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## Economics and/of Science: The Meaning(s) of Financial Bias and the Ideal of Interest-Free Science in Law

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# Economics and/of Science: The Meaning(s) of Financial Bias and the Ideal of Interest-Free Science in Law

David S. Caudill\*

## I. INTRODUCTION

Science costs money and incentives play a key role in science . . . .

Not all science is created equal when it comes to funding.<sup>1</sup>

At times, the controversy whether science is degraded or enhanced by relationships with (or financial support from) commercial industry seems to reflect the current political-ideological divide between Left and Right, Democrat and Republican, environmentalists and industrialists, and so forth. For example, a recent online issue of *The Scientist* included two opinion pieces offering conflicting viewpoints concerning the growing commercialization of science. The first opinion, after conceding science has always been funded and “social forces and political agendas have resulted in significant scientific progress,”<sup>2</sup> nevertheless warned “the current commercialization pressure . . . is an ethos that . . . permeates every corner of the research enterprise, . . . [raising] the possibility that this pressure could reduce *collaborative behavior*, thus undermining scientific progress, and contribute to premature application of technologies . . . .”<sup>3</sup> On the contrary, according to the second opinion, industry relationships with science are “unequivocally beneficial.”<sup>4</sup> Indeed, it is not the financial conflicts of interest that reduce collaborative behavior, but the “mania . . . that discounts the social value of collaboration and has mounted an inquisition . . . . Critics’ unwarranted allegations that such conflicts cause bias have limited the sources of intellect that can con-

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1. PAULA STEPHAN, *HOW ECONOMICS SHAPES SCIENCE* 127 (2012).
2. Timothy Caulfield, *Pressured to Commercialize: Is the Push for Science to Save the Still Flailing Economy a Threat to Scientific Research?*, *THE SCIENTIST* (May 28, 2012), available at <http://the-scientist.com/?articles.view/articleNo/32158/title/Opinion-Pressured-to-Commercialize/>.
3. *Id.*
4. Thomas P. Stossel, *What’s Wrong with COI?*, *THE SCIENTIST* (June 12, 2012), available at <http://the-scientist.com/?articles.view/articleNo/32190/title/Opinion—What-s-Wrong-with-COI-/>.

tribute to a given project.”<sup>5</sup> Note the term “collaboration,” with all of its positive connotations in both editorials, has a completely different meaning for its respective authors. In the first, collaboration implies the cooperation of scientists in sharing knowledge, to which commercialization is a threat.<sup>6</sup> In the second, collaboration refers to cooperation between scientists and industry, to which concerns about funding and implied conflicts of interest are a threat.<sup>7</sup>

This is a battle of images. The (i) threats to “traditional scientific standards of objectivity and independence” as well as the “normal open science,” brought on by commercialization of research (wherein scientists fail to “share their data and results freely”)<sup>8</sup> are pitted against the (ii) “hard-won” advances “in medical and surgical care” due to industry collaborations<sup>9</sup>—the latter of which are nowadays threatened by “sheer prejudice,” “blatant intellectual dishonesty,” and “a prosecutorial racket that forces companies to pour money into settling dubious allegations.”<sup>10</sup>

Images of scientific research and funding conventions have important legal ramifications. For example, when a trial judge or agency administrator evaluates the integrity of a scientific expert or risk assessment report, is industry affiliation or sponsorship of research a marker of bias, and should the results of “independent” research be given greater weight? In the discourse concerning the commercialization of science, there are various positions reflecting different images of how science is affected by, or alternatively rises above, financial or economic pressures or entanglements. One view, perhaps idealistic and caricatured by economist Phillip Mirowski as a linear narrative entitled “Annals of Decline,” longs for the virtue and purity of science free from economics. “Back in the golden day there may have been an invisible college, chorused sweetly in concert in the quest for truth, they lament, but now there are only feckless individual entrepreneurs scrabbling for the next short-term contract . . . .”<sup>11</sup>

In contrast, the more common view is that science is costly; for example, Robert Boyle’s wealth and Galileo’s Medici patrons betray the inevitable economic aspects of the scientific enterprise.<sup>12</sup> Then the real debate begins on the question of whether financial interests or entanglements are: (i) relatively

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5. *Id.*

6. *See* Caulfield, *supra* note 2.

7. *See* Stossel, *supra* note 4.

8. Caulfield, *supra* note 2.

9. Stossel, *supra* note 4.

10. *Id.*

11. PHILLIP MIROWSKI, *SCIENCE-MART: PRIVATIZING AMERICAN SCIENCE* 87 (2011).

12. *See* David Goodstein & James Woodward, *Inside Science*, 68 AM. SCHOLAR 83, 86, 90 (1999).

benign, insofar as science is *externally* supported, but not *internally* affected by money (except in the case of fraud, the occasional bad apple);<sup>13</sup> (ii) seriously influential, especially nowadays, but generally good for science by fostering efficiency and innovation;<sup>14</sup> or (iii) seriously influential, especially nowadays, with identifiable pernicious effects which variously degrade the quality of science, including the science on which law relies in litigation and policy contexts.

Financial conflicts of interest in the pharmaceutical industry drew an alarming headline in late 2012: “As Drug Industry’s Influence Over Research Grows, So Does Potential for Bias.”<sup>15</sup> Since the mid-1980s, research funding by pharmaceutical firms has exceeded the expenses of the National Institutes of Health.<sup>16</sup> Although the discovery of errors in industry-funded research does not mean money biased the researcher’s findings—“errors are part of science”—the “odds of coming to a conclusion favorable to industry are 3.6 times greater in research sponsored by the industry than in research sponsored by government and nonprofit groups.”<sup>17</sup> Concerns therefore arise that

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13. See generally *id.* (identifying an inevitable economic aspect of science, and numerous other structures, such as the reward system and authority structure of scientific activity that ensure scientific progress and the production of useful results, notwithstanding the fact that individual scientists may be motivated by selfish interests and not the public good). See also, e.g., Jeff Akst, *Anesthesiologist Fabricates 172 Papers*, THE SCIENTIST (July 3, 2012), available at <http://www.the-scientist.com/?articles.view/articleNo/32312/title/Anesthesiologist-Fabricates-172-Papers/>; Hayley Dunning, *Parkinson’s Researcher Fabricated Data*, THE SCIENTIST (June 29, 2012), available at <http://www.the-scientist.com/?articles.view/articleNo/32305/title/Parkinson-s-Researcher-Fabricated-Data/> (fraud continues to be a temptation for a relatively small number of scientists).
  14. See MIROWSKI, *supra* note 11, at 87-88. (“At the risk of caricature,” Mirowski entitles this “linear narrative,” “‘Ripping Tales of Progress’ . . . . Admittedly, many of these purveyors of glad tidings would still regard themselves as defending the preservation of an ‘optimal’ sphere of research reserved for open public science and pure unfocused curiosity . . . .”).
  15. Peter Whoriskey, *As Drug Industry’s Influence Over Research Grows, So Does Potential for Bias*, WASH. POST, (Nov. 25, 2012), available at [http://articles.washingtonpost.com/2012-11-24/business/35511825\\_1\\_drug-companies-avan-dia-steven-e-nissen](http://articles.washingtonpost.com/2012-11-24/business/35511825_1_drug-companies-avan-dia-steven-e-nissen). See also, e.g., Katherine Eban, *Dirty Medicine*, FORTUNE BLOG [http://features.blogs.fortune.cnn.com/2013/05/15/ranbaxy-fraud-lipitor/?section=magazines\\_fortune](http://features.blogs.fortune.cnn.com/2013/05/15/ranbaxy-fraud-lipitor/?section=magazines_fortune) (a more recent investigation into fabricated data in the pharmaceutical industry, involving generic drugs).
  16. Whoriskey, *supra* note 15.
  17. *Id.* (construing Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 454 (2003)). “Aggregating the results of [1140 original studies] showed a statistically significant association between industry sponsorship and pro-industry

companies can shape “their research to obscure the dangerous side effects.”<sup>18</sup> Specifically, “when the company is footing the bill, the opportunities for bias are manifold: . . . design[ing] research that makes their products look better . . . select[ing] like-minded academics to perform the work . . . [a]nd . . . run[n]g statistics in ways that make their own drugs look better than they are.”<sup>19</sup>

Moreover, the concerns over bias extend beyond biomedical research into fields such as nutrition-related scientific articles, where industry funding “may bias conclusions in favor of a sponsor’s products, with significant implications for public health.”<sup>20</sup> Even when ethicists (or bioethicists) are engaged to oversee the work of laboratories, conflicts of interest arise if the laboratories fund the oversight; “overt and covert pressures may be placed upon ethicists to make conclusions conducive to the progression and advancement of the overall science of a project.”<sup>21</sup>

Distinctions need to be made among those who identify pernicious effects of the commercialization of science, including industry-sponsored research and university-industry linkages between those who focus on bad actors (scientists who are willing to compromise scientific integrity for money), and those who focus on the indirect, negative effects of economic pressures on even the best science and best scientists. Critics in the former category tend to hold fairly conventional ideals concerning science—independence, transparency, and social disengagement—while those in the latter category tend to see scientific knowledge as co-produced, or “mutually constituted” by, economic and social structures.<sup>22</sup> Most importantly, critics in the former category tend to predominate in legal discourse concerning the adverse effects of industry on science and scientific expertise, and the purpose

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conclusions (pooled Mantel-Haenszel odds ratio, 3.60; 95% confidence interval, 2.63–4.91).” *Id.*

18. *Id.*

19. *Id.*; see also Sheldon Krimsley, *The Ethical and Legal Foundations of Scientific “Conflict of Interest”*, in LAW AND ETHICS IN BIOMEDICAL RESEARCH: REGULATION, CONFLICT OF INTEREST, AND LIABILITY 63, 63-81 (T. Lemmens & D.R. Waring eds., 2006).

20. Lenard I. Lesser et al., *Relationship between Funding Source and Conclusion Among Nutrition-Related Scientific Articles*, 4 PUB. LIB. SCI. MED. 41, 41 (2007) (studying the financial sponsorship of three commonly consumed beverages).

21. Lynne Kiesling et al., *Paved with Good Intentions: Rethinking the Ethics of ELSI Research*, 42 J. RES. ADMIN., no. 2, 2011 at 15, 23 (discussing Ethical, Legal, and Social Implications [“ELSI”] research and the role of ethics centers funded by a larger grant for scientific research).

22. PHILLIP MIROWSKI, *THE EFFORTLESS ECONOMY OF SCIENCE?* 117, 132 (2004). See also, e.g., Brendon Swedlon, *Cultural Coproduction of Four States of Knowledge*, 37 SCI. TECH. & HUM. VALUES 151 (2012).

of this article is to highlight the significance of critics in the latter category for law and legal discourse.

In section II, I briefly introduce the notion that the economy “shapes” science, and in section III, I discuss the perceived *direct*, adverse effects of industry on science in legal contexts. In section IV, I discuss the *indirect* effects of commercial culture—“less overt, but far more pervasive”<sup>23</sup>—on science. I conclude, in section V, that legal discourses concerning scientific expertise would be enriched by viewing science as structured and constituted, not merely influenced or supported, by economic forces.

## II. ECONOMICS AND SCIENCE

While the idea that the 20th century was a golden age of science free from outside influence is clearly mythic . . . [,] it is also clear that the relations between public science and private profit have shifted dramatically over the past 30 years . . . .<sup>24</sup>

### A. No Cause for Alarm

While much of the literature concerning recent changes in the funding of scientific research is alarmist, some of it is not. For example, Paula Stephan’s highly descriptive analysis in her recent *How Economics Shapes Sciences*,<sup>25</sup> borders on identifying economic factors in science as mundane. Of course “costs affect the way research is conducted” and “the pace of discovery;” of course scientists *and* “universities respond to incentives;” and while scientists are motivated by puzzle solving and recognition, “scientists take some interest in financial rewards.”<sup>26</sup> Typically, a scientist’s work is rewarded with higher salaries, external funding (which, in turn, affects salary), and royalties from patents; all of which provide incentives for productivity.<sup>27</sup> While the landscape is changing dramatically, there is little drama in Stephan’s description. “By the early 1960s, the notion of keeping a distance between the university and commercial operations was in decline. Universities had begun to develop their own offices for technology transfer . . . . By the mid-1990s, almost all research universities had an office of technology

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23. DANIEL LEE KLEINMAN, *IMPURE CULTURES: UNIVERSITY BIOLOGY AND THE WORLD OF COMMERCE* 5 (2003).

24. Rebecca Lave, Philip Mirowski & Samuel Randalls, *Introduction: STS and Neoliberal Science*, 40 *SOC. STUD. SCI.* 659, 660 (2010).

25. See STEPHAN, *supra* note 1.

26. *Id.* at 2–3, 16.

27. See *id.* at 42–43, 45, 50–51. There is “nothing new about faculty patenting. What is new is the rate at which faculty are patenting, the amount of revenues universities and faculty receive from patents, and the direct involvement of universities in managing patents.” *Id.* at 45.

transfer.”<sup>28</sup> More faculty members in the sciences are involved in start-up companies, lucrative consulting arrangements with industry, and industry-sponsored research.<sup>29</sup>

Is there a cause for alarm? Is science impeded, is the quality of scientific knowledge decreased, and do patents limit academic scientists’ access to materials and instruments?<sup>30</sup> There are “some [who] argue, for example, that the financial rewards associated with inventive activity encourage faculty to substitute applied research for basic research. Others argue that patenting diverts faculty from doing research that is published and hence made publicly available.”<sup>31</sup> For Stephan, the evidence suggests “patenting and publishing go hand in hand,” as scientists generate “both fundamental insights and solutions to problems.”<sup>32</sup> There are potential impediments to research if patents are “managed poorly” or if universities “become overly aggressive” and discourage knowledge diffusion.<sup>33</sup> There are also concerns over transparency (e.g., not disclosing industry support) and ghost-writing by industry (i.e., recruiting academic scientists as co-authors).<sup>34</sup> Industry support is also worrisome due to “the control that industry may exert over publications and intellectual property coming out of the research,” and university/industry alliances “clearly dampen the speed with which knowledge is disseminated” and limit faculty ability “to choose their own research topics.”<sup>35</sup> However, “research is an expensive business,” and, unfortunately, the current system of

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28. *Id.* at 46.

29. *See id.* at 52–57.

30. *See id.* at 57.

31. STEPHAN, *supra* note 1, at 57. *See also, e.g.*, Hanna Hottenrott & Susanne Thorwath, *Industry Funding of University Research and Scientific Productivity*, CTR. EUR. ECON. RES. 1 (2011), <ftp://ftp.zew.de/pub/zew-docs/dp/dp10105.pdf> (showing a higher share of industry funding of a professor’s research budget results in lower subsequent publication outcomes, both quantitatively and qualitatively); Liza Vertinsky, *Making Knowledge and Making Drugs? Experimenting with University Innovation Capacity*, 62 EMORY L. J. 741, 745–76 (2013) (proposing legal reforms to “address the tensions between open science and proprietary development,” to support “innovation in the public interest,” and to expand “university monitoring, disclosure, and reporting requirements designed to increase the transparency, accountability, and responsibility of universities in the management of drug development activities.”).

32. STEPHAN, *supra* note 1, at 57. *See also, e.g.*, Rosa Grimaldi et al., *30 Years After Bayh-Dole: Reassessing Academic Entrepreneurship*, 40 RES. POL’Y 1045, 1055 (2011) (“[T]he rise of commercialization associated with the Bayh-Dole Act has *not* resulted in less basic research”).

33. STEPHAN, *supra* note 1, at 58.

34. *Id.* at 58, 59.

35. *Id.* at 118.

government funding leads faculty to be risk averse.<sup>36</sup> We can certainly do better, Stephan concludes, than a system that “discourages faculty from pursuing research with uncertain outcomes,” as well as discouraging collaboration and inefficiently producing too many scientists and not enough grants for job security.<sup>37</sup> Possible solutions are focused on efficient allocation of resources (e.g., discourage soft-money faculty hiring, uncouple research and training, fund more training grants, reward collaboration),<sup>38</sup> but there is seemingly no cause for alarm over the systematic effects of the economy on scientific research.

## B. The Alarmist Perspective

Other authors seem to go beyond a sense of worry to a sense of crisis. Some, for example, do not consider themselves to be “alarmist” in their view that the production and dissemination of science has been *impeded* by commercialization.<sup>39</sup> That alarmist label is reserved for those who long for the ideal scientific community—independent, freely sharing knowledge—that never really existed.<sup>40</sup> However, Mirowski and Van Horn distance themselves radically from the sanguine authors who treat “the ‘producers’ (universities) and ‘consumers’ (firms) as persisting relatively unscathed through the process of commercialization . . . [T]heir central tendency is to . . . argue

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36. *Id.* at 148–49. *See also, e.g.,* Joel Werner, *What’s Ailing our Science?*, THE AUSTRALIAN 33 (2012), available at <http://www.theaustralian.com.au/higher-education/whats-ailing-our-science/story-e6frgcjx-1226428415568> (“Research is becoming more conservative in its nature,” says [Darren] Saunders, [senior research officer at the Garvan Institute in Sydney]. “Truly groundbreaking science is inherently risky. There’s a chance it might not work. Because the system is trying to do its best with a small amount of money, it wants to bet on a sure-fire winner.”). *See also* Jewel Topsfield, *Science Subject Comes Under Fire*, THE AGE 7 (2012), available at <http://www.theage.com.au/national/education/science-subject-comes-under-fire-20120718-22alp.html> (Australian national secondary science curriculum, according to some teachers, “panders to the mining industry in . . . [e]arth and [e]nvironmental [s]cience, with climate change, sustainability and biodiversity barely rating a mention;” one of the textbooks used “was partly funded by Woodside Petroleum,” and teachers “have a whole lot of money thrown at them from mining companies for personal development and textbooks.”).

37. STEPHAN, *supra* note 1, at 229–30.

38. *See id.* at 232–35.

39. *See* Lave et al., *supra* note 24, at 667.

40. *See* Philip Mirowski & Robert Van Horn, *The Contract Research Organization and the Commercialization of Scientific Research*, 35 SOC. STUD. SCI. 503, 503 (2005) (“Their writing tends to be long on anecdotal horror stories, but rather short on specifics . . .”). Mirowski wants to “raise the historical question of whether . . . images of the disinterested operation of science ever actually corresponded to research practices on the ground.” *Id.* at 508.



that the growing modern commercialization of scientific research was 'inevitable,' and that there exists little evidence that it has 'significantly changed the allocation of university research efforts.'"<sup>41</sup>

While Mirowski and Van Horn are critical of such conclusions with respect to university science,<sup>42</sup> they are also critical of

[T]he unexamined presumption that the university is the primary field upon which the privatization of research has played out. We contend that the re-engineering of the structures of scientific research since the 1980s . . . was nurtured by the creation of new social structures of research, which act as prototypes outside the university: new forms of intellectual property, new communication technologies, new research protocols, new career paths, and new institutions of command and control . . . . In other words, universities may not necessarily be the most perspicuous of entities for a study of those consequences.<sup>43</sup>

Focusing on the corporate sphere, and particularly the pharmaceutical sector,<sup>44</sup> Mirowski and Van Horn identify the post-1980 "Contract Research Organization" (CRO) as paradigmatic of privatized science as well as the perfect foil to those who insist "science conducted in a for-profit modality has had no deleterious effects upon the conduct of research."<sup>45</sup> However, in contrast to "alarmists" who see the commercialization of science as a marker of decline, Mirowski and Van Horn add that "accusations of corruption must be judged on a case-by-case basis."<sup>46</sup>

Mirowski and Van Horn begin with a "conventional" historical account of the rise of CROs.<sup>47</sup> Since the Food and Drug Administration "require[s] that drug companies . . . demonstrate the safety and efficiency of a drug

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41. *Id.* at 504 (construing Richard Nelson, *Observations on the Post Bayh-Dole Rise of Patenting at American Universities*, 26 J. TECH. TRANSFER 13, 14 (2001)).

42. Mirowski & Van Horn, *supra* note 40, at 504. *See also, e.g.*, Lave et al., *supra* note 24, at 664, 669 ("[P]articular regimes of science management and funding have specific and profound impacts on the character of scientific production;" "the character of the university is changing as new privatized regimes of scientific management shift the sources and quantities of funding, the organization of research and teaching, and the intellectual and commercial status of knowledge claims.").

43. Mirowski & Van Horn, *supra* note 40, at 504.

44. *See id.* at 537. Significantly, Mirowski and Van Horn believe that "the new phenomena of research we have identified in the pharmaceutical sector may also become more prevalent elsewhere."

45. *Id.* at 507.

46. *Id.* at 508.

47. *See id.* at 508.

before marketing it,” and mandates an expensive and time-consuming four-stage process for drug development (preclinical or animal, clinical, regulatory delay, and post-clinical), pharmaceutical companies in the postwar period looked for ways to reduce costs and delay.<sup>48</sup>

Recruiting subjects, managing diverse trials in different settings, monitoring and recording data, subjecting data to statistical controls and higher level analyses, and writing up the results for publication all absorb vast amounts of time and money. . . . [Thus] there arose the impression of a conflict between conventional norms of (academic) science and the commercial imperatives operating in the drug development process.<sup>49</sup>

Although deregulation initiatives in the 1990s reduced the time between a new drug application and FDA approval,

[T]he duration of the clinical development cycle was lengthening . . . . In the corporate view, the remedy . . . was a new breed of scientific researcher who was more comfortable with the deadlines, and who focused more intently upon the specific of the FDA guidelines . . . . The pharmaceutical companies were casting about for a specifically engineered research entity to impose cost constraint, and some far-sighted entrepreneurs provided it in the 1980s . . . in the form of the contract research organization.<sup>50</sup>

While the explanations for the trend of outsourcing research and development, and the rise of CROs varied, the efficiency and cost-savings were obvious—CROs offered “targeted drug expertise, timely clinical trial completion, and eventually ‘end-to-end outsourcing support for all phases of clinical research’ at a comparatively low cost.”<sup>51</sup> Globalization also played a role, as the CRO industry could provide “cross-cultural expertise in international clinical studies.”<sup>52</sup> In terms of advances in instrumentation, “pharmacogenetics and pharmacogenomics . . . opened up further opportunities for CROs to displace AHCs [academic health centers],” their primary competitor.<sup>53</sup>

For Mirowski and Van Horn, this conventional account of the rise of CROs is significant because it focuses on economic pressures and cost-savings, thereby eclipsing the advantages (to the pharmaceutical industry) of reconstructing clinical research “within a more thoroughly privatized frame-

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48. *Id.* at 508–509.

49. Mirowski & Van Horn, *supra* note 40, at 509–10.

50. *Id.* at 510.

51. *Id.* at 511.

52. *Id.* at 511–12.

53. *Id.* at 512.

work.”<sup>54</sup> Data is “rendered more dependably proprietary”—information about the “conduct of CRO research is less accessible than “under the earlier academic regime”—such that the “conduct of scientific research has been profoundly altered” to adjust to the “traffic and rhythms of corporate privatized science.”<sup>55</sup> Mirowski and Van Horn offer five examples of “structural changes in the organization of science.”<sup>56</sup>

### 1. Research on Human Subjects

Unlike the often busy, slow institutional review boards (IRBs) at universities and non-profit institutions, independent IRBs (permitted by the FDA in 1981)—usually bioethics consultants (a commodification of the function)—are used by CROs to expedite research.<sup>57</sup> CROs are “not tied to any particular geographic locale or academic setting” and can negotiate lower cost clinical trials overseas.<sup>58</sup> Overseas, scientific protocols are often re-engineered to involve coercion and less than informed consent. For example, “some of these countries waive or reduce the requirement of pre-clinical animal trials,” and CROs can avoid United States physicians’ demand for generous recruitment fees.<sup>59</sup>

Jeanne Lenzer’s article on the problem, published in the *British Medical Journal*, confirms the notion that CROs have taken much of the clinical trial market away from academic medical centers, and raises concern that “CROs face a fundamental conflict of interest—if they do not please their commercial clients, they may be less likely to get more work from them. Instances of study bias favouring the sponsor . . . suggest that independence may have its limits.”<sup>60</sup> Lenzer also notes “CROs reduce costs partly by [recruiting] volunteers quickly and partly by recruiting from impoverished regions of the world,” and “the ability of a sponsor to pick and choose which organisation will conduct a trial, raises questions about who, ultimately, is in control of

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54. *Id.* at 513.

55. Mirowski & Van Horn, *supra* note 40, at 513–14.

56. *Id.* at 514.

57. *See id.* at 515.

58. *Id.* at 516.

59. *Id.* at 517. *See also* Roy Spece Jr., *Direct and Enhanced Disclosure of Researcher Financial Conflicts of Interest: The Role of Trust* (May 2012), available at <http://ssrn.com/abstract=2088244> (discussing the problem of conflicts of interests in payments to physicians to enroll subjects in clinical trials and the need for enhanced disclosure).

60. Jeanne Lenzer, *Truly Independent Research?*, 337 *BRIT. MED. J.* 602, 602, 604 (2008) (statement of Professor Lisa Bero, Univ. Cal. S.F.: “[Y]ou can ask a question which you know will give a favourable answer for the funder—and not ask other questions.”).

the research design and the questions being asked.”<sup>61</sup> However, Lenzer concludes “academic research organizations are little better than commercial CROs . . . . [I]n the process of competing for research dollars [they have] started looking and acting just like their commercial counterparts in order to placate their sponsors.”<sup>62</sup>

## 2. Disclosure and Confidentiality

Mirowski and Van Horn argue the “actual structures of disclosure and confidentiality have become much more complicated” than simply recognizing we need some level of “open science” for scientific progress and some level of confidentiality to protect the proprietary interests of commercial entities or the research and publication priorities of scientists.<sup>63</sup> Once “commercialization gets institutionalized, a completely different menu of possibilities is on offer”—for example, conflicts of interest, typically associated with the fear of bias (“industry funding is highly correlative with results favorable to the study’s sponsor”), also raise concerns about open science and disclosure (“scientists with industry support are more likely . . . to deny others access to data and research materials”).<sup>64</sup>

With respect to disclosure of financial sponsorship, the literature warning of conflicts of interest in industry funding of scientific research is substantial. “Growing evidence from the tobacco, pharmaceutical and medical fields suggests that financial interests of researchers may compromise their professional judgment and lead to research results that are biased in favor of commercial interests.”<sup>65</sup> For example, concerns over industry involvement in alcohol science—including sponsorship of research funding organizations, direct funding of university scientists, and CRO studies—have given rise to guideline proposals, such as recommendations that alcohol researchers should (i) pay attention to hidden funding sources, (ii) be prepared to demon-

61. *Id.* at 603–04.

62. *Id.* at 605 (statement of Jennifer Washburn, Senior Fellow at the New Am. Found. in Washington, D.C.).

63. Mirowski & Van Horn, *supra* note 40, at 517.

64. *Id.* at 517–18. *See, e.g.,* David Blumenthal et al., *Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty*, 277 J. AM. MED. ASS’N 1224, 1224 (1997) (“Withholding of research results is not a widespread phenomenon among life-science researchers. However, withholding is more common among the most productive and entrepreneurial faculty.”). *But see* John P. Walsh & Wei Hong, *Secrecy is Increasing in Step with Competition*, Correspondence, 422 NATURE 801, 802 (2003) (“Secrecy is strongly predicted by scientific competition . . . The effects of commercial activity, on the other hand, are quite mixed. Patenting has no effect; industry funding is associated with greater secrecy; but having industry collaborators is associated with less secrecy.”).

65. Kerstin Stenius & Thomas F. Babor, *The Alcohol Industry and Public Interest Science*, 105 ADDICTION 181, 191 (2009).

strate no funding source dictates or influences the research design, data collection, or interpretation, and (iii) retain ownership of data and rights to publish.<sup>66</sup> Mirowski and Van Horn view recommendations such as retaining publication and ownership rights as idealistic.<sup>67</sup> Guidelines have also been proposed for financial conflicts of interest in food science, recommending researchers (i) avoid favoring a particular outcome [or accepting] remuneration geared to the outcome of a research project, (ii) disclose financial interests in publications, and (iii) guarantee accessibility to all data.<sup>68</sup> In the investigation of panels that write guidelines for the diagnosis and treatment of drug patients, the “links with pharmaceutical companies are more worrying than the financial conflicts known to plague clinical trials and reviews, . . . because the guidelines have such a direct effect on the drugs that doctors prescribe . . . . ‘Drug company sponsors see guideline-issuing bodies as perfect places to exert influence.’”<sup>69</sup>

Again there is a call for ethical guidelines (to govern those who produce clinical guidelines) on the basis that “the influence exerted by industry money is unconscious but powerful;” but avoiding conflicts of interest may be unrealistic—“bodies that produce [clinical] guidelines maintain that there just aren’t enough experts without conflicts of interest.”<sup>70</sup>

This tension also arises in the context of peer review functions generally:

Setting a scientist with commercial interests in pharmaceuticals to review papers on the effects of pharmaceuticals, or to write a review article on it, would endanger the autonomy and credibility of science and call for only ‘pure’ academics to perform such tasks. On the other hand, taking part in the review of . . . a programme may disqualify the evaluator. . . from applying for grants from the programme . . . [and] conflict[ing] with a scholar’s research interests. . . .<sup>71</sup>

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66. *Id.* at 192, 195–96.

67. See Mirowski & Van Horn, *supra* note 40, at 517–18 (A study conducted in 1990 suggests clinical trial contracts often contain “restraint clauses, confidentiality provisions, publication embargoes, and a host of other legal controls over proprietary information.”).

68. Sylvia Rowe et al., *Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity*, 89 AM. J. CLINICAL NUTRITION 1285, 1288 (2009).

69. Rosie Taylor & Jim Giles, *Cash Interests Taint Drug Advice*, 437 NATURE 1070, 1070 (2005) (quoting Drummond Rennie, deputy editor of the JAMA.).

70. *Id.* at 1071.

71. Liv Langfeld & Svein Kyvik, *Researchers as Evaluators: Tasks, Tensions and Politics*, 62 HIGHER EDUC. 199, 205 (2011).

Moreover, perhaps “judging research by who funded it is simply not the way the academic community proceeds.”<sup>72</sup> Kevin Quinn, a professor at Berkeley states, “[w]hile it may well be the case that some research that is funded by interested parties is bad research . . . , it is not necessarily the case that all, or even most, such research is biased or inaccurate.”<sup>73</sup>

Criticizing Justice Souter’s rejection of research funded in part by Exxon in *Exxon Shipping Co. v. Baker*,<sup>74</sup> Lee Epstein and Charles Clarke argue that while “treating funded research with some degree of skepticism is not without merit,” Justice Souter “implies that, even if research is reliable, valid, and transparent, it is still biased or otherwise lacking integrity if parties with a direct interest in the lawsuit support it . . . . [T]hese standards [i.e., reliability, validity, and transparency] are the best available criteria to detect bias in research.”<sup>75</sup> While “associations between the conclusion of a study and the source of its funding” have been demonstrated, commercial research is not “a bad thing per se,” and research integrity has not been widely undermined by “financial conflicts of interest.”<sup>76</sup>

Mirowski and Van Horn question the “tendency to cast the problem” of conflicts of interest “as a matter of individual responsibility, rather than a structural problem in the organization of science.”<sup>77</sup> The problem in most of science is not “personal biases or special interests,” or that “investigators are crudely falsifying the data or otherwise abandoning their commitment to truth.”<sup>78</sup> There have always been “small but cumulatively decisive ways for the data to be biased [in] the selection of subjects, . . . protocols for handling and reporting side effects, deciding whether to use placebos . . . , decisions about what constitutes a drug’s efficacy . . . , and decisions about when to end a trial.”<sup>79</sup>

The privatization of science in the form of CROs, however, “tends to insulate them from internal and external critique,” and “conflicts of interest

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72. Lee Epstein & Charles E. Clarke, Jr., *Academic Integrity and Legal Scholarship in the Wake of Exxon Shipping*, Footnote 17, 21 STAN. L. & POL’Y. REV. 33, 42 (2010).

73. *Id.* at 42–43. See also Donald J. Kochan, *The Political Economy of the Productions of Customary International Law: The Role of Non-Governmental Organizations in U.S. Courts*, 22 BERKELEY J. INT’L L. 240, 261–63 (2004) (Financial interests are not limited to “industry,” as nonprofit institutions are typically identifiable as “interest groups.”).

74. *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 501 n.17 (2008).

75. Epstein & Clarke, *supra* note 72, at 41, 50.

76. *Id.* at 37, 40 (quoting Editorial, *A New Policy on Financial Disclosure*, 4 NATURE NEUROSCIENCE 961, 961 (2001)).

77. Mirowski & Van Horn, *supra* note 40, at 521.

78. *Id.* at 519, 521.

79. *Id.* at 519.

are not perceived [by CROs] as a problem requiring special remedy or concern.”<sup>80</sup> Of course, CROs do not worry about “open science”—but some universities with industry relationships also readily “accept restrictions on proprietary information” and align “their practices to better resemble those of CROs” to compete for industry funds.<sup>81</sup>

The demise of free sharing of information to advance science is also the subject of some controversy in science literature. Some scientists divulge “results only after . . . accepted for publication” because they see science as “often a cutthroat venture.”<sup>82</sup> Secrecy is therefore not necessarily associated with the commercialization of science, and some studies have found that increased secrecy over the last thirty years “seems to result from a combination of increasing commercial linkages and increased pressures from scientific competition.”<sup>83</sup>

A survey of data withholding among geneticists found an increase in the practice, due perhaps to recent progress in the field, “since scientists are generating large numbers of new findings that stimulate . . . jockeying for scientific priority [, but] commercial applications of genetic research, along with increased dependence on industry funding and the rise of commercial norms in the academy, may be particularly responsible as well.”<sup>84</sup> Moreover, “having engaged in commercialization of university-based research was significantly associated with increased likelihood of data withholding.”<sup>85</sup>

This raises the question of whether scientific progress is slowed by secrecy. In the field of plant research, for example, a recent study found that while research is more *open* in academic science than in private research, “it becomes more closed as the two collaborate . . . [I]ndustry collaborators reach through academic collaborators to alter academic interactions and exchanges, curbing the spread of scientific materials and ideas.”<sup>86</sup>

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80. *Id.* at 519, 522.

81. *Id.* at 518.

82. Frederick Southwick, *All's Not Fair in Science and Publishing*, THE SCIENTIST, July 2012, available at <http://the-scientist.com/2012/07/01/all-s-not-fair-in-science-and-publishing/>.

83. Wei Hong & John P. Walsh, *For Money or Glory? Commercialization, Competition, and Secrecy in the Entrepreneurial University*, 50 SOC. Q. 145, 145 (2009). “[C]ompetition for priority . . . spurs effort [but] also produces negative effects that recent trends toward commercialization . . . seem to be exacerbating.” Nevertheless, the “focus on commercialization as the cause [of increased secrecy] may understate the effects of scientific competition.” *Id.* at 163.

84. Eric G. Campbell et al., *Data Withholding in Academic Genetics*, 287 JAMA 473, 479 (2002).

85. *Id.*

86. James A. Evans, *Industry Collaboration, Scientific Sharing, and the Dissemination of Knowledge*, 40 SOC. STUD. SCI. 757, 781 (2010).

Finally, the question arises whether patenting is a major concern in restricting access to data; some researchers have concluded that patents “are not determinative” in existing “restrictions imposed on the flow of information” among “biomedical researchers.”<sup>87</sup> Mirowski and Van Horn, however, see a significant effect of patents on the *process* of research—not its *products*—in research tool patents and materials transfer agreements.

### 3. IP and Research Tools

“[Materials Transfer Agreements (MTAs)] may stipulate payment for using a device, organism, reagent, database or software program; but . . . [they] have become the most common means to impose prepublication review [and] disclosure restrictions upon . . . actual use.”<sup>88</sup> MTAs often include “reach-through” or “grantback” provisions that render them “the logical complement of the CRO. The CRO is prohibited by its original service contract from appropriating IP; the academic researcher is dissuaded from seeking to appropriate IP through the MTA contract.”<sup>89</sup> Mirowski is particularly critical of the social science research claiming “patents rarely interfere with research, and even materials transfers are processed without incident.”<sup>90</sup> Hard “quantitative data on MTAs” is hard to find, and Mirowski not only doubts the reliance on surveys and questionnaires sent to samples of scientists, but highlights the strikingly different results in surveys conducted by biomedical professionals.<sup>91</sup> Somewhat reflecting a fear of conspiracy theories, Mirowski points out that the researchers who find little effect of MTAs “have themselves displayed long track records of propounding and defending the commercialization of scientific research and the privatization of the university more generally.”<sup>92</sup> Moreover, the survey evidence from this group is not so different from that of the biomedical researchers “except, of course, in its interpretation.”<sup>93</sup> “The bottom line is that these social scientists, if and when they venture to ask the ‘right’ questions, find [the same or larger] proportions of scientists inconvenienced or worse by the whole panoply of IP surround-

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87. Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, 8 INNOVATION POL’Y & ECON. 1, 1 (2008).

88. Mirowski & Van Horn, *supra* note 40, at 525.

89. *Id.* at 526.

90. MIROWSKI, *supra* note 11, at 174 (construing John P. Walsh, Charlene Cho & Wesley M. Cohen, Supporting Online Materials for *View From the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005), [www.sciencemag.org/cgi/content/full/309/5743/2002/DC1](http://www.sciencemag.org/cgi/content/full/309/5743/2002/DC1)).

91. *Id.* at 174–75.

92. *Id.* at 175.

93. *Id.* at 176. *See also id.* at 176–79 (critiquing the methodology used by these social scientists.).



ing research tools requested from external sources.”<sup>94</sup> Their failure is that they do not “combine all common legal means of discouraging research into a single portmanteau category in order to ask: what constitutes the totality of effects of fortified IP on scientific research?”<sup>95</sup> Their defense is that scientists have always withheld findings, but since there is an *increase* in withholding, the “relevant question is what happened to contemporary structural changes in how scientists interact in treating the communal aspects of research tools.”<sup>96</sup> For example, while there is evidence that “faculty who are more actively engaged in patenting may be less likely to collaborate with outsiders on research. . . . [which] appear[s] to be hindering innovation,”<sup>97</sup> another study shows increased secrecy among university scientists even when *not* seeking patents.<sup>98</sup>

#### 4. Publication and Authorship

“[T]he commercialization of science has not only had an impact on the level of disclosure of findings, but is also slowly changing the very meaning of the ‘scientific author.’”<sup>99</sup> Honorary or “gift” co-authorships to “famous or otherwise influential figures” provide a conventional example of “authorial voices . . . becom[ing] unhinged from authorial identities.”<sup>100</sup> However, the practice of ghost authorship, wherein “researchers agree to put their names on texts . . . composed by unnamed third parties, who [have] final control over the content of the manuscript,”<sup>101</sup> signals a “breakdown of ethical standards and editorial oversight.”<sup>102</sup> In one recent assessment, ghostwriting function alongside seeding trials (marketing under the guise of a clinical trial), publication planning (turning industrial data into journal articles), and selective publication to “distort the medical literature and undermine clinical trial research, explicitly by obscuring information that is relevant to patients

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94. *Id.* at 179.

95. *Id.* at 180.

96. MIROWSKI, *supra* note 11, at 180–81.

97. Joshua B. Powers & Eric G. Campbell, *Technology Commercialization Effects on the Conduct of Research in Higher Education*, 52 RES. HIGHER EDUC. 245, 245 (2011).

98. See Jeremy M. Grushcow, *Measuring Secrecy: A Cost of the Patent System Revealed*, 33 J. LEGAL STUD. 59 (2004). This increased secrecy could be related to a loss of a sense of reciprocity and collegiality, which could be related to commercialization. *Id.* at 78.

99. Mirowski & Van Horn, *supra* note 40, at 527.

100. *Id.* at 528.

101. *Id.*

102. *Id.* at 531.

and physicians.”<sup>103</sup> “Ghost authorship is ethically questionable in that it may be used to mask conflicts of interest with industry.”<sup>104</sup> Thus it has been suggested that medical journals should not publish commercially-sponsored articles.<sup>105</sup>

However, this assessment “unduly personalizes what is clearly a structural phenomenon” with respect to CROs.<sup>106</sup> Commentators and concerned editors “are still operating within the parameters of an older conception of science, in which authorship credit in journals is framed as a ‘reward’ for scientific effort, linked to an identifiable personality . . . . But the CROs participate in an altogether different kind of economy . . . .”<sup>107</sup> There is “no single person or small number of people . . . behind the information disseminated . . . there are only the contractual obligations of the corporation.”<sup>108</sup>

## 5. The Ends of Science

There is a strong tendency in the literature commenting upon the contemporary regime of commercialized science . . . to discount its impact by suggesting that, at most, industry funding may have had some minor influence on changing the *means* by which research is prosecuted, but by no stretch of the imagination has it transformed the *ends* of science.<sup>109</sup>

Perhaps that tendency is due to a narrow focus on universities, but there is a “possibility that the commercialization of science actually changes

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103. Joseph S. Ross et al., *Promoting Transparency in Pharmaceutical Industry-Sponsored Research*, 102 AM. J. PUB. HEALTH 72, 78 (2012).

104. Stephanie Ngai et al., *Haunted Manuscripts: Ghost Authorship in the Medical Literature*, 12 ACCOUNTABILITY RES. 103, 103 (2005).

105. See Sergio Sismondo & Mathieu Doucet, *Publication Ethics and the Ghost Management of Medical Publication*, 24 BIOETHICS 273, 273 (2010). But see Epstein & Clarke, *supra* note 72 at 35–36 (disagreeing with that proposal). Sismondo had earlier recommended “divorc[ing] the pharmaceutical industry from published research” on the basis that the “causal connections between funding and outcomes are relatively unaffected by such commonly proposed solutions as: stronger disclosure requirements, rigorous trial reporting standards, and trial registries . . . . [B]ias is not the result of simple methodological problems . . . .” Sergio Sismondo, *Pharmaceutical Company Funding and its Consequences: A Qualitative Systematic Review*, 29 CONTEMP. CLINICAL TRIALS 109, 112 (2008) (“The causes of [publication] bias are complicated, ranging from ghost-management of the literature by pharmaceutical companies to subtle actions provoked by relationships between companies and researchers.”).

106. Mirowski & Van Horn, *supra* note 40, at 531.

107. *Id.*

108. *Id.*

109. *Id.*

whatever it is that we get at the end of the process . . . .”<sup>110</sup> An identifiable reduction in productivity, the “vast volume of clinical trial information that never leaks out from proprietary boundaries,” and research oriented to marketing (e.g., seeding and switching trials), all point to a reduction in the pursuit of research objectives.<sup>111</sup> The changes in university science reflect a view “largely symptomatic of re-engineered science in the pharmaceuticals and the CRO industry.”<sup>112</sup>

The alarmist perspective is not without its critics, as discussed above, but for my purposes I want to compare and contrast (with other commentators) Mirowski’s unique (in legal literature) focus on the systemic and structural effects of commercialization and the economy on science, which effects are primarily indirect and unrelated to either the intentions of scientists or scientific misconduct.

### III. DISTORTING SCIENCE IN LAW

#### A. Direct Effects

When Law Professors McGarity and Wagner discuss the shaping of science in its association with industry, the term is pejorative.<sup>113</sup> Referring to (i) the Bayh-Dole Patent Amendments of 1980 allowing universities to patent federally-funded inventions, (ii) the resulting university/industry collaborations in an era of dwindling state support for higher education, (iii) the increased potential for conflicts of interest among university scientists, and (iv) the pressures on scientists to withhold publication critical of a sponsor’s products, “shaping” constitutes the first (in a list of six) strategies for “bending” science in legal contexts.<sup>114</sup> “[C]ollective scientific knowledge does not always result from scientists dutifully applying the scientific method, but instead sometimes reflects successful efforts by advocates to influence researchers and research outcomes.”<sup>115</sup> Rigging clinical trials, distorting methods, and biasing interpretations, alongside the empirically identifiable “funding effect” on research (making it favorable to the sponsor), raise concerns about the quality of science in law.<sup>116</sup> Other strategies include “hiding

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110. *Id.* at 532.

111. *Id.* at 533–36. *See also* Jean O. Lanjouw & Mark Schankerman, *Patent Quality and Research Productivity: Measuring Innovation with Multiple Indicators*, 114 *ECON. J.* 441, 441 (Apr. 2004). (“Research productivity . . . has declined sharply over the last 40 years, in many different industries and countries.”).

112. Mirowski & Van Horn, *supra* note 40, at 536.

113. *See* THOMAS O. MCGARITY & WENDY E. WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* 60, 60–61 (2008).

114. *Id.* at 88–91.

115. *Id.* at 95.

116. *Id.* at 95–96. *See generally* Sheldon Krimsky, *The Funding Effect in Science and Its Implications for the Judiciary*, 13 *J.L. & POL’Y* 43, 44 (2005).

science” from regulators, courts, and the public; attacking reliable science; harassing scientists who produce research perceived as damaging; packaging expertise to advance a desired outcome; and spinning science by framing and public relations.<sup>117</sup> The authors recommend transparency through disclosures of conflicts of interest (in litigation and policy contexts),<sup>118</sup> requiring access to data in *all* (not just federally-funded) completed studies,<sup>119</sup> discouraging suppression of adverse effects information,<sup>120</sup> independent advisory panels,<sup>121</sup> peer review of expertise,<sup>122</sup> informal consensus statements,<sup>123</sup> greater penalties for abuse of process,<sup>124</sup> and enhanced scrutiny of policy-relevant science.<sup>125</sup>

Without questioning the efforts and compelling examples offered by McGarity and Wagner, their analysis is focused on, and presumes, *direct* influences on science by bad actors—profit-making corporations and the “bent” scientists they hire. While the authors do mention (i) the biases, perhaps unconscious, reflected in the work of well-intentioned scientists, (ii) the pressures on scientists from industry support and threat of lawsuits, and (iii) the potential exodus of scientific talent due to harassment strategies,<sup>126</sup> the indirect or systemic effects of the commercialization of science are generally eclipsed in favor of stories about bad companies and bad people.

## B. Indirect Effects

By contrast, Daniel Lee Kleinman’s study of the commercialization of university biology readily acknowledges criticism (by McGarity and Wagner) that “commercially motivated collaborations between university biologist and science-based companies can skew research agendas, prompt inappropriate restrictions on the flow of information, and create conflicts of interest.”<sup>127</sup> However, Kleinman is more interested in the “subtle landscape” of academic capitalism—not the direct shaping of research agendas by corporate funding, but how “corporate domination of a field of scientific investigation early in its development can indirectly affect the questions that are asked and the answers that are acceptable at a later time, even if the later

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117. See generally MCGARITY & WAGNER, *supra* note 113, at 97.

118. See *id.* at 233.

119. See *id.* at 241.

120. See *id.* at 246.

121. See *id.* at 261–62.

122. See *id.* at 271–72.

123. See MCGARITY & WAGNER, *supra* note 113, at 273–74.

124. See *id.* at 275.

125. See *id.* at 28–84.

126. See *id.* at *passim*.

127. KLEINMAN, *supra* note 23, at x.

research is not funded by the industry.”<sup>128</sup> “[M]y claim is that by placing the focus of our attention on possible threats to the university from direct and explicit relationships between university scientists and commercial concerns, we have neglected to notice the less overt, but far more pervasive effects of . . . commercial *culture*.”<sup>129</sup> The laboratory that is the subject of Kleinman’s study is *not* restricted by its industry sponsors, and there are no “egregious violations of academic norms”—no unusual secrecy or conflicts of interest—but “there are indirect, systemic effects of the commercial world.”<sup>130</sup>

Highlighting such indirect effects is, however, controversial. To say “research patrons may shape research agendas, conceptual orientations, and ultimately experimental practice,” and to talk about withholding data or maintaining secrecy in IP protection practices, is threatening to the self-image and assumptions of many scientists—these topics sound like accusations of substandard work and greed.<sup>131</sup> In much of science writing,

Outcomes and effects are explained in *individual* terms . . . [, paying] little attention to the shaping and constraining influences of the larger environment in which scientists do their work. [For example, Natalie] Angier [in *Natural Obsessions* (1988, 47)] assigns personalities a pivotal role in . . . laboratories. She points to idiosyncrasies in an individual’s biography. . . . [T]he commercial world hardly seems to exist in Angier’s account.<sup>132</sup>

Scientists are likely more comfortable with such representations of individual conscious action,<sup>133</sup> since

[A] person with an individualist or agency-centered outlook might find it disconcerting to see a portrayal of her world that attributes great importance to the impact of *structural factors* on her daily life. The portrait might seem to implicate the individual’s motives, and if the representation is critical, that criticism might be perceived . . . as a condemnation of the person.<sup>134</sup>

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128. *Id.* at xi.

129. *Id.* at 5.

130. *Id.* at 4, 6, 17.

131. *Id.* at 24–26.

132. *Id.* at 28 (citing NATALIE ANGIER, *NATURAL OBSESSIONS: STRIVING TO UNLOCK THE DEEPEST SECRETS OF THE CANCER CELL* 47, 170, 299 (First Mariner Books eds. 1998)).

133. KLEINMAN, *supra* note 23, at 28 (“Individualist beliefs run deep in U.S. culture. We learn to see the world as the product of individual conscious action. This orientation permits us to take credit for our success and blame others for their failures.”).

134. *Id.* at 29.

Kleinman's study, however, does not suggest "an unrestrained commercial orientation . . . rather than a dedication to the higher ideals of science," it instead suggests "scientists are shaped by the larger world in which they operate," which may be beyond their control and reflects the influences of the "world of commerce."<sup>135</sup> In the laboratory on which Kleinman focuses his analysis, "the world of commerce does not explicitly dominate the day-to-day lives of [its] members . . . . I found no evidence of the kind of violations of the norms of academic science that concern many analysts of university-industry relations."<sup>136</sup> Even in the absence of *direct* industry funding, Kleinman argues "research practices can be *indirectly* shaped by industry."<sup>137</sup>

Perennial concerns over "corporate influences on the creation of university research agendas, corporate restrictions on the free flow of information, and questions of control over intellectual property" often reflect a contrast of our current situation with an assumption "the academy was once an isolated ivory tower."<sup>138</sup> Kleinman rejects this contrast, both because

[P]eriods of relatively high levels of faculty autonomy regarding their capacity to define research agendas and set priorities are relatively few in the history of the American university . . . [and because] the attention on the impact of *direct relations* between academic scientists and science-based firms . . . overlooks the *indirect but pervasive* influences of the world of commerce . . . .<sup>139</sup>

On the first point, "university patrons have affected research agendas and priorities" since the Civil War, and "private sources of support never meant absolute autonomy."<sup>140</sup> Federal government patronage of academic research, focused on military interests beginning with World War II, continued after

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135. *Id.* at 29–30. See also Sergio Sismondo, *How Pharmaceutical Industry Funding Affects Trial Outcomes: Causal Structures and Responses*, 66 SOC. SCI. & MED. 1, 2–3 (2008) ([The term] "conflicts of interest". . . [i]s misleading. The term suggests that researchers act inappropriately to further their own interests. However, it is not clear that medical researchers have material interests in particular results. When funding affects individual researchers' actions, we might interpret those actions in roughly behaviorist terms, rather than as calculated . . . . If we see funding as a form of gift giving . . . gifts create strong dispositions or obligations to reciprocate . . . . Sponsorship, then, creates subtle influences through the building of relationships that lead researchers to see the pharmaceutical companies with which they interact, and their products, in a more favorable light than they would otherwise.).

136. KLEINMAN, *supra* note 23, at 31.

137. *Id.* at 32.

138. *Id.* at 33, 35.

139. *Id.* at 35.

140. *Id.* at 37–38.

the war and cannot be viewed as "unrestricted support."<sup>141</sup> Withholding data or other materials from colleagues is more likely to be a function of protecting one's own discoveries and publication opportunities, as it is a function of financial arrangements with a sponsor; research has always been influenced by research group affiliation, pressures from colleagues, and "professional norms [that] shape criteria for accepting results."<sup>142</sup> There was never a period of disinterested and freely-shared scientific knowledge in the university.<sup>143</sup>

On the second point, Kleinman tries to account for organizational and institutional structures (i.e., not sustained only by individually chosen acts) that "establish distinctive resource distributions, capacities and incapacities, and define specific constraints and opportunities for actors depending on structural location."<sup>144</sup> For example, the dominance of the chemical industry in agricultural pest-control research is reflected in

[T]he ways scholarly writing in the field is framed, the way experiments are organized, the measures of success that are used and the tools that are available . . . [I]ndustry affected [more recent] scientific practice not directly through research funding, but indirectly through institutionalized standards and tools developed through earlier industry-supported research.<sup>145</sup>

After funding "some but not other research," and establishing standards and tools, "no direct intervention . . . by industry needed to occur for the influence to be felt."<sup>146</sup>

Legal structures play a significant role in Kleinman's analysis of indirect effects in the world of commerce, insofar as "resources and power asymmetries" affect scientific findings.<sup>147</sup> Kleinman recounts an episode he observed in the university laboratory when an academic scientist questioned the reliability of test results provided at reduced cost by a company analyzing on a contract basis.<sup>148</sup> The scientist asked the company to repeat the analysis

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141. *Id.* at 38-39.

142. KLEINMAN, *supra* note 23, at 42-43.

143. *Id.* at 42.

144. *Id.* at 61 (citing Leon Lindberg, *The Problems of Economic Theory in Explaining Economic Performance*, 459 ANNALS AM. ACAD. POL. & SOC. SCI. 14, 15-17 (1982)).

145. *Id.* at 88-89.

146. *Id.* at 89. Kleinman offers the example of kits "to increase efficiency and reliability by providing all (or many) of the materials necessary to undertake a test or procedure in a standardized form." *Id.* at 107. Today's scientists' "outlook and daily practice . . . has been shaped by the widespread availability of standardized research tools." *Id.* at 112.

147. *Id.* at 92.

148. KLEINMAN, *supra* note 23, at 99-101.

(for free) or report the risk of unreliability; the company responded to the lab's "extortion" by threatening legal action if the scientist's "erroneous and untrue" charges were to be published.<sup>149</sup> Having no power to pressure the company, and no resources to conduct independent tests (or, even if the lab did, to fight a legal battle), the lab backed down.<sup>150</sup> Thus "we see a particular structure that constitutes a distinctive set of resource distributions, capacities and incapacities; it defines variations in opportunity and constraint by structural location."<sup>151</sup> Intellectual property law is also an example of indirect or structural effects: "some researchers and policymakers express concern that commitments to intellectual property protection in university settings can undermine traditions of free intellectual exchange . . . . Recent developments illustrate how the patenting of research tools could hinder scientific investigation."<sup>152</sup> Consider how the intellectual property regime shapes university science when a "threat of legal action could prompt university labs *not* to do something they might do under different circumstances."<sup>153</sup> A company "has the capacity to enforce its position through litigation, [while individual] university scientists are unlikely to have this ability."<sup>154</sup>

Beyond issues of research funding, academic scientists work within a world of constraints. Kleinman concedes the "extent of these indirect influences on academic science is difficult to measure," and the "indirect effects of the commercial world on the practice of academic science are difficult to see and easier to ignore than the direct factors that have been the focus of controversy."<sup>155</sup> He recommends universities start to notice that some areas are vibrant and others stunted, and suggests universities develop "institutionalized reflexivity" to identify the costs and benefits of seeking IP protection in their laboratories.<sup>156</sup>

Mirowski has more recently, and more comprehensively, focused on measuring these indirect effects of the economy on science.

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149. *Id.* at 100–01.

150. *Id.* at 102. This is an example of scientific "self-censorship." See generally James Robert Brown, *Self-Censorship*, in *LAW AND ETHICS IN BIOMEDICAL RESEARCH: REGULATION, CONFLICT OF INTEREST AND LIABILITY* 82, 82–94 (T. Lemmens & D.R. Waring eds., 2006). Other examples include ignoring "certain medical problems . . . because they are financially unrewarding; choosing a lucrative field of research; deliberate ignorance in light of legal liability; and avoiding criticism of industry." *Id.* at 86–88.

151. KLEINMAN, *supra* note 23, at 103.

152. *Id.* at 114–15.

153. *Id.* at 123.

154. *Id.* at 125.

155. *Id.* at 89, 162; see also Brown, *supra* note 150, at 82 ("self-censorship is almost wholly non-quantitative, and its extent is thus very difficult to measure").

156. KLEINMAN, *supra* note 23, at 161.



### C. Returning to Mirowski

If we avoid viewing these phenomena as the dubious behaviors of a few misguided individuals or transgressions of the terminally greedy, and instead approach them as structural changes in the organization of science, then it will become possible to regard them as harbingers of the future of privatized science.<sup>157</sup>

Mirowski acknowledges the problem of measurement in assessing the “harm” to science through commercialization. Bibliometric research provides some measure of the decline in the United States’ scientific publication “output.”<sup>158</sup> Mirowski explains that phenomenon in terms of the decline in the United States’ dominance in science, a shrinking of the corporate sector, globalization and outsourcing of research and development, and the hobbling of “research output of state universities . . . by commercialized demands and the relinquishment of their public service orientation.”<sup>159</sup> Measuring the degradation of science quality is even more difficult, but Mirowski—rejecting the focus on individual responsibility and the possibility of fraud—tries to “set out some relatively tractable notions of ‘good science,’ starting from some aggregate measure, and [ask] what has happened to them.”<sup>160</sup>

Mirowski offers three examples, beginning with the rise of “just-in-time” science: “the forced inducement of quick and dirty techniques to produce attenuated results on schedule, under budget, and within the parameters of contractual relations.”<sup>161</sup> Mirowski’s second example is the “sound science” (or “anti-junk science”) movement wherein hidden organizations promote industry-friendly, or, in litigation terms, “defense-friendly science.”<sup>162</sup> This segment of Mirowski’s argument mirrors McGarity and Wagner, and seems less compelling because it appears to be an example of fraud, or “bad apples,” rather than a structural phenomenon. His third example is the degradation of patent quality; this argument finds support in IP literature.<sup>163</sup> As the rate of patenting has dramatically increased, there has been a rapid increase in low-quality (lower relative importance and generality) patents granted to universities.<sup>164</sup> One recent study estimated “28% of patents would be found

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157. Mirowski & Van Horn, *supra* note 40, at 514.

158. MIROWSKI, *supra* note 11, at 266–67.

159. *Id.* at 285.

160. *Id.* at 288.

161. *Id.* at 290.

162. *Id.* at 297–99 (providing examples such as casting doubt on good science, demanding more research or more “sound” science to order, or harass scientists).

163. *Id.* at 305–06.

164. See Rebecca Henderson et al., *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting*, 80 REV. ECON. & STAT. 1, 1–2 (1998).

at least partially invalid if subject to an anticipation or obviousness decision.”<sup>165</sup>

#### IV. CONCLUSION

Legal literature on scientific expertise too often focuses on the need for “fair, unbiased testimony and opinions” not “swayed by monetary reward.”<sup>166</sup> Legal scholars highlight direct conflicts of interest, but rarely discuss the systemic and structural effects on “how we do research or what we find there.”<sup>167</sup> The purpose of this article is to suggest a broader discourse in law concerning the “economic impacts on the directions of scientific thought, argument, and controversy,” toward conceptualizing the interaction of science and economy as a “process of ongoing (re)construction [wherein] each conditions the development of the other.”<sup>168</sup>

In short, an individualistic focus on more frequent disclosure of financial conflicts of interest,<sup>169</sup> higher methodological quality,<sup>170</sup> or ensuring one avoids favoring “a particular outcome . . . [or accepting] remuneration geared to the outcome of a research project,”<sup>171</sup> does not begin to address the systematic and structural changes brought about by economic forces on science. Such changes are not only hard to identify, and even more difficult to measure, but also require a new vocabulary or discursive regime. An interdisciplinary engagement with the growing literature regarding the economics of science reveals the appropriate analytical division for legal assessments of scientific reliability is not simply between good scientists and those guilty of misconduct (an easier problem to identify), or between commercially funded and “independent” research (because either may be biased), but rather a more complex, albeit fundamental, division between open and privatized science.

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165. Shawn P. Miller, *Where's the Innovation? An Analysis of the Quantity and Qualities of Anticipated and Obvious Patents*, unpublished manuscript (Feb. 10, 2012), available at SSRN: <http://ssrn.com/abstract=2029263>.

166. GLEN R. BROWN, *THE ART AND SCIENCE OF EXPERT WITNESSING: THE DEFINITIVE GUIDE FOR ATTORNEYS AND EXPERTS* 281 (Cypress Publishing Group, 2002).

167. MIROWSKI, *supra* note 22, at 24.

168. DAVID TYFIELD, *THE ECONOMICS OF SCIENCE: A CRITICAL-REALIST OVERVIEW* 24-26 (Routledge 2012).

169. See Rowe, *supra* note 68 and accompanying text.

170. Sismondo, *supra* note 135, at 2 (noting that most investigations into commercial funding of scientific research have “found no association between sponsorship and overall methodological quality”).

171. See Rowe, *supra* note 68 and accompanying text.

