

November 2020

## Professional Medical Judgment and Pharmaceutical Marketing: Drawing Legal and Ethical Lines Around Conflict of Interest

Steven R. Salbu

Follow this and additional works at: <https://scholarship.law.wm.edu/wmblr>



Part of the [Food and Drug Law Commons](#), and the [Health Law and Policy Commons](#)

---

### Repository Citation

Steven R. Salbu, *Professional Medical Judgment and Pharmaceutical Marketing: Drawing Legal and Ethical Lines Around Conflict of Interest*, 12 Wm. & Mary Bus. L. Rev. 23 (2020), <https://scholarship.law.wm.edu/wmblr/vol12/iss1/3>

# PROFESSIONAL MEDICAL JUDGMENT AND PHARMACEUTICAL MARKETING: DRAWING LEGAL AND ETHICAL LINES AROUND CONFLICT OF INTEREST

STEVEN R. SALBU\*

## ABSTRACT

*Pharmaceutical manufacturers develop relationships with healthcare providers for several purposes, including the marketing and sale of their products. Professional associations give guidance to physicians and companies for managing these relationships ethically. Some practices permitted by these associations entail conflicts of interest. This Article explores two of these practices: (i) company funding of external educational seminars, conferences, and continuing medical education; and (ii) company-hosted speaker programs. The conflict of interest concerns raised by the former practice are manageable, and the practice should continue to be permitted subject to appropriate safeguards; however, the conflict of interest concerns raised by the latter practice create an unacceptable ethical hazard that cannot be managed. Company-hosted speaker programs should be prohibited.*

---

\* Professor and Cecil B. Day Chair, Georgia Institute of Technology. BA, Hofstra University; MA, Dartmouth College; JD, College of William and Mary; MA, PhD, The Wharton School of the University of Pennsylvania. With thanks to Georgia Tech Graduate Assistant Nicholas Cheek for his excellent research support.

TABLE OF CONTENTS

INTRODUCTION .....	26
I. THE AMERICAN MEDICAL ASSOCIATION CODE OF MEDICAL ETHICS OPINION 9.....	32
<i>A. Current Opinion 9.6.2.....</i>	33
<i>B. Current Opinion 9.2.7.....</i>	36
II. THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS .....	39
<i>A. Informing and Educating Healthcare Professionals as a         Rationale for Relationships with Physicians .....</i>	41
<i>B. Supporting Medical Research as a Rationale for         Relationships with Physicians.....</i>	55
<i>C. Obtaining Feedback About Products from Medical Experts         as a Rationale for Relationships with Physicians .....</i>	57
1. <i>Why the Feedback Loop from Practitioners to Drug             Companies Is Important.....</i>	58
2. <i>Why Gifts and Payments by Drug Companies for             Lecturing Are Unnecessary to the Feedback Loop .....</i>	61
III. EXAMINING THE CONFLICT OF INTEREST IN TRANSACTIONS BETWEEN DRUG COMPANIES AND DOCTORS.....	63
<i>A. Conflict of Interest When Pharmaceutical Companies Fund         the Continuing Medical Education Offered by External         Professional Organizations.....</i>	63
<i>B. Conflict of Interest in Drug Company-Hosted Speaker         Programs .....</i>	69
1. <i>The Risk that Paid Pharmaceutical Company Speakers             Will Not Present Information Accurately and             Objectively.....</i>	71
2. <i>The Risk That Paid Program Speakers Lose Their             Objectivity in Decisions Regarding Prescription of the             Company's Products .....</i>	72
<i>a. The Operation of Reciprocity Norms and Informal                 Indebtedness.....</i>	73
<i>b. The Creation of Warped Incentives for the Speaking                 Physicians .....</i>	75

<i>c. The Risk that Company Provision of Dining, Drinks, and Social Entertainment Will Hinder the Objectivity of Physicians Who Attend the Programs as Learners.....</i>	77
<i>d. The Relative Likelihood of Pharmaceutical Company Speaker Programs Being Predominantly Beneficial or Predominantly Harmful .....</i>	78
<i>e. Disclosure of Conflict of Interest Is a Positive Step, but It Is Insufficient to Protect Patients' Interests.....</i>	79
<i>i. Evidence Suggests that Few Patients Consult the Currently Available Information Regarding Physician Payments.....</i>	81
<i>ii. Systemic Conditions Limit the Effectiveness of Information and Disclosure as Means to Manage Conflicts of Interest.....</i>	84
RECOMMENDATIONS AND CONCLUSION .....	87
<i>A. Conflict of Interest Is a Serious Problem Affecting the Ethically, Medically Sound Treatment of Patients.....</i>	87
<i>B. The Issues Identified Should Be Addressed by Changes in the Professional Ethics Codes of Both the Medical Profession and the Pharmaceutical Industry.....</i>	90

## INTRODUCTION

Over the years, critics have questioned the relationship between drug manufacturers and medical practitioners.<sup>1</sup> Recently, this relationship has faced a heightened level of scrutiny.<sup>2</sup> A 2008 study concluded that pharmaceutical companies in the U.S. “spend almost twice as much on promotion as they do on [research and development].”<sup>3</sup> The study stated that annual promotional expenditures in the U.S. might be as high as \$57.5 billion.<sup>4</sup> At the same time, other sources suggest that the figure might be as low as \$27 billion<sup>5</sup>—still a formidable number.

Growing concern about marketing to practitioners has been fueled in part by the opioid crisis.<sup>6</sup> Opioid manufacturers

---

<sup>1</sup> See Susan Heilbrunner Fisher, Note, *The Economic Wisdom of Regulating Pharmaceutical “Freebies,”* 1991 DUKE L.J. 206, 209 (1991) (discussing Congressional scrutiny, going back to 1990, of pharmaceutical company detailing practices).

<sup>2</sup> See John R. Washlick & Sidney Summers Welch, *Physician-Vendor Marketing and Financial Relationships Under Attack*, 2 J. HEALTH & LIFE SCI. 151, 153 (2008) (“The interaction between healthcare professionals and healthcare product manufacturers has come under increasing scrutiny.”).

<sup>3</sup> 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 (Jan. 2008).

<sup>4</sup> *Id.* at 31.

<sup>5</sup> *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, PEW PRESCRIPTION PROJECT (Nov. 11, 2013), <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients> [https://perma.cc/Y55Z-MFBR] (citing CEGEDIM STRATEGIC DATA, 2012 U.S. PHARMACEUTICAL COMPANY PROMOTION SPENDING (2013)) [hereinafter *Pew Fact Sheet*].

<sup>6</sup> See, e.g., Jessica Bartlett, *Opioid Marketing Contributed to Overdose Epidemic, Boston Medical Center Report Says*, BOS. BUS. J. (Jan. 18, 2019, 11:11 AM), <https://www.bizjournals.com/boston/news/2019/01/18/opioid-marketing-contributed-to-overdose-epidemic.html> [https://perma.cc/NZG5-5ZA3]; Andrew Joseph, *Purdue Cemented Ties with Universities and Hospitals to Expand Opioid Sales, Documents Contend*, STAT (Jan. 16, 2019), <https://www.statnews.com/2019/01/16/purdue-pharma-cemented-ties-to-universities-hospitals/> [https://perma.cc/KXV8-EH2B] (“Purdue ... saw the sponsorship of a pain program at Mass. General as a way to gain sway at one of the most influential academic medical centers in the country and boost its revenues—by encouraging doctors to prescribe OxyContin and Purdue’s other opioids to more patients at higher doses and for longer periods of time ....”).

face litigation over their marketing practices, and the first major settlement, with the state of Oklahoma, included an agreement by one manufacturer to refrain from “visiting doctors to persuade them to buy its products, until 2026.”<sup>7</sup> In the spring of 2019, five executives from Insys were convicted for paying doctors to boost sales of fentanyl, on the heels of earlier convictions of the company’s former Chief Executive and former Vice President of Sales.<sup>8</sup>

As a part of its strategic emphasis on marketing, the modern pharmaceutical industry exerts a strong influence on the prescription patterns of physicians.<sup>9</sup> According to one recent commentary, “[P]harmaceutical marketing can distort prescribing behaviors, exposing patients to concomitant risks. Physicians tend to prescribe drugs more frequently and non-rationally in response to pharmaceutical promotions.”<sup>10</sup>

This phenomenon is highlighted in Wazana’s review of sixteen studies that provide some data on the impact of pharmaceutical gratuities to doctors.<sup>11</sup> The data synthesis summary of Wazana’s analysis states in part,

Physician interactions with pharmaceutical representatives were generally endorsed, began in medical school, and continued at a rate of about 4 times per month. Meetings with pharmaceutical representatives were associated with requests by physicians for adding the drugs to the hospital formulary

---

<sup>7</sup> Lenny Bernstein & Katie Zezima, *Purdue Pharma, State of Oklahoma Reach Settlement in Landmark Opioid Lawsuit*, WASH. POST (Mar. 26, 2019, 6:05 PM), [https://www.washingtonpost.com/national/health-science/purdue-pharma-state-of-oklahoma-reach-settlement-in-landmark-opioid-lawsuit/2019/03/26/69aa5cda-4f11-11e9-a3f7-78b7525a8d5f\\_story.html?noredirect=on&utm\\_term=.1f121abb544f](https://www.washingtonpost.com/national/health-science/purdue-pharma-state-of-oklahoma-reach-settlement-in-landmark-opioid-lawsuit/2019/03/26/69aa5cda-4f11-11e9-a3f7-78b7525a8d5f_story.html?noredirect=on&utm_term=.1f121abb544f) [https://perma.cc/X5B5-V72K].

<sup>8</sup> Hannah Kuchler, *Insys Founder Convicted in Opioid Bribery Case*, FIN. TIMES (May 2, 2019), <https://www.ft.com/content/f83fc974-6d09-11e9-80c7-60ee53e6681d> (last visited Oct. 30, 2020).

<sup>9</sup> Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 CARDOZO L. REV. 2241, 2254, 2254 n.65 (2004).

<sup>10</sup> Recent Case, *First Amendment—Commercial Speech—Second Circuit Holds That Prohibiting Truthful Off-Label Promotion of FDA-Approved Drugs by Pharmaceutical Representatives Violates First Amendment*.—United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), 127 HARV. L. REV. 795, 802 (2013) (citations omitted).

<sup>11</sup> Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 375 (2000).

and changes in prescribing practice.... Attending presentations given by pharmaceutical representative speakers was also associated with nonrational prescribing.<sup>12</sup>

These trends continue despite physicians' recognition of the associated risks.<sup>13</sup> Wazana notes, "Most [residents and physicians in the studies] believe that representatives prioritize product promotion above patients' welfare and are likely to use unethical practices."<sup>14</sup>

In light of such concerns, are pharmaceutical company relationships with medical practitioners good or bad, or does it vary according to the behaviors and the circumstances? There are arguments to be made for and against the currently aggressive practices of pharmaceutical companies.<sup>15</sup> These are explored in this Article, which recommends maintaining some practices and changing others.

The Article focuses specifically on the close transactional relationships that develop between doctors and drug companies.<sup>16</sup> Cozy connections among these two groups raise troubling conflict of interest concerns.<sup>17</sup> We would hope that moral peril created by such conflict of interest among doctors in these situations is isolated and rare. If so, at least the overall social impact might be contained, rather than pervasive.

Financial relationships between physicians and industry are the rule, however, rather than the exception.<sup>18</sup> A study by Campbell et al. tallied the prevalence of "physician-industry relationships."<sup>19</sup> The research revealed that in both 2004 and

---

<sup>12</sup> *Id.* at 373.

<sup>13</sup> See, e.g., Nicole Van Groningen, Opinion, *Big Pharma Gives Your Doctor Gifts. Then Your Doctor Gives You Big Pharma's Drugs.*, WASH. POST (June 13, 2017), [https://www.washingtonpost.com/opinions/big-pharma-gives-your-doctor-gifts-then-your-doctor-gives-you-big-pharmas-drugs/2017/06/13/5bc0b550-5045-11e7-b064-828ba60fbb98\\_story.html](https://www.washingtonpost.com/opinions/big-pharma-gives-your-doctor-gifts-then-your-doctor-gives-you-big-pharmas-drugs/2017/06/13/5bc0b550-5045-11e7-b064-828ba60fbb98_story.html) [<https://perma.cc/KB8N-ZMWE>].

<sup>14</sup> Wazana, *supra* note 11, at 375 (citations omitted).

<sup>15</sup> *Id.* at 373; see also Van Groningen, *supra* note 13.

<sup>16</sup> See *infra* Part II.

<sup>17</sup> See *infra* Part III.

<sup>18</sup> Eric G. Campbell et al., *Physician Professionalism and Changes in Physician-Industry Relationships from 2004 to 2009*, 170 ARCHIVES INTERNAL MED. 1820, 1820 (2010).

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

2009, over 80% of doctors had one or more forms of financial relationship with drug or medical device companies.<sup>20</sup>

Although this figure decreased from 94% in 2004 to 84% in 2009,<sup>21</sup> this reduction reflects a more focused industry strategy for recruiting doctors as prescribers, rather than a curtailment of industry influence on prescription decisions.<sup>22</sup> According to Campbell, “The old approach was just to try to get as many docs as you can, blanket coverage, and establish relationships .... I think they’re being much more targeted and specific.”<sup>23</sup>

Vukadin has described the sophisticated methods used by drug companies to target physicians for relationship-building and the marketing of their products.<sup>24</sup> The companies begin by paying for data on physician prescribing habits and patterns.<sup>25</sup> These data enable pharmaceutical representatives to understand physician behavior and identify who among physicians are professional opinion leaders.<sup>26</sup>

Vukadin further observes, “The pharmaceutical industry closely monitors all contacts with physicians. One service counts the number of visits by pharmaceutical representatives and ranks physicians based on their willingness to see pharmaceutical representatives: completely open, sometimes willing to see pharmaceutical representatives, or completely unwilling.”<sup>27</sup> Well before business analytics initiatives ushered in the age of data-driven business and marketing practices,<sup>28</sup> pharmaceutical companies were honing this approach.<sup>29</sup>

---

<sup>20</sup> Charles Ornstein & Eric Sagara, *How Much Are Drug Companies Paying Your Doctor?*, PROPUBLICA (Sept. 30, 2014), <https://www.scientificamerican.com/article/how-much-are-drug-companies-paying-your-doctor/> [https://perma.cc/VHP6-R97Q].

<sup>21</sup> *Id.*

<sup>22</sup> Campbell et al., *supra* note 18, at 1825.

<sup>23</sup> Ornstein & Sagara, *supra* note 20.

<sup>24</sup> Katherine T. Vukadin, *Failure-to-Warn: Facing Up to the Real Impact of Pharmaceutical Marketing on the Physician’s Decision to Prescribe*, 50 TULSA L. REV. 75, 79–83 (2014).

<sup>25</sup> *Id.* at 79.

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

<sup>27</sup> *Id.* at 79–80 (internal citation omitted).

<sup>28</sup> For discussion of the trend toward using big data and analytics in making business decisions, see MCKINSEY GLOB. INST., *THE AGE OF ANALYTICS: COMPETING IN A DATA-DRIVEN WORLD* 4 (Dec. 2016), <https://www.mckinsey>



In 2012, Cegedim studied how pharmaceutical companies invest in marketing.<sup>30</sup> They classified these as detailing (described as “face-to-face promotional activities directed toward physicians and pharmacy directors”), samples, educational and promotional meetings, promotional mailings, journal and web advertisements, direct-to-consumer advertising, continuing medical education, and grants to health advocacy organizations.<sup>31</sup> All but two of these categories—direct-to-consumer advertising and grants to health advocacy organizations—are aimed at medical and pharmaceutical practitioners.<sup>32</sup>

Historically, it makes sense that pharmaceutical marketing has focused primarily on healthcare practitioners.<sup>33</sup> Until recently, direct-to-consumer (DTC) mass advertising was not practiced in the United States.<sup>34</sup> Traditional self-restraint among pharmaceutical firms reflected the “learned intermediary” doctrine, under which access to drugs was—as it still in many ways is—moderated through a gateway of trained healthcare professionals.<sup>35</sup>

---

.com/business-functions/mckinsey-analytics/our-insights/the-age-of-analytics-competing-in-a-data-driven-world [https://perma.cc/UQE4-B5B6].

Five years ago, the McKinsey Global Institute (MGI) released *Big data: The next frontier for innovation, competition, and productivity*. In the years since, data science has continued to make rapid advances, particularly on the frontiers of machine learning and deep learning. Organizations now have troves of raw data combined with powerful and sophisticated analytics tools to gain insights that can improve operational performance and create new market opportunities. Most profoundly, their decisions no longer have to be made in the dark or based on gut instinct; they can be based on evidence, experiments, and more accurate forecasts.

*Id.* at Preface.

<sup>29</sup> Kalman Applbaum, *Pharmaceutical Marketing and the Invention of the Medical Consumer*, 3 PLOS MED. 445, 445 (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1434507/pdf/pmed.0030189.pdf> [https://perma.cc/CQR3-4BCW].

<sup>30</sup> See *Pew Fact Sheet*, *supra* note 5.

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

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

<sup>33</sup> See Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 665, 669 (2006).

<sup>34</sup> See *id.* at 674 (observing that no companies from the 1950s through the early 1980s engaged in DTC mass marketing of pharmaceuticals).

<sup>35</sup> According to the learned intermediary doctrine, “the physician is ‘best situated to weigh the risks and benefits’ associated with a drug in relation to the needs of the patient.” *In re Avandia Mktg., Sales Pracs. & Prods. Liab.*

As the FDA notes, DTC advertising was never prohibited by federal law.<sup>36</sup> Nonetheless, it was only in the 1980s that pharmaceutical companies began DTC advertising in the U.S.<sup>37</sup> Because, for many years, pharmaceutical companies promoted their products solely to qualifying healthcare professionals, it isn't surprising that marketing practices over most of the 20th century developed primarily around physicians.<sup>38</sup>

What follows is an in-depth examination and assessment of two pharmaceutical company marketing practices that target physicians: company funding of and influence on the continuing medical education (CME) seminars and conferences of third-party professional organizations,<sup>39</sup> and company hosting of their own speaker programs.<sup>40</sup> These practices are analyzed in terms of conflict of interest concerns.<sup>41</sup> The analysis suggests that some current practices are beneficial and ethically manageable,<sup>42</sup> whereas others provide insufficient social benefit while creating unmanageable and therefore unacceptable moral perils.<sup>43</sup> The Article makes recommendations to address these issues.

Parts I and II explore the guidelines of the two key professional/industry groups on the relationship between drug companies

---

Litig., 286 F. Supp. 3d 667, 671 (2017) (quoting *Fisher v. Pro. Compounding Ctrs. of Am., Inc.*, 311 F. Supp. 2d 1008, 1020 (D. Nev. 2004)).

<sup>36</sup> *Background on Drug Advertising*, FDA, <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm> [<https://perma.cc/AB8R-7CED>] (last updated June 19, 2015).

<sup>37</sup> *Id.* ("Until the mid-1980s, drug companies gave information about prescription drugs only to doctors and pharmacists. When these professionals thought it appropriate, they gave that information to their patients. However, during the 1980s, some drug companies started to give the general public more direct access to this information through DTC ads.").

<sup>38</sup> Donohue, *supra* note 33, at 669.

<sup>39</sup> *See infra* Section III.A.

<sup>40</sup> *See infra* Section III.B.

<sup>41</sup> For a broad background discussion of conflict of interest in the medical profession, see generally INST. OF MED. OF THE NAT'L ACADS., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE (Bernard Lo & Marilyn J. Field eds., 2009).

<sup>42</sup> I refer here specifically to whether conflicts of interest can be justified due to social benefits. *See infra* Section III.A. Some conflicts of interest are avoidable or are acceptably manageable in order to achieve otherwise desirable ends.

<sup>43</sup> *See infra* Section III.B.

and medical practitioners. Specifically, Part I explores the American Medical Association (AMA) Code that governs physicians, and Part II examines the Pharmaceutical Research and Manufacturers of America (PhRMA) Code that governs the drug companies. Part III examines conflict of interest concerns raised by the relationships between these two groups. The last Part provides recommendations and concluding remarks.

### I. THE AMERICAN MEDICAL ASSOCIATION CODE OF MEDICAL ETHICS OPINION 9

The medical profession has addressed the relationship between doctors and drug companies through its umbrella professional organization, the American Medical Association (AMA).<sup>44</sup> The AMA Code of Medical Ethics (AMA Code) was originally drafted in 1847 and has been amended haphazardly over the course of 169 years.<sup>45</sup> It was systematically revised only twice: first half a century ago and then more recently in 2016.<sup>46</sup>

This Section looks at two relevant parts of the 2016 version that is currently in effect: Opinion 9.6.2<sup>47</sup> and Opinion 9.2.7.<sup>48</sup> This Article refers periodically as well to an important Opinion from the previous version of the AMA Code, which was called Opinion 8.061.<sup>49</sup> As a reminder of the status of each Opinion discussed herein, this Article refers to them throughout as “Current” to denote the AMA Code presently in effect,<sup>50</sup> and “Previous” to denote the AMA Code that was replaced by the 2016 revisions.<sup>51</sup>

---

<sup>44</sup> See *AMA’s Leadership in Medical Ethics Guides Teachers and Learners in Medicine*, AM. MED. ASS’N (Jan. 15, 2014), <https://www.ama-assn.org/delivering-care/ethics/amas-leadership-medical-ethics-guides-teachers-and-learners-medicine> [<https://perma.cc/GR55-HDN7>].

<sup>45</sup> See *Code of Medical Ethics Modernized for First Time in 50 years*, AM. MED. ASS’N (June 14, 2016), <https://www.ama-assn.org/about/publications-newsletters/code-medical-ethics-modernized-first-time-50-years> [<https://perma.cc/37L2-UYZ3>] [hereinafter *Code Modernized*].

<sup>46</sup> *Id.*

<sup>47</sup> Am. Med. Ass’n, Code of Med. Ethics, Opinion 9.6.2 (2016).

<sup>48</sup> Am. Med. Ass’n, Code of Med. Ethics, Opinion 9.2.7 (2016).

<sup>49</sup> See *Opinion 8.061—Gift to Physicians from Industry*, 16 AM. MED. ASS’N J. MED. ETHICS 261 (2014), <http://journalofethics.ama-assn.org/2014/04/coet2-1404.html> [<https://perma.cc/BDE4-65FZ>] [hereinafter *Opinion 8.061*].

<sup>50</sup> See generally Am. Med. Ass’n, Code of Med. Ethics, Opinions 9 (2016).

<sup>51</sup> See *Opinion 8.061*, *supra* note 49.

*A. Current Opinion 9.6.2*

Current Opinion 9.6.2 regarding gifts to physicians from industry observes that “[r]elationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public.”<sup>52</sup>

This reasonable statement improves on a more troubling assertion that was in Previous Opinion 8.061, which extended beyond relationships to actual gifts,<sup>53</sup> and stated that “[m]any gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function.”<sup>54</sup> The validity of this assertion was, on its face, suspect,<sup>55</sup> so it’s good that the AMA replaced it with more measured and accurate language.<sup>56</sup> After all, what is there that drug companies can give to doctors that they cannot buy themselves, or get elsewhere, without taint of favor or indebtedness? One commentator describes the situation:

[P]atients are unaware of industry marketing practices that create conflicts of interest for doctors. Drug companies sponsor and publish shoddy research and present it to doctors at free educational programs, often hosted at fashionable resorts with complimentary gourmet meals and rounds of golf. They pay doctors to attend and to present the marketing programs. They also pay doctors to prescribe their drugs under the guise of “research” which is scientifically worthless. They shower doctors with gifts and free samples to encourage prescribing. The strategy works. According to studies reported in the *Journal*

---

<sup>52</sup> See Opinion 9.6.2, *supra* note 47.

<sup>53</sup> See Opinion 8.061, *supra* note 49.

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

<sup>55</sup> See *id.* The suspect part of this earlier version’s introductory assertion is its questionable assumption that gifts are important and beneficial in maintaining what are otherwise useful relationships between industry and doctors. See Elaine K. Howley, *Do Drug Company Payments to Doctors Influence Which Drugs They Prescribe?*, U.S. NEWS (Aug. 31, 2018), <https://health.usnews.com/health-care/patient-advice/articles/2018-08-31/do-drug-company-payments-to-doctors-influence-which-drugs-they-prescribe> (last visited Oct. 30, 2020) (explaining that the actual impact of gift-giving “is still an active area of research”).

<sup>56</sup> See generally *Code Modernized*, *supra* note 45.

*of the American Medical Association*, in response to drug company promotions doctors prescribe drugs more frequently and nonrationally.<sup>57</sup>

Previous Opinion 8.061 posited only one example of a “socially beneficial function” of gifts to practitioners: the fact that “companies have long provided funds for educational seminars and conferences.”<sup>58</sup> Certainly, educational seminars and conferences for physicians do have social value, assuming that the information provided in the programs is both objective and accurate.<sup>59</sup> However, Previous Opinion 8.061 provided only this single example, probably because other types of gifts to physicians are difficult to justify and support.<sup>60</sup>

*Ceteris paribus*, a broad range of high-quality seminars and conferences for doctors, prescribing physician assistants (PAs), and nurse practitioners, is a good thing.<sup>61</sup> Multiple seminar offerings give medical professionals choices, increasing the chance they will get knowledge and information that will improve patient care.<sup>62</sup> More seminars and conferences may enhance attendance by helping match educational offerings to practitioners’ calendars, schedules, geographic areas, and specific subject matter needs.

Funding these events also is likely to increase attendance simply by virtue of the personal economics that drives decision-making generally.<sup>63</sup> As practitioners weigh a variety of ways to

---

<sup>57</sup> Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest*, 58 HASTINGS L.J. 967, 970 (2007).

<sup>58</sup> *Opinion 8.061*, *supra* note 49.

<sup>59</sup> See Sundeep Mishra, Editorial, *Do Medical Conferences Have a Role to Play? Sharpen the Saw*, 68 INDIAN HEART J. 111 (2016). Logic tells us that this is a big and perhaps unjustified assumption, given the conflicts of interest discussed in detail later in this Article. See also *infra* Part III.

<sup>60</sup> *Opinion 8.061*, *supra* note 49.

<sup>61</sup> See Mishra, *supra* note 59, at 111.

<sup>62</sup> There is a relationship between provision of choices and engagement of learners. See generally Frieda Parker et al., *To Engage Students, Give Them Meaningful Choices in the Classroom*, 99 PHI DELTA KAPPAN 37 (2017).

<sup>63</sup> See Jeffrey A. Tabas et al., *Clinician Attitudes About Commercial Support of Continuing Medical Education*, 171 ARCHIVES INTERNAL MED. 840, 840, 843 (2011) (survey found less than half were willing to pay increased registration fees to decrease or eliminate commercial support. In addition, 77% of physicians said the cost of registration is an important factor in their decision about which accredited continuing medical education activity to select.).

spend their time and money, financial support provided by anyone—including pharmaceutical companies—naturally makes seminars and conferences more affordable and appealing to potential attendees.<sup>64</sup>

Industry funding of conferences and seminars does raise conflict of interest concerns.<sup>65</sup> While most readers will already be familiar with the concept of conflict of interest as a legal and ethical issue, it may be helpful to define conflict of interest. Lo suggests that conflicts of interest exist under “circumstances that create ‘a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.’”<sup>66</sup> In regard to physicians, Thompson states that “[a] conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).”<sup>67</sup>

Primary interests are the socially sanctioned, intended, desired goals of a drug company or a medical practitioner, and Lo agrees with Thompson that the welfare of patients should logically be a key primary interest of doctors.<sup>68</sup> Lo offers a more expansive list of doctors’ secondary interests, including “financial gain, ... prestige, professional recognition, intellectual commitments to an idea or approach, and favors to friends, colleagues, or relatives.”<sup>69</sup>

For pharmaceutical companies, financial gain is likely to be either the primary interest or the logical main secondary interest.<sup>70</sup> Whichever is the case, if financial gain or other self-serving

---

<sup>64</sup> See *id.* at 840, 843.

<sup>65</sup> See *infra* Part III.

<sup>66</sup> Bernard Lo, *The Future of Conflicts of Interest: A Call for Professional Standards*, 40 J.L. MED. & ETHICS 441, 443 (2012) (internal quotation omitted).

<sup>67</sup> Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 573 (1993).

<sup>68</sup> Lo posits “the well-being of patients” as a primary interest of doctors. See Lo, *supra* note 66, at 443; see also Thompson, *supra* note 67, at 573.

<sup>69</sup> Lo, *supra* note 66, at 443.

<sup>70</sup> Whether profit is the primary interest of pharmaceutical companies or a secondary interest depends on one’s philosophy of what is the predominant social responsibility of business. Milton Friedman’s classic stance is that the “social responsibility of business ... [is] to increase its profits.” Milton Friedman, *The Social Responsibility of Business is to Increase its Profits*, N.Y. TIMES MAG.

benefits might undermine patient treatment decisions, we should be concerned.<sup>71</sup>

*B. Current Opinion 9.2.7*

Current Opinion 9.2.7 addresses physicians' financial relationships with industry in continuing medical education.<sup>72</sup> It begins, appropriately, by recognizing and stating the risk:

Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.<sup>73</sup>

The Current Version then states that, when possible, CME funding and staffing should come from independent sources that do not have a financial relationship with either the industry or the educational subject matter:

CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have

---

36 (Sept. 13, 1970). This approach suggests that profit is the primary objective of all business entities. *See id.* Conversely, applying a stakeholder model, "a variety of other interests [besides shareholder profit] are considered such as employees, suppliers, environmental, social and other interests." Joel Slawotsky, *The Virtues of Shareholder Value Driven Activism: Avoiding Governance Pitfalls*, 12 HASTINGS BUS. L.J. 521, 521 (2016). The social interest of public health can arguably lead us to conclude that, under a stakeholder model, patient safety should be the primary interest of pharmaceutical companies, with profit coming in as secondary. *See generally id.*

<sup>71</sup> David J. Rothman, *Medical Professionalism—Focusing on the Real Issues*, 342 NEW ENG. J. MED. 1284, 1284 (2000) (mentioning overtreatment of patients, self-referral, and fee splitting).

<sup>72</sup> *See* Opinion 9.2.7, *supra* note 48.

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

financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.<sup>74</sup>

As this “when possible” language implies, the Current Opinion 9.2.7 suggests that at times, CME cannot avoid financial conflicts of interest.<sup>75</sup> It states, “In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME.”<sup>76</sup> It then enumerates a variety of steps that should be taken when financial conflicts of interest cannot be avoided.<sup>77</sup> These include disclosing any financial relationships that might influence educational activities, the sources and nature of any commercial support and financial relationships, and any steps taken to mitigate influence of financial relationships.<sup>78</sup> In addition, the Current Opinion outlines a variety of mechanisms that should be undertaken to protect the independence of educational activities.<sup>79</sup>

Previous Opinion 8.061 has two simple instructions for managing conflicts of interest when companies subsidize conferences and professional meetings.<sup>80</sup> First, it attempted to manage any conflict of interest of such funding by requiring that company subsidies benefit practitioners only indirectly.<sup>81</sup> Section 4 of Previous Opinion 8.061 thus stated:

Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company’s representative may create a relationship that could influence the use of the company’s products, any subsidy should be accepted by the conference’s sponsor who in turn can use the money to

---

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

<sup>75</sup> *See id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *See Opinion 8.061, supra* note 49.

<sup>81</sup> *Id.*



reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.<sup>82</sup>

Secondly, Previous Opinion 8.601 also required that pharmaceutical companies funding the conferences or lectures of various medical organizations not directly influence the content.<sup>83</sup> Item 7 stated, "when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures."<sup>84</sup>

Item 7 of the Previous Version thus recognized that industry control of content is problematic, and prohibited outright any content control by company sponsors.<sup>85</sup> It is important to note that this restriction was limited to situations where companies are underwriting conferences and lectures "other than their own."<sup>86</sup> As we shall see, this left the door open for companies to influence and skew content through the provision of their own speaker programs aimed at invited groups of physicians, and using handsomely paid practitioner-speakers as the presenters.<sup>87</sup>

While the revised AMA Code regrettably still does not include these two specific restrictions that were in the Previous Version, the Pharmaceutical Industry's Code of Ethics does replicate both of them in the standards it lays out for the drug companies.<sup>88</sup> Unfortunately, this still leaves physicians free, under their own code of ethics, to accept direct compensation for attending CME events, or to turn a blind eye to improper industry influence over CME content, in cases where a drug company might violate their own industry's code.<sup>89</sup>

---

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> See *infra* Section III.B.

<sup>88</sup> Compare Opinion 9.2.7, *supra* note 48, and *supra* text accompanying notes 73–74, with Opinion 8.061, *supra* note 49, and *infra* text accompanying notes 100–02.

<sup>89</sup> See Opinion 9.2.7, *supra* note 48.

## II. THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

Just as the AMA has its Code of Ethics for doctors, so the drug industry has established its own code to govern pharmaceutical marketing practices.<sup>90</sup> While the AMA is concerned with the ethics of medical practitioners,<sup>91</sup> the Pharmaceutical Research and Manufacturers of America (PhRMA) addresses ethical issues facing drug companies.<sup>92</sup>

The PhRMA first introduced what is now called its *Code on Interactions with Health Care Professionals* (PhRMA Code) in 2002, under the name *PhRMA Voluntary Code of Marketing Practices*.<sup>93</sup> The PhRMA Code was revised effective January 2009,<sup>94</sup> and again effective January 2020.<sup>95</sup> Unsurprisingly, like the AMA Code, the PhRMA Code takes the position that there are benefits to current pharmaceutical industry promotional practices.<sup>96</sup>

Specifically, the Preamble of the current PhRMA Code notes, “Ethical relationships with health care professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines,

---

<sup>90</sup> *PhRMA Voluntary Code of Marketing Practices*, RELIAS MEDIA (Nov. 1, 2002), <https://www.reliasmedia.com/articles/110376-phrma-voluntary-code-on-marketing-practices> [<https://perma.cc/P3Q8-AQ86>].

<sup>91</sup> See Opinion 9.2.7, *supra* note 48.

<sup>92</sup> As of August 19, 2018, the PhRMA’s web page lists the organization’s mission as follows: “Our mission is to conduct effective advocacy for public policies that encourage the discovery of important, new medicines for patients by biopharmaceutical research companies. To accomplish this mission, we are dedicated to achieving these goals in Washington, D.C. and across the country.” *Our Mission*, PHARM. RSCH. & MFRS. AM., <https://www.phrma.org/about/our-mission> [<https://perma.cc/DJ6M-BK5P>].

<sup>93</sup> *PhRMA Voluntary Code of Marketing Practices*, *supra* note 90.

<sup>94</sup> PHARM. RSCH. & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTH CARE PROS. 3 (2009), <https://www.acpe-accredit.org/pdf/Code%20on%20Interactions%20HC%20Professionals.pdf> [<https://perma.cc/4HND-CKRG>].

<sup>95</sup> PHARM. RSCH. & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTH CARE PROS. 3 (2020), [https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction\\_FINAL21.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction_FINAL21.pdf) [<https://perma.cc/33LF-44CH>] [hereinafter PHARMA 2020 CODE].

<sup>96</sup> *Id.* at 2; see also Opinion 8.061, *supra* note 49.

which play an ever-increasing role in patient healthcare.”<sup>97</sup> This initial statement focuses on drug companies’ role in education and information provision to healthcare professionals.<sup>98</sup>

The Preamble then elaborates in a set of bullet points that frame the industry’s relationship and educational role with healthcare professionals as “critical” to meeting four goals: to “inform health care professionals about the benefits and risks of our products to help advance appropriate patient use, provide scientific and educational information, support medical research and education, and obtain feedback and advice about our products through consultation with medical experts.”<sup>99</sup>

Section 4 of the PhRMA Code maintains the two important restrictions that were contained in the previous version of the AMA Code,<sup>100</sup> but which are missing in the current version.<sup>101</sup> Under the PhRMA Code, company support of CME conferences and seminars is required to be indirect—i.e., to the conference providers in order to reduce registration fees for all—rather than directly paid to attendees; and companies are not permitted to select “content, faculty, educational methods, materials and venue,” but must leave these selections up to the conference organizers “in accordance with their guidelines.”<sup>102</sup>

Section 7 of the PhRMA Code covers pharmaceutical company speaker programs that ostensibly help serve the educational role.<sup>103</sup> It notes:

Company decisions regarding the selection or retention of health care professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communication skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.<sup>104</sup>

---

<sup>97</sup> PHARMA 2020 CODE, *supra* note 95, at 2.

<sup>98</sup> *Id.*

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

<sup>100</sup> *See Opinion 8.061, supra* note 49.

<sup>101</sup> *See Opinion 9.2.7, supra* note 48.

<sup>102</sup> *See* PHARMA 2020 CODE, *supra* note 95, at 6.

<sup>103</sup> *See id.* at 9.

<sup>104</sup> *Id.*

While this is a nice general edict, it is a requirement that eludes any kind of conceivable monitoring. We can never get into the mind of a sales representative or manager to know whether they select and retain speakers based on expertise and reputation. Similarly, we can never know if speaking arrangements are being used as inducements or rewards. Let's not be naïve: sales managers and representatives under pressure to meet goals will inevitably violate these rules,<sup>105</sup> and the violation is undetectable because we can never know the state of mind of the person who selects the speakers.

Recall also that the Preamble to the PhRMA Code states that the current relationship between drug companies and doctors is "critical."<sup>106</sup> Are gifts, gratuities, and benefits from industry to doctors also critical to accomplish important goals, or are they achievable in other ways? If they can be achieved by other means, should the goals noted in the Preamble<sup>107</sup> be accomplished through the touted industry-practitioner relationship, or through alternative means?

Because the four PhRMA Code Preamble goals<sup>108</sup> have some redundancy, this Article consolidates them for assessment purposes into three discrete categories: informing and educating healthcare professionals, supporting medical research, and obtaining feedback about products from medical experts.<sup>109</sup> The following Subsections explore and evaluate each of these justifications for the relationship between companies and doctors.

#### *A. Informing and Educating Healthcare Professionals as a Rationale for Relationships with Physicians*

Pharmaceutical company funded events can be educational, and the companies have knowledge and information

---

<sup>105</sup> See, e.g., Radha Chitale, *Pfizer Pays \$2.3B, But Will It Change the Pharmaceutical Industry?*, ABC NEWS (Sept. 2, 2009, 6:31 PM), <https://abcnews.go.com/Health/PainManagement/pfizers-23-billion-settlement-change-practices/story?id=8476391> [<https://perma.cc/GTX8-7UZN>] ("At Pfizer, I was expected to increase profits at all costs ....").

<sup>106</sup> See PHARMA 2020 CODE, *supra* note 95, at 2.

<sup>107</sup> *Id.*

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

<sup>109</sup> This consolidation combines "inform[ing] health care professionals about the benefits and risks of our products to help advance appropriate patient use," with "provid[ing] scientific and educational information," as it is difficult to distinguish the crux of these two justifications. *Id.* They are both education functions. *Id.*

about treatment of the conditions they research.<sup>110</sup> Pharmaceutical company expenditures on research and development have soared over the past few years, rising steadily from \$48.6 billion in 2011 to \$71.4 billion in 2017.<sup>111</sup> This investment gives drug companies a wealth of information to impart to medical practitioners.<sup>112</sup>

Educating doctors about treatments is, of course, important.<sup>113</sup> That said, are drug companies the entities we should entrust with accurately and objectively achieving this educational function? Levy, from the National Pharmaceutical Council Inc., supports the educational role of pharmaceutical marketing, stating, “Pharmaceutical marketing is the last element of an information continuum, where research concepts are transformed into practical therapeutic tools and where information is progressively layered and made more useful to the health care system. Thus, transfer of information to physicians through marketing is a crucial element of pharmaceutical innovation.”<sup>114</sup> Arguably, in the absence of drug marketing, “few physicians and patients would become aware of a new drug, and, thus, few patients would obtain its benefits.”<sup>115</sup>

However, drug companies have a fundamental conflict of interest as they seek billions of dollars in potential profits.<sup>116</sup> This

---

<sup>110</sup> For discussion of roles of medical information in the pharmaceutical industry, see Sukhpreet & P. Tiwari, *Role of Medicine Information in Pharmaceutical Industry*, 68 INDIAN J. PHARM. SCIS. 801, 802 (2006).

<sup>111</sup> Matej Mikulic, *Research and Development Expenditure of Total U.S. Pharmaceutical Industry from 1995 to 2018*, STATISTA (Mar. 9, 2020), <https://www.statista.com/statistics/265085/research-and-development-expenditure-us-pharmaceutical-industry/> [<https://perma.cc/BJT2-L29P>].

<sup>112</sup> See Sukhpreet & Tiwari, *supra* note 110, at 801.

<sup>113</sup> See *id.* at 802.

<sup>114</sup> Richard Levy, *The Role and Value of Pharmaceutical Marketing*, 3 ARCHIVES FAM. MED. 327, 327 (1994).

<sup>115</sup> Richard A. Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation*, 297 JAMA 646, 646 (2007) (book review).

<sup>116</sup> See U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS (2017), <https://www.gao.gov/products/GAO-18-40> [<https://perma.cc/UL9A-XBNF>] [hereinafter GAO REPORT] (estimating that pharmaceutical and biotechnology sales revenue increased from \$534 billion to \$775 billion from 2006 to 2015 and that the largest 25 companies achieved annual average profit margins between 15 and 20 percent). Although pharmaceutical companies have the knowledge and information to educate doctors, their motivation is fundamentally compromised. See Ameet Sarpatwari et al., *The*

conflict justifies skepticism about an educational function of pharmaceutical marketing.<sup>117</sup> Fortunately, in any business, some players will have strong ethical principles.<sup>118</sup> Unfortunately, others may gladly skew medical information, engage in deceptive behavior, or otherwise cut corners in maintaining an objective educational role, in order to grow sales and profits.<sup>119</sup>

The stakes are high when pharmaceutical companies are tempted and permitted to place profit-seeking over ethics in their purportedly educational practices.<sup>120</sup> No example is more compelling than the present, pernicious opioid crisis.<sup>121</sup> Sarpatwari et al.

---

*Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L. & POL'Y REV. 463, 472–73 (2017). The primary driver of these companies—like all companies—is not education. It is profit. *Id.* Pharmaceutical company executives and scientists work for a business, and businesses have the charge of making money. High R&D costs, combined with finite timeframes for patented products, put enormous financial pressure on drug companies to sell their products. See GAO REPORT, *supra* note 116, at 4–5, 7. Profit orientation, aggressive sales expectations, and incentive structures encourage companies to pass these substantial pressures on to employees. See Sarpatwari et al., *supra* note 116, at 467.

<sup>117</sup> For example, one study found pharmaceutical advertising to go beyond awareness-raising, seeking to “persuade through presentation of research findings.” David R. Gutknecht, *Evidence-Based Advertising? A Survey of Four Major Journals*, 14 J. AM. BD. FAM. PRAC. 197, 199–200 (2001). The finding suggested that “[d]escriptions of research in pharmaceutical advertisements were brief and incomplete, and they inconsistently provided the basic design and statistical information needed to judge the results reported.” *Id.* at 197.

<sup>118</sup> See generally Melissa Horton, *The Importance of Business Ethics*, INVESTOPEDIA (July 1, 2020), <https://www.investopedia.com/ask/answers/040815/why-are-business-ethics-important.asp> [<https://perma.cc/DL6X-TCL8>] (discussing the incentives that players in business industries have to be ethical).

<sup>119</sup> For an example discussing misleading information in drug marketing, see Adrienne E. Faerber & David H. Kreling, *Content Analysis of False and Misleading Claims in Television Advertising for Prescription and Nonprescription Drugs*, 29 J. GEN. INTERNAL MED. 110 (2013).

<sup>120</sup> See *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE (May 27, 2020), <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> [<https://perma.cc/B22N-9RTP>].

<sup>121</sup> The National Institute on Drug Abuse refers to the present situation as an “opioid overdose crisis.” See *id.*

The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease



list “fraudulent marketing” as one of four problems that have exacerbated the opioid epidemic.<sup>122</sup> They note that “to boost profits, pharmaceutical companies have often engaged in false or misleading marketing. Over the past twenty-five years, the industry has paid \$35.7 billion to settle claims of illegal marketing, including making false or misleading claims or failing to disclose known risks.”<sup>123</sup>

Ho & Rovzar describe one company’s marketing of a prescription opioid: “Through aggressive advertising and marketing efforts, the company conducted more than forty national conferences from 1996 through 2001, through which it endorsed liberal prescription of opioids ....”<sup>124</sup> They further note that in 2001, the company’s sales representatives received average sales bonuses of \$71,500.<sup>125</sup>

Not all entities and actors will manage the conflict of interest with integrity and place ethics ahead of self-interest.<sup>126</sup> Are there, then, better societal players to engage in the role of education of healthcare providers than drug companies? Arguably, academic scientists are better positioned to play this role.<sup>127</sup> In addition to pharmaceutical company scientists, government grant-funded scientists working at universities are the other main group that do research on pharmaceutical products.<sup>128</sup>

---

Control and Prevention estimates that the total “economic burden” of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

*Id.*

<sup>122</sup> See Sarpatwari et al., *supra* note 116, at 480.

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

<sup>124</sup> Jeremiah A. Ho & Alexander O. Rovzar, *Preventing Neonatal Abstinence Syndrome Within the Opioid Epidemic: A Uniform Facilitative Policy*, 54 HARV. J. ON LEGIS. 423, 437 (2017).

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

<sup>126</sup> For discussion of conflict of interest challenges, see Pilar N. Ossorio, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues*, 8 WIDENER L. SYMP. J. 75 (2001).

<sup>127</sup> See Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 50 SURV. ANESTHESIOLOGY 282, 282 (2006).

<sup>128</sup> See INST. OF MED., F. ON DRUG DISCOVERY, DEV., AND TRANSLATION, BREAKTHROUGH BUSINESS MODELS: DRUG DEVELOPMENT FOR RARE AND NEGLECTED DISEASES AND INDIVIDUALIZED THERAPIES: WORKSHOP SUMMARY 2

Of course, academic scientists employed by universities are also subject to both institutional pressures and conflicts of interest.<sup>129</sup> As Taylor observes, “Conflicts of interest are ubiquitous and inevitable in academic life, indeed, in all professional life. The challenge for academic medicine is not to eradicate them, which is fanciful and would be inimical to public policy goals, but to recognize and manage them sensibly and effectively.”<sup>130</sup>

The most direct of these pressures can come from industry itself when academic scientists receive either benefits from a company or direct industry funding for their research.<sup>131</sup> In these situations, the potential conflict of interest is an attenuated version of the conflict faced by company-employed scientists.<sup>132</sup> The latter group faces greater pressures because their stakes are higher—their livelihood depends on the company’s willingness to continue their employment.<sup>133</sup> In other words, the job security of a scientist employed by a drug company logically exerts a greater pressure than a single project funded by the company to a university, whose faculty’s base salaries are paid by the employing university.<sup>134</sup>

Academic scientists can, of course, be subjected to other pressures as well.<sup>135</sup> If a pharmaceutical company has been a

---

(2009), [https://www.ncbi.nlm.nih.gov/books/NBK50977/pdf/Bookshelf\\_NBK50977.pdf](https://www.ncbi.nlm.nih.gov/books/NBK50977/pdf/Bookshelf_NBK50977.pdf) [<https://perma.cc/49XF-NHVF>] (noting that drug development is a combined effort of not only drug companies, but also government-funded organizations).

<sup>129</sup> See Ossorio, *supra* note 126, at 75.

<sup>130</sup> Patrick L. Taylor, *Innovation Incentives or Corrupt Conflicts of Interest? Moving Beyond Jekyll and Hyde in Regulating Biomedical Academic-Industry Relationships*, 13 YALE J. HEALTH POL’Y, L. & ETHICS 135, 142 (2013) (quoting David Korn, *Conflicts of Interest in Biomedical Research*, 284 JAMA 2234, 2234 (2000)).

<sup>131</sup> See Paul M. Ridker & Jose Torres, *Reported Outcomes in Major Cardiovascular Clinical Trials Funded by For-Profit and Not-for-Profit Organizations: 2000–2005*, 295 JAMA 2270, 2270 (2006) (reporting findings that “[clinical] trials funded by for-profit organizations were more likely to report positive findings than those funded by not-for-profit organizations”).

<sup>132</sup> Sheldon Krinsky, *Do Financial Conflicts of Interest Bias Research? An Inquiry into the “Funding Effect” Hypothesis*, 38 SCI. TECH. & HUM. VALUES 566, 577 (2012).

<sup>133</sup> Compare *id.*, with Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at US Universities*, 284 JAMA 2203 (2000).

<sup>134</sup> Compare Krinsky, *supra* note 132, at 577, with Cho et al., *supra* note 133, at 284.

<sup>135</sup> See Marjorie Valbrun, *Letting the Donor Decide*, INSIDE HIGHER ED. (Oct. 8, 2018), <https://www.insidehighered.com/news/2018/10/08/professors-question>



donor to the university that employs a scientist, administrators who consider that funding relationship important might exert pressures on the scientist to support the relationship.<sup>136</sup> If this becomes inappropriate pressure to report company-friendly results, scientists at universities may be subject to influences other than pristine research methodology.<sup>137</sup>

We hope that core values of the academy—objectivity and the quest for truth<sup>138</sup>—are powerful drivers of disinterested research. Given that a fundamental goal of academic research is the quest for a true, objective understanding of the world, university researchers are well-positioned to provide practitioners with reliable information.<sup>139</sup>

Pressures on research faculty to report donor company-friendly results are nonetheless concerning.<sup>140</sup> Theoretically, any support from industry to universities—either general support or support of research—should have no strings.<sup>141</sup> Yet to assume that this ideal consistently reflects reality is naïve.<sup>142</sup> Indeed, there is an axiom among university development professionals that there is no such thing as corporate philanthropy—when companies give, they expect to get some direct or indirect benefit in return.<sup>143</sup>

---

-big-donation-saint-louis-university-because-conditions-attached [https://perma.cc/PL2Q-LD3T].

<sup>136</sup> Maintaining research independence and integrity in the face of donor pressures is a compelling and thorny problem. *See id.* (“Record \$50 million gift to Saint Louis University gave donors the right to help pick head of research institute and give that person a faculty title. Professors see dangerous erosion of academic values.”). While this kind of explicit quid pro quo agreement is likely uncommon and considered inappropriate and unacceptable, universities may naturally and unofficially defer to multimillion-dollar financial supporters to curry favor and encourage ongoing support. *See id.*

<sup>137</sup> *See* Krinsky, *supra* note 132, at 576.

<sup>138</sup> *See* Michael J. Bolton & Gregory B. Stolcis, *Ties That Do Not Bind: Musings on the Specious Relevance of Academic Research*, 63 PUB. ADMIN. REV. 626, 627 (2003) (observing that “[a]cademics are trained to generate knowledge in their respective disciplines”).

<sup>139</sup> *See* Krinsky, *supra* note 132, at 567.

<sup>140</sup> For an example of research initiatives guided by donor objectives, see *University Donations: No Strings Attached?*, TIMES HIGHER EDUC. SUPP. (Jan. 3, 2019), <https://www.timeshighereducation.com/features/university-donations-no-strings-attached> [https://perma.cc/FX36-BJ5Z] [hereinafter *University Donations*].

<sup>141</sup> For discussion of this issue, see generally *id.*

<sup>142</sup> *See* Cho et al., *supra* note 133, at 2203.

<sup>143</sup> Companies that support research or provide ostensibly philanthropic support to a university often view these activities as investments. *See* Alaka

Industry influence on academic research can be divided into two scenarios. Scenario 1 exists when a company gives financial support to a university in one guise, and a professor is doing research that is unrelated to that university support, but in which the company has a stake.<sup>144</sup> An example would be when a pharmaceutical company provides scholarship support for students, while a professor in the Chemistry department is simultaneously doing research that might affect the company.<sup>145</sup>

Scenario 1 can create pressure, albeit attenuated.<sup>146</sup> If a chemist gets called to the university president's office to discuss how her research results might influence continued scholarship support, there is pressure—implicit, explicit, or both.<sup>147</sup> This kind of pressure can affect research objectivity, and therefore creates ethical concerns.<sup>148</sup> The pressure is attenuated, however, because on their faces, the scholarship and the research are separate activities independent of one another, unless someone makes the connection and exerts pressure based on that connection.<sup>149</sup>

Scenario 2 occurs where a pharmaceutical company is providing direct funding for a chemist's research.<sup>150</sup> If the company

---

Malwade Basu, *Are Millennium Development Goals Relevant for Academic Research?*, 42 ECON. & POL. WKLY. 4235 (2007). Not surprisingly, given their mission to make profits, they are seeking some kind of business advantage. See Cho et al., *supra* note 133, at 2203. They may seek access to universities' talent pools for hiring or may be looking for relationships with faculty to reap the benefits of their knowledge and expertise. See *id.* They may seek influence of some kind—potentially including influence over research results. See Basu, *supra*, at 4235. This last category of influence is the principle concern regarding whether universities can be objective in research that is funded by industry. See *id.*

<sup>144</sup> See *University Donations*, *supra* note 140.

<sup>145</sup> See Valbrun, *supra* note 135.

<sup>146</sup> See *University Donations*, *supra* note 140.

<sup>147</sup> Basu notes that while research should not be politicized or improperly influenced, the current reality is that it is:

The whole point of university affiliation is that the academic can be an independent researcher whose research interests and output are not dictated by university administrators, politicians or corporations. This is a mission that is already severely eroded by what has been called the corporatization of the university and university research.

See Basu, *supra* note 143, at 4235.

<sup>148</sup> See *University Donations*, *supra* note 140.

<sup>149</sup> See *id.*

<sup>150</sup> For discussion of the “funding effect” correlating funding sources with study outcomes, see Krinsky, *supra* note 132, at 577.

places any pressure on the chemist to report favorable outcomes, that is unattenuated pressure since the company is directly attempting to influence the findings of research it is financially supporting.<sup>151</sup> Even if the company sponsoring research does not overtly communicate any pressure in regard to research outcomes, investigators might nonetheless infer or presume such pressure.<sup>152</sup>

Scenario 2 likely creates the greater moral jeopardy for two reasons. First, in Scenario 1, we can and should hope that the university president will exert her own professional ethics, declining to intervene in any way that might influence the chemist's results. At the very least, a savvy president will recognize that such intervention creates an appearance of academic impropriety.<sup>153</sup> Second, industry funding of faculty research under Scenario 2 exerts a pressure that is immediate.<sup>154</sup> It creates a direct dependency on the part of the investigator that is potentially powerfully corrupting.<sup>155</sup>

University research objectivity has been challenged as well by those suggesting a liberal bias in the academy.<sup>156</sup> While political leanings do not necessarily imply political research bias, humans

---

<sup>151</sup> *See id.*

<sup>152</sup> *See id.* Faculty researchers are likely to be smart and savvy enough to recognize that an industry sponsor has interests in the outcome of their research, and that faculty whose results are favorable to a company are more likely to receive future funding than faculty whose conclusions are unfavorable to the company. *See id.* Even if a company places no express pressure on faculty to arrive at desired conclusions, faculty can infer that there are potential stakes in the direction of their findings. *See id.*

<sup>153</sup> *See Basu, supra* note 143, at 4235.

<sup>154</sup> *See Krinsky, supra* note 132, at 577.

<sup>155</sup> *See Cho et al., supra* note 133, at 2203–04.

There is a growing body of literature showing that faculty who have industry ties are more likely to report research results that are favorable to a corporate sponsor, are more likely to conduct research that is of lower quality, and are less likely to disseminate their results to the scientific community.

*Id.* (internal citations omitted).

<sup>156</sup> *See, e.g., Robert Maranto & Matthew Woessner, Diversifying the Academy: How Conservative Academics Can Thrive in Liberal America*, 45 PS: POL. SCI. & POL. 469 (2012) (discussing the domination of higher education by politically liberal faculty and suggesting strategies for conservative faculty to avoid unnecessary conflict and thrive).

are subject to unconscious bias generally,<sup>157</sup> and concern has been raised about possible political bias bleeding over into research.<sup>158</sup>

Recent data suggest that “[a]cademics, on average, lean to the left.”<sup>159</sup> In 2010–2011, survey results showed 62.7 percent of full-time faculty at four-year colleges and universities identifying as either far-left or liberal,<sup>160</sup> while only 11.9 percent identified as far-right or conservative.<sup>161</sup>

Ideological biases among the professoriate could affect research projects funded through grants.<sup>162</sup> The peer review process in a liberally slanted academy may tend to favor both grant proposals and refereed article submissions that appear to have liberal leanings.<sup>163</sup>

If so, this can be a confounding influence on how well universities achieve the ideal of impartial, objective research.<sup>164</sup> In the arena of pharmaceutical research, political biases could be a

---

<sup>157</sup> For a sampling of discussions of unconscious bias in a variety of contexts, see Philip E. Tetlock et al., *Detecting and Punishing Unconscious Bias*, 42 J. LEGAL STUD. 83, 84 (2013); Jean Moule, *Understanding Unconscious Biases and Unintentional Racism*, 90 PHI DELTA KAPPAN 320, 321 (2009); see also Jeffrey Mervis, *U.S. Study Shows Unconscious Gender Bias in Academic Science*, 337 SCI. MAG. 1592 (2012).

<sup>158</sup> See Robert J. MacCoun & Susannah Paletz, *Citizens’ Perceptions of Ideological Bias in Research on Public Policy Controversies*, 30 POL. PSYCH. 43 (2009) (discussing ideological bias in research and finding that persons with conservative beliefs tend to attribute studies with liberal findings to the researcher’s own political leaning).

<sup>159</sup> Scott Jaschik, *Moving Further to the Left*, INSIDE HIGHER ED. (Oct. 24, 2012), <https://www.insidehighered.com/news/2012/10/24/survey-finds-professors-already-liberal-have-moved-further-left> [<https://perma.cc/AB3Y-WRNV>].

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> See Marc T. Law et al., *Earmarked: The Political Economy of Agricultural Research Appropriations*, 30 REV. AGRIC. ECON. 194 (2008) (exploring political influence over allocation of research funds); Carol J. Lee, *Commensuration Bias in Peer Review*, 82 PHIL. SCI. 1272 (2015) (observing that reviewers’ systematic prioritization among various review criteria problematically influences publication and funding decisions).

<sup>163</sup> See Maranto & Woessner, *supra* note 156, at 470.

<sup>164</sup> For discussion of the risks of politicization of research and findings in universities, see Hannah Forsyth, *Disinterested Scholars or Interested Parties? The Public’s Investment in Self-Interested Universities*, in THROUGH A GLASS DARKLY: THE SOCIAL SCIENCES LOOK AT THE NEOLIBERAL UNIVERSITY, 19 (Margaret Thornton ed., 2015).

concern, as liberal and conservative positions may vary in regard to the value of particular drugs, medical interventions, and policies around them.<sup>165</sup>

Despite the conflicts of interest that faculty face, universities are a better resource than companies for objectively educating and informing practitioners about drug treatments.<sup>166</sup> There is an inherent, fundamental difference between the mission of a company and the mission of a university.<sup>167</sup> Companies exist primarily to make profits,<sup>168</sup> whereas universities exist primarily to create and disseminate knowledge.<sup>169</sup>

---

<sup>165</sup> This could be true, for example, in regard to research concerning drugs being explored as potential interventions to terminate pregnancy. For a discussion of the difficulty in establishing scientific objectivity in abortion-linked breast cancer research and the political controversy surrounding the issue, see Patricia Jasen, *Breast Cancer and the Politics of Abortion in the United States*, 49 MED. HIST., 423, 423–44 (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1251638/> [<http://perma.cc/LYQ2-KSJX>].

<sup>166</sup> See Brennan et al., *supra* note 127, at 282.

<sup>167</sup> See Margaret Thornton, *Introduction: The Retreat from the Critical*, in *THROUGH A GLASS DARKLY: THE SOCIAL SCIENCES LOOK AT THE NEOLIBERAL UNIVERSITY*, 3 (Margaret Thornton ed., 2015).

<sup>168</sup> This mission doesn't necessarily imply a duty to maximize profits at any cost. See Einer Elhauge, *Sacrificing Corporate Profits in the Public Interest*, 80 N.Y.U. L. REV. 733, 738 (2005). Management has discretion under the business judgment rule to consider tradeoffs between lawfully maximizing corporate profits and serving the public interest. See *id.* ("Corporate managers have never had an enforceable legal duty to maximize corporate profits. Rather, they have always had some legal discretion (implicit or explicit) to sacrifice corporate profits in the public interest."). The very discussion of whether corporate managers have any discretion ever to put public interest ahead of profits highlights how central the profit mission is to company endeavors. The business judgment rule is the exception that proves the more overarching rule: the primary role of companies is to make money. See *id.* at 736. Indeed, the case widely viewed as a primary source of the business judgment rule itself asserts shareholder primacy, the notion that "[a] business corporation is organized and carried on primarily for the profit of the stockholders." *Dodge v. Ford Motor Co.*, 170 N.W. 668, 684 (Mich. 1919).

<sup>169</sup> In other words, the most central core value of a business is to sell its products. *Ford Motor Co.*, 170 N.W. at 684. In contrast, the core values of academic research are knowledge and truth. See Lisa D. Ordóñez et al., *On Good Scholarship, Goal Setting, and Scholars Gone Wild*, 23 ACAD. MGMT. PERSPS. 82, 84 (2009). At least in their pristine forms, one is fundamentally partisan, whereas the other is intended to be impartial. See *id.* at 84–85.

Although people in any organization can be tempted toward unethical behavior, profit-seeking is likely to exert stronger pressures than knowledge seeking.<sup>170</sup> The sales goals of pharmaceutical company employees demand that they place their own products in the best possible light.<sup>171</sup> In contrast, the research goals of scholars are, at least in their pristine form, manifestly aimed at the pure and objective discovery of truth and knowledge.<sup>172</sup> Moreover, tenure provides significant protection of academic freedom, so that tenured university faculty are uniquely insulated from pressures regarding their research, at least in terms of their basic job security.<sup>173</sup>

For these reasons, information provided to doctors about drug treatments is likely to be more objective when coming from academic researchers than when coming from pharmaceutical companies.<sup>174</sup> This distinction forms part of the basis for the two recommendations to come in the Conclusion: first, that drug company sponsorship of external conferences does yield a net social benefit, and therefore should be permitted, provided appropriate safeguards are in place to deal with conflict of interest.<sup>175</sup> Such conferences often feature university researchers as speakers, and as we shall see, the conflict of interest in these situations can be managed.<sup>176</sup>

Likewise, the lower susceptibility of academic investigators to industry influence relative to company-compensated investigators helps to justify the second recommendation to come in the Conclusion: that companies' own speaker series, featuring

---

<sup>170</sup> See Ordóñez et al., *supra* note 169, at 86.

<sup>171</sup> See Amanda L. Connors, Comment, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 ALB. L. REV. 243 (2009).

<sup>172</sup> Ordóñez et al., *supra* note 169, at 84–85 (defining good scholarship as addressing important questions, generating knowledge, empirics, generating implications, and being widely consumed).

<sup>173</sup> See Ralph S. Brown & Jordan E. Kurland, *Academic Tenure and Academic Freedom*, 53 L. & CONTEMP. PROBS. 325, 328–29 (1990) (defining academic tenure and discussing it as the main protector of academic freedom).

<sup>174</sup> See Basu, *supra* note 143, at 4235.

<sup>175</sup> See *infra* Recommendations and Conclusion.

<sup>176</sup> See Marcia M. Boumil et al., *Pharmaceutical Speakers' Bureaus, Academic Freedom, and the Management of Promotional Speaking at Academic Medical Centers*, 40 J.L. MED. & ETHICS 311 (2012).

practitioners they compensate as the paid speakers, in balance are likely to cause more social harm than benefit and should be prohibited by the professional and industrial codes of ethics.<sup>177</sup>

One final concern does remain, though: is academic scholarship relevant to physicians' treatment decisions? Is the basic research that comprises much university scholarship<sup>178</sup> even applicable to practitioners?

Traditional basic research is unlikely to be of direct use to practitioners.<sup>179</sup> A classic description of basic research is found in a report from the National Science Foundation:

Basic research is performed without thought of practical ends. It results in general knowledge and understanding of nature and its laws. The general knowledge provides the means of answering a large number of important practical problems, though it may not give a complete specific answer to any one of them.<sup>180</sup>

Since basic research does not seek utility, much of it is unlikely to be of great help to doctors when they are selecting the best treatment for a patient.<sup>181</sup>

In the years since 1945, however, universities increasingly are homes for applied research.<sup>182</sup> Applied research has been described by the National Institutes of Health as including patient-oriented research, epidemiologic and behavioral research, outcomes research, and health services research.<sup>183</sup> Applied research, as the term suggests, focuses on how science can be used.<sup>184</sup> Medical

---

<sup>177</sup> See *infra* Recommendations and Conclusion.

<sup>178</sup> For comprehensive discussion on the role and function of basic research in universities, see generally Désirée Schauz, *What is Basic Research? Insights from Historical Semantics*, 52 MINERVA 273, 274–75 (2014).

<sup>179</sup> NAT'L SCI. FOUND., THE THIRD ANNUAL REPORT OF THE NATIONAL SCIENCE FOUNDATION 38 (1953), [https://www.nsf.gov/pubs/1953/annualreports/ar\\_1953.pdf](https://www.nsf.gov/pubs/1953/annualreports/ar_1953.pdf) [<https://perma.cc/75LB-PB8U>].

<sup>180</sup> *Id.*

<sup>181</sup> See *id.*

<sup>182</sup> Indeed, scientists at universities often are entrepreneurs operating businesses. See Melissa S. Anderson, *The Complex Relations Between the Academy and Industry*, 72 J. HIGHER ED. 226, 230 (2001).

<sup>183</sup> Doris McGartland Rubio et al., *Defining Translational Research: Implications for Training*, 85 ACAD. MED. 470 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2829707/#R4> [<https://perma.cc/QH8Y-957N>].

<sup>184</sup> See Charles S. Reichardt & Melvin M. Mark, *Quasi-experimentation*, in THE SAGE HANDBOOK OF APPLIED SOCIAL RESEARCH METHODS 193 (Leonard Bickman & Debra J. Rog eds., 2009) (observing that applied research “strives



applied research has been divided into two somewhat murky classifications: clinical research and translational research.<sup>185</sup>

Clinical research refers to medical experimentation with human subjects.<sup>186</sup> Clinical trials of drug products as required by the FDA are done on pharmaceuticals being developed for possible use.<sup>187</sup> Translational research has been described to include “translating research into practice ... ensuring that new treatments and research knowledge actually reach the patients,” and enabling “clinicians and patients to change behaviors and make more informed choices.”<sup>188</sup>

Whereas universities historically focused on basic research,<sup>189</sup> scientific papers today often have commercial applications.<sup>190</sup> This shift reflects the profitability of research, having practical applications that can be monetized for both faculty and

---

to improve our understanding of a ‘problem,’ with the intent of contributing to the solution of that problem.”). Of course, the bifurcation of research into categories of basic and applied is in some ways an unrealistic construct, as there is no clear delineation between the two. See Schauz, *supra* note 178, at 274–75. As Hammersley observes, harkening to Kurt Lewin, good theory itself is useful. Martyn Hammersley, *Action Research: A Contradiction in Terms?*, 30 OXFORD REV. ED. 165, 166 (2004).

<sup>185</sup> For general discussion of these two categories of medical research, see Rubio et al., *supra* note 183, at 470, 470–71.

<sup>186</sup> See Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 386 n.134 (2002) (quoting ALBERT R. JONSEN ET AL., CLINICAL ETHICS 192 (4th ed. 1998)) (“Clinical research is defined as any clinical intervention involving human subjects, patients or normal volunteers, performed in accord with a protocol designed to yield generalizable scientific knowledge.”). For a very practical and informative explanation by the FDA on clinical trials, see *Learn About Drug and Device Approvals, The Drug Development Process, Step 3: Clinical Research*, FDA (Jan. 4, 2018), <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> [<https://perma.cc/BCY9-AUEX>].

<sup>187</sup> See Joanna K. Sax, *Protecting Scientific Integrity: The Commercial Speech Doctrine Applied to Industry Publications*, 37 AM. J.L. & MED. 203, 222 (2011) (“In order to obtain FDA drug approval, the results of clinical trials must be reported to the FDA.”).

<sup>188</sup> Steven H. Woolf, Commentary, *The Meaning of Translational Research and Why it Matters*, 299 JAMA 211, 211 (2008).

<sup>189</sup> See David Korn, *Financial Conflicts of Interest in Academic Medicine: Whence They Came, Where They Went*, 8 IND. HEALTH L. REV. 1, 6 (2010–11) (observing that an “enormous, world-leading American basic research enterprise” developed after World War II).

<sup>190</sup> Daniel Benoliel, *The Impact of Institutions on Patent Propensity Across Countries*, 33 B.U. INT’L L.J. 129, 144 (2015).



universities.<sup>191</sup> It likely also reflects growing pressures on universities to demonstrate economic impact,<sup>192</sup> as well as a societal shift to an increasingly entrepreneurial model of the university.<sup>193</sup>

Going back as far as 1992, Chew noted that 31% of university research was applied or developmental,<sup>194</sup> and suggested that universities are becoming increasingly entrepreneurial.<sup>195</sup> Notwithstanding the importance of basic research, practical applications can provide more readily appreciated public optics regarding the value universities create.<sup>196</sup>

Seventeen years after Chew's article, Frischmann observed that "[m]ost university science and technology research systems serve *mixed* commercial, public, and social ends by enabling the production of a wide variety of private, public, and nonmarket goods."<sup>197</sup> Thus, the trend toward more applied research appears to continue.<sup>198</sup>

---

<sup>191</sup> See Philip G. Pardey et al., *Creating, Protecting, and Using Crop Biotechnologies Worldwide in an Era of Intellectual Property*, 6 MINN. J.L. SCI. & TECH. 213, 225 (2004) (discussing dynamics that "could shift the emphasis of university research from fundamental basic research toward more applied research that is potentially more rewarding financially for the university or its research faculty ....").

<sup>192</sup> See Chanphirun Sam & Peter van der Sijde, *Understanding the Concept of the Entrepreneurial University from the Perspective of Higher Education Models*, 68 HIGHER ED. 891, 891 (2014) ("[C]hanges have been seen in the evolutionary roles of universities, which share the common trend from traditional missions of teaching and research to the third mission for economic development.").

<sup>193</sup> See Alice Lam, *From 'Ivory Tower Traditionalists' to 'Entrepreneurial Scientists'?*, 40 SOC. STUD. SCI. 307 (2010) (suggesting that an entrepreneurial model of the university is transforming academic sciences in a way that stresses "knowledge capitalization").

<sup>194</sup> Pat K. Chew, *Faculty-Generated Inventions: Who Owns the Golden Egg?*, 1992 WIS. L. REV. 259, 307.

<sup>195</sup> *Id.* at 308.

<sup>196</sup> Indeed, there are societal expectations that some form of practical return on investment will come from funding academic research. See Benjamin F. Jones & Mohammad Ahmadpoor, *Tracing the Links Between Basic Research and Real-World Applications*, THE CONVERSATION (Aug. 10, 2017, 2:01 PM), <http://theconversation.com/tracing-the-links-between-basic-research-and-real-world-applications-82198> [<https://perma.cc/BN34-AQJY>] ("But what kind of return are we as a society recouping on this large investment in new discoveries? Does scientific research reliably lead to usable practical advances?").

<sup>197</sup> Brett M. Frischmann, *The Pull of Patents*, 77 FORDHAM L. REV. 2143, 2154 (2009) (emphasis in original).

<sup>198</sup> See *id.*

Why is this trend relevant? The trend addresses the question, even if universities might be expected to be the most disinterested, objective sources of good drug treatment for physicians, do university investigators do that kind of research? Increasingly, the answer is yes, they often do.<sup>199</sup>

*B. Supporting Medical Research as a Rationale for Relationships with Physicians*

The second function of interaction between drug companies and healthcare professionals that is posited in the PhRMA Code is the support of medical research.<sup>200</sup> Let's start with an axiom: research on pharmaceutical products to determine their efficacy and safety is critically important.<sup>201</sup> A second axiom is that pharmaceutical companies have the interest, the resources, the stakes, and indeed the legal obligation under current regulations to engage in such testing as part of the drug approval process.<sup>202</sup>

This research role of the pharmaceutical industry certainly does entail interaction with healthcare professionals.<sup>203</sup> But what should that interaction look like? Consider the range of interactions. One is identification of medical experts to engage in research.<sup>204</sup> Another is cooperation with those experts in the development of research questions, projects, and protocols. In fact, drug companies accomplish these important tasks by hiring qualified researchers to perform the clinical trials required by law.<sup>205</sup>

---

<sup>199</sup> *See id.*

<sup>200</sup> *See* PHARMA 2020 CODE, *supra* note 95, at 2 and text accompanying note 199.

<sup>201</sup> *Why is Pharmacology Research Important?*, NAT'L INSTS. HEALTH (Dec. 1, 2016), <https://www.nichd.nih.gov/health/topics/pharma/conditioninfo/important> [<https://perma.cc/B5FB-LMZM>] (observing that pharmacology research serves to determine both safety and effectiveness of medications).

<sup>202</sup> *See generally Development and Approval Process: Drugs*, FDA (Oct. 28, 2019), <https://www.fda.gov/drugs/development-approval-process-drugs> [<https://perma.cc/32CH-UMVY>].

<sup>203</sup> *See id.*

<sup>204</sup> *See* Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. TRANSLATIONAL MED. 105, 110 (2016) (observing that the pharmaceutical industry traditionally has relied on third parties for specialized expertise).

<sup>205</sup> Under the U.S. regulatory model, clinical trials are conducted and financed by pharmaceutical companies. *See* Jennifer S. Bard, *What to do When You Can't Hear the Whistleblowing: A Proposal to Protect the Public's Health*

In these ways, pharmaceutical research benefits from, and indeed relies on, corporate interaction with medical professionals.<sup>206</sup> But interaction and employment of medical staff are one thing; subsidies, honoraria and perquisites to non-employee practitioners are another thing entirely.<sup>207</sup> There is no rational link that requires the latter to enable the former.<sup>208</sup>

If pharmaceutical research is to be objective, the relationship between companies and external researchers should be as unsullied as possible.<sup>209</sup> On this research purity dimension, the marketing functions of drug companies cannot, in any reasonable way, be justified as serving the “supporting medical research” function.<sup>210</sup> The two are simply unrelated: selling the company’s product to doctors has no connection to researching products.<sup>211</sup> If anything, these two functions are incompatible with one another: doctors who receive perquisites from a company are no longer the disinterested, objective scientists best qualified to investigate and evaluate the company’s products.<sup>212</sup>

Given that companies do have the stakes and the resources to sponsor research on their products, and in light of resource scarcity and the inability of government to support all the research

---

by *Providing Whistleblower Protection for Medical Researchers*, 9 IND. HEALTH L. REV. 1, 4 (2012) (“It is the fragmented way research and drug development is structured in the United States which makes it so hard to protect the public. U.S. law divides human subjects’ safety oversight into two separate jurisdictions: first, research funded by agencies of the Federal Government and second, drug trials paid for by pharmaceutical companies.”) (internal citations omitted).

<sup>206</sup> See Schuhmacher et al., *supra* note 204, at 109.

<sup>207</sup> See Bard, *supra* note 205, at 36.

<sup>208</sup> See Cole Wayant et al., Research Letter, *Financial Conflicts of Interest Among Oncologist Authors of Reports of Clinical Trials*, 4 JAMA ONCOLOGY 1426, 1427 (2018).

<sup>209</sup> Sameer S. Chopra, *Industry Funding of Clinical Trials: Benefit or Bias?*, 290 JAMA 113, 113 (2003) (“[S]cientists who design, conduct, analyze, and report clinical trials often receive monetary compensation from drug companies, in the form of either salaries or consulting fees. These arrangements raise several concerns.”).

<sup>210</sup> Mace L. Rothenberg & David H. Johnson, *Conflict of Interest, Conflicting Interests, and Effective Collaboration Between Academia and Industry on Preclinical and Clinical Cancer Research*, 3 JAMA ONCOLOGY 1621 (2017).

<sup>211</sup> See Wayant et al., *supra* note 208, at 1427.

<sup>212</sup> For discussion of the relationship between investigator conflict of interest and quality of scientific research, see *id.*; see also Rothenberg & Johnson, *supra* note 210, at 1621–22.

needed,<sup>213</sup> we do not have the luxury of disqualifying industry funding as a source of scientific research sponsorship.<sup>214</sup> However, we can and should impose legal and ethical constraints on the relationship and the funding.

These constraints ought to comprise three main categories: disqualification of research when, for whatever reason, an investigator is subject to conflicts of interest that cannot be managed;<sup>215</sup> a requirement that researchers with manageable conflicts of interest disclose the conflict;<sup>216</sup> and a prohibition of unnecessary, ancillary forms and sources of conflict of interest. This last category is the relevant one to this discussion: there is no benefit to anyone, apart from the pharmaceutical company and the doctors who benefit, to providing perquisites directly to physicians, beyond the funding of research itself.<sup>217</sup>

### *C. Obtaining Feedback About Products from Medical Experts as a Rationale for Relationships with Physicians*

The final function of the corporate relationship with doctors noted in the PhRMA Code is the receipt by drug manufacturers of feedback from practitioners regarding their products.<sup>218</sup> While

---

<sup>213</sup> See Joanne Waldstreicher & Michael E. Johns, Viewpoint, *Managing Conflicts of Interest in Industry-Sponsored Clinical Research*, 317 JAMA 1751, 1751 (2017) (“Companies engaged in health care research and development share, with health professionals, academic health centers, patient advocacy organizations, and other medical and health-related institutions, the mission to improve human health. Companies play indispensable roles in advancing almost all aspects of this mission, including sponsoring clinical research and generating clinical data that serve as the basis for drug and device approvals, guidelines, and prescribing information.”).

<sup>214</sup> See Bard, *supra* note 205, at 34.

<sup>215</sup> See Opinion 9.2.7, *supra* note 48.

<sup>216</sup> An example of the disclosure approach is Japan’s Clinical Practice Guidelines, under which pharmaceutical company payments to physicians are disclosed. Hiroaki Saito et al., *Evaluation of Pharmaceutical Company Payments and Conflict of Interest Disclosures Among Oncology Clinical Practice Guideline Authors in Japan*, JAMA NETWORK OPEN (Apr. 26, 2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2731682> [<https://perma.cc/28XD-DA99>] (“In accordance with the Japanese Pharmaceutical Manufacturers Association guidelines for transparency, pharmaceutical company payments to physicians have been disclosed since 2013.”).

<sup>217</sup> See *infra* Section II.C.2.

<sup>218</sup> See PHARMA 2020 CODE, *supra* note 95 and text accompanying note 99.

the feedback function is important, it neither requires nor justifies giving company benefits directly to doctors.<sup>219</sup> The following subsections explore why the feedback loop from practitioners to drug companies is so important, and why gifts and payments to physicians for lecturing are unnecessary to the feedback loop.

*1. Why the Feedback Loop from Practitioners to Drug Companies Is Important*

The FDA new drug approval process is inherently imperfect: it is impossible to devise a drug approval system that evaluates efficacy and safety with complete accuracy.<sup>220</sup> Medical research is subject to uncertainty and error.<sup>221</sup> Moreover, if clinical trials are to have any hope of giving us useful pharmaceuticals, approval processes need to be reasonably expedient,<sup>222</sup> and of course, there is a natural, unavoidable tension between expediency and thoroughness.<sup>223</sup>

Accordingly, FDA drug approval protocols balance the desire to approach research perfection with the need of patients for promising and timely treatments, especially when the alternatives are limited and prognoses are poor.<sup>224</sup> Moreover, long-term

---

<sup>219</sup> *See id.*

<sup>220</sup> *See* Nicholas S. Downing et al., Original Investigation, *Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010*, 317 JAMA 1854 (2017) (observing that for 222 novel therapeutics during the time period studied, there were 123 postmarket safety events that led to withdrawals, boxed warnings, and safety communications).

<sup>221</sup> *See id.*

<sup>222</sup> This need has led to expedited FDA review processes. *See* Thomas J. Hwang et al., Research Letter, *The FDA's Expedited Programs and Clinical Development Times for Novel Therapeutics, 2012–2016*, 318 JAMA 2137 (2017) (discussing four expedited FDA programs: “(1) priority review leads to FDA review in 6 months (vs 10 months for standard review); (2) accelerated approval permits approval based on surrogate measures; and (3) fast-track and (4) breakthrough therapy programs are intended to reduce the duration of clinical trials.”).

<sup>223</sup> Anupam B. Jena et al., *The Trade-off Between Speed and Safety in Drug Approvals*, 3 JAMA ONCOLOGY 1465 (2017).

<sup>224</sup> *See* Aaron S. Kesselheim et al., *Four Ways to Address the Ethical Tensions Around Expedited Approval of New Prescription Drugs*, HEALTH AFFS. BLOG (June 23, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog.20160623.055507/full/> [<https://perma.cc/9GJV-P6RE>] (“Because testing new

risks and harms take years to appear, therefore clinical trials will not discover them prior to approval.<sup>225</sup>

The AIDS crisis in the 1980s illustrates the tension between rigorous thoroughness and the need to provide promising treatments without undue delay.<sup>226</sup> When effective treatments did not yet exist, growing numbers of patients lacked the time to wait for perfect research.<sup>227</sup> Both the FDA and pharmaceutical companies were faced with the challenge of balancing meticulous, time-consuming studies with the need for promising, yet-to-be-proven options.<sup>228</sup> Accordingly, fast-track approval processes proliferated.<sup>229</sup> However, whenever pre-marketing approvals are expedited or abbreviated, the need for post-approval surveillance becomes increasingly important.<sup>230</sup>

---

drugs requires a delay between identification of an important, novel prescription drug and FDA approval, some patients with serious or life-threatening illnesses and no satisfactory options will not live to see a potentially life-saving medication approved for public use. To address this concern, the FDA and Congress have established several programs—with the support of pharmaceutical manufacturers and some patient advocacy groups—that allow new drug approval based on less evidence, so that patients and their physicians have faster access and potentially a greater choice of therapies.”).

<sup>225</sup> See Krishnan Vengadaraga Chary, Editorial, *Expedited Drug Review Process: Fast, but Flawed*, 7 J. PHARMACOLOGY & PHARMACOTHERAPEUTICS 57, 58 (2016) (discussing drug approvals that were later withdrawn due to outcomes unpredicted in the original research that supported the approvals).

<sup>226</sup> Jon Scott Batterman, Note, *Brother Can You Spare a Drug: Should the Experimental Drug Distribution Standards Be Modified in Response to the Needs of Persons with AIDS?*, 19 HOFSTRA L. REV. 191, 193–95 (1990).

<sup>227</sup> See *id.* (“Based on the lack of FDA-approved drugs for the treatment of AIDS, many persons suffering from the syndrome are desperately seeking access to drugs which have been approved for experimental testing on humans, but which have not satisfied the rigid safety and effectiveness testing criteria of the Federal Food, Drug and Cosmetic Act.”) (internal citations omitted).

<sup>228</sup> See Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 403 (1994) (observing the conflict that existed in the 1980s between rigorous scientific research and the time-sensitive needs of patients seeking effective HIV and AIDS treatment options).

<sup>229</sup> Aaron S. Kesselheim et al., *Trends in Utilization of FDA Expedited Drug Development and Approval Programs, 1987–2014: Cohort Study*, 351 THE BMJ 1 (2015) (“In the past two decades, drugs newly approved by the FDA have been associated with an increasing number of expedited development or review programs.”).

<sup>230</sup> This need is especially important given concerns that fast-track processes may have been motivated not simply by concern for patients, but also

Thus, FDA new drug approvals cannot be viewed as conclusive; rather, they aim to optimize the balance between approaching research perfection and the realities of error and a need for reasonable speed in bringing promising pharmaceuticals to market.<sup>231</sup> Because new drug approvals are based on inconclusive determinations, mechanisms for post-approval monitoring and feedback are crucial.<sup>232</sup>

The PhRMA Code appropriately recognizes the experience of prescribing physicians and their patients as essential to this ongoing, post-approval assessment.<sup>233</sup> The Code correctly posits post-approval monitoring and feedback as a good reason for a relationship to exist between pharmaceutical companies and doctors.<sup>234</sup> However, as we shall see in the next Subsection, this relationship need not and should not entail some common but ethically tainted practices and transactions.

---

as FDA payback to the powerful drug companies that underwrite much of the FDA budget. See Caroline Chen, *FDA Repays Industry by Rushing Risky Drugs to Market*, PROPUBLICA (June 26, 2018, 5 AM), <https://www.propublica.org/article/fda-repays-industry-by-rushing-risky-drugs-to-market> [https://perma.cc/UK8A-4STH] (“As pharma companies underwrite three-fourths of the FDA’s budget for scientific reviews, the agency is increasingly fast-tracking expensive drugs with significant side effects and unproven health benefits.”).

<sup>231</sup> See *Fast Track*, FDA (Jan. 14, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track> [https://perma.cc/QWK9-YXRR] (stating fast track processing is meant to expedite review of drugs that meet two criteria: “treat[ing] serious conditions and fill[ing] an unmet medical need.”). The breadth of these criteria for fast track review highlights the importance the FDA places on speed in getting promising drug treatments to patients in need.

<sup>232</sup> See Paul Kubler, *Fast-Tracking of New Drugs: Getting the Balance Right*, 41 AUSTL. PRESCRIBER 98, 99 (2018) (observing that “[a]ccess to new therapies is a balance between evidence (determining the risk of acceptable adverse effects versus efficacy) and the speed of availability, intersected by the issue of affordability[,]” and therefore “[r]apidly approved drugs should receive provisional registration for a period of three years and the drug company should be required to provide annual data on the postmarketing experience.”).

<sup>233</sup> PhRMA, BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES 16 (2015) (stating “[r]esearch on a new medicine does not end when the discovery and development phases are completed and the medicine is available to patients.”).

<sup>234</sup> See Opinion 9.6.2, *supra* note 47.

*2. Why Gifts and Payments by Drug Companies for Lecturing Are Unnecessary to the Feedback Loop*

Practitioner and patient feedback to drug manufacturers neither requires nor benefits from various perquisites currently provided to doctors.<sup>235</sup> Relationships do not require emolument, especially in areas where the public good demands professional and commercial ethical commitments from associations like the AMA, the PhRMA, and the constituencies they represent.<sup>236</sup>

An effective and appropriate mechanism already exists for feedback from doctors to pharmaceutical companies: the FDA's adverse event reporting system.<sup>237</sup> The agency's MedWatch web-site is a vehicle for both physicians and patients "to voluntarily report a serious adverse event, product quality problem, product use/medication error, or therapeutic inequivalence/failure that [they] suspect is associated with the use of an FDA-regulated drug, biologic, medical device, dietary supplement or cosmetic."<sup>238</sup> Moreover, this voluntary reporting mechanism is not the only vehicle for feedback on drug efficacy and safety.<sup>239</sup> Rather, it enhances mandatory reporting by facilities, distributors, importers, applicants, and manufacturers.<sup>240</sup>

There is no justifiable connection between this important feedback loop and gifts or payments from companies to doctors.<sup>241</sup>

---

<sup>235</sup> See PHARMA 2020 CODE, *supra* note 95, at 11 (suggesting items and gifts provided to doctors should not be offered); see also Opinion 9.6.2, *supra* note 47 (suggesting the risk of gifts causing bias on "professional judgment in the care of patients.").

<sup>236</sup> See PHARMA 2020 CODE, *supra* note 95, at 11; Opinion 9.6.2, *supra* note 47.

<sup>237</sup> See *Reporting Serious Problems to the FDA*, FDA (May 22, 2018), <https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> [<https://perma.cc/6Q2C-J39H>].

<sup>238</sup> *Id.*

<sup>239</sup> U.S. FOOD & DRUG ADMIN., ADVERSE EVENT REPORTING FOR OUTSOURCING FACILITIES UNDER SECTION 503B OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY 2, 9 (Oct. 2015).

<sup>240</sup> *Id.* (referring to "postmarketing adverse experience reports required under 21 CFR 310.305, 314.80, 314.98, and 600.80 ... 760 of the FD&C Act ... and [u]nder section 503B ....") (internal citations omitted).

<sup>241</sup> See PHARMA 2020 CODE, *supra* note 95, at 11 (suggesting certain items should not be offered to health care professionals); see also Opinion 9.6.2, *supra* note 47 (stating "[g]ifts to physicians from industry create conditions that carry



The argument might be made that paid physician speaker programs enhance feedback about products because they provide a venue where pharmaceutical representatives and doctors meet, mingle, and interact, and that such opportunities might increase the chance that drug companies will learn about the clinical experiences of the doctors who prescribe their products.<sup>242</sup> Anything that increases interactions between manufacturers and prescribers also increases communication generally, and ideally also specifically around product strengths and weaknesses.<sup>243</sup>

However, serious conflict of interest problems to be discussed in the following Section outweigh any dubious and tenuous value of paid speaker programs as events supporting the feedback loop.<sup>244</sup> Physicians are highly trained professionals from whom we rightly expect the highest level of commitment and rectitude.<sup>245</sup> If we do not adequately do so already, we should train them to report all adverse clinical experiences to manufacturers, without the need for artificially constructed interaction opportunities that are grounded in ethically troubling payments, and we should both expect and professionally require that they do so. While feedback to drug companies does justify their relationship with physicians, it cannot justify transactions that are tainted by unacceptable conflicts that can compromise optimal patient treatment decisions.<sup>246</sup>

---

the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.”).

<sup>242</sup> See Manasa Shankar, *Are Promotional Speaker Programs Going the Distance?*, BEROE (July 30, 2019), <https://www.beroeinc.com/whitepaper/are-promotional-speaker-programs-going-the-distance/> [https://perma.cc/UZ72-WT23] (suggesting the importance of speaker programs and how they “help physicians stay up-to-date on information about new medicines, new uses of medicines, the latest clinical data, appropriate dosing, and emerging safety issues.”).

<sup>243</sup> See *id.* (stating that speaker programs “help professionals stay up-to-date on the latest developments in the industry.”).

<sup>244</sup> INST. OF MED. OF THE NAT’L ACADS., *supra* note 41, at 166–67.

<sup>245</sup> Along these lines, Mehlman suggests that doctors have a fiduciary role. Maxwell J. Mehlman, *Why Physicians Are Fiduciaries for Their Patients*, 12 IND. HEALTH L. REV. 1, 2, 15, 57, 63 (2015).

<sup>246</sup> Johns, *supra* note 57, at 968–70 (describing the present issues of off-label prescriptions and how conflicts of interest arising from drug sponsorships can hurt optimal patient treatment).

### III. EXAMINING THE CONFLICT OF INTEREST IN TRANSACTIONS BETWEEN DRUG COMPANIES AND DOCTORS

As noted in Part I, the previous version of the AMA Code, prior to the 2016 revision, provided one, but only one, example of a benefit of gifts to practitioners: the provision of educational seminars and conferences.<sup>247</sup> It makes sense that the drafters chose it, because it is the sole plausible justification of pharmaceutical industry gratuities provided to medical and pharmaceutical practitioners.<sup>248</sup> Yet even this strongest case example has flaws, all related to conflicts of interest or both pharmaceutical companies and medical practitioners under current practices.<sup>249</sup>

This Section explores two of the most prevalent and potentially concerning of these conflicts. Subsection A below discusses the nature of the conflict of interest that exists when pharmaceutical companies fund the educational seminars and conferences of external professional organizations. Subsection B examines the conflict of interest when pharmaceutical companies sponsor their own speaker programs. The analysis suggests that the conflict of interest explored in Subsection A is an acceptable one that can be effectively managed,<sup>250</sup> whereas the conflict in Subsection B is unacceptable and cannot be rendered acceptable through conflict of interest management protocols.<sup>251</sup>

#### *A. Conflict of Interest When Pharmaceutical Companies Fund the Continuing Medical Education Offered by External Professional Organizations*

Recall that Opinion 9.2.7 of the current version of the AMA Code of Medical Ethics says whenever possible, CME funding and staffing should come from independent sources that do not have a financial relationship with either the industry or the educational

---

<sup>247</sup> See *Opinion 8.061*, *supra* note 49.

<sup>248</sup> See *id.*

<sup>249</sup> See *id.*

<sup>250</sup> See *id.* (describing one perspective of the intentions set forth in previous opinion 8.061).

<sup>251</sup> See *id.* (describing another perspective of the intentions set forth in the same opinion).

subject matter.<sup>252</sup> When funding and staffing from independent sources is not possible, those who “organize ..., teach ..., or have other roles in ... CME”<sup>253</sup> must:

- (a) Be transparent about financial relationships that could potentially influence educational activities.
- (b) Provide the information physician-learners need to make critical judgments about an educational activity, including:
  1. The source(s) and nature of commercial support for the activity
  2. The source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity
  3. What steps have been taken to mitigate the potential influence of financial relationships
- (c) Protect the independence of educational activities by:
  1. Ensuring independent, prospective assessment of educational needs and priorities
  2. Adhering to a transparent process for prospectively determining when industry support is needed
  3. Giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter
  4. Ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter
  5. Permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual’s specific financial interest is disclosed
  6. Taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.<sup>254</sup>

This current approach liberalizes a more stringent position in Previous Version Opinion 8.061 of the AMA Code of Medical Ethics, which sought to reduce potential conflicts of interest

---

<sup>252</sup> See Opinion 9.2.7, *supra* note 48 (stating “[w]hen possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.”).

<sup>253</sup> See *id.*

<sup>254</sup> See *id.*

regarding CME in two clear, direct, simple, straightforward ways.<sup>255</sup> It required company subsidies that benefit professional conference attendees to be indirect,<sup>256</sup> and it prohibited company sponsors from influencing conference content, materials, and presenters.<sup>257</sup>

Current Opinion 9.2.7 contains no language expressly prohibiting the payment of conference subsidies directly to physicians who attend the event.<sup>258</sup> Likewise, it no longer contains the outright prohibition that was in Previous Opinion 8.061 against sponsors exercising influence over content, materials, or presenters.<sup>259</sup> The more elaborate list of relatively vague steps contained in Current Opinion 9.2.7 for managing transparency and objectivity are slippery: they lack the substance, gravitas, and straightforward clarity of the previous, more concise restrictions of Previous Opinion 8.061.<sup>260</sup> They make it hard or impossible to pin down what is or is not a violation.<sup>261</sup> They leave far too much judgment and discretion to physicians facing tempting, remunerative opportunities to serve themselves rather than their patients.<sup>262</sup>

Motives for the change can only be speculated, as professional codes do not come with the historic documentation that we get in legislative history.<sup>263</sup> At best, the changes were intended to create more CME opportunities by removing the previously tight, clear restrictions. At worst, they may be motivated in part or in full by self-interested industry pressures, practitioner pressures, or both.

The requirements in both the current version and the previous version do evince recognition by the medical profession of the need to address conflict of interest when pharmaceutical companies provide benefits to doctors.<sup>264</sup> But do they sufficiently

---

<sup>255</sup> See *Opinion 8.061*, *supra* note 49.

<sup>256</sup> See *id.* (stating “[s]ubsidies from industry should not be accepted directly ....”).

<sup>257</sup> See *id.* (describing how sponsor subsidies should be used for conferences).

<sup>258</sup> See *Opinion 9.2.7*, *supra* note 48 (lacking any prohibition regarding the direct payment of conference subsidies towards physicians).

<sup>259</sup> See *id.* (lacking restriction of sponsors influencing conferences).

<sup>260</sup> See *id.*

<sup>261</sup> See *id.*

<sup>262</sup> See *id.*

<sup>263</sup> See generally *Opinion 8.061*, *supra* note 49; *Opinion 9.2.7*, *supra* note 48.

<sup>264</sup> See *Opinion 8.061*, *supra* note 49 (stating “there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect

manage and control the conflict of interest? Previous Opinion 8.061 did sufficiently manage the conflict of interest for doctors,<sup>265</sup> but the muddier expectations in Current Opinion 9.2.7 fail to acceptably address the conflict of interest.<sup>266</sup>

Opinion 8.061 did not eliminate the subsidy running from companies to doctors, but it did strongly attenuate it by channeling it through the conference sponsors.<sup>267</sup> Physicians still received conference cost savings, and of course they saw conference program recognition lists of the sponsors of the conferences they attend.<sup>268</sup> So conference attendees had the information to be aware that they are paying less to attend the conference, or getting more benefits, or both, because Company X was a sponsor.<sup>269</sup>

In theory, of course, this could still have created a sense of gratitude and indebtedness.<sup>270</sup> However, because medical conferences typically have multiple pharmaceutical company<sup>271</sup> sponsors providing only indirect financial support under Former Opinion 8.061,<sup>272</sup> the conflict of interest was diluted and attenuated via the indirect nature of the sponsorship.<sup>273</sup> A doctor is unlikely to be swayed in her prescriptions by minor and indirect financial support.<sup>274</sup>

---

customary practices of industry may not be consistent with the Principles of Medical Ethics.”); Opinion 9.2.7, *supra* note 48 (stating “[f]inancial or in-kind support from ... companies that have a direct interest in physicians’ recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME).”).

<sup>265</sup> See *Opinion 8.061*, *supra* note 49.

<sup>266</sup> See Opinion 9.2.7, *supra* note 48.

<sup>267</sup> See *Opinion 8.061*, *supra* note 49 (stating “any subsidy should be accepted by the conference’s sponsor who in turn can use the money to reduce the conference’s registration fee.”).

<sup>268</sup> See *id.*

<sup>269</sup> See *id.*

<sup>270</sup> See *id.* (stating “[s]ome gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics.”).

<sup>271</sup> ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC., ACCME DATA REPORT: GROWTH AND DIVERSITY IN CONTINUING MEDICAL EDUCATION—2017, 6 (2018).

<sup>272</sup> See *Opinion 8.061*, *supra* note 49 (describing how financial support provided by sponsors is utilized).

<sup>273</sup> See *id.* (describing all the limitations to the directness of sponsorship gifts to physicians).

<sup>274</sup> See *id.*

Indeed, many or most attendees might not even be thinking about any informal or implied sense of indebtedness, given that the transaction's influence was spread across all attendees and made remote through the intermediary of the conference organizers.<sup>275</sup> In addition, when a number of the manufacturers of competing treatments sponsor a professional meeting, their subsidies effectively cancel each other out in terms of corrupt influence over patient treatment decisions.<sup>276</sup>

Given the social value of continuing medical education as well as the substantial cost of conferences,<sup>277</sup> the Former Opinion 8.061 requirement that conference subsidies were not directly paid to attendees was a reasonable compromise between encouraging continuing education and managing conflicts of interest.<sup>278</sup> The subsidies contributed to the goal of keeping practitioner knowledge fresh and updated, yet they were unlikely to taint patient treatment decisions generally and prescription patterns specifically.<sup>279</sup>

---

<sup>275</sup> See *id.* An analogy easily comes to mind to any law scholar: the sponsorship of law faculty conference events by textbook publishers. Technically, those who attend benefit from sponsorship. But all or virtually all textbook publishers sponsor, and it is unlikely that any law professor's textbook adoption decisions are influenced by this attenuated benefit. The benefit is diluted when most of all the publishing companies sponsor, and law faculty likely are not making the connection between the benefit and their decisions. Quid-pro-quo dynamics are negligible if most competitors in an industry are sponsors, and the benefit passes through the organizer of the conference.

<sup>276</sup> See *id.* (explaining how conference resources should be allocated and organized. Here, conference organizers are able to control the conference context rather than sponsoring companies).

<sup>277</sup> Attending a conference will typically entail a substantial cash outlay. These costs to attendees typically include payment of a registration fee, purchase of airfare and hotel accommodation, payment of ground transportation, and the cost of meals. See Joseph Hong, *The High Cost of Opportunity: Paying for Academic Conferences*, DIVERSE EDUC. (Jan. 15, 2018), <https://diverseeducation.com/article/108234/> [<https://perma.cc/VE2T-M4VF>] (demonstrating that conferences serve as "economic barriers for early-career academics."). The amount of the registration fee, and how many meals are included with that fee, obviously are affected by how much of these are underwritten by conference sponsors. See *Opinion 8.061*, *supra* note 49 (stating "any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee.").

<sup>278</sup> See *Opinion 8.061*, *supra* note 49 (demonstrating the difficulty in balancing the social benefits and violation of ethics in regard to industry gifts to physicians).

<sup>279</sup> See *id.*

Former Opinion 8.061's prohibition of company sponsors' influencing of conference content, materials, and presenters was an effective and appropriate second prong in addressing the conflict of interest challenges in these situations.<sup>280</sup> One peril that both society and patients should worry about is that drug company payments will subvert the objective medical judgment of practitioners.<sup>281</sup> The content, materials, and presenters restriction effectively covered the various ways that a corporate sponsor might, if allowed, attempt to sway practitioner judgment by injecting biased content into the conference proceedings themselves.<sup>282</sup>

In other words, the two prongs of Opinion 8.061—banning direct payment to doctors, and prohibiting influence over content, materials, and presenters—elegantly and effectively covered the two avenues by which company sponsorship might undermine practitioner objectivity: payoffs and biased indoctrination.<sup>283</sup>

Unfortunately, these safeguards that rendered industry sponsorship of CME acceptable in light of conflict of interest challenges have been eviscerated in a smokescreen of replacement language that may seem impressive on its face, but actually achieves little.<sup>284</sup> The ephemeral, slippery, vague edicts in Current Opinion 9.2.7 simply fail to provide the same protections of Previous Version 8.061.<sup>285</sup> A careful reading of the long new list of standards<sup>286</sup> demonstrates that they really do not require much that can be pinned down.<sup>287</sup>

Instead, they repeatedly exhort the parties to “ensure” to “adhere” to “take steps” to “give preference to.”<sup>288</sup> How do you determine exactly what these kinds of slippery edicts mean? The safeguards, even if created with the best intentions and in the best spirit, are illusory because they leave everything to the judgment of the very people who face highly tempting conflicts of interest.<sup>289</sup>

---

<sup>280</sup> *See id.*

<sup>281</sup> *See Johns, supra* note 57, at 970.

<sup>282</sup> *See Opinion 8.061, supra* note 49.

<sup>283</sup> *See id.*

<sup>284</sup> *See Opinion 9.2.7, supra* note 48.

<sup>285</sup> *See id.*; *see also Opinion 8.061, supra* note 49.

<sup>286</sup> *See Opinion 9.2.7, supra* note 48.

<sup>287</sup> *See id.*

<sup>288</sup> *Id.*

<sup>289</sup> *See id.*

*B. Conflict of Interest in Drug Company-Hosted Speaker Programs*

Pharmaceutical companies routinely host their own speaker programs, compensating the presenters with speaker fees and also inviting and entertaining attendees, typically with high-end dinners and drinks.<sup>290</sup> These companies have incentives to select both speakers and attendees based on their own marketing objectives, rather than on truly disinterested educational goals.<sup>291</sup> From the standpoint of marketing strategy, it makes good business sense if presenters are prescribing physicians, or prospectively prescribing physicians who regularly meet with the companies' pharmaceutical representatives, or physicians with whom the representatives want to create such a relationship.<sup>292</sup>

Company-hosted speaker programs are not inherently either noble or nefarious. They are, however, fraught with conflicts and a substantial risk that their content and objectives will be biased.<sup>293</sup> The serious risks associated with speaker programs are far from theoretical. While speaker programs are not legally prohibited, rampant abuses have resulted in many millions of dollars in settlements for charges under federal statutes that

---

<sup>290</sup> See Adriane Fugh-Berman & Nuria Homedes, *How Drug Companies Manipulate Prescribing Behavior*, 46 COLOM. J. ANESTHESIOLOGY 317, 318 (2018) ("A rep may invite a physician to give a dinner talk to a small group at an excellent restaurant. The subject of the talk does not matter, because this is a chance for the rep to both honor and pay the speaker, who then responds by prescribing more of the rep's drugs.").

<sup>291</sup> See *id.* at 318–19.

<sup>292</sup> See Alix Spiegel, *How to Win Doctors And Influence Prescriptions*, NPR (Oct. 21, 2010, 4:11 PM), <https://www.npr.org/templates/story/story.php?storyId=130730104> [<https://perma.cc/JL7V-ZJRX>]. Pharmaceutical representatives typically are assigned to a geographical district, where they are tasked to meet with a targeted group of physicians. See *What Does a Pharmaceutical Sales Representative Do?*, CAREEREXPLORER, <https://www.careerexplorer.com/careers/pharmaceutical-sales-representative/> [<https://perma.cc/A44U-VQ4W>]. These representatives organize the speaker programs and select both the speakers and the invitees. See *id.* Some are physicians who already substantially prescribe the company's products, and the task here is to maintain both the relationship and the strong prescription numbers. See *id.* Others are physicians who do not prescribe the company's products in desired numbers, whom the company seeks to win over. See *id.*

<sup>293</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318–20.



are not even aimed at the pharmaceutical industry.<sup>294</sup> These include a \$38 million settlement under the False Claims Act as well as several multimillion-dollar settlements under the Foreign Corrupt Practices Act.<sup>295</sup>

The main government tools to curtail continuing and rampant abuses are “Corporate Integrity Agreements” (CIAs) that can be required by the Office of Inspector General.<sup>296</sup> While CIAs likely do make some headway against abusive practices, the perils of company-sponsored speaker programs outweigh the benefits, and they should simply be eliminated.<sup>297</sup>

Granted, pharmaceutical companies’ own speaker programs do have a potential social benefit: the education of the health-care professionals who attend them.<sup>298</sup> If—and this is a big if—a company’s own programs can somehow maintain complete objectivity and not be tainted by conflict of interest—they can add to the knowledge of prescribing practitioners.<sup>299</sup>

Pharmaceutical companies are certainly in a good position to educate practitioners for two reasons. First, the companies are a source of much high quality, useful information.<sup>300</sup> By virtue of the time and expertise they invest in developing drug treatments,<sup>301</sup> they are among the institutions most likely to have a wealth of information.

Second, pharmaceutical companies have tremendous resources—arguably unmatched by other institutions—to devote

<sup>294</sup> Richard L. Cassin, *Compliance Alert: Speaker Fees Are Often Toxic*, FCPA BLOG (Jan. 4, 2017, 1:28 PM), <https://fcpablog.com/2017/1/4/compliance-alert-speaker-fees-are-often-toxic/> [<https://perma.cc/S4PB-JJAY>].

<sup>295</sup> *Id.*

<sup>296</sup> See COGNIZANT 20-20 INSIGHTS, *HELPING PHARMAS MANAGE COMPLIANCE RISKS FOR SPEAKER PROGRAMS* 4 (2017).

<sup>297</sup> See INST. OF MED. OF THE NAT’L ACADS., *supra* note 41, at 10, 184–85.

<sup>298</sup> See *id.* at 2, 9, 155.

<sup>299</sup> See *id.*

<sup>300</sup> See Geoffrey K. Spurling et al., *Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians’ Prescribing: A Systematic Review*, 7 PLOS MED 1, 2 (Oct. 2010).

<sup>301</sup> See Matej Mikulic, *Total Global Pharmaceutical R&D Spending 2010–2024*, STATISTA (Apr. 6, 2020), <https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/> [<https://perma.cc/YZ6E-2WQK>] (reporting global pharmaceutical industry R&D expenditure for 2018 as \$179 billion).

to the education of healthcare professionals.<sup>302</sup> They have the funds to be among the most effective providers to physicians of current scientific and medical information regarding treatment options.<sup>303</sup>

However, great risks are associated with pharmaceutical company speaker series. The following subsections examine these risks: the risk that pharmaceutical companies will not present information entirely accurately and objectively; the risk that paid speakers will not be objective and impartial; the risk that paid program speakers lose their objectivity in decisions regarding prescription of the company's products; and the risk that company provision of dining, drinks, and social entertainment will hinder the objectivity of physicians who attend the programs as learners.

After examining all these risks, we examine the relative likelihood of pharmaceutical company speaker programs being predominantly beneficial or predominantly harmful. Finally, we discuss whether disclosure of conflict of interest is a sufficient safeguard to protect patients' interest such that drug company speaker programs should be acceptable as long as the disclosure is made.

*1. The Risk that Paid Pharmaceutical Company Speakers Will Not Present Information Accurately and Objectively*

Pharmaceutical companies do not spend money educating physicians as philanthropy; they are profit-seeking businesses.<sup>304</sup> There is a conflict of interest when companies host speaker programs to increase sales.<sup>305</sup> Revenue goals put pressure on companies to sell, and not simply to provide forums where information is objectively presented.<sup>306</sup>

---

<sup>302</sup> See STATISTA, INDUSTRY REPORT, MANUFACTURING: PHARMACEUTICALS & MEDICINE IN THE U.S. 2020, 65 (June 2018), <https://www.statista.com/study/45278/manufacturing-pharmaceuticals-and-medicine/> [<https://perma.cc/Z2B9-KMUM>] ("The industry realized a total value of shipments of US\$268.6 billion in 2017, a growth of 8.8% compared to 2016.").

<sup>303</sup> See *id.*

<sup>304</sup> Margaret Visnii, *Understanding the New Pharma Business Model*, R&P (Feb. 4, 2019), <https://revenuesandprofits.com/understanding-the-new-pharma-business-model/> [<https://perma.cc/2SHH-AJPM>] ("Pharma companies like any other business are here to make money.").

<sup>305</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318.

<sup>306</sup> This pressure has led, for example, to accounts and FDA documentation of "repeated instances of pharmaceutical representatives presenting one-sided

It can be argued that professional ethics can and should deter pharmaceutical companies from slanting information in their speaker programs.<sup>307</sup> It would be foolish and naïve to expect professional ethics to curtail the conflict of interest regularly and consistently, given the intense financial performance pressures that pharmaceutical companies face.<sup>308</sup>

Indeed, there is a crucially important logical inconsistency in how the AMA Code addresses the danger of drug companies skewing the content of professional education.<sup>309</sup> The AMA Code recognizes the ethical risks when drug companies sponsor external conferences and continuing medical education.<sup>310</sup> It fails, however, to address the even greater risks of company speaker programs that feature highly paid practitioner speakers.<sup>311</sup>

## *2. The Risk That Paid Program Speakers Lose Their Objectivity in Decisions Regarding Prescription of the Company's Products*

When pharmaceutical companies pay speaker fees, the compensated doctors can easily lose their impartiality in prescription decisions.<sup>312</sup> We would hope that doctors would rise

---

information that downplays risks and negates warnings.” Vukadin, *supra* note 24, at 84. For discussion of revenue drivers in the pharmaceutical industry, see generally Ajay Gautam, *The Changing Model of Big Pharma: Impact of Key Trends*, 21 DRUG DISCOVERY TODAY 379, 384 (Mar. 2016).

<sup>307</sup> See ADRIAN KILCOYNE ET AL. EDS., PHARMACEUTICAL MEDICINE 363 (2013) (“[T]he pharmaceutical industry has an obligation to communicate health information with integrity, accuracy, clarity, and completeness. This ethical obligation goes above and beyond any legal requirements.”).

<sup>308</sup> See Matthias Evers et al., *How Pharma Manufacturers Can Enhance Their Medical Information Teams*, MCKINSEY & CO. (May 9, 2018), <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/how-pharma-manufacturers-can-enhance-their-medical-information-teams> [<https://perma.cc/HS7Z-NNGK>] (“[P]harmaceutical manufacturers are under pressure to find more efficient operating models to reduce operating costs ....”).

<sup>309</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318; *infra* text accompanying notes 316–17.

<sup>310</sup> See Opinion 9.2.7, *supra* note 48 and text accompanying note 73.

<sup>311</sup> The ethical risks of company speaker programs are even greater than the risks of company involvement in external CME programs, because in the former, no impartial host exists who can at least try to focus on and ensure objectivity and purity of motives.

<sup>312</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318–20.

above the conflict of interest and maintain their objectivity, but this is naïve and unrealistic.<sup>313</sup>

Disturbingly, one study found that while 85 percent of medical students recognize the impropriety of politicians accepting gifts, only 46 percent believe it is improper for themselves to accept a gift of the same value from a pharmaceutical company.<sup>314</sup> This is distressing because a physician's ethical responsibility when treating patients is to provide them with the best possible care.<sup>315</sup> This duty is undermined by paid speaker programs in two ways: through the operation of reciprocity norms and informal indebtedness,<sup>316</sup> and through the creation of warped incentives for the speaking physicians.<sup>317</sup>

*a. The Operation of Reciprocity Norms and Informal Indebtedness*

A physician who is handsomely paid by a drug manufacturer may feel indebted to the company that provided the opportunity.<sup>318</sup>

---

<sup>313</sup> See *id.*

<sup>314</sup> Paul Palmisano & Joan Edelstein, *Teaching Drug Promotion Abuses to Health Professional Students*, 55 J. MED. EDUC. 453, 455 (1980).

<sup>315</sup> See AM. MED. ASS'N, AMA PRINCIPLES OF MEDICAL ETHICS, <https://www.ama-assn.org/about/publications-newsletters/ama-principles-medical-ethics> [<https://perma.cc/G3EQ-K3V4>] (Jun. 2001) ("A physician shall, while caring for a patient, regard responsibility to the patient as paramount.").

<sup>316</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318.

<sup>317</sup> See *id.*

<sup>318</sup> Henry et al. have also identified the problem of "entanglement," a tendency for pharmaceutical companies and clinical researchers to build bundles of relationships that contribute to reciprocation of favor. David Henry et al., *Ties that Bind: Multiple Relationships Between Clinical Researchers and the Pharmaceutical Industry*, 165 ARCHIVES INTERNAL MED. 2493, 2493 (2005) ("Research collaboration, an important and growing area of engagement between industry and clinical researchers, may lead to other significant relationships, such as advisory panel membership, payment for consultation to the industry, and substantial recompense to attend international conferences. These ties may create a sense of collegiality, and the resulting obligation and need to reciprocate may not be consciously felt.") (citation omitted). Such multi-layered bundles of entanglement exacerbate the concerns about paid speaker series. *Id.* at 2495–96. Not only may paid physicians skew their prescription patterns out of a sense of indebtedness; they may also consciously or unconsciously skew their findings or actions relating to any research component that is included in the bundle of activities. *Id.*

This is simply human nature, the playing out of well-documented human reciprocity norms.<sup>319</sup> Payment can create in the recipient both gratitude and a desire or even a tacit requirement<sup>320</sup> to return commensurate value to the payer.<sup>321</sup> Reciprocity norms are so ingrained in us that they have become culturally and linguistically entrenched;<sup>322</sup> for example, we say that we need to invite friends to dinner because “we owe them” in return for past hospitality that they provided to us.

This language reflects an urge to approach transactional equilibrium in relationships.<sup>323</sup> Reciprocity norms do not end when we leave the dinner table and go to work.<sup>324</sup> Pharmaceutical representatives who regularly visit a set of physicians strive to develop strong relationships with their doctors;<sup>325</sup> indeed, basic attributes for which pharmaceutical representatives are hired are their persuasive abilities and their skill at building strong relationships.<sup>326</sup> After all, their job is sales.<sup>327</sup>

---

<sup>319</sup> See Alvin W. Gouldner, *The Norm of Reciprocity: A Preliminary Statement*, 25 AM. SOCIO. REV. 161, 161, 177–78 (1960) (examining in detail the nature of human reciprocity norms); Mark A. Whatley et al., *The Effect of a Favor on Public and Private Compliance: How Internalized is the Norm of Reciprocity?*, 21 BASIC & APPLIED SOC. PSYCH. 251, 251–52 (1999) (discussing and examining reciprocity norms).

<sup>320</sup> This tacit requirement aspect of reciprocity is a function of what Keohane calls the “conditional action” implication of reciprocity. Robert O. Keohane, *Reciprocity in International Relations*, 40 INT’L ORG. 1, 5 (1986). There is an exchange of benefits, each understood to be conditional on the other. See *id.*

<sup>321</sup> The social exchange literature discusses this in terms of “equivalence.” PETER M. BLAU, ON THE NATURE OF ORGANIZATIONS 208–09 (1974).

<sup>322</sup> See Gouldner, *supra* note 319, at 171–72.

<sup>323</sup> See Michael E. McCullough et al., *An Adaptation for Altruism? The Social Causes, Social Effects, and Social Evolution of Gratitude*, 17 CURRENT DIRECTIONS PSYCH. SCI. 281, 281 (2008) (“People feel grateful when they have benefitted from someone’s costly, intentional, voluntary effort on their behalf. Experiencing gratitude motivates beneficiaries to repay their benefactors ....”).

<sup>324</sup> See BLAU, *supra* note 321, at 209.

<sup>325</sup> See Michael J. Oldani, *Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices*, 18 MED. ANTHROPOLOGY Q. 325, 332 (2004) (discussing building rapport, creating alliances, and gaining returns as measured in script numbers as among the multiple goals of pharmaceutical salespersons).

<sup>326</sup> Job listing templates recommend stating this job expectation upfront. See, e.g., *Pharmaceutical Sales Representative Job Description*, WORKABLE, <https://resources.workable.com/pharmaceutical-sales-representative-job-description> [<https://perma.cc/3PHP-U883>] (including among the three recommended job responsibilities to list, “[l]iaising with and persuading targeted doctors to prescribe our products utilizing effective sales skills.”).

<sup>327</sup> See *id.*

The scenario is this: the pharmaceutical representative, who has developed a good relationship with a doctor over time, communicates over the course of their many meetings a desire to have the doctor increase her prescription count for a drug the representative is marketing. At a strategic time, the pharmaceutical representative offers the doctor a lucrative opportunity to be a paid speaker.

The doctor meets reciprocity norm expectations by returning the favor and increasing the number of prescriptions.<sup>328</sup> Whenever a physician's prescription decisions are influenced by anything other than what is in the best interest of the patient's treatment, there exists a problem.<sup>329</sup>

*b. The Creation of Warped Incentives for the Speaking Physicians*

If reciprocity norms were the only dynamic at play in pharmaceutical company speaker programs, we might hope that professional ethics would prevail, and prescription decisions might remain immune to improper influences. Unfortunately, given human self-interest, this would be an unrealistic hope.<sup>330</sup>

Moreover, the inclination to establish relational equilibrium by returning favors<sup>331</sup> is not the only peril of drug company speaker programs.<sup>332</sup> Physicians' desire for repeat paid speaking invitations may influence the content of their presentations.<sup>333</sup>

Doctors presumably agree to accept speaker invitations because such engagements are highly desirable.<sup>334</sup> Of course, there are innocuous or even positive factors that might encourage

---

<sup>328</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318–19.

<sup>329</sup> See *id.* at 320.

<sup>330</sup> See BLAU, *infra* note 331, at 2–7.

<sup>331</sup> This cycle of back-and-forth favors is at the heart of reciprocity norms. See PETER BLAU, *EXCHANGE AND POWER IN SOCIAL LIFE* 6 (1964) (observing that reciprocity entails “actions that are contingent on rewarding reactions from others and that cease when these expected reactions are not forthcoming”).

<sup>332</sup> See Fugh-Berman & Homedes, *supra* note 290, at 317.

<sup>333</sup> See *id.* at 319–20.

<sup>334</sup> See *id.* at 318–19.

doctors to be speakers.<sup>335</sup> If a doctor's ego is gratified by having a platform to speak as an expert, this may well be an innocuous inducement.<sup>336</sup> It is not likely to cause the speaker to sacrifice objectivity in the content delivered.<sup>337</sup> Likewise, if part of the desirability of speaking is benevolent—a desire to share expertise and knowledge to benefit the profession and patients—participation in a speaker program certainly can have positive effects. Not all speakers at pharmaceutical company programs lack objectivity or are improperly influenced in the content they present.<sup>338</sup>

Nonetheless, emolument is a potent factor in the desirability of speaking engagements.<sup>339</sup> Speaker programs pay doctors generously.<sup>340</sup> They are typically attractive dining and drinking events in expensive restaurants as well, creating a pleasant opportunity to socialize with colleagues and professional friends.<sup>341</sup> Some doctors will value these engagements and work to encourage future invitations.<sup>342</sup> Presenting material favorable to the host company and its products increases the prospect of repeat invitations.<sup>343</sup> This creates an unacceptable risk to patients, whose treatments may be affected by biased content presented at these events.<sup>344</sup>

---

<sup>335</sup> See Spiegel, *supra* note 292.

<sup>336</sup> See Freek Fickweiler et al., *Interactions Between Physicians and the Pharmaceutical Industry Generally and Sales Representatives Specifically and Their Association with Physicians' Attitudes and Prescribing Habits: A Systematic Review*, 7 BMJ OPEN, Sept. 27, 2017, at 1 (majority of physicians believe pharmaceutical industry interactions have no impact on them).

<sup>337</sup> See Fugh-Berman & Homedes, *supra* note 290, at 319–20.

<sup>338</sup> See *id.*

<sup>339</sup> See Cassie Demeter, *69% of Pharmaceutical Companies Pay Their Speakers Based on Quality*, BUS. WIRE (Jan. 6, 2014, 10:16 AM), <https://www.businesswire.com/news/home/20140106005287/en/69-Pharmaceutical-Companies-Pay-Speakers-based-Quality> [<http://perma.cc/3KSD-3HZ8>].

<sup>340</sup> See *id.* (reporting that speaker payments among surveyed companies averaged \$1,677, and that “[c]ompanies may spend as much as \$6,000 on a single speaker to entice him or her to speak at an event”).

<sup>341</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318.

<sup>342</sup> See *id.*

<sup>343</sup> See *id.* at 320.

<sup>344</sup> See *Under the Influence*, WAIKATO TIMES, Apr. 12, 2014, at 6.

*c. The Risk that Company Provision of Dining, Drinks, and Social Entertainment Will Hinder the Objectivity of Physicians Who Attend the Programs as Learners*

Pharmaceutical company speaker programs raise another concern: the provision of education and entertainment directly from a manufacturer to an audience of invited physicians.<sup>345</sup> Like the speakers, these doctors can be selected based on the company's sales objectives.<sup>346</sup> And given the profit motive of business, why would they not be?

As the direct recipients of education, dining, drinks, and entertainment, they are subject to both of the dynamics discussed in the preceding two subsections.<sup>347</sup> This direct provision of benefit to company speaker series attendees, which was deemed unacceptable by Previous Opinion 8.061 of the AMA Code at continuing medical education events,<sup>348</sup> is not prohibited by either the AMA or the PhRMA.<sup>349</sup>

Yet attendees are subject to reciprocity norms at these events, at least as much as they would be at CME conferences.<sup>350</sup> Moreover, they have incentives to curry future invitations, since unlike CME events that are open to all doctors, company-hosted speaker series are invitational events.<sup>351</sup> As we have seen, we should be concerned that the content of the talk they will hear will not be scientifically objective, but rather skewed in favor of the host company's product.<sup>352</sup>

While the same quid pro quo dynamics apply to physicians in the audience as to physicians engaged to speak, the magnitude

---

<sup>345</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318–19.

<sup>346</sup> See Allan S. Brett et al., *Are Gifts from Pharmaceutical Companies Ethically Problematic? A Survey of Physicians*, 163 ARCH. INTERNAL MED. 2213, 2217 (2003) (“[T]he AMA guidelines focus inordinately on fine distinctions regarding the value or type of gifts, and are not sufficiently concerned with the ultimate rationale for industry-sponsored gifts and activities, ie, to establish relationships with physicians that yield increased sales of a company's products.”).

<sup>347</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318.

<sup>348</sup> See *Opinion 8.061*, *supra* note 49.

<sup>349</sup> See Brett et al., *supra* note 346, at 2217.

<sup>350</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318.

<sup>351</sup> See *id.* at 319.

<sup>352</sup> See *id.* at 320.



of the conflict-based risk is, of course, lower for those attending than for those speaking.<sup>353</sup> This is a function of the degree of the benefit conferred. Speaker fees are likely to be valued higher than receipt of a free seminar and meal.<sup>354</sup> Of course, to the extent that a target group of physicians is rotated from occasional speaker roles at some programs to audience member roles at others, an overall package of treats for physicians results.<sup>355</sup> Sometimes a doctor is the paid speaker; other times she is a generously entertained guest.<sup>356</sup> This overall relational package is fraught with implications of indebtedness, undesirable incentives, and potentially skewed content.<sup>357</sup>

*d. The Relative Likelihood of Pharmaceutical Company  
Speaker Programs Being Predominantly Beneficial or  
Predominantly Harmful*

The harms of company speaker programs outweigh the benefits.<sup>358</sup> The single possible benefit is the education of doctors.<sup>359</sup> Even this benefit is not weighty, given the various alternative sources of knowledge and information available to medical practitioners in 2020, including that which now comes out of research universities.<sup>360</sup> This single benefit of company speaker programs is tainted by all the conflicts of interest we have explored.<sup>361</sup>

Abundant external medical conferences and seminars, as noted earlier, can ethically be financially supported by companies under appropriate guidelines, which this Article has already suggested are those that were contained in Previous Opinion 8.061 of the AMA Code, rather than the diluted guidelines that

---

<sup>353</sup> See *infra* note 354 and accompanying text.

<sup>354</sup> This proposition seems likely, given the generous fees speakers are paid at these events. See Demeter, *supra* note 339.

<sup>355</sup> See Fugh-Berman & Homedes, *supra* note 290, at 318.

<sup>356</sup> See *id.*

<sup>357</sup> See *id.*

<sup>358</sup> See *infra* notes 359–66 and accompanying text.

<sup>359</sup> See Howard Brody, *Pharmaceutical Industry Financial Support for Medical Education: Benefit, or Undue Influence?*, 37 J. L. MED. & ETHICS 451, 451 (2009).

<sup>360</sup> See *supra* Section II.A.

<sup>361</sup> See generally Fugh-Berman & Homedes, *supra* note 290.

replaced it in 2016.<sup>362</sup> Scholarly and professional medical journals also are widely available,<sup>363</sup> and of course the Internet provides a wealth of information.<sup>364</sup> Although Internet information on all subjects must be carefully assessed for credibility,<sup>365</sup> it is reasonable to expect trained physicians to evaluate sources with a critical eye.

No laws, regulations, professional or industrial codes, or policies presently prohibit pharmaceutical company-hosted speaker programs.<sup>366</sup> And as we shall see in the following Subsection, disclosure requirements are inadequate to address the conflict of interest and attendant moral peril that we have explored here regarding speaker programs.

*e. Disclosure of Conflict of Interest Is a Positive Step, but It Is Insufficient to Protect Patients' Interests*

In several countries, law or regulation requires the public disclosure of payments that doctors receive from drug companies.<sup>367</sup> In the United States, the Physician Payments Sunshine Act requires that drug manufacturers disclose comprehensive information regarding payments, including honoraria, to “covered recipients.”<sup>368</sup> Failure to disclose financial conflicts of interest may be considered research misconduct.<sup>369</sup>

---

<sup>362</sup> See *supra* Section III.A.

<sup>363</sup> See Karen M. Albert, *Open Access: Implications for Scholarly Publishing and Medical Libraries*, 94 J. MED. LIBR. ASS'N 253 (2006) (discussing how open access publishing facilitates access to research publications).

<sup>364</sup> See *id.* at 255.

<sup>365</sup> See Karen Struthers, *Assessing the Credibility of Online Sources*, LEO: LITERACY EDUC. ONLINE (Jan. 7, 2005), <https://leo.stcloudstate.edu/research/credibility1.html> [<https://perma.cc/N5L4-BKMP>] (offering a checklist of criteria for evaluating the credibility of an online source, based on authorship, publisher, currency, perspectives, coverage, and accuracy or verifiability).

<sup>366</sup> See Fugh-Berman & Homedes, *supra* note 290, at 320.

<sup>367</sup> See *Under the Influence*, *supra* note 344 (“Around the world, countries are increasingly requiring public disclosure of drug company gifts and payments to doctors.”).

<sup>368</sup> 42 U.S.C. § 1320a-7h(a)(1)(A) (2010) (requiring, *inter alia*, that “any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic

This reported information is readily accessible to patients, as well as prospective patients who want to research their options, via a government website.<sup>370</sup> As the header to the website states, “[t]he Open Payments Search Tool is used to search payments made by drug and medical device companies to physicians and teaching hospitals.”<sup>371</sup> The site also discloses the amounts of these payments, and as of this writing, the most recent aggregate data on the disclosed payments is for 2019, showing a total reported of \$10.03 billion.<sup>372</sup>

The site has a tab that explains the function of the data: “Open Payments is a national disclosure program that promotes a more transparent and accountable health care system by making the financial relationships between applicable manufacturers and group purchasing organizations (GPOs) and health care providers (physicians and teaching hospitals) available to the public.”<sup>373</sup>

---

form as the Secretary shall require, the following information with respect to the preceding calendar year: (i) The name of the covered recipient. (ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient. (iii) The amount of the payment or other transfer of value. (iv) The dates on which the payment or other transfer of value was provided to the covered recipient. (v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—(I) cash or a cash equivalent; (II) in-kind items or services; (III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or (IV) any other form of payment or other transfer of value (as defined by the Secretary). (vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—(I) consulting fees; (II) compensation for services other than consulting; (III) honoraria; (IV) gift; (V) entertainment; (VI) food; (VII) travel (including the specified destinations); (VIII) education; (IX) research; (X) charitable contribution; (XI) royalty or license; (XII) current or prospective ownership or investment interest; (XIII) direct compensation for serving as faculty or as a speaker for a medical education program; (XIV) grant; or (XV) any other nature of the payment or other transfer of value (as defined by the Secretary).”).

<sup>369</sup> See generally Jeffrey R. Botkin, *Should Failure to Disclose Significant Financial Conflicts of Interest Be Considered Research Misconduct?*, 320 JAMA 2307, 2308 (2018).

<sup>370</sup> See *Search Open Payments*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://openpaymentsdata.cms.gov> [<https://perma.cc/53PG-43FR>].

<sup>371</sup> *Id.*

<sup>372</sup> *Id.*

<sup>373</sup> *Id.* at *Learn More About Open Payments* tab, <https://www.cms.gov/open-payments> [<https://perma.cc/6G9Y-DVK9>].

Unfortunately, disclosure is inadequate to address conflict of interest concerns.<sup>374</sup> If disclosure of physician payments is to protect patients, we would want evidence that patients actually retrieve and use the information. The evidence, however, suggests otherwise.<sup>375</sup> In addition, there are systemic conditions in place that limit the effectiveness of information and disclosure as means of managing conflicts of interest.<sup>376</sup> The following discussion addresses these two limitations, and concludes that disclosure does not sufficiently address the conflict of interest when drug companies pay prescribing physicians as presenters in their speaker programs.

*i. Evidence Suggests that Few Patients Consult the Currently Available Information Regarding Physician Payments*

Unfortunately, the information collected and published under the Physician Payments Sunshine Act is rarely used.<sup>377</sup> Of 3,500 adult patients in one year studied, sixty-five percent had seen physicians who had received a payment or gift from either a drug or medical device company, but only five percent were aware of the payment or gift.<sup>378</sup>

It is not surprising that few patients use the data available. Some will be unaware that the database exists.<sup>379</sup> People are busy, life is complex, and information on every conceivable topic abounds on the Internet.<sup>380</sup> Moreover, information is often conflicting, even information provided by “experts,”<sup>381</sup> tempting the

---

<sup>374</sup> See *infra* Section III.B.2.e.i–ii.

<sup>375</sup> See *infra* Section III.B.2.e.i.

<sup>376</sup> See *infra* Section III.B.2.e.i.

<sup>377</sup> See *Many Doctors Get Payments from Drug Companies, Study Shows*, HEALTHDAY (Mar. 21, 2017), <https://consumer.healthday.com/general-health-information-16/doctor-news-206/many-doctors-get-payments-from-drug-companies-study-shows-720434.html> [<https://perma.cc/K6XZ-S9BD>].

<sup>378</sup> See *id.*

<sup>379</sup> See *id.*

<sup>380</sup> See Ira S. Nathenson, *Internet Infoglut and Invisible Ink: Spamdexing Search Engines with Meta Tags*, 12 HARV. J.L. & TECH. 43, 52 (1998) (“The amount of information has expanded far beyond our ability to process or comprehend it.”).

<sup>381</sup> See Nathan F. Dieckmann et al., *Public Perceptions of Expert Disagreement: Bias and Incompetence or a Complex and Random World?*, 26 PUB. UNDERSTANDING OF SCI. 325 (2017) (noting expert disagreement may be perceived by

public to give up on disclosure models created to ensure their safety.<sup>382</sup> We are both weary and wary of seeking and evaluating disclosures and warnings.<sup>383</sup>

What remains is a philosophical question: Does it matter that few patients are aware of conflicts of interest, given that the conflicts can easily be discovered?<sup>384</sup> Some will say it does not matter, and that the information is readily available, thus individual patients should be responsible for doing research relating to their treatment choices, including the doctor they select.<sup>385</sup> This approach would lean toward a philosophy of minimal regulation and even minimal professional and industry self-regulation.<sup>386</sup> Under this philosophy, as many potential hazards as possible should be addressed solely through disclosure, rather than through legal or ethics code prohibitions or self-prohibitions, with the goal of minimizing government, professional, and industry controls and maximizing freedoms of both consumers and businesses.<sup>387</sup>

A counterargument focuses on realities rather than on theory: the vast majority of patients are not aware of pharmaceutical company payments to their physician, despite the information

---

knowledgeable, educated people as reflecting things such as complexity, randomness, and financial bias).

<sup>382</sup> See Petra Persson, *Attention Manipulation and Information Overload*, 2 BEHAV. PUB. POL'Y 1, 78 (2018).

<sup>383</sup> The literature discusses this phenomenon in terms of information overload. See, e.g., *id.* at 78 (discussing how “[c]ompetitive information supply from firms competing for attention can reduce consumers’ knowledge by causing information overload.”); Josephine B. Schmitt et al., *Too Much Information? Predictors of Information Overload in the Context of Online News Exposure*, 21 INFO. COMM. & SOC. 1151, 1151 (2018) (“The difficulty to evaluate and select relevant information increases as more and more diverse sources and content are available.”).

<sup>384</sup> See *Many Doctors Get Payments from Drug Companies, Study Shows*, *supra* note 377.

<sup>385</sup> See *id.*

<sup>386</sup> For discussion of this regulation reduction philosophy, see John W. Mayo, *The Evolution of Regulation: Twentieth Century Lessons and Twenty-First Century Opportunities*, 65 FED. COMM'NS L.J. 119, 126 (2013) (“[B]eginning in the 1960s, economists began to look upon the institution of regulation with newfound skepticism. This skeptical inquiry revealed that regulation was an imperfect governance mechanism that could not be assumed to promote the public interest. A second, more subtle but potentially more profound driver came from policymakers who saw deregulation as a means to promote an ideological end, specifically to ease governmental coercion and promote economic freedoms.”).

<sup>387</sup> See *id.* at 120.

being available online.<sup>388</sup> While patients can protect themselves from improperly influenced treatment, almost none actually do.<sup>389</sup> Arguably, regulation or professional/industry self-regulation protective of the public is sometimes justified, even when it constrains some freedoms such as physicians' freedom to contract with companies.<sup>390</sup> If so, this is one such situation. Prohibition or curtailment of conflicts may be the only way to protect the public, since the disclosure does not provide appreciable protection.<sup>391</sup>

One final consideration: when disclosure is used to shield the public from perils, there may be socio-economic differences in who is protected and who is not, due to the digital divide.<sup>392</sup> The poor have less ready access than the wealthy to computers, connections, and the Internet, and therefore to information disclosed and retrievable on websites,<sup>393</sup> and minorities have less access than non-minorities.<sup>394</sup> Unsurprisingly, studies suggest that those with lower educational and income levels are generally disadvantaged in the quality of both the healthcare that they receive and their health generally.<sup>395</sup>

Should this socio-economic discrepancy influence our decision between allowing the conflict of interest activities we have been discussing subject to disclosure, versus outright prohibiting

---

<sup>388</sup> See *supra* text accompanying note 378.

<sup>389</sup> See *supra* text accompanying note 378.

<sup>390</sup> See generally INST. OF MED., PROMOTING HEALTH: INTERVENTION STRATEGIES FROM SOCIAL AND BEHAVIORAL RESEARCH (Brian D. Smedley et al. eds., 2000).

<sup>391</sup> See *Many Doctors Get Payments from Drug Companies, Study Shows*, *supra* note 377.

<sup>392</sup> Edwards describes the digital divide as "the increasingly disparate access to, knowledge of, and use of technology in this country that is a function of race or ethnic group, physical disability, income, education, gender, household composition, age, and location." Yolanda D. Edwards, *Looking Beyond the Digital Divide*, 57 FED. COMM'NS L.J. 585 (2005) (reviewing ANTHONY G. WILHELM, *DIGITAL NATION: TOWARD AN INCLUSIVE INFORMATION SOCIETY* (2004)).

<sup>393</sup> *Id.*

<sup>394</sup> *Id.*

<sup>395</sup> See Nicholas C. Arpey et al., *How Socioeconomic Status Affects Patient Perceptions of Health Care: A Qualitative Study*, 8 J. PRIMARY CARE & CMTY. HEALTH 169 (2017) ("There is evidence that socioeconomic status (SES) affects individual's [sic] health outcomes and the health care they receive. People of lower SES are more likely to have worse self-reported health, lower life expectancy, and suffer from more chronic conditions when compared with those of higher SES. They also receive fewer diagnostic tests and medications for many chronic diseases and have limited access to health care due to cost and coverage.") (internal citations omitted).

the activities? It can be argued that in a free society with free markets, the wealthy can justifiably buy advantages less available to others.<sup>396</sup> This is easier to accept in regard, say, to purchasing Rolls-Royce automobiles than to healthcare. Regarding physician conflicts of interest, the idea is unsatisfying on two levels.

First, we are not talking about who can and cannot purchase luxury consumables; rather, we are talking about fundamental and basic safeguards in how people are provided with medical treatment, which should be sound, safe, and effective for everyone, not just for the wealthy.<sup>397</sup> Second, to the extent that there are racial or ethnic discrepancies in protection levels under a disclosure model, we should rise to the challenge of affording the same basic protections for all.<sup>398</sup> In sum, disclosure as the means to address these conflicts of interest is ineffectual and inadequate.

*ii. Systemic Conditions Limit the Effectiveness of  
Information and Disclosure as Means to Manage  
Conflicts of Interest*

Using disclosure to provide information to consumers, and then expecting consumers to protect themselves, depends on consumers having real choice in the marketplace.<sup>399</sup>

---

<sup>396</sup> See *id.* at 172.

<sup>397</sup> This argument might follow a philosophy wherein “a political and legal order should be maximally accountable to the representative occupants of the most powerless positions defined by that order, consistent with the equal liberties and fair equality of opportunity principles.” Xavier Marquez, *Maximizing Accountability to the Least Privileged: The Difference Principle, the Fair Value of the Political Liberties, and the Design of Democratic Institutions*, 47 *POLITY* 484, 484 (2015). For analysis of healthcare as a basic right, see generally Anita Pereira, Note and Comment, *Live and Let Live: Healthcare is a Fundamental Human Right*, 3 *CONN. PUB. INT. L.J.* 481 (2004).

<sup>398</sup> See Aleksandra Jovic-Vranes et al., *Education on Human Rights and Healthcare: Evidence from Serbia*, 30 *HEALTH PROMOTION INT’L* 101 (2014) (“Regardless of gender, age, race or socioeconomic background, we consider our health to be our most important and essential asset. Increasing attention has been paid to the right to the highest attainable standard of healthcare, especially by human rights monitoring bodies, such as the World Health Organization and the Commission on Human Rights.”) (citation omitted).

<sup>399</sup> See Serge-Christophe Kolm, *On Real Economic Freedom*, 35 *SOC. CHOICE & WELFARE* 351, 351–52 (2010) (observing that “possible choice” is a component of actual freedom) (citation omitted).

Choice of physician, however, is often constrained, and therefore illusory, under managed health care.<sup>400</sup> Many patients cannot just choose the doctor they prefer.<sup>401</sup> We depend on insurance coverage to pay for health care,<sup>402</sup> and managed healthcare has evolved to limit our free choice of physician.<sup>403</sup> Participation in a Health Maintenance Organization (HMO) requires the use of HMO doctors.<sup>404</sup> Patients covered by Preferred Provider Organizations (PPOs) instead of HMOs are required by the plans to use designated preferred provider physicians in order to get the plan's lower rates.<sup>405</sup> While we might like the idea of avoiding regulation and ethics code constraints and leaving free agents in free markets to make informed choices subject to disclosure of conflicts, free agency under managed healthcare is seriously constrained.<sup>406</sup>

The absence of choice for many in selecting a physician is not the only aspect of managed health care that undermines our ability to try to protect ourselves. It is exacerbated by a second phenomenon: prescription plans contract favorable rates with certain manufacturers, and they substitute a prescribing physician's choice with a contractually favored, cheaper option.<sup>407</sup> While

---

<sup>400</sup> Goran Ridic et al., *Comparisons of Health Care Systems in the United States, Germany and Canada*, 24 MATERIA SOCIO MEDICA 112, 119 (2012).

<sup>401</sup> *See id.* at 116.

<sup>402</sup> *See, e.g.*, Amy Davidoff et al., *The Effect of Parents' Insurance Coverage on Access to Care for Low-Income Children*, 40 INQUIRY 254, 255 (2003) ("Parents' insurance coverage ... may affect access to care for their children.").

<sup>403</sup> Ridic et al., *supra* note 400, at 119.

<sup>404</sup> DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., PHYSICIAN PERSPECTIVES OF MEDICARE HMOS 1 (1998) ("Most HMOs operate on a gate-keeper system, in which a patient selects a primary care physician from a group of approved plan providers to act as her or his first point of contact within the health care system. This physician must authorize any specialist, hospital, or other type of care the patient receives.").

<sup>405</sup> Ridic et al., *supra* note 400, at 116 ("PPOs are a third party payer that offers financial incentives such as low out-of-pocket prices, to enrollees who acquire medical care from a preset list of physicians and hospitals.").

<sup>406</sup> *See id.*

<sup>407</sup> This process typically entails drug formularies, which list specific medications that an insurance plan will cover. Michael Ollove, *New Rules Aim to Keep Patients on Medications that Work*, PEW TRUSTS (Feb. 2, 2017), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/02/02/new-rules-aim-to-keep-patients-on-medications-that-work> [https://perma.cc/EUV9



this practice does not itself directly concern conflicts of interest that may cause doctors to sub-optimally treat or prescribe, it does have ethical and policy implications of its own, and it compounds the fact that patients often have little control over the quality of the treatments they will receive.<sup>408</sup> It contributes to the overall problem we are addressing here: that physicians uninfluenced by extraneous influences often are not the ultimate decision-makers about a patient's specific pharmaceutical treatment.<sup>409</sup>

The containment of health care costs is a pressing social and economic concern, so these issues created by managed healthcare are not created without some justification.<sup>410</sup> On the other hand, it is not clear that cost savings are actually passed on to consumers, rather than simply retained by insurers and pharmaceutical retailers as additional profit.<sup>411</sup> As compelling as

---

-XYVS]. Formularies are sometimes changed abruptly, financially causing patients to be put on alternative medications to those that may be working well for them. *Id.* There has been some consumer protection movement to curtail or restrict perceived formulary abuses, but formularies remain a reality for many patients. *Id.*

<sup>408</sup> While this secondary consideration does not trigger the prescribing doctor conflict of interest concerns that are the subject of this Article, it does exacerbate the current precariousness for patients hoping to receive the best possible care. *Recent Cases, First Amendment—Commercial Speech—Second Circuit Holds That Prohibiting Truthful Off-Label Promotion of FDA-Approved Drugs by Pharmaceutical Representatives Violates First Amendment.*—United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), 127 HARV. L. REV. 795, 802 (2013) (internal citations omitted). It adds an additional layer of risk and suboptimal drug selection, increasing the chances that a patient will get inferior rather than ideal treatment. *Id.* This dynamic adds to an overall environment that reduces patient control and autonomy over treatment due to augmented corporate prerogative in drug choices. See Hannah Fresques, *Doctors Prescribe More of a Drug if They Receive Money from a Pharma Company Tied to It*, PROPUBLICA (Dec. 20, 2019, 12 PM), <https://www.propublica.org/article/doctors-prescribe-more-of-a-drug-if-they-receive-money-from-a-pharma-company-tied-to-it> [<https://perma.cc/P5PF-V9NK>]. In such an environment, disclosure protections are less convincingly adequate than regulatory restrictions.

<sup>409</sup> See Ollove, *supra* note 407.

<sup>410</sup> See Alfonso R. Oddo, *Healthcare Ethics: A Patient-Centered Decision Model*, 29 J. BUS. ETHICS 125, 125 (2001) (observing the tension between high-quality healthcare and a need to keep costs contained).

<sup>411</sup> See, e.g., Barak Richman et al., *Mergers between health insurers and pharmacy benefit managers could be bad for your health*, STAT (June 1, 2018), <https://www.statnews.com/2018/06/01/mergers-health-insurers-pharmacy-benefit-managers/> [<https://perma.cc/5FV5-NZC5>].

containment of healthcare costs is, patient safety and ensuring basic integrity in the delivery of healthcare must ultimately be our primary goals. Methods of controlling costs should not come at the expense of patient safety.

#### RECOMMENDATIONS AND CONCLUSION

Our analysis so far leads to two overarching observations. First, conflict of interest is a serious problem affecting the ethically, medically sound treatment of patients.<sup>412</sup> Second, these issues should be addressed by changes in the professional ethics codes of both the medical profession and the pharmaceutical industry.<sup>413</sup>

##### *A. Conflict of Interest Is a Serious Problem Affecting the Ethically, Medically Sound Treatment of Patients*

Conflict of interest often creates untenable temptations for doctors to alter their prescription patterns for reasons other than the best interests of their patients.<sup>414</sup> Survey research has suggested that, “[d]espite the recent publicity about ethical problems in relationships between physicians and the pharmaceutical industry, ... physicians ... continue to have a rather permissive view about a variety of marketing activities.”<sup>415</sup>

Consider the example of physicians treated to free travel and expenses to attend symposia on a company’s new drugs.<sup>416</sup> According to a recent article, “[e]ighty-five percent of [such] physicians interviewed stated that accepting such invitations would not influence their use of the drugs. Nevertheless, their prescriptions for those drugs nearly tripled after the meetings, far above increases in the use of those drugs nationally.”<sup>417</sup> This suggests that some physicians are unaware of unconscious biases that may affect their patient treatment decisions.<sup>418</sup>

---

<sup>412</sup> Oddo, *supra* note 410.

<sup>413</sup> PHARMA 2020 CODE, *supra* note 95, at 2.

<sup>414</sup> Aaron E. Carroll, *Doctors’ Magical Thinking About Conflicts of Interest*, N.Y. TIMES (Sept. 8, 2014), <https://www.nytimes.com/2014/09/09/upshot/doctors-magical-thinking-about-conflicts-of-interest.html> [<https://perma.cc/F8A9-674P>].

<sup>415</sup> Brett et al., *supra* note 346, at 2217–18 (reflecting on data surveying both experienced and inexperienced physicians at one institution).

<sup>416</sup> Carroll, *supra* note 414.

<sup>417</sup> *Id.*

<sup>418</sup> *Id.*

Other data confirm that self-serving temptations are related to patient treatment decisions.<sup>419</sup> ProPublica, for example, has found a connection between drug company payments/entertainment and brand-name prescription levels:

Doctors who got money from drug and device makers prescribed a higher percentage of brand-name drugs overall than doctors who didn't .... Even those who simply got meals from companies prescribed more brand-name drugs, on average. Moreover, as payments increased, brand-name prescribing rates tended to as well. Doctors who received more than \$5,000 from companies in 2014 typically had the highest brand-name prescribing percentages. Among internists who received no payments, for example, the average brand-name prescribing rate was about 20 percent, compared to about 30 percent for those who received more than \$5,000.<sup>420</sup>

Of course, such research identifies only correlation, not causality.<sup>421</sup> Yet suspicion of causality is reasonable. Humans can be self-serving, and alternative explanations are hard to fathom.<sup>422</sup> The observed relationship between higher physician compensation and higher prescription activity suggests a corrupt causality.<sup>423</sup>

There is another reason to suspect a causal relationship between emolument and brand name prescription: the proliferation of brand name prescribing associated with industry payments thrives despite concerted professional efforts to decrease brand name prescriptions in favor of more inexpensive generics.<sup>424</sup> In 2015, the American College of Physicians called on doctors to prescribe generic drugs rather than branded medications when possible, in part to contain costs.<sup>425</sup>

---

<sup>419</sup> Charles Ornstein et al., *Drug-Company Payments Mirror Doctors' Brand-Name Prescribing*, NPR (Mar. 17, 2016, 5:00 AM), <https://www.npr.org/sections/health-shots/2016/03/17/470679452/drug-company-payments-mirror-doctors-brand-name-prescribing> [<https://perma.cc/GM2T-6EL9>].

<sup>420</sup> *Id.*

<sup>421</sup> *See id.*

<sup>422</sup> ANDREW M. KAMARCK, *ECONOMICS AS A SOCIAL SCIENCE: AN APPROACH TO NONAUTISTIC THEORY* 22 (2002).

<sup>423</sup> Ornstein et al., *supra* note 419.

<sup>424</sup> Honor Whiteman, *Doctors Should Prescribe Generic Drugs Over Branded Medications, Say Experts*, MED. NEWS TODAY (Nov. 24, 2015), <https://www.medicalnewstoday.com/articles/303039.php> [<https://perma.cc/4QN8-HWX6>].

<sup>425</sup> *Id.*

Cheaper generic drugs are in patients' and the health care system's interest, as "[t]he majority of peer-reviewed studies [have] found that generic equivalents to brand-name drugs produce similar clinical outcomes ...."<sup>426</sup> If generics are professionally considered preferable to branded drugs, it strains credulity to think that the ProPublica study's findings reflect anything but improperly subverted motives.<sup>427</sup> There is a lack of convincing alternative explanations for why industry payments to doctors are associated with increased brand-name prescribing.

Other data also suggest that pharmaceutical company payment to doctors corrupts prescription patterns.<sup>428</sup> Direct evidence links corporate benefit conferral to an increased prescription of the benefactor's products.<sup>429</sup> Consider an analysis done jointly by Harvard researchers and CNN, which examined Medicare Part D prescription data, as well as pharmaceutical company payment data obtained from the Center for Medicare and Medicaid Services, from 2014–2015.<sup>430</sup> CNN's report noted the following findings:

Doctors were more likely to get paid by drug companies if they prescribed a lot of opioids—and they were more likely to get paid a lot of money. Among doctors in the top 25th percentile of opioid prescribers by volume, 72% received payments. Among those in the top fifth percentile, 84% received payments. Among the very biggest prescribers—those in the top 10th of 1%—95% received payments. On average, doctors whose opioid prescription volume ranked among the top 5% nationally received twice as much money from the opioid manufacturers, compared with doctors whose prescription volume was in the median. Doctors in the top 1% of opioid prescribers received on average four times as much money as the typical doctor. Doctors in the top 10th of 1%, on average, received nine times more money than the typical doctor.<sup>431</sup>

---

<sup>426</sup> *Id.*

<sup>427</sup> See Ornstein et al., *supra* note 419.

<sup>428</sup> Aaron Kessler et al., *The More Opioids Doctors Prescribe, the More Money They Make*, CNN (Mar. 12, 2018, 8:45 AM), [https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html?utm\\_source=feedburner&utm\\_medium=feed&utm\\_campaign=Feed%3A+rss%2Fcnn\\_health+%28RSS%3A+CNN+-+Health%29](https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+rss%2Fcnn_health+%28RSS%3A+CNN+-+Health%29) [https://perma.cc/ZC3U-E6RA].

<sup>429</sup> *Id.*

<sup>430</sup> *Id.*

<sup>431</sup> *Id.*

The implications of this study are compelling. As with the other correlational findings we have discussed here, the relationship could of course theoretically be coincidental, or caused by variables other than corruption. Yet once again, if we try to theorize alternative explanations, they strain belief. The probability of coincidence or alternative causality explanations across all these studies decreases with each data set that essentially finds the same basic phenomenon.<sup>432</sup>

We are left with two possibilities: drug companies reward high prescribers with emoluments, or physicians become high prescribers in hope of currying personal, profitable favor with drug companies. Or both. Whichever might come first here, the chicken or the egg, is really irrelevant, as the implied exchange relationship is a loop of mutually desired give-and-take.<sup>433</sup> Either of these two explanations suggests an ethically unacceptable quid pro quo that harms the public.<sup>434</sup>

*B. The Issues Identified Should Be Addressed by Changes in the Professional Ethics Codes of Both the Medical Profession and the Pharmaceutical Industry*

Both the American Medical Association and the Pharmaceutical Researchers and Manufacturers of America have addressed potential conflicts of interest among doctors and drug companies.<sup>435</sup> Sometimes these professional organizations have created effective constraints and ethical restrictions, and sometimes they have left troubling practices in place.<sup>436</sup>

Our analysis has focused on two practices that continue to raise conflict of interest challenges to law, public policy, and professional and industry ethics codes: subsidization of professional

---

<sup>432</sup> Sarah Elizabeth Adler, *Drug Firm Payments to Doctors Boost Prescription Spending*, AARP (Feb. 21, 2020), <https://www.aarp.org/politics-society/advocacy/info-2020/drug-firm-payments-to-doctors-impact-consumers.html> [https://perma.cc/8ENF-D2QT].

<sup>433</sup> Henry et al., *supra* note 318, at 2493.

<sup>434</sup> *Id.*

<sup>435</sup> *See supra* Part I.

<sup>436</sup> Christy Ford Chapin, Opinion, *How Did Health Care Get to Be Such a Mess?*, N.Y. TIMES (June 19, 2017), <https://www.nytimes.com/2017/06/19/opinion/health-insurance-american-medical-association.html> [https://perma.cc/6E6S-M5K9] (criticizing the AMA for its past actions).

conferences and CME, and company-hosted speaker series. This examination has suggested that subsidization of professional conferences and CME under Former Opinion 8.061 of the AMA Code passed muster and provided more value than peril,<sup>437</sup> but that the diluted protections in Current Opinion 9.2.7 are inadequate.<sup>438</sup> If the AMA is to continue to condone industry involvement in these activities, it should revert to the former, more robust standards that it eliminated in 2016.<sup>439</sup> Otherwise, the conflict of interest is not acceptably managed and should not be considered ethically defensible.

Company-hosted speaker series are a different matter, and they simply do not pass serious ethical scrutiny. These programs create an unacceptable risk that treatment decisions may be undermined by temptations of self-interest.<sup>440</sup>

We have seen that pharmaceutical speaker programs provide dubious social benefit while exacting substantial social costs.<sup>441</sup> We also observed that current disclosure requirements are not adequate to address these costs.<sup>442</sup> If pharmaceutical company speaker programs are untenable from the standpoints of ethics and public policy, what can and should we do about them?

One approach might be to try to prohibit them by law. Legislation and regulation both, however, open the door to potential First Amendment challenges.<sup>443</sup> Arguably, there might be defenses supporting the regulation of the speaker programs, as they ostensibly would not attempt to prohibit companies from speaking, but rather would restrict the time, place and manner in which they speak.<sup>444</sup>

---

<sup>437</sup> See *Opinion 8.061*, *supra* note 49.

<sup>438</sup> See *Opinion 9.2.7*, *supra* note 48.

<sup>439</sup> See *Opinion 8.061*, *supra* note 49.

<sup>440</sup> Stephen A. Jonas et al., *Speaker Programs and the Pharmaceutical Industry*, N.Y.U. SCH. L. (Feb. 6, 2020), [https://wp.nyu.edu/compliance\\_enforcement/2020/02/06/speaker-programs-and-the-pharmaceutical-industry/](https://wp.nyu.edu/compliance_enforcement/2020/02/06/speaker-programs-and-the-pharmaceutical-industry/) [https://perma.cc/7BUD-W6RY].

<sup>441</sup> See *supra* Section III.B.2.d.

<sup>442</sup> See *supra* Section III.B.2.e.

<sup>443</sup> See *Ward v. Rock Against Racism*, 491 U.S. 781, 803 (1989).

<sup>444</sup> See *id.* (“[T]he government may impose reasonable restrictions on the time, place, or manner of protected speech, provided the restrictions ‘are justified without reference to the content of the regulated speech, that they are

In any event, professional and industry exercise of ethical responsibility is preferable to externally imposed legal accountability. It is always preferable to avoid government regulation when the public good can be achieved by voluntary self-restraint instead.<sup>445</sup> AMA and PhRMA self-policing is a cleaner way to eliminate pharmaceutical company speaker programs. The AMA should prohibit doctors from participating in them and the PhRMA should prohibit companies from continuing to host them.

Self-interest may lead both physicians and pharmaceutical companies to seek less restrictive means of self-policing.<sup>446</sup> They may look for ways to continue some version of company speaker programs that arguably address the concerns raised here. What that would look like is not immediately apparent, given that the incentives for doctors to speak and companies to host are likely to largely be self-interested ones.

It would therefore be a thorny challenge to save the general concept of company-hosted speaker series while sufficiently addressing all the ethical concerns. Whatever the ultimate approach to these issues, it is time that healthcare professionals and industry alike make a clear, unequivocal commitment to placing the well-being of patients above personal and commercial advantage.

---

narrowly tailored to serve a significant governmental interest, and that they leave open ample alternative channels for communication of the information.”) (quoting *Clark v. Comty. for Creative Non-Violence*, 468 U.S. 288, 293 (1984)).

<sup>445</sup> See Peter Grajzl et al., *Allocating Lawmaking Powers: Self-regulation vs Government Regulation*, 35 J. COMPAR. ECON. 520 (2007) (“Inefficient regulation occurs more frequently than inefficient self-regulation.”).

<sup>446</sup> Melissa Davey, *Self-Regulation by the Pharmaceutical Industry Isn’t Working, Say Experts*, THE GUARDIAN (Feb. 6, 2019), <https://www.theguardian.com/australia-news/2019/feb/07/self-regulation-by-the-pharmaceutical-industry-isnt-working-say-experts> [<https://perma.cc/2Q4G-QYKY>].