and

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<sup>151</sup> See *supra* text accompanying note 109.

<sup>152</sup> See *supra* text accompanying note 90.

management, provided that the standard is set high enough. It is therefore of paramount importance that the bar be set high, for both disclosure and management.

### C. MANDATORY FULL DISCLOSURE

It is important to ensure that negative effects of industry ties on academic research are minimized before federal funding is granted. It is therefore necessary that the agency personnel that evaluate grant applications for funding by NIH and other federal agencies have complete and accurate information about the financial contacts that the Institution and individual Investigators have with industry.

The present disclosure regulation requires that each Institution report to PHS only the *existence* of a potential conflict;<sup>153</sup> it does not require that the details of that conflict be disclosed.<sup>154</sup> It is important that this aspect of the federal regulation change immediately. By requiring Institutions to completely disclose all actual and potential conflicts of interest to PHS and the specific funding agency, the agency personnel responsible for evaluating grant applications and ultimately deciding what research to fund can have a more complete picture of the potential conflicts that are or are likely to be present. With federal funds at an all-time low,<sup>155</sup> grant reviewers need to be able to make sure that the most deserving applicants receive the funding—and one measure of how deserving a candidate will be is the lack of potential and actual conflicts that could taint the research. It is in the best interests of the funding agency to ensure that the research conducted with their funds is uncompromised, and so a more thorough disclosure standard, which not only forces the Institutions and Investigators to specifically disclose all conflicts but also gives the funding agency the opportunity to analyze those conflicts for themselves, is necessary.

The disclosure standards set by the leading medical and biological sciences journals provide good examples for a federal regulatory standard.<sup>156</sup> Congress should create a panel of experts in medical research that will be tasked with creating the disclosure policy of the uniform federal conflict of interest policy. The disclosure policy should be premised upon exacting as much pertinent information from Institutions and Investigators as possible.

At the bare minimum, the threshold for a financial interest to be considered “significant” should be lowered and tailored to the individual’s situation; for example, a tenured professor may not have to report a stock holding of less than five thousand dollars, while a post-doctoral student or research technician may be required to report anything over five hundred dollars. By taking into consideration the financial impact the interest has on the individual involved, the policy will be more effective at shedding light on potential conflicts of interest. The routine exception can and should be

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<sup>153</sup> See *supra* text accompanying note 88.

<sup>154</sup> *Id.*

<sup>155</sup> See *supra* text accompanying notes 2–24.

<sup>156</sup> See *supra* text accompanying notes 127–43.

made, however, for holders of shares in mutual funds that may own shares of pharmaceutical companies. Since the ownership of companies by mutual funds is primarily out of the hands and control of the individuals, such financial interest in a company does not present a significant interest.

Additionally, rather than simply stating that a financial interest “exists,” the disclosure should include a detailed description of the exact nature of the interest, as is required by the leading journals.<sup>157</sup> This would allow the grant reviewers the ability to analyze the potential for conflict rather than having to speculate and trust that the Institution has adequately managed the conflict.<sup>158</sup> While an enhanced disclosure policy would not prevent Institutions or individuals from intentionally concealing information, it would serve to reduce the risk that Institutions or individual Investigators will decide that a particular conflict is not important enough to disclose, and it would also reduce the risk that conflicts will be deemed to be “managed” when they have actually been insufficiently controlled.

#### D. MANAGEMENT AND CONTROL OF ACTUAL AND POTENTIAL CONFLICTS OF INTEREST: MITIGATION RATHER THAN MANAGEMENT

A strict disclosure requirement in the uniform federal conflict of interest policy is necessary, but is not sufficient. Congress must also develop a procedure that Institutions must follow for the mitigation of actual and potential conflicts of interest. It is also necessary that the procedure require that the Institutions disclose to the funding agency exactly how the conflict was mitigated and managed.

The current Applicants’ Regulation simply requires that each Institution notify the applicable funding agency that a conflict has been “managed” in accordance with the guidelines (rather than requirements) supplied by the regulation.<sup>159</sup> This policy allows an individual Institution to manage conflicts to its own satisfaction, rather than to the satisfaction of a neutral authority, such as the funding agency. Under the current policy, there is a risk that the management of the conflict will be inappropriate. The risk is a bona fide concern because it is in the best interests of an Institution that is competing with other Institutions for federal funds to hastily state that the risk has been managed, rather than spend the time and effort required to adequately control the potential problem. While Institutions may be capable of adequately managing the financial conflicts that it uncovers, a uniform policy that has strict requirements for mitigation and management would give more assurance to the funding agencies that the potential problems have been controlled. In order to create such requirements, Congress should establish a special panel comprised of academic medical researchers—preferably researchers who have no financial ties to industry—that will be tasked with creating a required framework for the mitigation of financial conflicts. The requirements could include requiring Investigators to certify that they have not altered a research paper based on

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<sup>157</sup> *Id.*

<sup>158</sup> *See infra* pp. 33–34.

<sup>159</sup> *See supra* text accompanying note 90.

comments from a donor-company, and a requirement that a researcher with no ties to the donor-company be actively involved in the research. A properly composed panel of experts could use their experience and expertise to establish such a mitigation policy. By using polls such as those conducted by Campbell, et al.,<sup>160</sup> that demonstrate the beliefs that researchers have about the donations they receive from industry, the panel should devise rules that serve to insulate the researchers from possible conflicts that result from the financial ties they have to industry.

In addition to creating a strict mitigation policy that must be followed by all Institutions and individual Investigators seeking federal funding, the policy must include a disclosure requirement. Rather than allowing Institutions to simply state that they have managed the conflicts, Institutions must be required to show the steps that they have taken to mitigate and manage the conflict. This serves to hold the Institutions accountable to the funding agencies and forces them to comply with the regulation. In order to assure that the Institutions and Investigators understand the necessity of fully complying with the mitigation disclosure, the policy should also include meaningful consequences for Institutions and Investigators who do not comply with the mitigation requirements. By requiring that the Institutions and individual Investigators certify that they have followed the requirements of the regulation, and specify the steps that they have taken, the funding agencies will be more assured that the conflicts have been taken care of, because the consequences for deliberately misrepresenting the mitigation efforts will be severe. While the panel set up by Congress should decide on the consequences, penalties could include being banned from receiving federal funds for a specified period of time and having to return funds, with interest, that were procured by deliberate misrepresentation.

#### E. CONCLUSION

Academic research has come to terms with the fact that industry-based financial support is a necessary element of funding. While there is no question that the ties to industry create the potential for conflicts of interest, these conflicts vary in their impact on the quality of research and analysis of research performed by academic researchers. While the current regulatory framework set up by Congress is well intentioned—supporting the use of industry funds while attempting to control the conflicts it creates—it lacks the strength to meet the necessary goals. The Applicants' Regulation was crafted when industry funds did not play such a large role in academic medicine; the time has come for Congress to adapt the regulation to the current situation. By establishing a panel of experts that is charged with creating a stronger disclosure and mitigation requirement that will be codified as the new Applicants' Regulation, Congress will not only be making a difference in preventing conflicts of interest, it will be sending

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<sup>160</sup> See *supra* text accompanying notes 25–37.

a clear message to people involved in academic research and to industry that the important function that academic research performs in society must not be compromised.

