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### The Money Blind: How to Stop Industry Bias in Biomedical Science, Without Violating the First Amendment

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## The Money Blind: How to Stop Industry Bias in Biomedical Science, Without Violating the First Amendment

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# The Money Blind: How to Stop Industry Bias in Biomedical Science, Without Violating the First Amendment

Christopher T. Robertson<sup>†</sup>

*The pharmaceutical and medical device industries use billions of dollars to support the biomedical science that physicians, regulators, and patients use to make healthcare decisions—the decisions that drive an increasingly large portion of the American economy. Compelling evidence suggests that this industry money buys favorable results, biasing the outcomes of scientific research. Current efforts to manage the problem, including disclosure mandates and peer reviews, are ineffective. A blinding mechanism, operating through an intermediary such as the National Institutes of Health, could instead be developed to allow industry support of science without allowing undue influence. If the editors of biomedical journals fail to mandate that industry funders utilize such a solution, the federal government has several regulatory levers available, including conditioning federal funding and direct regulation, both of which could be done without violating the First Amendment.*

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## I. AN INTRODUCTION TO BIASED SCIENCE

Scholars estimate that between thirty and forty-five percent of the growth in medical spending is driven by the decisions of prescribers, patients, and payors to adopt new medical technologies produced by the drug and device industry.<sup>1</sup> This industry spends billions of dollars to create these innovative products, but also spends about as much to change the behavior of prescribers, consumers, and payors to ensure that they are purchased.<sup>2</sup> Against this onslaught, regulators restrict the industry's promotional efforts on behalf of these products, in order to protect patient welfare and to optimize the expenditure of public and private healthcare money, so that it is not wasted on products that are inefficient, ineffective, or even dangerous in a given application. These regulators of promotional efforts are, however, constrained by the First Amendment to the United States Constitution, which protects the industry's right to commercial speech.<sup>3</sup> Here, the battle lines are drawn.<sup>4</sup>

In some ways, however, the industry's efforts to influence biomedical *science* are more profound and more disconcerting than the industry's explicit promotional activities. When successful in its efforts to manipulate biomedical science, the industry transforms the very epistemological basis that scientists, regulators, juries, physicians, and patients rely upon to assess the safety and adequacy of industry products. Such influence literally changes what we think we know about these products. This section documents the problem of industry influence in biomedical science, and explains why status quo solutions are inadequate.

### A. INDUSTRIAL SCIENCE AS COMMERCIAL SPEECH

Biomedical science is the boundary-setting precondition for industry promotional efforts. As a veteran of the industry writes, "in the pharmaceutical industry, there are two ways to market an approved drug for a new use: the 'indication' route—performing studies necessary for regulatory

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<sup>1</sup> E. Ray Dorsey et al., *Funding of US Biomedical Research, 2003-2008*, 303 JAMA 137, 142 (2010) (citing Gail R. Wilensky, *Developing a Center for Comparative Effectiveness Information*, 25 HEALTH AFF. W572 (2006)).

<sup>2</sup> See Marc-Andre Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLoS MED. 29, 32 n.4 (2008); *id.* at 32 (discussing a PhRMA press release claiming that in the U.S. the industry spent \$29.6 billion on R&D in 2004 and \$27.7 billion for all promotional activities, which the authors note excluded several major categories of promotional activities, suggesting a conclusion that "pharmaceutical companies spend almost twice as much on promotion as they do on R&D"). Whatever its precise size, such an enormous investment in promotional activities would be irrational if it did not change the behavior of physicians and consumers. Some such changes in behavior are of course salutary, if they drive a doctor away from an obsolete treatment and towards one that is instead effective, safe, and economical—one that just happens to be patented by a major pharmaceutical company.

<sup>3</sup> See, e.g., *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (overturning certain regulations that pertained to prescription drug compounding as unconstitutional restrictions on commercial speech).

<sup>4</sup> See, e.g., *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 267 (2d Cir. 2010) (holding that a Vermont statute violated the First Amendment by restricting prescribing information available to manufacturers who used such information to send "detailers" to influence physicians), *cert. granted*, 131 S. Ct. 857 (2011).

approval—or the ‘publication’ strategy, which stimulates off-label prescribing by using research ‘to disseminate the information as widely as possible through the world’s medical literature.’<sup>5</sup> Both of these routes crucially turn on the industry’s ability to procure scientific studies that purport to support their product. Thus, in a practical sense, biomedical science is the industry’s first avenue of promotion. A longtime editor of the *British Medical Journal* provocatively titled his own article on the phenomenon, “Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies.”<sup>6</sup> The industry apparently concurs in this assessment. In a strikingly candid document produced by Pfizer, the company asks, “What is the purpose of publications?” The answer: the “purpose of data is to support, directly or indirectly, the marketing of our product.” Or in short: “Purpose of Publications: The Bottom Line.”<sup>7</sup>

There is a growing recognition that the information presented in biomedical journal articles is distorted by these companies that fund the research and create financial relationships with the researchers as consultants or equity owners.<sup>8</sup> The former editor-in-chief of a major biomedical journal writes that “the public trust in research has been eroded and there is a perception that professional fidelity and honesty on the part of investigators and clinicians has deteriorated.”<sup>9</sup> More bluntly, the editor of *The Lancet* states, “Journals have devolved into information laundering operations for the pharmaceutical industry.”<sup>10</sup> The judicial system has begun to notice. Judge Jack Weinstein writes, “The pervasive commercial bias found in today’s research laboratories means studies are often lacking in essential objectivity, with the potential for misinformation, skewed results, or cover-ups.”<sup>11</sup>

Empirical evidence supports these conclusions. The drug and device industry is the single largest source of funding for biomedical research, both directly in its own research centers and indirectly through grants to academic investigators.<sup>12</sup> In the United States, for example, industry funds about

<sup>5</sup> Adriane Fugh-Berman & Douglas Melnick, *Off-Label Promotion, On-Target Sales*, 5 PLoS MED. 1432, 1433 (2008).

<sup>6</sup> Richard Smith, *Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies*, 2 PLoS MED. 364 (2005); see Dan Wikler, *A Crisis in Medical Professionalism: Time for Flexner II*, in ETHICS AND THE BUSINESS OF BIOMEDICINE 249, 251 (Denis G. Arnold ed., Cambridge Univ. Press, 2009) (compiling this and other sources cited below).

<sup>7</sup> Barton Moffatt & Carl Elliott, *Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles*, 50 PERSP. BIOLOGY & MED. 18, 19 (2007) (quoting a document that was produced in *Motus v. Pfizer*, 358 F.3d 659 (9th Cir. 2004)).

<sup>8</sup> See generally THOMAS O. MCGARITY & WENDY E. WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* (2008) (describing ways in which scientific processes are corrupted by special interests).

<sup>9</sup> Richard S. Irwin, *The Role of Conflict of Interest in Reporting of Scientific Information*, 136 CHEST 253, 254 (2009) (writing as the former editor-in-chief of the journal).

<sup>10</sup> RICHARD HORTON, *The Dawn of McScience*, 51 N.Y. REV. BOOKS, Mar. 11, 2004, at 9.

<sup>11</sup> *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 106 (E.D.N.Y. 2008), *rev’d*, UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121 (2d Cir. 2010) (reversing on the question of causation).

<sup>12</sup> Dorsey et al., *supra* note 1, at 139; H. Moses III et al., *Financial Anatomy of Biomedical Research*, 294 JAMA, 1333, 1333 (2005); Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 454 (2003); see also D. E. Zinner, *Participation of Academic Scientists in Relationships with*

seventy percent of the clinical trials of its drugs and devices.<sup>13</sup> And even when the industry is not funding the trial, its stockholders, consultants, officers, and directors are often conducting the study.<sup>14</sup> As the federal government cuts budgets, the industry's role as the primary benefactor of biomedical science is likely to grow.<sup>15</sup>

The industry's expenditure on this publication strategy seems to be a worthwhile investment. In a landmark review of the literature, an Institute of Medicine report concluded that: "Several systematic reviews and other studies provide substantial evidence that clinical trials with industry ties are more likely to have results that favor industry."<sup>16</sup> Indeed, one meta-study showed that industry-funded research is eight times less likely to reach unfavorable conclusions compared to independent studies.<sup>17</sup> Industry-sponsored studies can be biased in favor of the product being studied due to choice of design and methodologies, selective analysis and interpretation of data, and conclusory statements in the resulting journal abstracts and articles that might not be supported by the data. Indeed, there are no less than eighteen such opportunities for motivated investigators to consciously or subconsciously bias their research discussed below.<sup>18</sup>

Admittedly, there may be benign explanations for some portion of the apparent biases. Perhaps industry-funded studies are more likely to reach favorable results simply because the industry is more conservative in deciding which studies it funds, compared to government and foundation funders who have the luxury of pursuing more conjectural hypotheses.<sup>19</sup> The industry's

*Industry*, 28 HEALTH AFF. 6, at 1814-25 (2009) (explaining further the financial conflicts of interest present in biomedical research).

<sup>13</sup> Thomas Bodenheimer, *Uneasy Alliance—Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539, 1539 (2000).

<sup>14</sup> Susannah L. Rose et al., *Relationships Between Authorship Contributions and Authors' Industry Financial Ties Among Oncology Clinical Trials*, 28 J. CLINICAL ONCOLOGY 1316, 1316 (2010).

<sup>15</sup> See Alex Wayne, *GOP Budget Cuts Likely to Hurt Research, NIH Says*, WASH. POST, Nov. 9, 2010, available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/11/09/AR2010110906764.html>.

<sup>16</sup> INSTITUTE OF MEDICINE, BOARD ON HEALTH SCIENCES POLICY, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 104 (2009) [hereinafter IOM REPORT]; see also Su Golder & Yoon K. Loke, *Is There Evidence for Biased Reporting of Published Adverse Effects Data in Pharmaceutical Industry-Funded Studies?*, 66 BRIT. J. CLINICAL PHARMACOLOGY 767, 767 (2008); Laurence Hirsch, *Conflicts of Interest, Authorship, and Disclosures in Industry-Related Scientific Publications: The Tort Bar and Editorial Oversight of Medical Journals*, 84 MAYO CLINIC PROC. 811, 812 (2009) (discussing evidence that these discrepancies may be due to publication bias, i.e., the industry's self-censoring of unfavorable results).

<sup>17</sup> Mark Friedberg et al., *Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology*, 282 JAMA 1453, 1455 (1999); see generally Joanna K. Sax, *Protecting Scientific Integrity: The Commercial Speech Doctrine Applied to Industry Publications*, 37 AM. J.L. & MED. 203 (2011); see also J. E. Bekelman, Y. Li & C.P. Gross, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 454-65 (2003); Joel Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 BRIT. MED. J. 1167 (2003) (showing that, over the course of multiple studies, research funded by drug companies was more likely to have outcomes favoring the sponsor than studies with non-drug company sponsors).

<sup>18</sup> See *infra* note 59 and accompanying text.

<sup>19</sup> See Dorsey et al., *supra* note 1, at 141 (describing the industry's "preference for [research] investments of lower risk").

strategy could be conceived of as an efficient use of research dollars, or it may degrade into a company's willful ignorance of unfavorable results, as they "decline[] to fund clinically important studies at least partly because the results might reduce sales of the drug."<sup>20</sup> The benign explanations can go only so far, because the evidence also shows that industry-funded studies are also biased towards being rather weak methodologically. A recent review of the methodological quality of 886 published studies in one field of medicine (orthopedics) found that "the level of evidence of industry-funded studies was lower than that for studies funded by governments, foundations, or universities."<sup>21</sup>

The problem is also one of trust. Even if all this industry money did not in reality create pernicious biases in science, it has clearly undermined the perceived legitimacy of this important institution.<sup>22</sup> The flood of industry funding creates an appearance of impropriety, one that is leading towards a "systematic distrust and devaluation of expertise" in this context.<sup>23</sup> A former editor-in-chief of the *New England Journal of Medicine (NEJM)* has lamented, "Physicians can no longer rely on the medical literature for valid and reliable information."<sup>24</sup> If physicians cannot rely on the medical literature, what are they doing instead? The very profession of medicine is at stake.

Together then, we have evidence showing that industry funds a huge portion of biomedical science, that industry studies tend to be favorable to industry (a seeming bias in their conclusions), but that the studies are relatively weak methodologically (a seeming bias in their evidentiary strength). As a result, some physicians may careen towards complete skepticism of industry science, but the remainder who must proceed to practice in this flood of industry science will rely upon it. Such physicians will be swayed to use drugs or medical devices in contexts where they might not be effective, where they might present unnecessary risks to patients, or where they simply are not economical compared to treatment alternatives. Thus, as the industry succeeds in warping biomedical science to represent industry interests rather than physiological reality, it degrades the practice of medicine, harms patient welfare, and raids the treasuries of state and national governments.

<sup>20</sup> See Bodenheimer, *supra* note 13 (describing an interview).

<sup>21</sup> Shahryar Noordin et al., *Relationship Between Declared Funding Support and Level of Evidence*, 92 J. BONE & JOINT SURGERY AM. 1647, 1647 (2010). *But see* Lexchin et al., *supra* note 17, at 1167 (finding that within the category of randomized controlled trials, that industry sponsored studies were no worse methodologically).

<sup>22</sup> For this distinction in another context, see *Caperton v. A.T. Massey Coal Co.*, 129 S. Ct. 2252, 2266 (2009), observing "[o]ne must also take into account the judicial reforms the States have implemented to eliminate even the appearance of partiality."

<sup>23</sup> Christopher T. Robertson, *Blind Expertise*, 85 N.Y.U. L. REV. 174, 178 n.11 (2010) (quoting John H. Langbein, *The German Advantage in Civil Procedure*, 52 U. CHI. L. REV. 823, 836 (1985)).

<sup>24</sup> Marcia Angell, *Industry-Sponsored Clinical Research: A Broken System*, 300 JAMA 1069, 1070-71 (2008). Angell goes on to say: "It is self-evidently absurd to look to investor-owned companies for unbiased evaluations of their own products. Yet many academic investigators and their institutions pretend otherwise, and it is convenient and profitable for them to do so." *Id.*

## B. THE FAILURE OF STATUS QUO SOLUTIONS

What can be done to reduce the potential corrupting influence of industry money in biomedical research? Current regulatory mechanisms include litigation, peer review, and mandatory disclosure. This section explains why they fail to solve the problem.

### 1. Litigation

To date, except for ex post reactions in the most egregious cases, the law has been largely silent with respect to the problem of biased science.<sup>25</sup> In theory, if the industry's manipulation of science rose to the level of outright fraud, a plaintiff could recover under state tort laws, the federal qui tam act, and federal racketeering statutes—assuming that the plaintiff had standing and that he or she could prove causation of a specific injury. Except in the most egregious cases, these barriers are nearly insurmountable.<sup>26</sup>

When drug- and device-makers promote their products beyond the uses approved by the Food and Drug Administration (FDA), such violations can lead to Department of Justice enforcement actions and seemingly-large settlements.<sup>27</sup> Such lawsuits do not, however, reach the fundamental problem of biased science, but instead focus on the downstream problems that arise when companies go too far in promoting their products.

There are also more creative theories available for litigators. In the recent case of *Merck v. Reynolds*, the U.S. Supreme Court heard a case involving a securities fraud class action against the manufacturer of rofecoxib (Vioxx), an anti-inflammatory drug approved to treat arthritis pain.<sup>28</sup> The plaintiffs alleged that the company had made various misrepresentations about the drug in order to inflate its stock price, including a March 2000 study supported by the company and published in the *NEJM*. The data showed a four-fold increased risk of adverse cardiovascular events with Vioxx over naproxen, but the industry-affiliated authors put the finding on its head. The authors wrote that the adverse event rate “was significantly lower in the naproxen group than in the rofecoxib group (0.1 to 0.4),”<sup>29</sup> a statement that

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<sup>25</sup> Section 801 of the Food and Drug Administration Act of 2007 does require researchers to register interventional clinical trials and, for marketed products, to disclose the results of such trials within twelve months after study completion, on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (to be codified in scattered sections of 21 U.S.C.). Following several state laws, as of 2013, federal law will also require the industry to disclose its financial relationships with physicians, though there are questions about the completeness and accuracy of such disclosures. See Charles Ornstein & Tracy Weber, *Drug Companies' Reports Aren't Always Accurate*, STAR-TRIB., Dec 12, 2010, available at <http://www.startribune.com/business/111704609.html> (discussing an analysis of Minnesota's required disclosures).

<sup>26</sup> See, e.g., *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) (holding that even if plaintiff could prove misrepresentations, it would be unable to prove a causal effect on the prices paid for drugs).

<sup>27</sup> See Aaron Kesselheim, *Off-Label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech*, 37 AM. J.L. & MED. 225, 241 tbl.1 (2011) (reviewing DOJ enforcement actions).

<sup>28</sup> 130 S. Ct. 1784 (2010).

<sup>29</sup> Claire Bombardier et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 NEW ENG. J. MED. 1520, 1526 (2000).



implies that the difference was due to a cardioprotective effect of naproxen rather than a toxic effect of Vioxx. In addition, the investigators had predetermined an endpoint for the study, and it was later revealed that additional post-endpoint cardiovascular adverse events occurred in Vioxx-treated patients in that trial, but these results were not included in the published article.<sup>30</sup> After the publication of this and other similarly-biased trials, annual sales of Vioxx reached billions of dollars, but the drug was later removed from the market due to concerns over its cardiovascular safety. The plaintiff stockholders argued in the securities fraud case that the biased biomedical journal articles misrepresented the safety of the product, and thus the financial security of the company. After a win for the plaintiffs in the Supreme Court on a preliminary procedural issue, this case remains pending.<sup>31</sup>

Thus, the pharmaceutical and medical device industries may face potential liability in the extreme cases that rise to outright fraud, but only on the rare occasion that it can be detected by plaintiffs, proven in *ex post* litigation, and where causation of a specific and tangible harm can be demonstrated. The concern here, on the other hand, is about a ubiquitous industry influence on biomedical science, a biasing pressure that is strong enough to change prescribing and consumer behavior, but not so blatant as to be prosecuted as outright fraud. That sort of manipulation appears to enjoy something near legal impunity.

## 2. Peer Review

The biomedical journals utilize a peer review process to police the methodological rigor of biomedical journal articles, and thus may be a bulwark against industry efforts to manipulate biomedical science. Biomedical journal editors have two primary tools in their arsenal: peer review and disclosure.<sup>32</sup> Peer review is in one sense an extreme form of non-governmental regulation, not unlike censorship, saying to rejected authors, “you cannot say that here.”<sup>33</sup> Thus, peer review is in theory a strong bulwark against the industry’s ability to manipulate science.<sup>34</sup>

Still, peer review focuses merely on the methods and data reported in the text of journal article drafts, and only indirectly addresses industry influence in a long chain of decisions that produce those drafts.<sup>35</sup> And, unlike a grant

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<sup>30</sup> Gregory D. Curfman et al., Editorial, *Expression of Concern: Bombardier et al., Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 353 *NEW ENG. J. MED.* 2813, 2813-14 (2005).

<sup>31</sup> See *Merck*, 130 S. Ct. 1784.

<sup>32</sup> There are also a variety of less prominent interventions. *JAMA*, for example, requires independent statistical analysis of industry-sponsored studies. See Hirsch, *supra* note 16, at 813 (discussing this policy and the backlash against it).

<sup>33</sup> See Arturo Casadevall & Ferric C. Fang, Editorial, 77 *INFECTION & IMMUNITY* 1273 (2009) (editor-in-chief of the journal, weighing the argument that peer review is censorship).

<sup>34</sup> See Catherine D. DeAngelis, Editorial, *The Influence of Money on Medical Science*, 8 *JAMA* 996, at 996-98 (2006) (arguing that certain studies were valid because they survived peer review, even though there were improprieties in the process of disclosing financial relationships with industry).

<sup>35</sup> Peer reviewers are often not provided with the authors’ financial disclosures. See Catherine D. DeAngelis et al., Editorial, *Reporting Financial Conflicts of Interest and Relationships Between Investigators and Research Sponsors*, 286 *JAMA* 89, 90 (2001). This

funding agency or an Institutional Review Board, the peer reviewers must assess the methodological rigor of the submitted articles *after* the studies have been designed and the research has been completed. Peer reviewers' choices are limited to accepting an article (with or without textual revisions) or rejecting an article (which effectively demotes it to another journal, which will then have the opportunity to publish the groundbreaking results, notwithstanding the limitations).

Thus, peer reviewers' decisions are necessarily pragmatic and comparative—weighing the clinical significance of the findings against the study's apparent methodological rigor, and asking whether there is likely to be a more significant or more rigorous article in the queue to fill the journal's pages instead. To the extent that industry-influenced studies dominate the medical literature, they define the range of alternative articles and thus set their own benchmarks for methodological rigor.

Some have argued that peer review is “slow, expensive[,] . . . something of a lottery, prone to bias[,] . . . easily abused,” and hopeless at spotting errors and fraud.<sup>36</sup> Without wading into the details of that debate, for our purposes the results speak for themselves; the foregoing evidence showing that industry-funded studies tend to be biased and methodologically weak are based on publications in peer-reviewed journals.<sup>37</sup> Thus, while one could speculate about how much worse the situation would be without peer review, it remains clear that peer review is not a complete solution.

### 3. Mandatory Disclosure

Another potential remedy is for biomedical journal editors to require authors to disclose industry funding and investigators' related financial interests. In theory, readers of biomedical journal article abstracts (i.e., physicians, payors, and regulators) would use disclosures of the authors' relationships with industry to calibrate their reliance on the abstracts they read.<sup>38</sup>

It is worthwhile to understand how this reliance-calibration mechanism is supposed to work in practice. Suppose that a physician is deciding whether to prescribe a certain drug for a given disease that is not listed on the label.<sup>39</sup> Since the FDA has not determined whether the drug is in fact safe and effective for the off-label indication, the physician must make her own

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policy is apparently intended to preserve the anonymity of the authors, so that the reviewers do not succumb to personal biases, pro or con. Some journals are moving towards a single-blind review, in part to allow reviewers to assess conflicts of interests.

<sup>36</sup> Richard Smith, *Peer Review: A Flawed Process at the Heart of Science and Journals*, 99 J. ROYAL SOC'Y MED. 178, 179 (2006).

<sup>37</sup> See sources cited *supra* Part I.B.1.

<sup>38</sup> The Supreme Court tells a similar story in the context of mandatory disclosures for political campaign finance. *Citizens United v. FEC*, 130 S. Ct. 876, 916 (2010) (asserting that a disclosure mandate “enables the electorate to make informed decisions and give proper weight to different speakers and messages”). *But see* Lloyd Hitoshi Mayer, *Disclosures About Disclosure*, 44 IND. L. REV. 255 (2010) (drawing on psychological literature to criticize this assumption as being too simplistic).

<sup>39</sup> Such “off-label” prescribing is quite common and is perfectly legal; physicians can prescribe a drug for *any* indication as long as the drug has been approved for one indication. *See generally* Kesselheim, *supra* note 27.

epistemic assessment.<sup>40</sup> The physician knows that the chance that any random chemical would be useful for alleviating a given disease is quite low, and the physician has no particular physiological theory that would predict that this drug would be effective in treating the given disease. Nonetheless, the physician has heard anecdotes that patients with the disease have improved after receiving the drug. So all this information could form the basis for a Bayesian prior of non-effectiveness. She might conclude that there is a 0.1 probability of the drug being effective for the given disease.<sup>41</sup>

Now, if the physician were then presented with a scientific research study funded by the National Institutes of Health showing that the drug is effective for the given disease, she might then update her prior belief and now conclude that the probability of efficacy is greater than 0.5. Perhaps she would then prescribe the drug.<sup>42</sup> On the other hand, suppose that a disclosure mandate instead revealed that the second study was funded by the company that makes the drug. Such a disclosure would presumably reduce the epistemic value of that second study (if the physician assumed that such industry-sponsored studies were generally less reliable). The physician with this disclosure might then hew closer to his or her original assessment, and thus perhaps adopt a revised assessment of only 0.2 probability of efficacy, still not enough to prescribe the drug off-label. In this context, a disclosure mandate may have a causal impact, one that protects the professional discretion of physicians from industry-biased science.<sup>43</sup>

That is the theory. In practice, the value of disclosures is quite limited. First, this discounting dynamic presumes that the physician has internalized the corollary assumption that industry-funded studies tend to be biased towards industry products.<sup>44</sup> Some experimental research supports the assumption that physicians tend to maintain some skepticism about industry-funded studies. In one study, readers of a biomedical journal article that included disclosures of conflicting interests found such articles “significantly less interesting, important, relevant, valid, and believable” compared to the reactions of readers who saw the same article with no disclosed conflicts.<sup>45</sup> Even then, it is hard to know if physicians will discount too much or too little.

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<sup>40</sup> Even with FDA approval of an on-label prescription, physicians still must make epistemic assessments when there are multiple competing treatment options, or where there are significant risks of side-effects, or generally if there is a risk that the FDA’s assessment may be unreliable.

<sup>41</sup> See generally Joshua B. Tenenbaum et al., *Theory-Based Bayesian Models of Inductive Learning and Reasoning*, 10 TRENDS COGNITIVE SCI. 309 (2006) (describing Bayesian reasoning).

<sup>42</sup> We are simply assuming, for the sake of argument, that a 0.5 estimate of the likelihood of efficacy is the threshold for a doctor prescribing the drug off-label. In reality, the threshold could be higher or lower, given the risks, costs, and benefits of the drug compared to alternative courses of treatment.

<sup>43</sup> See Christopher T. Robertson, *Biased Advice*, EMORY L.J. (forthcoming 2011) (an experimental study showing that disclosures of conflicting interests only helped laypersons when laypersons also had access to unconflicted advice).

<sup>44</sup> See sources cited *supra* notes 16-21.

<sup>45</sup> Samena Chaudhry et al., *Does Declaration of Competing Interests Affect Readers’ Perceptions? A Randomised Trial*, 325 BRIT. MED. J. 1391, 1392 (2002); see also Sara Schroter et al., *Does the Type of Competing Interest Statement Affect Readers’ Perceptions of the Credibility of Research? Randomised Trial*, 328 BRIT. MED. J. 742 (2004) (finding similar

Still, a primary problem with disclosure as a remedy for industry influence in science is that the consumers of biomedical journal articles often have little or no alternative sources of information.<sup>46</sup> To put it another way, physicians often find themselves in clinical situations in which they have very weak priors. If a physician has no information about the efficacy of a given chemical compound for treating a disease, then even the most highly-conflicted research study showing efficacy may push the physician over the threshold to begin prescribing the drug. An industry-funded study is better than no study at all. In such contexts of high epistemic uncertainty, a disclosure mandate would seem to have no causal impact.

Indeed, in a recent experimental study, physicians reviewed a biomedical journal abstract purporting to prove the efficacy of a new chemical compound, and were randomized into conditions with and without disclosed industry funding.<sup>47</sup> Although the physicians said that they generally would find industry-funded studies to be less persuasive, in fact they reported roughly equal likelihoods of prescribing the new drug, regardless of whether they were in the industry-funded or NIH-funded condition. The disclosure of industry funding made absolutely no causal difference.<sup>48</sup> This study suggests that if industry is successfully biasing science, then the physicians relying on those studies are being biased in their prescribing decisions. Even with disclosure and peer review, bad science is translating into bad medicine.

The foregoing study tested a clear and concise disclosure appended to a biomedical journal abstract. The situation is even worse in practice. Many of the most reputable biomedical journals now require authors to disclose *to the editors* their related financial interests, but journals vary widely in their practices as to what information is provided to the journals' own reviewers and physician readers, who rely on the journal articles to inform their clinical decision-making.<sup>49</sup> Many journals disclose to readers very rudimentary information about the authors' personal financial relationships (e.g., "Dr. X is a consultant for Pfizer"), but do not provide any details or sense of scale,

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results with multiple papers and testing both stock ownership and research grants disclosures).

<sup>46</sup> See Dennis F. Thompson, *Understanding Conflicts of Interest*, 329 *NEW ENG. J. MED.* 573, 575 (1993) (arguing that "[a] deficiency of disclosure is that those who receive the information may not know how to interpret it and may not in any case have reasonable alternative courses of action in the circumstances"); see also Kevin A. Kerber & A. Mark Fendrick, *The Evidence Base for the Evaluation and Management of Dizziness*, 16 *J. EVALUATION CLINICAL PRACT.* 186, 189 (2010) (concluding that "[p]hysicians rely on the medical literature to inform decisions, but our study suggests that the evidence base for dizziness evaluation and management is weak"); see generally David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, 3 *HEALTH AFF.* 74 (1984) (arguing that the practice of medicine is permeated by profound uncertainty about the comparative effectiveness of treatment options).

<sup>47</sup> Gabriel K. Silverman et al., *Failure to Discount for Conflict of Interest When Evaluating Medical Literature: A Randomised Trial of Physicians*, 36 *J. MED. ETHICS* 265, 265-70 (2010).

<sup>48</sup> See also Adam Licurse et al., *The Impact of Disclosing Financial Ties in Research and Clinical Care: A Systematic Review*, 170 *ARCHIVES INTERNAL MED.* 675, 681 (2010) (providing a literature review and concluding that "these disclosures appear to have a limited effect on behavioral outcomes"); Bonnie E. Glaser & Lisa A. Bero, *Attitudes of Academic and Clinical Researchers Toward Financial Ties in Research: A Systematic Review*, 11 *SCI. & ENGINEERING ETHICS* 553 (2005) (also reviewing this literature).

<sup>49</sup> See generally Jared A. Blum et al., *Requirements and Definitions in Conflict of Interest Policies of Medical Journals*, 302 *JAMA* 2230 (2009).

lumping a \$500 honorarium with a \$1,000,000 equity interest. Recently, there has been a push to increase the amount of disclosures that medical journals provide to readers.<sup>50</sup> Researchers have also found rampant discrepancies and inconsistencies in disclosure policies and practices.<sup>51</sup> Even worse, many readers do not even see those disclosures. Physicians commonly choose to read only the abstracts of biomedical journal articles, syndicated through services such as PubMed. Such abstracts usually do not include *any* disclosures. When journals do provide such disclosures to readers, they instead tend to do so in a long box located at the end of the article, which physicians may not notice or read, and which may provide little real guidance as to the significance or relevance of the disclosures.<sup>52</sup>

Too often, these abstracts inaccurately report the conclusions of the underlying articles.<sup>53</sup> Biomedical journal abstracts also usually include very little discussion of the limitations of the study, and physicians may fail to appreciate the statistical and methodological limitations, even when disclosed in technical terms.<sup>54</sup> Furthermore, psychological studies suggest that physicians likely are influenced by their initial reading of the abstract even when they do continue to read the full article, where they might find the discussion of limitations and disclosures of conflicting interests.<sup>55</sup> Thus, it seems quite unlikely that current or even foreseeable disclosure policies suffice to solve the problem of biased science.<sup>56</sup>

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<sup>50</sup> Jeffrey M. Drazen et al., *Uniform Format for Disclosure of Competing Interests in ICMJE Journals*, 361 NEW ENG. J. MED. 1896, 1896 (2009).

<sup>51</sup> Kevin P. Weinfurt et al., *Consistency of Financial Interest Disclosures in the Biomedical Literature: The Case of Coronary Stents*, PLOS ONE, MAY 7, 2008, available at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0002128>.

<sup>52</sup> See IOM REPORT, *supra* note 16, at 77.

<sup>53</sup> Roy M. Pitkin et al., *Accuracy of Data in Abstracts of Published Research Articles*, 281 JAMA 1110, 1110-11 (1999) (finding that 18-68% of abstracts (varying by journal) include findings “that are inconsistent with or absent from the article’s body . . . even in large-circulation general medical journals”). There is a debate about what information should be included in biomedical abstracts, and how they can be made more accurate. See generally Ad Hoc Working Group for Critical Appraisal of the Medical Literature, *A Proposal for More Informative Abstracts of Clinical Articles*, 106 ANNALS INTERNAL MED. 598, 598-604 (1987).

<sup>54</sup> See Scott T. Weiss & Jonathan M. Samet, *An Assessment of Physician Knowledge of Epidemiology and Biostatistics*, 55 J. MED. EDUC. 692, 697 (1980) (“[P]hysicians may not be prepared adequately to evaluate medical literature”); Bailey Kuklin, *Probability Misestimates in Medical Care*, 59 ARK. L. REV. 527, 537 (2006) (discussing physicians’ difficulties with statistical reasoning).

<sup>55</sup> Sally Hopewell, *Better Reporting of Randomized Trials in Biomedical Journal and Conference Abstracts*, 34 J. INFO. SCI. 173 (2008) (suggesting that physicians form their first impressions of articles based on the abstracts); Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCIENCE 1124, 1128 (1974) (describing research on the anchoring effect).

<sup>56</sup> For other research suggesting disclosure policies, see Mark A. Rodwin, *Physicians’ Conflicts of Interest: the Limitations of Disclosure*, 321 NEW ENG. J. MED. 1405, 1405-08 (1989); Baruch A. Brody et al., *Expanding Disclosure of Conflicts of Interest: The Views of Stakeholders*, 25 IRB: ETHICS & HUM. RES. 1, 1-8 (2003); Roger S. Foster, *Conflicts of Interest: Recognition, Disclosure, and Management*, 196 J. AM. COLL. SURGEONS 505, 505-15 (2003); Michael S. Jellinek, *IRBs and Pharmaceutical Company Funding of Research*, 4 IRB: ETHICS & HUM. RES. 9 (1982); Ron Roizen, *Why I Oppose Drug Company Payment of Physician/Investigators on a Per Patient/Subject Basis*, 10 IRB: ETHICS & HUM. RES. 9, 9-10 (1988); Howard M. Spiro, *Mammon and Medicine: The Rewards of Clinical Trials*, 255 JAMA 1174, 1174 (1986); Heidi P. Forster et al., *The 2000 Revision of the Declaration of Helsinki: A Step Forward or More Confusion?*, 358 LANCET 1449, 1449-53 (2001); and Kenneth J.

It should be noted that mandatory disclosure of conflicting interests does not even purport to prevent science from being biased. It is a downstream remedy, one that attempts to break the chain between biased science and biased medicine. In fact, some experimental research suggests that disclosure mandates may actually exacerbate the biases in science.<sup>57</sup> Daylian Cain and colleagues constructed an estimation task and assigned human subjects to the roles of “estimators” and “advisors,” and then manipulated whether the advisors had conflicting interests, and, if so, whether they would be mandatorily disclosed to the estimators. One might hypothesize that a disclosure mandate would cause conflicted advisors to be more self-aware and less strident in their biases, but it instead did the opposite. The mandatory disclosure policy apparently created a sense of moral license, or caveat emptor, such that the advisors who were forced to disclose their conflicts gave advice that was even more biased than those who had no such disclosure mandate.<sup>58</sup> If a similar dynamic is at work in biomedical science, then disclosures are not just useless; they are deleterious.

## II. RE-CONCEIVING THE PROBLEM AND A SOLUTION

### A. THE ROOT CAUSES OF BIASED SCIENCE

Any real solution to biased science must address the source of the problem. How does industry-funded science become biased?

First, the company chooses the investigator that it wishes to support. In the most egregious cases, the company actually performs the research in its own labs or through a contract organization. Then the company “ghost-writes” the article, and thereafter recruits reputable scholars to put their names on the publication to give it a patina of objectivity.<sup>59</sup> For example, in one of the Vioxx papers discussed above, first author Jeffrey Lisse said in an interview that “Merck designed the trial, paid for the trial, ran the trial . . . [.] Merck came to me after the study was completed and said, ‘We want your help to work on the paper.’ The initial paper was written at Merck, and then it was sent to me for editing.”<sup>60</sup>

In recent years, there have been efforts to crack down on the worst abuses of ghost-writing, but it is simply the tip of the iceberg because the industry still provides the vast majority of funding for research, and thus can hand-pick which researchers it wishes to support. With many aspiring scholars, each

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Rothman, *Conflict of Interest: The New McCarthyism in Science*, 269 JAMA 2782, 2782-84 (1993).

<sup>57</sup> Daylian M. Cain, George Loewenstein & Don A. Moore, *The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest*, 34 J. LEGAL STUD. 1, 18 (2005); see also Ming Li & Kristóf Madarász, *When Mandatory Disclosure Hurts: Expert Advice and Conflicting Interests*, 139 J. ECON. THEORY 47, 48–50, 60, 62–63 (2008).

<sup>58</sup> This dynamic is similar to that documented by behavioral researchers in which imposition of a fine for a given behavior actually caused the frequency of that behavior to increase. See Uri Gneezy & Aldo Rustichini, *A Fine is a Price*, 29 J. LEGAL STUD. 1 (2000).

<sup>59</sup> See generally Moffatt & Elliott, *supra* note 7.

<sup>60</sup> 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) (quoting Alex Berenson, *Evidence in Vioxx Suits Shows Intervention by Merck Officials*, N.Y. TIMES Apr. 24, 2005, available at <http://www.nytimes.com/2005/04/24/business/24drug.html>).

trying to move up in academia or in a contract research organization, it is not hard for a company to find a research team that will produce favorable results. As one scholar, John Ioannidis, comments, “There is an intellectual conflict of interest that pressures researchers to find whatever it is that is most likely to get them funded.”<sup>61</sup> As another scholar has written, investigators “with a reputation for producing favorable results for drug companies’ products are likely to flourish, while those with more scrupulous standards are likely to go out of business.”<sup>62</sup> If a researcher benefits from such a corporate largesse but refuses to produce favorable results, he is unlikely to be so favored again. This is the tyranny of the second grant.

And there is no shortage of opportunities for the funded scholar to do the bidding of his corporate sponsor, even if unintentionally. The investigator makes dozens of discretionary decisions, each one presenting an opportunity to raise or lower the bar for the company’s product. Here are a few questions that the investigator must answer in designing, conducting, and analyzing the study:

- Whom will I select as collaborators?
- What will be our primary outcome variables (endpoints or proxies)?
- What scale will we use to measure them?
- What data will we collect for potentially confounding variables?
- What dosage will we use for the experimental product?
- What products will we use as controls, for placebo, or standard of care comparisons?
- What dosage will we use for the controls?
- Which population are we going to study?
- How large will our sample be?
- What will be the inclusion and exclusion criteria for our sample, both initially and as the study proceeds?
- Whom will we recruit as raters?
- When will we stop the study?
- What statistical methods will we employ?
- How many different hypotheses will we test in our dataset, and will these multiple tests be disclosed in the final paper?
- Should we publish any of our findings at all?
- Which conclusions will we report?
- How will we characterize our findings verbally?
- Which findings will we emphasize in the abstract, and which will we bury in the back?

“At every step of the process, there is room to distort results, a way to make a stronger claim, or to select what is going to be concluded.”<sup>63</sup> One need

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<sup>61</sup> David H. Freeman, *Lies, Damned Lies, and Medical Science*, ATLANTIC MONTHLY, Nov. 2010, at 80, available at <http://www.theatlantic.com/magazine/archive/2010/11/lies-damned-lies-and-medical-science/8269/> (quoting John Ioannidis).

<sup>62</sup> Arthur Schafer, *Biomedical Conflicts Of Interest: A Defence of the Sequestration Thesis – Learning From the Cases of Nancy Olivieri and David Healey*, 30 J. MED. ETHICS 8, 23 (2004).

<sup>63</sup> *Id.* In a provocative article, Ioannidis offers a mathematical model that demonstrates that because of these rampant commercial and other biases, and the many opportunities to

not assume that all industry-funded scholars are nefarious cretins; a raft of behavioral research in recent decades has shown that such “observer effects,” “optimism biases,” and other heuristics can distort decisions even when a person has every intention and every incentive to be accurate.<sup>64</sup>

#### B. MONEY-BLINDING AS A SOLUTION TO THE ROOT CAUSES

Science requires the exercise of professional discretion. There simply is no way to eliminate the exercise of scientists’ professional discretion in designing and conducting research studies, and there would seem to be no way to monitor or modify those decisions as they are made.

And science requires money. Lots of it. Unless there is a gigantic influx of money from the government or non-commercial interests, industry funding of biomedical science is inevitable and, admittedly, desirable.<sup>65</sup> As Leo Goldman explains, “[C]ompanies translate biologic advances into useable products for patients. They do it for a profit motive, but they do it, and it needs to be done.”<sup>66</sup>

This combination of professional discretion and industry money together creates the problem of scientific bias, and harms the perceived legitimacy of science. Still, there are institutional solutions available, ones that should seem familiar to scholars, editors, and policymakers, because they borrow from current practices in related contexts. For decades, journal editors have insisted that whenever possible, biomedical research should be blinded. Indeed, “any process using a human as a perceptor, rater, or interpreter should be ‘as blind as possible for as long as possible.’”<sup>67</sup> The randomized, controlled “double-blind” study has become the scientific “gold standard.”<sup>68</sup>

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express them, “most claimed research findings are false.” John P. A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLoS MED. 0696, 0696 (2005); see also David L. Sackett, *Bias in Analytic Research*, 32 J. CHRONIC DISEASES 51, 51-63 (1979) (describing some of these sources of bias); Lisa A. Bero & Drummond Rennie, *Influences on the Quality of Published Drug Studies*, 12 INT’L J. TECH. ASSESS. HEALTH CARE 209, 209-37 (1996) (also describing some sources of bias).

<sup>64</sup> See Robertson, *supra* note 23, at 185-88 (reviewing some of this literature); D. Michael Risinger et al., *The Daubert/Kumho Implications of Observer Effects in Forensic Science: Hidden Problems of Expectation and Suggestion*, 90 CAL. L. REV. 1, 18 (2002) (reviewing the behavioral research literature).

<sup>65</sup> Many commentators opine that an outright ban on industry funding and a replacement with tax dollars is the only viable solution. See, e.g., Schafer, *supra* note 62, at 23 (“If the community values public science in the public interest then it will have to be paid for by public tax dollars.”). But see William M. Sage, *Some Principles Require Principals: Why Banning “Conflicts of Interest” Won’t Solve Incentive Problems in Biomedical Research*, 85 TEX. L. REV. 1413, 1448-49 (2007) (arguing for more direct regulation of privately funded biomedical research).

<sup>66</sup> Bodenheimer, *supra* note 13, at 1543.

<sup>67</sup> Robert Rosenthal, *How Often Are Our Numbers Wrong?*, 33 AM. PSYCHOLOGIST 1005, 1007 (1978); see generally D. Michael Risinger, *The NAS/NRC Report on Forensic Science: A Glass Nine-Tenths Full (This Is About the Other Tenth)*, 50 JURIMETRICS J. 21 (forthcoming 2011), available at <http://ssrn.com/abstract=1437276> (discussing similar problems and potential solutions in the forensic science field).

<sup>68</sup> See *TMJ Implants, Inc. v. Aetna, Inc.*, 498 F.3d 1175, 1195 (10th Cir. 2007) (recognizing that the double-blind study is the gold standard in medicine); Grade Working Group, *Grading Quality of Evidence and Strength of Recommendations*, 328 BRIT. MED. J. 1, 2 (2004) (explaining that reviewers assessing the quality of a study “may state that failure to blind



The requirement of randomization first effectively blinds the investigator in the selection process, preventing her from handpicking favorable subjects for the treatment condition versus the control condition. A double-blind study is one in which the human subjects are unaware of whether they are receiving a placebo or the studied intervention, and where the clinicians actually assessing the outcomes are also unaware of which subjects are in the “control” and the “treatment” conditions.<sup>69</sup> Biomedical journal editors, peer reviewers, and readers now expect blinding to be employed wherever feasible.<sup>70</sup>

These blinds do nothing for the eighteen opportunities to exercise biased discretion enumerated above. What is needed, then, is a more robust blind that covers all these other discretionary decisions. In short, companies should be allowed to fund studies by competent investigators who provide financial and scientific accountability, but companies should be blinded to the selection of investigators, just as investigators are blinded to the selection of human subjects. Companies should not be allowed to handpick the investigators who are most likely to run favorable studies, nor implicitly condition future funding on favorable performance by those investigators. Although companies should be free to tie their money to specific products and hypotheses, companies should not also be allowed to unduly influence the design or conduct of the scientific studies that they fund. This method for reducing industry influence could be called a “money blind.”<sup>71</sup>

Other scholars have, in passing, suggested such a reform, but it remains to be seen whether the concept is practicable and legally viable.<sup>72</sup> Such a money

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patients and physicians reduced the quality of evidence for an intervention’s impact on pain severity and that they considered this a serious limitation”).

<sup>69</sup> See David P. Byar et al., *Design Considerations for AIDS Trials*, 323 NEW ENG. J. MED. 1343, 1345 (1990) (“Blinding is especially desirable when subjective end points, such as pain, functional status, or quality of life, are studied, because such evaluations are open to substantial bias.”).

<sup>70</sup> In some contexts, it is simply not feasible to require single or double blinding. For example, in the testing of surgical techniques or medical devices, both the surgeon and the patient may need to know what is being done. See Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 391 (2002) (describing these limits).

<sup>71</sup> Alternatively, following on the “double blind” model, this method could be called a “triple blind.” Alas, the term has already been deployed for other purposes. *Triple Blind*, DORLAND’S MEDICAL DICTIONARY FOR HEALTH CONSUMERS (2007), available at <http://medical-dictionary.thefreedictionary.com/triple+blind> (defining “triple blind” as “pertaining to clinical trial other experiment in which neither the subject nor the person administering the treatment nor the person evaluating the response to treatment knows which subjects are receiving a particular treatment or lack of treatment”).

<sup>72</sup> Dennis Thompson has suggested that blinding could be employed in the medical context to solve conflict of interest problems. See Thompson, *supra* note 46, at 575 (“Because of the limitations of disclosure, more stringent methods of enforcement deserve consideration, especially in cases of more severe kinds of conflict of interest. Other methods (roughly in order of increasing stringency) include mediation (devices such as blind trusts that insulate the physician from the secondary interest) . . .”). Sheldon Krinsky has called for the establishment of a new National Institute for Drug Testing (NIDT), which would receive industry funds but then itself organize the clinical trial. SHELDON KRINSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? 229 (2003). Arthur Schafer has suggested that, “One practical possibility might be to require of any drug company which desires to bring a new drug to market that it provide to an independent institute all the funding necessary for the design and performance of a clinical trial of its drug. The institute would then allocate to qualified university and hospital

blind would require an intermediary agency between the funder and the investigator.<sup>73</sup> The funder would provide to the intermediary the product for testing and designate a testable hypothesis (i.e., that the product will be safe and/or effective for some specified clinical indication). The intermediary would then determine how much money would be necessary to properly test that hypothesis, and require such payment in advance.<sup>74</sup> The funder will demand assurances that the investigators will be competent and that the funds will be managed reasonably. The intermediary would then select an investigator, disburse the money, oversee design of the study, and provide financial accountability.<sup>75</sup>

Such an intermediary would have its own overhead costs that would need to be recouped, presumably from the funders. However, the funders are already performing the tasks of selecting investigators and overseeing their research, so there might be little net increase in expense. To the extent that NIH investigators enjoy more autonomy from the funder, and could develop an economy of scale, the oversight costs actually might be less.

In principle, a for-profit, non-profit, or governmental agency could be created to serve as the intermediary. However, the NIH would seem to be the natural candidate for this role, since it already has developed significant institutional legitimacy and the expertise to review approximately 65,000 grant applications per year, from which it distributes 14,600 grants totaling \$5.66 billion in awards per year.<sup>76</sup> The NIH could thus deploy its current procedures and infrastructure to disburse the industry money, alongside the

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researchers the task of conducting the necessary clinical trials.” Schafer, *supra* note 62, at 23. See also MARCIA ANGELL, *THE TRUTH ABOUT THE PHARMACEUTICAL INDUSTRY: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 245 (2004) (calling for an independent drug evaluation agency within the NIH).

<sup>73</sup> Some scholars have suggested that academic medical centers could act as an intermediary of sorts for unrestricted grants. See Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 JAMA 429, 432 (2006) (“To promote scientific progress, [Academic Medical Centers] should be able to accept grants for general support of research (no specific deliverable products) from pharmaceutical and device companies, provided that the grants are not designated for use by specific individuals. As long as the institution stands between the individual investigator and the company making the grant, the likelihood of undue influence is minimized but certainly not eliminated”); see also Bodenheimer, *supra* note 13, at 1543 (“Some investigators interviewed for this article felt that drug trials should be funded by industry but that design, implementation, data analysis, and publication should be controlled entirely by academic medical centers and investigators.”).

<sup>74</sup> In practice, some professional judgment will be required to assess whether the funder’s stipulations are reasonable, or whether they are instead attempts to bias the design of the study. For example, if a study is designed to explore safety, then severely underfunding the study could cause the resulting study to be underpowered, which would then increase the odds of falsely affirming the null hypothesis that there are no side effects.

<sup>75</sup> Alternatively, an investigator may conceive of a hypothesis and experiment to test some product and then seek funding from the intermediary. If the intermediary finds the proposal promising, it could then request support from the company. The company could then agree to disburse the funds to the intermediary, without knowing the identity of the researcher or the particular research design.

<sup>76</sup> NAT’L INST. OF HEALTH, *Research Project Grants & Other Mechanisms: Competing Applications, Awards, Success Rates, and Total Funding Made with Direct Authority and Superfund Funds*, by NIH Institutes/Center, *Grant Mechanisms, and Activity Codes*, NIH RES. PORTFOLIO ONLINE REPORTING TOOLS (Dec. 17, 2010), <http://report.nih.gov/FileLink.aspx?rid=601>.

federal government money. The NIH already works in 229 different disease areas, which suggests that it would have expertise to select and oversee investigators in virtually any area that industry would seek to fund research.<sup>77</sup> The NIH also appears to be quite selective in assessing investigators and research protocols. In 2010, the NIH approved only twenty-three percent of the grant applications it received.<sup>78</sup> Under NIH policies, grant reviewers must evaluate all aspects of a prospective research project, including “the competency of the proposed staff in relation to the type of research involved.”<sup>79</sup> Federal courts reviewing aspects of these protocols have found them “reasonable and fair.”<sup>80</sup> Given the NIH’s longstanding expertise, the drug and device industry should have some confidence that their money will be spent appropriately.

For clinical trials that will become the basis of an application to the FDA, it may instead be more sensible for the FDA to itself serve as the intermediary, if one is needed at all.<sup>81</sup> Intermediary services may be less critical in this context, since the FDA already consults closely with the industry in design and implementation of such studies, and thus may be able to police bias in a way that ex post peer reviewers cannot.<sup>82</sup>

The money blind would be applicable to double-blind randomized controlled trials, as well as other sorts of biomedical research.<sup>83</sup> Single-blind experiments, open-label experiments, retrospective cohort studies, and other observational studies all have a role in the literature, but they provide even more opportunities for the investigators to be biased. Even if it is not feasible to use double-blind randomized control methods for a given question, it would still be feasible to impose a blinding intermediary to create some distance between the industry funder and the investigator. Although this proposal is focused directly on industry funding of studies, this is admittedly not the only vector of potential industry influence. Companies also create relationships directly with investigators, including consultancies and grants to their academic institutions, which may curry favor. Even with a money blind in place, the companies may be able to identify the most likely recipients of funds and co-opt them with side payments or other forms of influence. When

<sup>77</sup> NAT’L INST. OF HEALTH, *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, NIH RES. PORTFOLIO ONLINE REPORTING TOOLS, <http://report.nih.gov/rcdc/categories/> (table data as of Mar. 15, 2011).

<sup>78</sup> See NAT’L INST. OF HEALTH, *supra* note 76 (reporting 14,600 grants distributed out of 65,000 grant applications in 2010).

<sup>79</sup> HHS Evaluation and Disposition of Applications, 42 C.F.R. § 52.5(b) (2010).

<sup>80</sup> *Grassetti v. Weinberger*, 408 F. Supp. 142, 151 (N.D. Cal. 1976).

<sup>81</sup> The FDA, however, has greater risks of regulatory capture, *see infra* note 92, and may be inadequately staffed to take on these responsibilities. See U.S. GOV’T ACCOUNTABILITY OFFICE, FOOD AND DRUG ADMINISTRATION: FDA FACES CHALLENGES MEETING ITS GROWING MEDICAL PRODUCT RESPONSIBILITIES AND SHOULD DEVELOP COMPLETE ESTIMATES OF ITS RESOURCE NEEDS 16 (2009), available at <http://www.gao.gov/new.items/d09581.pdf>.

<sup>82</sup> See, e.g., Early Consultation, 21 C.F.R. § 312.82 (2010) (encouraging drug makers to work with regulators “to review and reach agreement on the design” of studies before they are carried out).

<sup>83</sup> In 2009, a review of the literature that the FDA used to approve cardiovascular devices found that although almost all the studies were industry-funded, they were extremely weak methodologically, and only nine percent of them were double-blinded. Sanket S. Dhruva et al., *Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices*, 302 JAMA 2679, 2682 tbl.1 (2009).

these investigators then apply for and receive funding through the intermediary, they would be just as biased as if they had received it directly from the company.

When selecting investigators, the NIH should demand full disclosures of such relationships, just as it already reviews conflicts of interest. Using disclosures prospectively, to choose between potential researchers, avoids some of the problems with putting disclosures on journal articles, after the research is done.<sup>84</sup> All other things being equal, the intermediary should award grants to researchers that have the fewest such relationships, and that preference should create an incentive for competing investigators to avoid such relationships.

Still, one might worry that the investigators who have the closest relationships with industry will also have the greatest expertise in testing the drug, creating a Gordian knot for the intermediary.

On the other hand, it may be that much of the research that is now conducted by investigators closely affiliated with industry could instead be conducted by others who absolutely reject such relationships. After all, science has two different functions—the generation of novel hypotheses and the testing of those hypotheses.<sup>85</sup> Perhaps the top scholars in the field must necessarily have relationships with industry to advise and assist them in generating novel compounds and groundbreaking hypotheses. But it is not clear why those persons also need to be the ones testing those hypotheses, conducting the mundane and routine tests of efficacy and safety. After all, a well-run experiment is more about mechanical adherence to a protocol, methodical record keeping, complete transparency, financial accountability, and logistical management of thousands of patients at potentially a dozen research centers.<sup>86</sup> Thus, when the intermediary weighs proposals by research teams, it may perform an initial screen to eliminate investigators that appear to be conflicted or incompetent for the task, and then simply award the grant randomly to any one of the remaining research teams.<sup>87</sup>

One also should not be naïve about the possibility that this intermediary institution might become too cozy with the companies that are providing its revenue, and thereby shade its own decisions in favor of the companies' interests rather than patients' interests. The NIH had an embarrassing string of scandals in the early 2000s, which revealed that NIH officials also received

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<sup>84</sup> See discussion *supra* Part I.B.3.

<sup>85</sup> See DEAN KEITH SIMONTON, *SCIENTIFIC GENIUS: A PSYCHOLOGY OF SCIENCE* 5, 42 (1990) (discussing Thomas Kuhn's recognition of an "essential tension" between the "traditionalist" and the "iconoclast" roles of a scientist and F. C. Bartlett's differentiation between "original and routine information processing").

<sup>86</sup> Indeed, the industry already outsources much of these routine testing functions to contract research organizations, the key is simply to break the yoke of influence over them. See Schafer, *supra* note 62, at 23 (under the status quo, "[c]ontract research organisations with a reputation for producing favourable results for drug companies' products are likely to flourish, while those with more scrupulous standards are likely to go out of business"); see generally Phillip Mirowski & Robert Van Horn, *The Contract Research Organization and the Commercialization of Scientific Research*, 35 *SOC. STUD. SCI.* 503 (2005) (describing this trend).

<sup>87</sup> I thank Larry Lessig for this insight.

industry money through consulting and other relationships.<sup>88</sup> Some have argued that the FDA has been “captured” by the companies it regulates, a problem that has allegedly gotten worse after the creation of a user-fee driven financing system.<sup>89</sup> Still, the analysis must be comparative. Presumably, the NIH could maintain more independence from the commercial interests than the company managers that are currently administering these grants to investigators. Moreover, the randomization function would also be useful to prevent the intermediary from exercising biased discretion.

Admittedly, the money-blinding mechanism would not eliminate every sort of bias that currently infects biomedical science. As long as industry chooses the topics for the research it funds, those topics will be biased towards investigations of patented drugs and devices for indications that have large potential markets. Non-financial biases will also continue to exist. For example, published research will continue to be biased towards studies that purport to disprove null hypotheses, rather than those that affirm the null hypothesis.<sup>90</sup> The latter study, which simply shows that something does not work, seems less interesting and less exciting. One could craft other policies to address those problems while still conceding that the money-blind solves the problem it addresses.

### III. IMPLEMENTATION OF MONEY-BLINDING WITHOUT VIOLATING THE FIRST AMENDMENT

How would such a requirement of money-blinding be enforced? There are several options for bringing such a mechanism to fruition, including private ordering mechanisms, which do not raise First Amendment problems, and regulatory efforts, which raise surmountable First Amendment problems. This section considers each.

#### A. PRIVATE ORDERING

In a well-functioning market for information, one might hope that the industry would voluntarily adopt money-blinding as a way to maximize the persuasiveness of its publications, at least when its products really are as safe and effective as it claims.<sup>91</sup> This dynamic, however, assumes that biomedical

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<sup>88</sup> See David Willman, *Stealth Merger: Drug Companies and Government Medical Research*, L.A. TIMES, Dec. 7, 2003, <http://articles.latimes.com/2003/dec/07/nation/na-nih7>; David Willman, *Ex-NIH Director Now Favors Limiting Drug Company Ties*, L.A. TIMES, Mar. 13, 2004, <http://articles.latimes.com/2004/mar/13/nation/na-nih13>.

<sup>89</sup> Curt D. Furberg et al., *The FDA and Drug Safety: A Proposal for Sweeping Changes*, 166 ARCHIVES INTERNAL MED. 1938, 1940 (2006) (“Another problem may relate to the source of FDA funding. Critics of the FDA have claimed that the agency has gotten too close to the industry it is supposed to regulate, in part because of its dependence on user fees. Indeed, each of the past 3 iterations of the Prescription Drug User Fee Act has required that the FDA produce or perform something of value to the pharmaceutical industry in exchange for which the industry would agree to pay the fees. Until the last iteration, the FDA was prohibited from using any funds from user fees to support postmarketing studies of safety.”).

<sup>90</sup> See Gwendolyn B. Emerson & James D. Heckman, *Testing for the Presence of Positive-Outcome Bias in Peer Review*, 170 ARCHIVES INTERNAL MED. 1934, 1936 (2010) (showing positive-outcome bias in a randomized trial with peer reviewers for two journals).

<sup>91</sup> See generally Winand Emons, *Credence Goods and Fraudulent Experts*, 28 RAND J. ECON. 107, 107 (1997) (providing a skeptical analysis of a similar market for advice); Gillian

journal editors and readers are able to, and actually do, perceive the biases in un-blinded research and discount the credibility of such studies accordingly.<sup>92</sup> As the foregoing analysis shows, this assumption is false.<sup>93</sup>

Alternatively, one could imagine that the editors and peer reviewers of biomedical journals, such as the *New England Journal of Medicine* or the *Journal of the American Medical Association*, would simply refuse to publish studies that are not money-blinded, just as they currently disfavor studies that are not double-blinded. Of course, there is a transition problem. An intermediary institution will need to step forward, and there are currently thousands of merely double-blinded studies that are in the pipeline. But that problem is manageable.

More fundamentally, there are some reasons to think that the biomedical journals may not rise to this occasion. First, there is a race-to-the-bottom problem. No single journal will want to unilaterally exclude the large proportion of articles that are industry-funded, if there are other journals blithely continuing to accept merely double-blinded studies. No journal wants to be scooped in reporting a significant advance in medical practice.

Moreover, some of the biomedical journals are themselves addicted to industry money that comes either directly for the purpose of advertising, or to purchase reprints of favorable articles, or indirectly through the professional societies that run the journals and receive grants from industry.<sup>94</sup> Thus, journal editors may be susceptible to industry boycotts or more subtle commercial pressures, just as they have previously expressed gratitude, on their editorial pages, for the largesse they currently enjoy.<sup>95</sup>

Thus, if biomedical journals are going to succeed in implementing a money-blinding mandate, they may need to do so collectively, perhaps through the International Committee of Medical Journal Editors (ICMJE). Currently, nearly 1,000 journals follow the ICMJE's Uniform Requirements for Manuscripts Submitted to Biomedical Journals, which includes various requirements relating to conflicts of interests, but says nothing about blinding.<sup>96</sup> One may reasonably hope that biomedical journals will rise to this occasion, but there are also other available levers of influence.

Hadfield et al., *Information-Based Principles for Rethinking Consumer Protection Policy*, 21 J. CONSUMER POL'Y 131, 144 (1998) ("The complex nature of information also requires careful analysis of the potential for market mechanisms to provide the information consumers might want and need. Information is a notoriously difficult commodity over which to contract. Potential buyers of information have difficulty determining, in their uninformed state, the value of the information and thus the price they are willing to pay for it.")

<sup>92</sup> See Robertson, *supra* note 43 (discussing this dynamic, and showing empirical evidence that laypersons fail to perform such discounting).

<sup>93</sup> See discussion *supra* Part I.B (discussing peer review and disclosures as ineffective solutions).

<sup>94</sup> See Debbie Sieber et al., *Extent and Nature of Advertising in Leading Hematology-Oncology Journals*, 32 AM. J. CLINICAL ONCOLOGY 92, 92-93 (2009) (citing sources that the industry spent \$850 million on journal advertising in 2005).

<sup>95</sup> See David Orentlicher & Michael K. Hehir, *Advertising Policies of Medical Journals: Conflicts of Interest for Journal Editors and Professional Societies*, 27 J.L. MED. & ETHICS 113, 114 (1999) (discussing the conflicts of interest inherent in the practice of accepting industry money, and discussing journal editors' feelings and expressions of gratitude).

<sup>96</sup> See *Journals that Have Requested Inclusion on the List of Publications that Follow the ICMJE's Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, INT'L COMM. OF MED. JOURNAL EDITORS, <http://www.icmje.org/journals.html> (last visited Apr. 4,

Universities could exert influence in favor of money-blinding as a way to manage the conflicts of interests of its faculty. In recent years, several schools have made prominent efforts to revise their policies regarding whether and how faculty may accept money from the pharmaceutical and device industries.<sup>97</sup> Announcing such revisions, Dr. Philip A. Pizzo, Dean of Stanford Medical School, said, “We welcome interactions with industry that are positive and collaborative. But where I think the line should not be crossed and where we are not going to allow our full-time or part-time faculty to engage is in marketing.”<sup>98</sup> Yet, the industry itself seems to put biomedical science on the same side of the line as marketing, and thus university policies arguably should as well.<sup>99</sup> In principle, after transitional problems are resolved, faculties should welcome such a change towards money-blinding, if it allows them to continue to garner industry funding without having to be accountable to industry influence.

Still, a significant portion of biomedical science supported by industry is actually performed by the companies themselves through subsidiaries or clinical practice companies, without any involvement by university researchers.<sup>100</sup> This is the most extreme form of un-blinded research, given that industry scientists can be handpicked and then fired at will, creating the greatest incentives and temptations for bias. Arguably, this practice should be stopped, and to the extent that such research is intended to inform and influence prescribing behavior, it should be outsourced to credible academic researchers, working with the protection of blinding. By refusing to publish un-blinded studies, biomedical journal editors have the leverage to cause a shift in the economics of biomedical research.

If biomedical journal authors, editors, and/or universities succeed in enforcing a norm of money-blinding, the industry could comply by simply channeling their existing expenditures for biomedical research to the intermediary. On the margin, however, companies may decide that it is not worthwhile to fund some studies, and face the risk of adverse results, if they are unable to influence the study. Thus, it is possible that on net, fewer

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2011) (listing journals); *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*, INT’L COMM. OF MED. JOURNAL EDITORS (Apr. 2011) [http://www.icmje.org/urm\\_full.pdf](http://www.icmje.org/urm_full.pdf) (providing the policy).

<sup>97</sup> See, e.g., Natasha Singer, *Stanford Medical School to Expand Ethics Rules*, N.Y. TIMES, Mar. 21, 2010, at B3, available at <http://www.nytimes.com/2010/03/22/health/policy/22docs.html> (describing a new prohibition on adjunct faculty “giving paid speeches drafted by the makers of drugs or medical devices”); *School of Medicine Policy Overview*, STANFORD SCHOOL OF MEDICINE, <http://med.stanford.edu/coi/overview.html> (last visited Apr. 14, 2011). But see John Dorschner, *Investigators Question Drug-Makers Payments to University of Miami Doctors*, MIAMI HERALD, Dec. 20, 2010, <http://www.miamiherald.com/2010/12/20/1982509/investigators-question-drug-makers.html#ixzz18lCuiADQ> (“Stanford was the lead example [of non-compliance with its own policy], with two doctors earning more than \$100,000 in the past year for making speeches paid for by drug companies, even though Stanford forbids its faculty from taking such fees.”).

<sup>98</sup> Singer, *supra* note 97.

<sup>99</sup> See *supra* text accompanying note 7 (quoting Pfizer documents).

<sup>100</sup> Jef Akst, *Contract Research on the Rise*, THE SCIENTIST (Aug. 5, 2009), available at <http://www.the-scientist.com/blog/display/55878/> (describing the history of this industry and its recent changes); see also sources cited *supra* note 86.

research dollars will be spent, but the studies that are funded and published will be less biased.

#### B. NARROWLY CONDITIONING NIH FUNDING

Suppose that the biomedical journal authors and editors do not adopt money-blinding within a reasonable time. What levers are available to regulators to force such a transition? Are such governmental interventions consistent with the First Amendment?

One option would be to attach conditions to the billions of dollars that the NIH spends in support of biomedical research. The NIH could also require that the individual investigators who receive funding for specific projects publish the primary results only in journals that have a satisfactory money-blinding policy.<sup>101</sup> In effect, this policy would force journals to choose between publishing NIH-funded research or publishing un-blinded research.

The federal government already attaches all sorts of conditions to its research money, such as the requirement to submit protocols to Institutional Review Board and the requirement to publish raw data.<sup>102</sup> Indeed, the NIH has compiled a list of over seventy other conditions on grant funding, on a gamut of topics from animal welfare and patient confidentiality, to the use of seat belts and smoke detectors.<sup>103</sup>

Would such a condition on federal funding survive constitutional scrutiny? Arguably, it is a restriction on free speech, essentially telling investigators who receive federal money that they cannot write about their funded research in certain outlets, at least not until they have first published their primary results in money-blinded journals, as required by their grant contract. However, it is an extremely narrow restriction on speech, tailored to the expenditure of federal moneys. Likewise, one could imagine that when the United States Army purchases advertising from Madison Avenue agencies to support its recruiting efforts, the Army specifies which sorts of magazines to target and which to avoid (e.g., *Guns and Ammo* rather than *Creative Knitting*). Such an ad vendor could hardly raise a free speech objection to such a condition of federal funding.

Indeed, in *Rust v. Sullivan*, the government had chosen to subsidize certain family planning services, while also prohibiting the funds from being used for counseling about abortion as a form of family planning.<sup>104</sup> The Supreme Court upheld the law, holding that:

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<sup>101</sup> Schematically, this mandate would be most similar to the requirement that investigators register at ClinicalTrials.gov certain clinical trials within twenty-one days of the first subject being enrolled, and then report summary results within one year of the completion date. See Nat'l Inst. of Health, *NIH Grants Policy Statement*, NIH OFFICE OF EXTRAMURAL RESEARCH, § 4.1.3 exhibit 4, [http://grants.nih.gov/grants/policy/nihgps\\_2010/nihgps\\_ch4.htm#public\\_policy\\_requirements\\_other\\_mandates](http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch4.htm#public_policy_requirements_other_mandates) (last visited Apr. 4, 2011).

<sup>102</sup> See Basic HHS Policy for Protection of Human Research Subjects: To What Does this Policy Apply?, 45 C.F.R. § 46.101 (2008) (known as "the Common Rule"); Intangible Property, 45 C.F.R. § 74.36 (2008) (giving the government the right to publish data and requiring recipient to publish data after Freedom of Information Act requests).

<sup>103</sup> See Nat'l Inst. of Health, *supra* note 101, § 4.1.

<sup>104</sup> 500 U.S. 173, 191 (1991).



the Government is not denying a benefit to anyone, but is instead simply insisting that public funds be spent for the purposes for which they were authorized. The Secretary's regulations do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities.<sup>105</sup>

Likewise here, the strings on NIH funding would simply be a narrow insistence about the way those public funds should be used, and thus would easily survive constitutional scrutiny. If an investigator prefers to publish in journals that do not require money-blinding, then she can simply seek funding elsewhere. If, on the other hand, an investigator accepts federal funding, the publication requirement applies only to that investigator, not to other researchers who are free to take industry money directly and publish in any journal they see fit. Thus, the constitutional case is straightforward.

### C. ATTACHING STRINGS TO FEDERAL FUNDING

Suppose that the narrow conditions on funding would not suffice to change the behavior of top journal editors and authors, and thus the behavior of industry funders.<sup>106</sup> A more ambitious governmental policy would attach strings that reach beyond the individual funded projects to impact all of the funded investigator's work, and all of the work of other investigators at her institution. The government could require that any institution that receives NIH funding (or other federal funding) refuse all industry funding to the institution, unless the industry money is routed through an accredited blinding intermediary.<sup>107</sup> Many federal grant programs are already limited to non-profit and public entities, and thereby exclude industry from receiving such funds directly.<sup>108</sup> And, the federal government already requires all grant recipients to maintain a conflict of interest policy, and to police the conflicts of interest that might impact the federal grant.<sup>109</sup> This proposed policy extends that logic, building a taller wall between industry and the recipients of federal grants.

Such a proposed policy would force an institutional choice between federal government money versus un-blinded industry money. Of course, it is

<sup>105</sup> *Id.* at 196.

<sup>106</sup> In this situation, journals would likely become specialized, some accepting industry-funded papers without the money blind and others accepting NIH-funded, foundation-funded, and money-blinded papers (if any). This outcome may be better than the status quo, if it helps consumers of science more appropriately weigh their reliance on the studies they read, using the journal's name as a proxy for scientific objectivity. Nonetheless, the following analysis presumes that regulators want to go further to cause a more complete shift to money-blinding.

<sup>107</sup> An alternative policy would be to require all investigators at the funded institution to publish exclusively in money-blinded journals, regardless of the source of their funding. This would be a more direct regulation of speech, and is set aside for now.

<sup>108</sup> See, e.g., HEALTH RESOURCES AND SERVICES ADMIN., *The Health Center Program: Summary of Key Health Center Program Requirements*, <http://bphc.hrsa.gov/about/requirements.htm> (last visited Apr. 7, 2011) ("Health centers are non-profit private or public entities . . ."); THE OFFICE OF MINORITY HEALTH, *Non-Profit Organizations*, <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=2> (last visited Apr. 7, 2011) ("Only public or nonprofit private institutions of higher learning may apply for training grants . . .").

<sup>109</sup> See 40 C.F.R. § 50.605 (2010).

possible that some institutions would choose to reject all federal funding, rather than mandate money-blinding. Given the amount of money involved and the comparative prestige associated with NIH funding, it seems unlikely that major research institutions would reject federal funding with such strings attached.

This proposed policy is more expansive than the previous one (*see* Part III.B *supra*) because it does not merely govern how the institution will spend the public money it receives. By instead screening which institutions receive federal money, this policy promotes public policy goals that are related to, but distinct from, the expenditure of public money, and thus arguably cannot take advantage of the narrow holding in *Rust*. Of course, the federal government has long used such string-tying mechanisms to achieve various and sundry public policy purposes that are not directly relevant to the scientific research being funded. For example, Congress has prohibited recipient institutions from discriminating against women in college sports and also forced such institutions to cooperate with discrimination against homosexuals in the military.<sup>110</sup>

In 2008, the Supreme Court heard litigation over the Solomon Amendment, which required all institutions that receive federal funding to cooperate with military recruiters, notwithstanding their discriminatory practices.<sup>111</sup> The Solomon Amendment seemed particularly onerous to law schools since the federal money was given for biomedical research on specified projects and had no direct relationship to the career services offices at the law schools, which nonetheless fell under its regulatory ambit. In *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, the Supreme Court unanimously upheld the constitutionality of the statute, holding that it neither denies the institutions the right to speak, nor requires them to say anything.<sup>112</sup> By interpreting the ambit of the statute in this way, the Supreme Court avoided a clash with the First Amendment. Likewise, the instant policy does not directly regulate speech. Even if a university accepts federal funding, it can continue to say or write anything it wants, and thus there is no clash with the First Amendment. As the Supreme Court has said, “Congress is free to attach reasonable and unambiguous conditions to federal financial assistance that educational institutions are not obligated to accept.”<sup>113</sup>

Still, to the extent that the proposed policy restricts grant recipients from also receiving un-blinded money from industry, it could indirectly regulate scientific expression.<sup>114</sup> This analysis raises the “unconstitutional conditions”

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<sup>110</sup> *See* *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.* (FAIR), 547 U.S. 47, 58 (2006) (“Either allow military recruiters the same access to students afforded any other recruiter or forgo certain federal funds.”).

<sup>111</sup> *See* 10 U.S.C.A. § 983(b) (West 2011). The Solomon Amendment was repealed in early 2011.

<sup>112</sup> *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.* (FAIR), 547 U.S. at 60.

<sup>113</sup> *Grove City College v. Bell*, 465 U.S. 555, 575 (1984). In *Grove City*, the Supreme Court rejected a private college’s claim that conditioning federal funds on its compliance with Title IX of the Education Amendments of 1972 violated the First Amendment, without even reaching the First Amendment claims, because the school was free to decline federal money.

<sup>114</sup> In the context of political campaign finance, the Supreme Court has long scrutinized the regulation of money contributions because, in the mass media age, money is a necessary precondition to speech reaching its audience. *See generally* *Citizens United v. FEC*, 130 S. Ct. 876 (2010) (holding that corporations have free speech rights); *Buckley v. Valeo*, 424 U.S. 1, 19

doctrine.<sup>115</sup> “The government may not deny a benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit.”<sup>116</sup> For example, in *FCC v. League of Women Voters of California*, the Supreme Court struck down a statute that withheld federal funding to public radio stations that insisted upon doing editorials on the air, a form of expression that “lies at the heart of First Amendment protection.”<sup>117</sup>

On the other hand, because the government is here acting as contractor and not as sovereign, perhaps the indirect restrictions on speech would not compel strict scrutiny at all, but instead may require only a reasonableness analysis. In *Board of County Commissioners, Wabaunsee County, Kansas v. Umbehr*, the Supreme Court held that “[d]eference is therefore due to the government’s reasonable assessments of its interests as contractor.”<sup>118</sup> The argument would be that the NIH’s restrictions will “prevail if it can persuade the District Court that the [the Government’s] legitimate interests as contractor, deferentially viewed, outweigh the free speech interests at stake.”<sup>119</sup> If a court were to apply *Umbehr* to a situation involving the financing of medical research, then the regulation should be fairly easy to defend. Given

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(1976) (“A restriction on the amount of money a person or group can spend on political communication during a campaign necessarily reduces the quantity of expression by restricting the number of issues discussed, the depth of their exploration, and the size of the audience reached. This is because virtually every means of communicating ideas in today’s mass society requires the expenditure of money.”). Arguably, the proposed policy also regulates the grant recipient’s right of free association by proscribing the terms in which the recipient can associate with industry. In *Boy Scouts of America v. Dale*, 530 U. S. 640 (2000), the Supreme Court held that the Boy Scouts’ freedom of expressive association was violated by a state law that required the organization to accept a homosexual scoutmaster. The pattern in *Boy Scouts* was thus the opposite of the present proposal, which prohibits certain associations. Regardless of that distinction, the *Boy Scouts* holding is likely inapposite to the proposed policy for the same reason that the Court distinguished the case in *Rumsfeld v. FAIR*: the military recruiters were not members of the universities. *Id.* at 648.

<sup>115</sup> See generally Kathleen Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413, 1421 (1989).

<sup>116</sup> *United States v. Am. Library Ass’n, Inc.*, 539 U.S. 194, 210 (2003) (quoting Bd. of Cnty. Comm’rs, *Wabaunsee Cnty. v. Umbehr*, 518 U.S. 668, 674 (1996) (internal quotation marks omitted); see also *Perry v. Sindermann*, 408 U.S. 593, 597 (1972) (“[I]f the government could deny a benefit to a person because of his constitutionally protected speech or associations, his exercise of those freedoms would in effect be penalized and inhibited. This would allow the government to ‘produce a result which [it] could not command directly.’ Such interference with constitutional rights is impermissible.”).

<sup>117</sup> 468 U.S. 364, 381 (1984).

<sup>118</sup> 518 U.S. 668, 678 (1996). The Court wrote that the plaintiff “is correct that if the Board had exercised sovereign power against him as a citizen in response to his political speech, it would be required to demonstrate that its action was narrowly tailored to serve a compelling governmental interest. But in this case, as in government employment cases, the Board exercised contractual power, and its interests as a public service provider, including its interest in being free from intensive judicial supervision of its daily management functions, are potentially implicated. Deference is therefore due to the government’s reasonable assessments of its interests as contractor.” *Id.*

<sup>119</sup> *Id.* at 685 (part III). This analysis presumes that the speech at issue is a matter of public concern. Although the First Amendment protects government employees and contractors’ rights to speak freely “on matters of public concern[,] . . . speech on merely private employment matters is unprotected.” *Id.* at 675 (citing *Connick v. Myers*, 461 U.S. 138, 146 (1983)). It is not precisely clear where speech about the effectiveness of a drug would fall on this spectrum.

the problem of biased science and its impact on the practice of medicine and national healthcare costs, along with the failure of status quo remedies of peer review and disclosure mandates, this simple weighing of interests would seem to favor the proposed policy.

Aside from these complicated doctrines it is also true that, if the government could constitutionally use its power as a sovereign to directly regulate speech, it could thus use its power as a funder to do the same.<sup>120</sup> Therefore it is worthwhile to consider the constitutionality of direct regulation, even if such a mechanism were not in fact employed.

#### D. DIRECT REGULATION OF INDUSTRIAL SCIENCE

Regulators could directly target drug- and device-makers, prohibiting them from using their money to unduly influence the science that tests the safety and efficacy of their own products. The policy would say that, if a company wishes to support scientific tests of its own products, then it needs to use a money-blinding mechanism to allow the investigators to work independently, so that the science is as objective as it purports to be. The regulator's motivation would be to prevent physicians from being influenced by biomedical science that may appear to be robust and objective, but is actually biased and thus misleading.

Although such a regulatory intervention may seem far-reaching, it is in accordance with current policies that prohibit pharmaceutical companies from promoting drugs beyond those indications that the FDA has approved.<sup>121</sup> The FDA has held that "the ban on off-label promotion applies not just to pharmaceutical and medical device companies themselves, but also to financially-interested third-parties, such as physicians who participate in clinical trials or who are paid to promote the products on the manufacturer's behalf" or the providers of Continuing Medical Education (CME) programs.<sup>122</sup>

<sup>120</sup> See *Rumsfeld v. Forum for Academic & Inst. Rights, Inc. (FAIR)*, 547 U.S. 47, 59 (2006).

<sup>121</sup> These policies do not arise from a single statutory source. See generally 21 U.S.C.S. § 355 (LexisNexis 2006) (prohibiting the sale of unapproved drugs, and limiting their labels and accompanying material to "prescribing, recommending, or suggesting" uses which are supported by an adequate scientific basis); *Kordel v. United States*, 335 U.S. 345, 348-50 (1948) (adopting an expansive definition of "accompanying material" to many forms of industry communications about their products); 21 C.F.R. § 202.1(a)(1) (expanding this definition further to encompass virtually all efforts to promote the product); Gregory Conko, *Truth or Consequences: The Perils and Protection of Off-Label Drug and Medical Device Promotion*, 21 HEALTH MATRIX (forthcoming 2011) (Competitive Enterprise Institute, Working Paper No. 2010-9, 2010), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1677609](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1677609) (describing and criticizing this regulatory evolution).

<sup>122</sup> Conko, *supra* note 121, at 14 (citing FDA, Final Guidance on Industry-Supported Scientific and Educational Activities, Notice, 62 Fed. Reg. 64,074 (Dec. 3, 1997)); see also 21 C.F.R. § 202.1(a)(1) (2010) (regulating industry sponsored CME programs). The FDA's rationale for this broad regulatory power rests on the statutory requirement that labels must describe the product's intended use, and that industry efforts to promote another use suggest that the product is mislabeled in the first place. See 62 Fed. Reg. at 64,075 ("The 'intended use' of a drug or device refers to the objective intent of the persons legally responsible for the labeling of the product. This intent is determined by such persons' expressions or by the circumstances surrounding the distribution of the article including, for example, labeling claims, advertising matter, or oral or written statements by such persons or their

If the industry is using these people to promote their products off-label, then this would seem to show an intent to sell the product for off-label uses, which contravenes the current statute.<sup>123</sup>

Presently, the FDA declines to regulate industry financial support for scientific and educational activities when those activities are “independent” from the drug- or device-maker, even if the company has funded the activity. In short, if “an industry-supported activity is independent,” then it is “not generally subject to regulation.”<sup>124</sup> Arguably, because of the many vectors for influence discussed above, an industry-supported scientific research study could be independent only if the study was money-blinded.<sup>125</sup> Just as in CME programs, if the company “is involved in the selection of” investigators, and the investigators “have reason to believe that future financial support from the company depends upon producing” publications “that promote the company’s products,” then the investigator is not independent.<sup>126</sup> Accordingly, scholars have called for a central-pooling mechanism for CME funding, not unlike the solution for biased science proposed here.<sup>127</sup> On the other hand, “companies and [investigators] who wish to ensure that their activities will not be subject to regulation should design and carry out their activities free from the supporting company’s influence and bias.”<sup>128</sup> In short, adopt money-blinding.

The FDA has provided a compelling First Amendment analysis of its regulation of industry influence in educational and scientific activities, such as CME programs, applying the well-known *Central Hudson* test.<sup>129</sup> Rather than

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representatives.”) (citing 21 C.F.R. § 201.128 (2010); 21 C.F.R. § 801.4 (2006); *Alberty Food Prods. Co. v. United States*, 185 F.2d 321 (9th Cir. 1950) (drug product was misbranded because its labeling failed to state the intended use of the drug as suggested by the company in newspaper advertisements)).

<sup>123</sup> *But see* Coleen Klasmeyer & Martin H. Redish, *Off-Label Prescription Advertising, the FDA, and the First Amendment: A Study in the Values of Commercial Speech Protection*, 37 AM. J.L. & MED. 315, 343 (2011) (arguing that the FDA’s analysis is flawed because companies always *know* that their products will be used off-label, and thus such off-label promotion proves nothing). Klasmeyer and Redish seem to assume that knowledge is necessarily equivalent to intent, but the distinction is routinely made throughout the law. *See* *Holder v. Humanitarian Law Project*, 130 S. Ct. 2705, 2718 (2010) (distinguishing between knowledge and intent in another context: “Congress plainly spoke to the necessary mental state for a violation of § 2339B, and it chose knowledge about the organization’s connection to terrorism, not specific intent to further the organization’s terrorist activities”); *United States v. Delgado*, 631 F.3d 685, 695 (5th Cir. 2011) (“It is axiomatic that more is required than mere knowledge of the purpose of a conspiracy.”).

<sup>124</sup> FDA, Final Guidance on Industry-Supported Scientific and Educational Activities; Notice, 62 Fed. Reg. at 64,074 (Dec. 3, 1997).

<sup>125</sup> *See supra* Part II.A.

<sup>126</sup> FDA, Final Guidance on Industry-Supported Scientific and Educational Activities; Notice, 62 Fed. Reg. at 64,083 (referring to CME providers).

<sup>127</sup> Robert Steinbrook, *Financial Support of Continuing Medical Education*, 299 JAMA 1060, 1062 (discussing a solution of “eliminating direct or indirect commercial support of programs but allowing contributions to a central repository of funds, which, in turn, would disburse funds to approved programs”).

<sup>128</sup> 62 Fed. Reg. at 64,084.

<sup>129</sup> The FDA relies on this explanation from the Supreme Court:

The First Amendment’s concern for commercial speech is based on the informational function of advertising. Consequently, there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity. If the communication is neither

being an instance of political speech, which is at the core of the First Amendment, this regulation arises in the commercial context of healthcare—drugs and devices in particular—which are already deeply regulated in America. As shown in Part I, it is now widely recognized by both biomedical journal editors and by the industry itself that these efforts to fund and manipulate science are designed to sell more drugs.<sup>130</sup> The government's interest is quite compelling. At a time when healthcare costs are consuming more than a sixth of the entire economy, there can be little doubt that the government has a compelling interest in seeing that biomedical science is accurate and objective.<sup>131</sup>

Yet, the evidence shows that, at least in the aggregate, the speech in these industry-funded articles is biased and it misleads the physicians and regulators who rely upon it.<sup>132</sup> Still, one must concede that not *every* industry-funded article is biased, or that *every* biased article misleads physicians.<sup>133</sup> The blinding proposal merely acts as a filter, allowing industry to continue funding scientific speech, but stripping it of its bias. To the extent that the science is not actually biased, then the industry money will pass through the intermediary and allow the same speech that the company intended. Part II has also shown that less intrusive responses to this problem—disclosure and peer review—have been tried, but failed.<sup>134</sup> Thus, even while eliding over the nuances of a full-blown First Amendment analysis, it is clear that a money-blinding mandate may survive constitutional scrutiny.

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misleading nor related to unlawful activity, the government's power is more circumscribed. The State must assert a substantial interest to be achieved by restrictions on commercial speech. Moreover, the regulatory technique must be in proportion to that interest. The limitation on expression must be designed carefully to achieve the State's goal. Compliance with this requirement may be measured by two criteria. First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose. Second, if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.

Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 563-64 (1980) (citations omitted).

<sup>130</sup> See Fugh-Berman & Melnick, *supra* note 5; see also United States v. Caronia, 576 F. Supp. 2d 385, 395 (E.D.N.Y. 2008) (discussing whether “promotional activities amounted to scientific and academic speech, which resides at the core of the First Amendment”); Sax *supra* note 17, (discussing this point, and also concluding that industry-supported science is commercial speech). For a more foundational discussion, see Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever Be Noncommercial?* 37 AM. J.L. & MED. 388 (2011) (arguing that the answer to his titular question “is yes, but only if the stars align”). Arguably, industry-funded science could be regulated through blinding even if it was not deemed commercial speech.

<sup>131</sup> Christopher J. Truffer et al., *Health Spending Projections Through 2019: The Recession's Impact Continues*, 29 HEALTH AFF. 522, 522 (2010) (reporting that the health share of the gross domestic product was estimated at 17.3% in 2009).

<sup>132</sup> See discussion *supra* notes 16-21 and 38-48.

<sup>133</sup> For a similar argument in a related context, see Klasmeier & Redish, *supra* note 123, at 345 (“But it surely does not follow that *all* claims made on behalf of off-label uses are *inherently* false or misleading.”).

<sup>134</sup> Whitaker v. Thompson, 248 F. Supp. 2d 1, 9 (D.D.C. 2002) (“Under the *Central Hudson* analysis, it is ‘clear that if the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the Government must do so.’”) (citing Thompson v. W. States Med. Ctr., 535 U.S. 357, 371 (2002)).

The constitutional analysis can also be approached from an altogether different track, one that may avoid First Amendment scrutiny altogether. A money-blinding mandate could draw upon the bribery, kickback, gratuity, graft, and conflict of interest statutes that already exist to insulate the integrity of government officers from payments that would otherwise be protected as speech.<sup>135</sup> It would clearly be illegal for a company to pay a government official a quid pro quo to declare that its drug is safe and effective.<sup>136</sup> It would even be illegal to pay a government official to undertake a study that he otherwise would not have undertaken, or to do such a study on more favorable terms. Many courts have held that the laws proscribing this sort of behavior avoid First Amendment scrutiny altogether.<sup>137</sup> Notwithstanding the language of these holdings, it may be more accurate to say that these restrictions on speech *would withstand constitutional scrutiny*, on the facts presented in these cases.<sup>138</sup>

<sup>135</sup> See, e.g., 18 U.S.C. § 201(b) (1962) (setting forth conduct constituting bribery and related fines); 18 U.S.C. § 666(a)(2) (2004) (also describing conduct constituting bribery); 41 U.S.C. § 52(2) (2009) (defining “kickback”).

<sup>136</sup> See generally Kathleen Clark, *Financial Conflicts of Interest In and Out of Government*, at 6 (2011), available at <http://ssrn.com/abstract=1785520> (“If a government employee advises the government on how to handle a matter that could affect her own investments, she could end up in prison. A criminal statute prohibits government employees from participating in matters that can have a direct and predictable effect on their own financial interests.”).

<sup>137</sup> See *United States v. Marchetti*, 466 F.2d 1309, 1314 (4th Cir. 1972) (“Threats and bribes are not protected simply because they are written or spoken; extortion is a crime although it is verbal”); *United States v. Meachum*, No. 08-3082 Slip Copy, 2009 WL 1255520, at \*8 (W.D. Va. May 7, 2009) (same); *Roberts v. State*, 278 S.W.3d 778, 790 (Tex. App. 2008) (same); *Bulletin Displays, LLC v. Regency Outdoor Advertising, Inc.*, 448 F. Supp. 2d 1172, 1184 (C.D. Cal. 2006) (“[C]ampaign contributions made ‘with a corrupt intent to influence . . . the person to whom it is given, in his action, vote, or opinion, in any public or official capacity’ are not protected because they are not a ‘valid’ exercise of one’s constitutional rights of free speech or petition”) (quoting *Paul for Council v. Ricki Hanyecz*, 85 Cal. App. 4th 1356, 1366-67 (2001)); *United States v. Tutein*, 82 F. Supp. 2d 442, 447 (D. Virgin Is. 2000) (“[A] private party has no First Amendment right to petition the Government by means of . . . payment of bribes”) (quoting *In re Airport Car Rental Antitrust Litig.*, 474 F. Supp. 1072, 1087 (N.D. Cal. 1979)); *Dawkins v. State*, 208 So.2d 119, 124 (Fla. Dist. Ct. App. 1968) (“One cannot threaten, intimidate, bribe, or otherwise imminently seek to affect the outcome of grand or petit jury deliberations and then seek refuge in the First Amendment. . . .”); see also *United States v. Hutson*, 843 F.2d 1232, 1235 (9th Cir. 1988) (“extortionate speech . . . is undoubtedly within the government’s power to prohibit”); *United States v. Quinn*, 514 F.2d 1250, 1268 (5th Cir. 1975), cert. denied, 424 U.S. 955 (1976) (“It may categorically be stated that extortionate speech has no more constitutional protection than that uttered by a robber while ordering his victim to hand over the money, which is no protection at all”); *People v. Hickman*, 988 P.2d 628, 636-38 (Colo. 1999) (rejecting a First Amendment attack on a statute making it a crime to threaten a witness, so long as “threat” is limited to “expressions of intent to commit harm or injury to another’s person, property, or rights through commission of an unlawful act”); *State v. Lance*, 721 P.2d 1258, 1264-65, 1267 (Mont. 1986) (rejecting a First Amendment attack on a statute making it a crime to threaten to kidnap or unlawfully restrain any person).

<sup>138</sup> For an explanation of the doctrine, see KENT GREENAWALT, *SPEECH, CRIME, AND THE USES OF LANGUAGE* 249 (1989) (arguing that “[m]y basic position is that such utterances are genuinely situation-altering. They do not inform the listener about the environment he or she inhabits; they change that environment by generating options which did not previously exist and which would never have existed had it not been for the offer or threat. Because they *do* something rather than *say* something, they fall outside a principle of free speech.”). More accurately, an offer of a bribe *both does* something (create an incentive) and *says* something (notify of the incentive).

Extending this analysis, Kathleen Clark has suggested that government contractors should be held to similar standards as governmental employees, with regard to conflicts of interests.<sup>139</sup> As a matter of statute, Congress has already extended the wire and mail fraud crimes to protect the objectivity of state officials and even of private persons (such as union bosses or company CEOs) from improper influence.<sup>140</sup> In principle, the government could similarly proscribe industry efforts to improperly influence the discretion exercised by scientists. If Congress or the FDA extended such protection to biomedical researchers, it would not seem to cross any constitutional line, and thus the regulation deserves as little, or as much, First Amendment scrutiny as the current bribery, gratuity, and conflict of interest statutes.

#### IV. CONCLUSION

There can be little doubt that biomedical science drives a significant portion of the practice of medicine and the billions of dollars of spent on healthcare in America each year. Thus the integrity of biomedical science would seem to be foundational to a well-functioning healthcare system. It is critical that biomedical science *be* objective, and that it *appear* objective, so that physicians and regulators can confidently rely upon it.

Once the root causes of biased science are well understood, we will be left with two options to solve the problem: an outright ban on industry support of biomedical science, or something like money-blinding—which would preserve industry’s subsidy of science while attempting to cleanse the money of any biasing influence. A ban on industry funding would be devastating to scientific progress, and would likely face insurmountable constitutional and political obstacles. Money-blinding is thus a promising partial solution, even if it would not completely extirpate industry’s role in setting the agenda for biomedical science.

The legal analysis suggests that if private ordering fails there are multiple mechanisms for regulators to facilitate a move towards money-blinding, without running afoul of the Constitution. Whether a money-blinding mandate avoids First Amendment scrutiny altogether, is reviewed as commercial speech, or is reviewed under strict scrutiny, it has some reasonable likelihood of surviving.

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<sup>139</sup> See Clark, *supra* note 136, at 6 (sketching out the “the principles and policy considerations that should guide the development of financial conflict standards for outsiders who do the government’s work”).

<sup>140</sup> See 18 U.S.C § 1346 (2008) (proscribing honest services fraud); *Skilling v. United States*, 130 S. Ct. 2896 (2010) (construing the statute to cover only bribes and kickbacks, and arguing that the vague statute borrows content from the federal bribery statutes—which otherwise apply only to federal officials—or state officials who receive federal grant funds). I am not arguing here that the honest services statute actually criminalizes industry payments to independent biomedical researchers, though that argument would be provocative, given the seemingly limitless scope of the honest services fraud statute, even after *Skilling*.