

# FINANCIAL CONFLICTS IN THE NEW ERA OF SUNSHINE: WHAT WE KNOW AND STILL NEED TO KNOW

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## ABSTRACT

The health care system has entered a new era of sunshine about financial conflicts. Disclosure, an increasingly favored regulatory approach, significantly expanded with enactment of the Physician Payments Sunshine Act, the first comprehensive federal legislation mandating public reporting of payments between industry and medicine. But is it making any difference? And what is all the increased disclosure actually revealing? This article critically analyzes the mixed experience with the Sunshine Act, what has been learned from the information generated, and the ramifications for health law and policy. This article also considers how, even in the new era of sunshine, many still important unknowns remain that complicate and potentially undermine successful financial conflicts regulation.

One clear lesson from the Sunshine Act is that inherent implementation challenges, such as data identification and translation, can seriously undermine transparency as a regulatory tool. There are considerable doubts whether the law will significantly impact decision-making of primary audiences such as patients and physicians. At the same time, the Sunshine Act has generated valuable information about the nature and scope of financial ties between industry and medicine, such as variations by clinical specialty, type of payment, and physician gender, all of which have important implications for health law and policy and can inform future regulation. Notwithstanding greater transparency, a great deal unfortunately still remains unknown. A critical need for more evidentiary support exists in several key areas, including the actual causal impact of financial conflicts, the optimal way to disclose conflicts, what patients really think about financial relationships with industry, and the role of institutional conflict of interest committees in monitoring financial ties.

## I. INTRODUCTION

Financial conflicts pervade modern medicine.<sup>1</sup> According to data from the

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1. The terms “financial conflicts” and “conflicts of interest” are used throughout this Article as defined by the Institute of Medicine. A health care provider’s primary interests include rendering professional care to patients, engaging in credible, ethical research, and supporting quality medical education. INST. OF MED. OF THE NAT’L ACADS., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 6 (Bernard Lo & Marilyn J. Field, eds., 2009) [hereinafter IOM CONFLICT OF INTEREST REPORT]. A “conflict of interest” involves “circumstances that create a risk

Physician Payments Sunshine Act (Sunshine Act),<sup>2</sup> nearly half of all physicians (48%) received some form of payment from drug companies and device manufacturers in 2015.<sup>3</sup> Patients have broad exposure to physicians under financial influence, with estimates suggesting about two-thirds of patients see physicians receiving industry payments.<sup>4</sup> The high prevalence of financial conflicts raises numerous concerns for health law and policy. The Institute of Medicine's Conflict of Interest Report, for example, warns that medicine's financial ties to industry can harm patient care, increase costs, limit choice, erode trust, and threaten the integrity of medical research.<sup>5</sup>

It is tempting to view the Sturm und Drang about financial conflicts in health care as relatively new, resulting from medicine's increased commercialization and the expanded influence of drug companies and device manufacturers. However, financial conflicts of interest in health care have been long-standing.<sup>6</sup> Also long-standing have been confusion and disagreements about how best to address them. Indeed, "[t]he problem of pharmaceutical promotion . . . presents an enduring dilemma."<sup>7</sup> Financial conflicts in health care raise continual, thorny challenges for regulation, ranging from correctly identifying the problematic financial ties, to developing effective management strategies when the evidence base remains limited for many interventions, to avoiding deterrence of innovation and beneficial industry-medicine collaborations.

What is new about this enduring dilemma is far greater transparency. Disclosure about financial conflicts in health care, an increasingly favored regulatory approach, received a significant boost in 2010 from enactment of the Sunshine Act, the first comprehensive federal legislation mandating public reporting of payments between industry and medicine. The health care system has entered a new era of sunshine about financial conflicts. But is it making any difference? And what is all the increased disclosure actually revealing?

To address these questions, this article critically analyzes the experience with the Sunshine Act. The legislation offers an unprecedented opportunity to evaluate the effectiveness of financial conflicts disclosure on a wide scale. The law so far has a very mixed, uneven record. Among other limitations, the Sunshine Act demonstrates that commanding transparency through legislation is both difficult

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that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest," such as financial gain. *Id.*

2. Physician Payments Sunshine Act of 2010, Pub. L. No. 111-148, § 6002, 124 Stat. 689 (codified at 42 U.S.C. § 1320a-7h).

3. Kathryn R. Tringale et al., *Types and Distributions of Payments from Industry to Physicians in 2015*, 317 JAMA 1774, 1774 (2017).

4. Genevieve Pham-Kanter et al., *Public Awareness of and Contact with Physicians Who Receive Industry Payments: A National Survey*, 32 J. GEN. INTERNAL MED. 767, 770 (2017).

5. IOM CONFLICT OF INTEREST REP., *supra* note 1, at 23, 27.

6. Abigail Zuger, *What Do Patients Think About Physicians' Conflict of Interest? Watching Transparency Evolve*, 317 JAMA 1747, 1747 (2017).

7. Scott H. Podolsky & Jeremy A. Green, *A Historical Perspective of Pharmaceutical Promotion and Physician Education*, 300 JAMA 831, 833 (2008).

and can have unintended effects. The law has encountered serious implementation challenges in its rollout and uncertainty remains about the intended audiences and their ability to use the information about financial relationships effectively.

At the same time, the Sunshine Act is generating the most comprehensive data to date about the nature, scope, variation, and pervasiveness of financial ties between industry and medicine. As this article explores, this information has important implications for health law and policy. It offers valuable guidance for evidence-based regulation of financial conflicts moving forward, such as identifying predictors of significant financial entanglement and facilitating tailored regulatory responses depending on differing clinical contexts.

This article is part of a symposium that asks “what works and what doesn’t work?” in various areas of health law and policy. As applied to financial conflicts of interest regulation, answering these questions remains difficult, given the limited evidence base for many regulatory interventions. An equally important, threshold set of questions to ask: (1) what do we know and (2) what do we still need to know? The Sunshine Act’s greatest and likely most sustaining contribution is helping address the first question. Because of the law, we know a great deal more about the epidemiology of industry-medicine financial ties, such as the incidence, distribution, and predictive factors for financial conflicts, and this data can inform future regulation. However, as explained further below, there is also strong reason to doubt that the Sunshine Act’s increased transparency will result in significant changes in patient and physician decision-making. Moreover, notwithstanding increased transparency, a great deal still needs to be known about financial conflicts regulation. Evidentiary support remains critically missing on key issues. This article identifies several of the important remaining unknowns.

Part II of this article describes the Sunshine Act’s basic requirements and how it expands upon and amplifies previous disclosure laws and policies. Part III explores many of the stumbles encountered in the Sunshine Act’s rollout and the considerable implementation challenges in identifying and communicating the data about industry-medicine financial ties. It also considers the uncertainty about the intended audiences, the considerable doubts about their ability to act on the information, and the possible unintended effects of mandatory disclosure. Part IV analyzes what the Sunshine Act has revealed about industry-medicine financial ties and the important ramifications for evidence-based regulation of financial conflicts. Part V considers how, even in the new era of sunshine, significant unknowns about financial conflicts remain that complicate and potentially undermine effective regulation. These include the actual causal impact of financial conflicts, the comparative effectiveness of different regulatory approaches, the optimal methods for disclosing financial relationships, what patients really think about financial conflicts, and the appropriate role of institutional conflict of interest committees in the monitoring of financial ties. Part VI concludes.

## II. SUNSHINE ACT AND THE OPEN PAYMENTS DATABASE

The Sunshine Act, enacted in 2010 as part of the larger Affordable Care Act,

is the first comprehensive federal legislation to require reporting of industry-medicine financial relationships. The law does not prohibit or otherwise alter the financial relationships that can be created. But it does impose the reporting requirement, a form of regulation by transparency which, in theory, advances important goals. Public disclosure of financial ties, by subjecting the parties to increased scrutiny and market pressures, may deter problematic industry-medicine financial relationships.<sup>8</sup> Further, increased transparency may facilitate improved decision-making by patients, physicians, and other stakeholders.<sup>9</sup>

The Sunshine Act applies to drug companies and medical device firms manufacturing products covered by Medicare, Medicaid, or the Children's Health Insurance Program.<sup>10</sup> These manufacturers, as well as group purchasing organizations, must report annually to the Federal Government if they have physician owners or investors.<sup>11</sup> In addition, manufacturers must report annually all "transfers of value" to physicians and teaching hospitals.<sup>12</sup> A "transfer of value" is defined broadly and can cover not only direct monetary payments but provision of food, lodging, equipment and other items of tangible value.<sup>13</sup> The Centers for Medicare and Medicaid Services (CMS) compiles the reported data and releases it on a publicly available and searchable website, known as the Open Payments Database.<sup>14</sup> Physicians have the opportunity to review the manufacturer reports online during a limited forty-five day time window before public posting by CMS to the Open Payments Database and they may access a dispute resolution process if they disagree with particular reports.<sup>15</sup>

Even small dollar financial relationships need to be reported. Payments of greater than \$10 per instance or \$100 per year must be disclosed as "transfers of value."<sup>16</sup> In addition, in reporting each payment a manufacturer must place it within a limited number of categories defined by the statute and implementing regulations, such as consulting fees, travel and lodging, research payments, royalty and license fees, and grants.<sup>17</sup> Manufacturers began collecting data in

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8. Alison Hwang & Lisa Lehmann, *Putting the Patient at the Center of the Physician Payment Sunshine Act*, HEALTH AFF. BLOG (June 13, 2012), <http://healthaffairs.org/blog/2012/06/13/putting-the-patient-at-the-center-of-the-physician-payment-sunshine-act/> [<https://perma.cc/6H4E-EU3Z>].

9. Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9458-59 (2013) (codified at 42 C.F.R. pts. 402, 403).

10. 42 U.S.C. § 1320a-7h(a)(1)(A), (e)(2), (e)(4), (e)(5) (2012).

11. 42 U.S.C. § 1320a-7h(a)(2).

12. 42 U.S.C. § 1320a-7h(a)(1), (e)(6).

13. 42 U.S.C. § 1320a-7h(e)(10).

14. See *Open Payments*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/openpayments/> [<https://perma.cc/BDP7-VEJE>] (last modified July 11, 2017, 1:32 PM).

15. 42 C.F.R. § 403.908(g).

16. 42 U.S.C. § 1320a-7h(e)(10); 42 C.F.R. § 403.904(h).

17. 42 U.S.C. § 1320a-7h(a)(1)(A)(vi); 42 C.F.R. § 403.904(e)(2) (providing that the possible payment categories are consulting fees, compensation for non-consulting services such as

August 2013 and reporting it to the government in March 2014. CMS has released the data in batches. Industry-medicine financial transactions currently posted to the Open Payments Database cover the latter part of 2013, and all of 2014–2016.<sup>18</sup>

Manufacturers who violate the reporting requirements risk civil fines up to \$10,000 for each violation, capped annually at \$150,000.<sup>19</sup> Knowing violations are subject to civil fines of up to \$100,000 for each incident, capped annually at \$1 million.<sup>20</sup> The fines are one-sided in application. Recipients of payments, such as physicians and teaching hospitals, have no direct reporting obligation. Instead the manufacturers making the payments bear the full reporting burden and face possible sanction for non-compliance.

The Sunshine Act expands upon and amplifies previous disclosure laws and programs.

As for institutional policies and rules, many medical journals now require authors to disclose financial relationships with industry.<sup>21</sup> Similarly, health care institutions commonly have internal policies requiring medical staff to disclose industry financial ties to conflicts of interest committees within their institution for further evaluation and management.<sup>22</sup> As for direct reporting laws, a handful of states, such as Massachusetts, Minnesota, and Vermont, have previously enacted their own sunshine laws,<sup>23</sup> but the state laws vary in terms of the minimum value that triggers reporting of payments, the exceptions that apply, and other material terms. Also, the Department of Justice has negotiated fraud and abuse settlements with several pharmaceutical companies, such as Eli Lilly and Co., requiring public disclosure of their payments to physicians.<sup>24</sup>

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speaker fees, honoraria, gifts, entertainment, food and beverage, travel and lodging, education, research-related payments, charitable contributions, royalties and license fees, payments related to ownership and investment interests, speaker/faculty fees for non-accredited educational events, speaker/faculty fees for accredited continuing education programs, grants, and space rental or facility fees).

18. See *Open Payments*, *supra* note 14.

19. 42 U.S.C. § 1320a-7h(b)(1).

20. 42 U.S.C. § 1320a-7h(b)(2).

21. See, e.g., Int'l Comm. Med. J. Editors, *Form for Disclosure of Potential Conflicts of Interest*, ICMJE, <http://www.icmje.org/conflicts-of-interest/> [<https://perma.cc/67UT-3CJH>] (last visited June 23, 2017).

22. See, e.g., U. Mich. Office of Res., *Conflict of Interest*, RES. ETHICS & COMPLIANCE U. MICH. (March 31, 2017), <http://research-compliance.umich.edu/conflict-interest-coi> [<https://perma.cc/F3P4-ETEX>]; WFBMC Conflict of Interest Office, *Policy on Conflict of Commitment and Conflict of Interest*, WAKE FOREST BAPTIST MED. CTR. 8&9, file:///C:/Users/sdrs8/Downloads/approved%20McConnell\_COI\_Policy%202012\_09\_05[1]%20(1).pdf [<https://perma.cc/PQT6-Y7YH>] (last updated Aug. 24, 2012).

23. See MASS. GEN. LAWS ch. 111N, § 6 (2012); MINN. STAT. § 151.47(f) (2013); VT. STAT. ANN. tit. 18, § 4632 (2016).

24. *Eli Lilly & Co. Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa*, DEP'T OF JUSTICE (Jan. 15, 2009), <https://www.justice.gov/archive/opa/pr/>

Federal regulations also require reporting of certain medical industry financial ties, but these apply only in the research context. National Institutes of Health (NIH) regulations require grantees to disclose to their institutions significant financial ties (\$5,000 or more) with industry and the institutions, in turn, to disclose how they managed perceived financial conflicts to the Public Health Service.<sup>25</sup> Meanwhile Food and Drug Administration (FDA) rules require a company seeking FDA approval of its product to report to the agency certain financial relationships (payments over \$25,000 and equity interests over \$50,000) with clinical investigators testing the product in FDA-regulated clinical trials.<sup>26</sup>

The Sunshine Act thus breaks new ground as the first comprehensive reporting program and it establishes uniform requirements through federal law. It is also far broader than the previous laws and disclosure programs, as it has a low dollar threshold to trigger reporting and more types of transactions are generally covered. In addition, the public can more easily access the information in the Open Payments Database than the information disclosed under several of the state sunshine laws and settlement agreements.<sup>27</sup>

### III. IMPLEMENTATION CHALLENGES AND UNINTENDED EFFECTS

The Sunshine Act has been bedeviled by considerable implementation problems. Its troubled rollout demonstrates that despite the theoretical appeal of disclosure as a regulatory tool, challenges in data selection and communication, which arise in many disclosure programs, make achieving meaningful transparency in action quite difficult. In addition, there is reason to doubt that increased transparency will result in significantly changed medical decision-making by primary audiences such as patients and physicians. Moreover, mandatory disclosure can have unintended effects.

#### A. Data Gathering

A well-functioning transparency program depends, in the first instance, on selecting representative data to disclose. Unfortunately, gathering all the relevant information regarding industry-medicine financial ties has proven to be disappointingly difficult. This is understandable because of the many moving

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2009/January/09-civ-038.html [https://perma.cc/8GDG-M6CK]; *Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Eli Lilly and Company*, SEC.Gov, 28-29 (Jan. 14, 2009), <https://www.sec.gov/Archives/edgar/data/59478/000095015209001897/c49534exv10w17.htm> [https://perma.cc/8QNX-K9TB].

25. 42 C.F.R. §§ 50.601–605; 45 C.F.R. §§ 94.1–5.

26. 21 C.F.R. pt. 54.

27. For example, Minnesota's sunshine law initially provided only public access to the data on paper, with no aggregate reports made available to the public, while West Virginia's law required disclosure of payments to state regulators but did not make this information, in turn, readily available to the public. See Susan Chimonas et al., *Show Us the Money: Lessons in Transparency from State Pharmaceutical Marketing Disclosure Laws*, 45 HEALTHSERVS. RES. 98, 100 (2010).

parts. Financial ties between industry and medicine arise in a complex web of relationships between individual physicians, larger medical groups, hospitals, multi-provider health systems, drug companies, device manufacturers, wholesalers, distributors, educational and conference providers, and research support organizations, among others. Further, financial influence can take many forms, such as returns to physician investors, direct payments for services such as consulting, research grants, educational support, and intellectual property-related fees. Against this backdrop, the Sunshine Act, while broad in scope, still misses important data points.

For one, it fails to account for all important recipients of industry payments. According to the statute, transfers of value to “physicians” must be reported.<sup>28</sup> CMS interprets this provision as requiring the disclosure of payments to a physician licensed and legally authorized to practice medicine in any state.<sup>29</sup> Under this interpretation, payments to medical residents, nurse practitioners, physician assistants and other ancillary personnel are excluded from the reporting obligation.<sup>30</sup> Medical residents and ancillary providers are, however, in an important position to make referrals and prescriptions as they have independent prescribing authority in several states and otherwise can generate significant referrals.<sup>31</sup> They also have financial entanglements with industry similar to physician-industry financial relationships.<sup>32</sup> It can be expected that these providers will be additional targets of industry financial influence and that manufacturers, wary of reporting to the Open Payments Database, will restructure transactions and allocate more industry spending toward residents and non-physician personnel. As a result, the Sunshine Act may end up obscuring important new forms of financial influence in the health care market. In addition, focus group research indicates that many physicians view the Sunshine Act as unfair because of its focus only on physician interactions with industry and not potentially conflicting relationships between other prescribers and industry.<sup>33</sup> This perceived disparity contributes to physician distrust and cynicism about the

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28. 42 U.S.C. §§ 1320a-7h(a)(1)(A), (e)(6) (2012).

29. Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9466 (Feb. 8, 2013) (codified at 42 C.F.R. § 403.902).

30. *Id.* at 9467.

31. Nurse practitioners and physician assistants wrote approximately ten percent of all prescriptions in 2013 under Medicare’s Part D prescription drug program and they are among the top prescribers for certain narcotic controlled substances. Charles Orenstein, *Transparency Program Obscures Pharma Payment to Nurses, Physician Assistants*, PROPUBLICA (July 6, 2015), <https://www.propublica.org/article/transparency-program-obscures-pharma-payments-nurses-physician-assistants> [https://perma.cc/PP9Z-C9LC].

32. See, e.g., Quinn Grundy et al., *Marketing and the Most Trusted Profession: The Invisible Interactions Between Registered Nurses and Industry*, 164 ANNALS INTERNAL MED. 733, 735 (2016).

33. Susan Chimonas et al., *Powered by Sunshine: Next Steps for Making Transparency Matter*, 17 AM. J. BIOETHICS W1, W1 (2017).

law, making it more difficult to enforce.

The Sunshine Act also misses important data with regards to the entities making payments. The statute imposes reporting obligations only on manufacturers (and, in more limited circumstances, GPOs). CMS has interpreted this to mean that only companies that have title to a drug, device, or other reimbursable product must report their payments to physicians.<sup>34</sup> However, before a product reaches the market, and is ordered by a physician, it often passes through other entities in the production chain, such as wholesalers and distributors. Because these downstream entities economically benefit from greater utilization of the product, they also have an interest in wielding financial influence over health care providers to induce more prescriptions and referrals. But when wholesalers and distributors (if not also holding title to the product) enter into financial relationships with physicians, the transactions are not reported to the Open Payments Database. Not only does this obscure important sources of financial influence, it may encourage manufacturers to evade reporting obligations by restructuring transactions to make greater use of downstream entities as the source of payments.<sup>35</sup>

Data glitches have also arisen because of the difficulty, given the complex web of industry-medicine financial ties, keeping straight which companies and which medical products are involved in a financial relationship. Reporting into the Open Payments Database has not always been consistent. For example, multiple corporate affiliates can make payments to the same physician with regard to the same drug or device.<sup>36</sup> Each payment is reported separately by the distinct corporate affiliate's name. Many end-users of the Open Payments Database may be unaware when related corporate entities are making coordinated payments, as the distinct payment reports are not linked and the companies' affiliation may not be common knowledge or apparent from name alone. Likewise, despite the expectation that each payment report will identify which product was involved in the disclosed financial relationship, manufacturers have submitted several reports with no identified drug or device to match to a payment, or with more than one underlying drug or device and no breakdown of how much

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34. Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9461–62 (Feb. 8, 2013) (codified at 42 C.F.R. pts. 402, 403).

35. A manufacturer that tries to "pass through" payments to physicians by first paying a distributor, which, in turn, relays the funds to the physician, would still likely have to report such payments as the Sunshine Act does require reporting of indirect payments. *See* 42 C.F.R. § 403.902 (definition of "indirect payments or other transfers of value"). However, more sophisticated business models where the cooperating distributor is arguably making the physician payment independently, and not under the control or direction of the manufacturer, would likely not trigger reporting as indirect payments.

36. *See* Charles Ornstein et al., *Data on Payments from Drugmakers to Doctors is Marred by Error*, N.Y. TIMES (Jan. 22, 2015), <https://www.nytimes.com/2015/01/23/upshot/data-on-payments-from-drugmakers-to-doctors-is-marred-by-error.html> [<https://perma.cc/RS6F-B94D>].



of the payment was allocated to each product.<sup>37</sup> As a result of such data glitches, the full extent of financial influence behind a particular drug or device at times remains obscured even after disclosure into the Open Payment Database.

One supposed advantage of the Sunshine Act, compared to many previous disclosure programs, is that it does not depend upon physician reporting. The reporting obligations fall entirely upon manufacturers, the entities making payments. Previous disclosure programs have been marred by low physician compliance in identifying and disclosing payments,<sup>38</sup> perhaps because physicians are already over-burdened by other reporting obligations or because they cannot keep accurate track of all the payments they typically receive from multiple sources, and may be reluctant to draw attention to their receipt of payments.

However, putting reporting obligations entirely on manufacturers has not fully avoided the challenge of ensuring physician compliance. Physicians are not fully engaging with the data. In the beginning of the Open Payments Database rollout, a sizeable number of physicians did not fully participate in the verification process, meaning that much of the posted data had not been fully vetted.<sup>39</sup> According to a market research survey conducted several weeks after the Open Payments Database went public, only 46% of physicians reported having checked the website, for reasons ranging from curiosity to verifying the accuracy of payments reported to them.<sup>40</sup> Other physicians who did register and identified payment reports they thought inaccurate complained about the inability to get the information timely corrected and problems with the dispute resolution process.<sup>41</sup>

These problems may be arising in part because of the misaligned incentives under the Sunshine Act for reporting compliance. Companies can incur substantial fines for insufficient reporting of their payments to physicians.<sup>42</sup> They may be inclined to err on the side of over-reporting, identifying some payments even if unsure really whether they needed to be reported or if unsure which

37. *Id.*

38. See IOM CONFLICT OF INTEREST REPORT, *supra* note 1, at 63; Kanu Okike et al., *Accuracy of Conflict-of-Interest Disclosures Reported by Physicians*, 361 NEW ENG. J. MED. 1466, 1470–71 (2009); Gardiner Harris, *Top Psychiatrists Didn't Report Drug Makers' Pay*, N.Y. TIMES (Oct. 3, 2008), <http://www.nytimes.com/2008/10/04/health/policy/04drug.html> [<https://perma.cc/E9FW-ZQN5>].

39. Sachin Santhakumar et al., *The Physician Payment Sunshine Act: Testing the Value of Transparency*, 313 JAMA 23, 23 (2015) (noting that only 4.8% of physicians and 29.8% of teaching hospitals engaged in the vetting process for the 2013 Open Payments data).

40. Ed Silverman, *What Money? Many Docs Haven't Visited the Open Payments Database*, WALL ST. J. (Feb. 20, 2015), <https://blogs.wsj.com/pharmalot/2015/02/20/what-money-most-docs-havent-visited-the-open-payments-database/> [<https://perma.cc/CY2Z-9F83>].

41. Elizabeth Richardson, *Health Policy Briefs: The Physician Payments Sunshine Act*, HEALTH AFF. 1, 4 (Oct. 2, 2014), [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=127](http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=127) [<https://perma.cc/VZ57-AMG8>]; see also Susan Chimonas et al., *Bringing Transparency to Medicine: Exploring Physicians' Views and Experiences of the Sunshine Act*, 17 AM. J. BIOETHICS 4, 10 (2017) (noting that physician participation “has been exceedingly low”).

42. See 42 U.S.C. § 1320a-7h(b) (2012).

physician recipients were involved. Physicians, however, face no direct sanctions under the Sunshine Act as to whether their financial relationships were reported inaccurately or not at all. Thus, physicians have limited direct incentives to engage with and verify the data. While presumably reputational concerns associated with public disclosure would motivate a fair number of physicians to want to review the accuracy of reports appearing in the Open Payments Database, physician engagement still could be considerably improved.

### *B. Data Translation and Communication*

A successful transparency program attends to data translation and communication. Even with the most accurate and meaningful information gathered, a disclosure program can be rendered ineffective by how the data is interpreted and displayed. There is considerable risk that end users may simply tune out, misinterpret, or fail to engage with the disclosed information. Thus, effective disclosure programs translate the gathered data in a way that is comprehensible to end-users and compatible in format and other features with their typical decision-making so that the information likely becomes “embedded” in user decisions.<sup>43</sup> Likewise, end users must obtain the relevant data with low enough information costs to justify their expected benefits, and end users must perceive that the information has value because they are in a position to act on and make meaningful choices with the information.<sup>44</sup>

Like many transparency programs, the Sunshine Act struggles with these inherent challenges in data translation and communication. Presenting the information in a manner compatible with patient decision-making and facilitating comprehension about industry-medicine financial ties proves enormously difficult. A problem fundamental to financial conflicts disclosure is how to provide all the information actually relevant to the risk of bias? The literature on physician financial incentives cautions that there is a great deal more to consider than simply the amount of money conveyed.<sup>45</sup> Risk of bias and undue influence in an industry-medicine financial relationship depends on number of variables, including the amount of money at stake, but importantly also how the payment compares relative to the recipient physician’s other sources of income, the nature of physician services involved in the transaction, the historical relations between the transacting parties and any power imbalances that may exist, how long the financial relationship will continue, the number of patients affected, whether many other physicians enjoy the same financial relationship with the company,

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43. ARCHON FUNG ET AL., FULL DISCLOSURE: THE PERILS AND PROMISES OF TRANSPARENCY 56–62 (2007).

44. *Id.* at 55–56.

45. See, e.g., Bernard Lo et al., *Payments to Physicians: Does the Amount of Money Make a Difference?*, 317 JAMA 1719, 1719 (2017) (“The degree of concern will vary . . . according to the type of financial relationship and the nature of the physician’s advice or activity.”).

the recipient physician's ability to direct referral and prescription decisions for the company's products, and the physician's interest in maintaining relations with the company in other settings.<sup>46</sup> How is a transparency program supposed to disclose all this, and yet still be easily comprehensible and readily accessible to the public?

The architects of the Open Payments Database have opted to keep the disclosure deceptively simple, omitting much of the relevant background and important contextual information. A payment report in the database displays the company and physician/teaching hospital in the transaction, the dollar value conveyed, and the type of payment involved by referencing one of the limited payment categories (consulting, travel/lodging, speaker fees, etc.). End-users do not necessarily understand, from just the associated category descriptor, the fuller context as to what the underlying payments are about and where there may be greater risks of bias and undue influence. As an example, learning that a financial relationship involved "consulting" by the physician to a drug company for a certain dollar amount does not really provide the end user with much relevant information as to the legitimacy of the relationship and the actual risk of bias involved. Moreover, in the face of such disclosure, many users will not even know what additional contextual questions to ask.

Not only does the Open Payments Database omit key contextual information, but the limited information it does display risks skewing patient responses in ways that mask the real risks of bias and undue influence. As noted, particularly prominent in payment reports in the Open Payments Database are the payment amount and type of payment category (consulting fee, research payment, royalty and license fee, etc.). As for payment amount, end users likely instinctively react primarily to this factor, assuming there is greater concern the greater the payment. However, such assumptions reflect misunderstandings about how bias and undue influence arise in industry-medicine financial relationships. The conflict of interest literature cautions that the risk of undue influence and bias does not necessarily correlate with the amount of money at stake.<sup>47</sup> Small gifts and de minimis payments can also warrant serious concern because of accompanying non-economic influences. The underlying relationships arising from the financial ties, even if involving low dollars, can create indebtedness, unconscious gratitude,

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46. See, e.g., Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145, 207–10 (2003); Brian Armour et al., *The Effect of Explicit Financial Incentives on Physician Behavior*, 161 ARCHIVES INTERNAL MED. 1261, 1265–66 (2001); 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, 154–63 (2013).

47. See, e.g., Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest*, 295 JAMA 429, 430–32 (2006); Dana Katz et al., *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 10 AM. J. BIOETHICS 11, 11–14 (2010) ("[W]hile it might seem both logical and practicable to distinguish small gifts from larger, seemingly more problematic gifts, a large body of evidence from the social sciences shows that behavior can be influenced by gifts of negligible value.").

and reciprocation obligations for the physician recipients.<sup>48</sup> These cumulative pressures can exert potential bias in subtle but powerful ways.<sup>49</sup> For example, a study of Open Payments Database reports found significant correlation between a physician's receipt of a single meal (cost around \$12-\$18) promoting a brand name drug and higher prescribing of that medication relative to alternatives within the same drug class.<sup>50</sup>

Additional problems arise with the prominence of payment categorization in the Open Payments Database. A study of patient views about financial conflicts, modeled on the Sunshine Act disclosures, found that patients generally reacted more negatively to a reported financial relationship when the underlying payment amount was larger.<sup>51</sup> However, even more salient to patients was the payment category, which seemingly exerted strong influence on patient perceptions.<sup>52</sup> For example, patients generally viewed physicians who received consulting payments as experts with more knowledge about medical advances.<sup>53</sup> Meanwhile, physicians paid for travel or with ownership interests were perceived as less trustworthy than physicians receiving other categories of payment,<sup>54</sup> perhaps because payments such as travel were viewed as "unearned" by the recipient physicians. Other research also indicates that payment categorization influences patient and research subject perceptions to a large degree.<sup>55</sup>

Thus, Open Payments Database reports may cause patients to react vigorously to some disclosures and minimally to others, if influenced primarily by amount of money involved and payment category. Importantly, these skewed responses do not necessarily correspond to the payment's actual risk of bias and undue influence. For example, despite the perception that industry selects physicians as consultants because of their expertise, fraud and abuse

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48. See, e.g., William W. Stead, *The Complex and Multifaceted Aspects of Conflicts of Interest*, 317 JAMA 1765, 1765 (2017).

49. See generally JASON DANA, HOW PSYCHOLOGICAL RESEARCH CAN INFORM POLICIES FOR DEALING WITH CONFLICTS OF INTEREST IN MEDICINE, in IOM CONFLICT OF INTEREST REPORT, *supra* note 1, app. D at 358–74.

50. Colette Dejong et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, 176 JAMA INTERNAL MED. 1114, 1114, 1116, 1121 (2016). The study looked at physician prescribing behavior with regard to statins, angiotensin receptor blockers, selective serotonin reuptake inhibitors and several other commonly prescribed classes of drugs. *Id.* at 1114.

51. Joshua E. Perry et al., *Trust and Transparency: Patient Perceptions of Physicians' Financial Relationships with Pharmaceutical Companies*, 42 J. L. MED. & ETHICS 475, 478, 485 (2014).

52. *Id.* at 475, 478, 485.

53. *Id.* at 484, 487.

54. *Id.* at 480–82, 487.

55. See, e.g., Adam Licurse et al., *The Impact of Disclosing Financial Ties in Research and Clinical Care*, 170 ARCHIVES INTERNAL MED. 675, 678 tbl.2, 680 (2010) ("[W]e find that, across multiple studies, patients and research participants are able to distinguish between different types of [financial relationships] as well as the relative importance of disclosure of each.").

investigations have revealed various drug companies' and device firms' use of consulting payments as schemes to secure physician loyalty.<sup>56</sup> Likewise, certain small dollar financial ties may warrant vigorous attention and management because they do present real risk of actual bias,<sup>57</sup> even if typical end users would assume they have limited impact.

Further difficulties arise because the Open Payments Database lacks important comparative benchmarks. How a particular physician's financial relationships compare to peers in the field is very material information for patients and other stakeholders. Only in 2017 did CMS add at least some comparative information in response to ordinary searches. But this is rather limited, showing how a physician's payments compare to national and specialty peers, not regional, and not addressing which general payment categories are involved.<sup>58</sup>

Missing contextual and comparative information are recurring problems for transparency programs generally. This information is often necessary for the disclosures to be meaningful, accurate, and practical to end users. However, for certain complex topics such as financial conflicts, this means a great deal of additional contextual and comparative information will need to be disclosed. The more that needs to be disclosed, the greater the risk that the transparency program overloads end-users with too much information and additional search costs, and displays the information in formats that are not likely to be compatible with their typical decision-making. The Sunshine Act demonstrates that, at bottom, achieving transparency that is simultaneously accurate, meaningful, comprehensible, accessible, and compatible with end users' decision-making frequently requires working at cross purposes.

### *C. Audience and Unintended Effects*

To be truly effective, a disclosure program needs to account for the needs and abilities of the targeted information recipients. The Sunshine Act lacks this fine-tuned design. Indeed, uncertainty remains as to who is the intended audience? Regulatory guidance from CMS has been unclear, mentioning that "the public" will be able to use the Open Payments Database information to make informed

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56. See, e.g., *Avoiding Medicare Fraud and Abuse: A Roadmap for Physicians*, CTRS. FOR MEDICARE & MEDICAID SERVS. 8 (August 2016), [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding\\_Medicare\\_FandA\\_Physicians\\_FactSheet\\_905645.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_FandA_Physicians_FactSheet_905645.pdf) [<https://perma.cc/E695-W6QP>]; *United States of America v. Reinstein*, 1:12CV09167, WL 9307035 (N.D. Ill. Feb. 13, 2015); Press Release, Dep't of Justice, *Drug Maker Forest Pleads Guilty to Pay More Than \$313 Million to Resolve Criminal Charges and False Claims Act Allegations*, JUSTICE NEWS (Sept. 15, 2010), <https://www.justice.gov/opa/pr/drug-maker-forest-pleads-guilty-pay-more-313-million-resolve-criminal-charges-and-false> [<https://perma.cc/9G4R-LYY5>].

57. See Lo, *supra* note 45, at 1720.

58. See *Open Payments Data*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://openpaymentsdata.cms.gov/> [<https://perma.cc/A7US-5G4L>].

decisions about their health care, and otherwise being vague as to specific audiences.<sup>59</sup>

### 1. Patients

Patients presumably form part of the core intended audience. But the Sunshine Act's disclosure program seems poorly designed for patients' abilities and preferences and its direct impact on patient decision-making remains questionable for several reasons. First, the search costs for patients may dissuade many from using the Open Payments Database. While searching an electronic database with simple name queries may not seem daunting, patients must factor this in along with the many other searches they ordinarily have to undertake in arranging for treatment, such as finding an available physician that is covered by the patient's insurance, evaluating the physician's qualifications, and ascertaining the cost and quality of proposed treatments. Data about financial ties may simply be less salient, or not worth the effort due to informational fatigue, in light of all the other search costs patients typically must endure.

Another reason to question patient engagement with financial conflicts information concerns the timing of disclosure. Many healthy patients might agree, in the abstract, that they would want to know information about provider financial conflicts of interest because this could affect them therapeutically and financially. But most patients must engage with this information when they are sick and seeking treatment. In these circumstances, financial conflicts information may be more easily tuned out as extraneous to the more immediate questions of proposed treatments and their risks and benefits. "When people get sick, all they really want is to get well again, and even the enlightened 21st century patient undoubtedly cares much less about how that happens than it happens at all."<sup>60</sup>

In fact, the early Sunshine Act data indicates that patients are engaging with the information in only modest numbers. From September 30, 2014 to August 1, 2015, the Open Payments Database received 1.1 million page views from visitors.<sup>61</sup> During the same time period, data within the Open Payments Database

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59. See CTRS. FOR MEDICARE & MEDICAID SERVS., ANNUAL REPORT TO CONGRESS ON THE OPEN PAYMENTS PROGRAM 2 (2016) [hereinafter 2016 CMS ANNUAL REPORT TO CONGRESS] ("This public website is designed to increase access to, and knowledge about, healthcare industry financial relationships and provide the public with information to enable them to make informed decisions about their healthcare."); *Open Payments Data in Context*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/OpenPayments/About/Open-Payments-Data-in-Context.html> [<https://perma.cc/26HF-9HJE>] (last modified Nov. 28, 2016, 6:57 AM) ("Open Payments means different things to different people and audiences. For patients, consumers, and the public, Open Payments can be used to learn about the relationships between physicians and applicable manufacturers and GPOs. . . . For physicians and teaching hospital representatives, reviewing the data reported about you in the Open Payments System can ensure that this information is accurate. You can also . . . use the information reported about you to plan for questions from patients.").

60. Zuger, *supra* note 6, at 1748.

61. CTRS. FOR MEDICARE & MEDICAID SERVS., ANNUAL REPORT TO CONGRESS ON THE OPEN PAYMENTS PROGRAM 20 (2016).

was searched over 6.5 million times and data downloaded close to 50,000 times.<sup>62</sup> It is not clear whether this volume of page views and searches was undertaken primarily by patients, or by physicians, companies, information intermediaries, or other stakeholders. Nonetheless, even if this volume represented entirely patient searches, it still is a relatively small number when one considers there are over 57 million patients enrolled in the Medicare program alone,<sup>63</sup> and the Open Payments Database covers financial relationships related to products covered not only by Medicare but also Medicaid and the Children's Health Insurance Program. Likewise, physician focus group participants indicate that their patients are not asking about any information appearing in the Open Payments Database,<sup>64</sup> suggesting limited patient engagement with the data. Some commentators are optimistic that over time more patients will interact with the Open Payments Database as general awareness of the Sunshine Act increases,<sup>65</sup> but this remains to be seen.

Moreover, while patients may desire to learn about financial conflicts, this does not mean they are prepared to seek out this information themselves. The Open Payments Database assumes patients have the inclination to engage with and search the database on their own and can ask follow-up questions to their physicians later. But a recent focus group survey indicates that patients have a strong preference not to learn of financial conflicts via searchable websites, and instead desire live discussion of the conflict with their physicians during an office visit oriented around the treatment for which the financial relationship is relevant.<sup>66</sup> As the Sunshine Act rollout demonstrates, there is a key distinction in disclosure programs between making information *accessible* to patients and ensuring that the information is *actually accessed* by patients.

More generally, financial conflicts disclosures to patients can have limited impact or even counterproductive effects. As noted previously, patients may not recognize the many contextual factors that increase the risk of undue influence and bias in a financial relationship. Instead, they may react more strongly to information about the dollar amount of payment, or how a payment is categorized, and may not even know what further questions to ask.<sup>67</sup> Other behavioral research suggests that disclosure can have unintended consequences for patients. In the face of financial conflicts information, patients may experience "insinuation anxiety" to follow the physician's recommendation, as to not follow

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62. *Id.*

63. *Medicare Enrollment Dashboard*, CTRS. FOR MEDICARE & MEDICAID SERVS. (April 2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html> [<http://perma.cc/7GLD-R6DY>].

64. Chimonas et al., *supra* note 41, at 7.

65. See Joseph S. Ross, *Having Their Cake and Eating It Too: Physician Skepticism of the Open Payments Program*, 17 AM. J. BIOETHICS 19, 20 (2017).

66. J. Michael Oaks et al., *How Should Doctors Disclose Conflicts of Interest to Patients? A Focus Group Investigation*, 98 MINN. MED. 38, 40–41 (2015).

67. See *supra* notes 46–55 and accompanying text.

it would send an implied message that the patient believes the physician is dishonest, something the patient prefers to avoid.<sup>68</sup> Also, perhaps counter-intuitively, patients may become more trusting of the physician after a financial conflicts disclosure because the act of disclosure may signal the physician's candor and openness.<sup>69</sup> Even if a patient might be on guard and want to discount a conflicted physician's recommendation, the patient may be unsure how much actually to discount.<sup>70</sup>

Moreover, a growing body of research suggests that financial ties disclosures have limited sway over patient/research subject decision-making, possibly because they care more about other factors or may not appreciate the true risk posed by conflicted financial ties. Many patients and subjects report that they would like to know about financial ties, but far fewer report that this information would cause them to change their choice of treatment or provider. For example, a majority of research subjects consider it acceptable for an investigator to own stock in the company making the experimental drug or to have a consulting agreement with the company sponsoring the research.<sup>71</sup> A survey of orthopedic surgery patients indicated that a large majority of the patients would want to know if their doctor was involved with industry in design of a device the doctor was recommending.<sup>72</sup> At the same time, a majority of the same patients were nonetheless not bothered by surgeons paid to act as consultants for device manufacturers in this manner and an even larger majority of patients viewed it as beneficial if their doctor could provide consulting advice to device manufacturers.<sup>73</sup> A more systematic review of several previous studies and surveys indicates that while a majority of patients and subjects say they wish to know about financial ties, only smaller numbers indicate that this information would affect their decision-making about the type of clinical care to receive or whether to participate in research.<sup>74</sup>

Finally, patients may not be in a position to act on their concerns about financial conflicts. They may have insurance coverage with limited provider networks, where changing physicians is not always readily feasible. There may also be a limited number of available physicians in the area who do not have the

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68. George Loewenstein et al., *The Unintended Consequences of Conflict of Interest Disclosure*, 307 JAMA 669, 669–70 (2012).

69. George Loewenstein et al., *The Limits of Transparency: Pitfalls and Potential of Disclosing Conflicts of Interest*, 101 AM. ECON. REV. 423, 424 (2011).

70. *Id.* at 424.

71. Lindsay A. Hampson et al., *Patients' Views on Financial Conflicts of Interest in Cancer Research Trials*, 355 NEW ENG. J. MED. 2330, 2330 (2006).

72. M.H. Khan et al., *The Surgeon as Consultant for Medical Device Manufacturers: What Do Our Patients Think?*, 32 SPINE 2616, 2617 (2007).

73. *Id.* at 2619.

74. Licures et al., *supra* note 55, at 675; see also Christine Grady et al., *The Limits of Disclosure: What Research Subjects Want to Know about Investigator Financial Interests*, 34 J. L. MED. & ETHICS 592 (2006); Kevin P. Weinfurt et al., *Effects of Disclosing Financial Interests on Attitudes Toward Clinical Research*, 23 J. GEN. INTERNAL MED. 860 (2008).



same financial relationships the patient deems concerning.

## 2. Physicians

Physicians would seem a better audience than patients for making productive use of Sunshine Act data. Faced with public disclosure of their financial ties with industry, physicians may more carefully self-scrutinize such relationships. Sunshine Act disclosures could pressure physicians to decline certain questionable payments. Physicians can also perform the traditional role of learned intermediary for their patients, as they are in a position to evaluate *other* physicians' reported financial relationships. For example, a physician may be inclined to view more critically the favorable research results reported out of a study where the physician-investigators had publicly disclosed financial ties to the industry sponsor. As a result, the physician can change her clinical recommendations to patients about the underlying study drug or device.

But it remains to be seen whether transparency really impacts physician behavior in this way. According to a market research survey conducted early in the Sunshine Act rollout, only 21% of physicians reported that their activities with industry had decreased.<sup>75</sup> A more recent focus group study found that many of the participating physicians were unfamiliar with key details of the Sunshine Act and had only limited interactions with the Open Payments Database.<sup>76</sup> This disengagement may reflect the additionally expressed views of a fair number of the physicians, however accurate or not, that disclosures would mislead patients, damage physician reputations, the typical disclosed financial relationships were inconsequential, and any biased behavior involved only a small number of other clinicians and did not relate to their own practices.<sup>77</sup> These responses cast doubt on whether many physicians are ready and willing to use the Open Payments Database as a resource for managing financial conflicts and to discuss their financial ties to industry with patients and other stakeholders.<sup>78</sup>

Also, the experience with the few state sunshine laws calls into question whether financial conflicts disclosure programs strongly influence physician behavior. A study of Maine and West Virginia's sunshine laws looked at physician prescribing rates of brand name statins and selective serotonin reuptake inhibitors (SSRIs), two classes of drugs where pharmaceutical marketing of brand name drugs is very active and where it is suspected financial ties influence physicians to prescribe costlier, brand name drugs instead of cheaper, clinically suitable generics.<sup>79</sup> But the study found almost no difference in physician prescribing rates in the Maine and West Virginia of the brand name drugs before and after each state's disclosure law went into effect.<sup>80</sup> One important caveat is that the West Virginia and Maine disclosure programs required reporting of

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75. Silverman, *supra* note 40.

76. Chimonas et al., *supra* note 41, at 6–7.

77. *Id.* at 8–10.

78. *Id.* at 9–10.

79. Genevieve Pham-Kanter et al., *Effect of Physician Payment Disclosure Laws on Prescribing*, 172 ARCHIVES INTERNAL MED. 819, 819–20 (2012).

80. *Id.* at 820.

financial ties only to state regulators and the information was not made easily accessible to the public at large, unlike the Open Payments Database.<sup>81</sup> Thus, it is unclear how generalizable the results are to the Sunshine Act's broader transparency program.<sup>82</sup>

Additionally, behavioral analysis suggests that disclosure may have, like patients, unintended effects on physicians. Studies of advisors with financial conflicts suggest that when they have to disclose financial conflicts they may end up giving more biased advice. One possible explanation is "strategic exaggeration," where advisors, to offset anticipated discounting of their recommendations, give more exaggerated advice.<sup>83</sup> Another possibility is "moral licensing," where advisors may feel more emboldened to give biased advice because their advisees have been warned about the underlying financial conflict through disclosure.<sup>84</sup>

#### IV. REVELATIONS FROM SUNSHINE ACT DISCLOSURES AND THE IMPLICATIONS

While its impact on physician and patient decision-making remains unclear and possibly confounded by unintended behavioral effects, the Sunshine Act still offers the most comprehensive accounting to date of the financial ties between industry and medicine. This emerging epidemiology of financial relationships is crucial to developing evidence-based regulation of financial conflicts. This section explores what has been learned so far from the Sunshine Act about industry-medicine financial ties and the ramifications for financial conflicts

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81. Chimonas et al., *supra* note 27, at 100.

82. A more recent study reached contrary results. The investigators examined the impact of Massachusetts' sunshine law during the time period before rollout of the federal Sunshine Act. They reviewed physician prescribing rates within three common drug classes: statins, antidepressants, and antipsychotics. Tong Guo et al., *Let the Sun Shine In: The Impact of Industry Payment Disclosure on Physician Prescription Behavior* 1, 1–2 (April 18, 2017), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2953399](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2953399) [<https://perma.cc/N68M-GNV3>]. The study authors compared prescribing of Massachusetts physicians under the state sunshine law with their counterparts in bordering counties in New York and Connecticut, states without a sunshine law. *Id.* at 2. They concluded the Massachusetts sunshine law did correlate with a decline in physician prescribing in all three drug classes. *Id.* at 2–3. However, it is again unclear how generalizable these results are to the Sunshine Act. *See id.* at 21–22. Among other limitations, the investigators noted that they could not definitively conclude whether the lower prescribing rates seen in the Massachusetts physicians were due to changed payment practices by industry in their dealings with Massachusetts physicians, as opposed to self-monitoring by the physicians themselves, because payment data before the state sunshine law went into effect was not available. *Id.* at 22. Moreover, the use of counterpart physicians as controls in the bordering counties in different states raises questions how comparable these physicians were because of possible state-specific differences. *Id.* at 13.

83. Loewenstein et al., *supra* note 68, at 669.

84. *Id.* See also Sunita Sah, *Conflicts of Interest and Your Physician: Psychological Processes That Cause Unexpected Changes in Behavior*, 40 J. L. MED. & ETHICS 482, 485 (2012).

regulation.

#### A. How Common?

A threshold question for regulators in addressing financial ties between industry and medicine is how commonly they occur. An oft-cited statistic, that as many as 94% of physicians have financial relationships with industry, comes from a national survey of physicians in 2003-2004 published in the *New England Journal of Medicine*.<sup>85</sup> Other recent surveys have estimated about 70-80% of physicians receive gifts from industry.<sup>86</sup>

However, the emerging Sunshine Act data suggests lower prevalence rates for financial conflicts, between 40% and 50%. An analysis of data from the first five months of Sunshine Act disclosures suggests that about 40% of physicians received some form of payment reported into the Open Payments Database.<sup>87</sup> Review of all of the 2015 data in the Open Payments Database indicated about 48% of all physicians nationally received form of payment from drug companies and device manufacturers.<sup>88</sup>

These generally lower prevalence rates (40–50%), based on analysis of Open Payments Database records, likely have greater accuracy because of the Sunshine Act's inclusion of more physicians than earlier disclosure programs and surveys. The lower prevalence rates likely also reflect changing industry practices. To avoid increased public scrutiny, manufacturers may have ended certain payments to physicians in anticipation of the Sunshine Act's implementation. Likewise, physicians may have started to decline transaction opportunities. Nonetheless, in the 2013–2016 data in the Open Payments Database, there is no indication of major changes year-to-year in terms of number of physicians reported or overall general payments spending,<sup>89</sup> suggesting that any such blanket deterrence more

85. Eric G. Campbell et al., *A National Survey of Physician-Industry Relationship*, 356 NEW ENG. J. MED. 1742, 1742 (2007).

86. See Aaron Kesselheim et al., *Distribution of Industry Payments to Massachusetts Physicians*, 368 NEW ENG. J. MED. 2049, 2049 (2013) (citing surveys that indicate about 83% of physicians received industry gifts in 2004 and about 71% in 2009).

87. Deborah C. Marshall et al., *Disclosure of Industry Payments to Physicians: An Epidemiologic Analysis of Early Data from the Open Payments Program*, 91 MAYO CLINIC PROC. 84, 93 (2016).

88. Tringale, *supra* note 3, at 1774.

89. The Open Payments Database contains only five months of reported data for 2013. As for full year comparisons, for 2014 the Open Payments Database shows \$2.68 billion in general payments, \$4.07 billion in research payments, with a combined total of \$6.75 billion. For 2015, there were \$2.68 billion in general payments, \$4.45 billion in research payments, with a combined total of \$7.13 billion. For 2016, there were \$2.80 billion in general payments, \$4.36 billion in research payments, with a combined total of \$7.16 billion. These estimates refer to payment transfers and do not include ownership or investment interests held by the physicians and teaching hospitals. See *The Facts on Open Payments, Summary Data*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://openpaymentsdata.cms.gov/summary> [<https://perma.cc/8W6L-GL6J>].

likely had stronger impact in the run-up to the Sunshine Act data going public than afterward.

Still, even with the somewhat lower prevalence rates associated with the Open Payments Database reviews, regulators still have reason for concern that patients remain widely exposed to potential financial conflicts. How often patients encounter physicians with financial conflicts does not necessarily correlate with how many physicians nationally have reported payments. Physicians who accept more industry payments may care for more patients than those physicians who do not accept industry payments, or patients may more regularly visit clinicians who practice in specialties with greater industry influence.<sup>90</sup> Researchers estimated patient exposure to physicians with financial conflicts by reviewing a full year of Open Payments Database reports, compared to a national patient sample group's physician contacts for the same period. They found that about 65% of patients had seen a physician in the measurement period who had received a reportable general payment from industry.<sup>91</sup> In other words, about two-thirds of patients had contact with physicians with industry payments, suggesting patient exposure to physicians under industry influence remains quite broad.

#### *B. Variation by Physician Specialty*

Industry-medicine financial ties have not developed uniformly between medical fields. The Open Payments Database indicates that tremendous specialty variation exists as to prevalence of financial relationships. For example, Open Payments Database reports for August 1, 2013 to December 31, 2013 indicate that a large number of cardiologists (78%) and gastroenterologists (68%) received some form of reportable industry payment.<sup>92</sup> This contrasts with primary care physicians as less than half of internal medicine physicians (42%) and pediatricians (23%) had a reportable financial relationship, and a slim majority of family medicine practitioners (55%) received some form of reportable payment.<sup>93</sup> Lower prevalence rates were not limited to primary care fields, however. For the same measurement period, a small number of physicians within the fields of anesthesiology (22%), radiology (17%), and psychiatry (34%) had any form of reportable financial tie.<sup>94</sup> Similar trends in terms of prevalence and specialty variation were seen in the 2015 Open Payments Database reports.<sup>95</sup>

Apart from prevalence of financial ties, how much money flows within each financial relationship also varies tremendously between physicians in different clinical fields. According to Open Payments Database reports for the last five months of 2013, the mean value of general payments (excluding research

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90. Pham-Kanter, *supra* note 4, at 768.

91. *Id.* at 769.

92. Marshall, *supra* note 87, at 88.

93. *Id.*

94. *Id.*

95. See Tringale, *supra* note 3, at 1774.

payments) per surgeon (\$2383) was more than twice as much as reported for physicians in general medical specialties (\$976).<sup>96</sup> Analysis of the 2015 Open Payments Database information revealed similar trends, with surgeons more likely receiving industry payments and of higher value per physician than primary care physicians.<sup>97</sup>

Orthopedic surgeons are at the top in terms of lucrative financial ties with industry. For the reporting period from August 1, 2013, through December 31, 2013, the mean value of general payments per orthopedic surgeon was \$7114, the highest among all physician groups, and driven largely by the high value of royalty and license payments.<sup>98</sup> The mean value of general payments per practitioner was also relatively large in interventional specialties such as cardiology (\$1866).<sup>99</sup> But certain primary medical specialties attracted much lower overall value of payments. Family medicine practitioners, pediatricians, and obstetrics and gynecology physicians, for example, had less than \$500 as the mean value of general payments per physician.<sup>100</sup> Meanwhile, a specialty like neurology had relatively average rates of physicians having any form of financial relationship (49%), yet the dollar amounts attracted by those physicians were still relatively large (\$2342 mean value of general payments per physician).<sup>101</sup>

Thus, the Open Payments Database has revealed considerable specialty variation across several dimensions with regard to financial relationships. In some clinical fields, like orthopedic surgery, a large number of physicians have some form of financial relationship with industry and the mean amount of general payments received by each physician is high relative to other fields. In other fields such as obstetrics/gynecology, although a large number of payments occur, the dollar value of payments is relatively small. In primary fields like pediatrics, only a smaller relative number of physicians have reportable ties to industry and the dollar amounts involved are also relatively low.

Because different clinical fields have interacted with industry in such divergent ways, this raises doubt about generalized regulatory rules for addressing industry-medicine financial ties. The tremendous variation of industry financial influence in different medical sectors strongly suggests that the underlying financial conflicts' actual risks, facilitating conditions, and optimal responses, likely vary between specialties as well. At the very least, monolithic approaches for managing financial conflicts may need reevaluation. For example, transactional bans based on certain dollar thresholds or requiring second medical opinions from non-conflicted peers within the same clinical field, may be ill-

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96. Marshall et al., *supra* note 87, at 88.

97. Tringale, *supra* note 3, at 1774, 1780 (finding that 61% of surgeons, compared with 47.7% of primary care physicians, were reported to have received industry payments, and that surgeons had a mean per-physician general payment value of \$6879, compared to \$2227 for primary care physicians).

98. Marshall, *supra* note 87, at 90, 92–93.

99. *Id.* at 88.

100. *Id.*

101. *Id.*

fitting and over- or under-inclusive with regard to how financial ties are actually developing on the ground within particular specialties.

In addition, probing why such specialty variation exists can also improve financial conflicts regulation. Variation in prevalence rates likely arises because of different incentives within each field to engage with industry and the accepted legitimacy within each specialty of physicians entering into financial relationships with drug companies and device manufacturers.<sup>102</sup> Consideration of each medical field's distinct incentives and facilitating conditions for financial relationships can help guide development of regulation responsive to conditions on the ground. For example, the high degree of financial entanglement in orthopedic surgery reflects that orthopedic surgeons have historically taken the lead in product invention and development around new devices. The resulting royalty and license arrangements with device companies differs markedly from other medical fields' interactions with pharmaceutical companies around drug development.<sup>103</sup> Thus, financial conflicts regulation may need to be more specifically tailored and modified for orthopedic surgery, such as developing new safe harbor regulations for the very large royalty and license fee relationships to minimize risk of bias but still permit valuable collaborations.<sup>104</sup>

The variation between specialties in prevalence of financial ties also reveals industry interest in leveraging certain physician groups more than others. Manufacturers will have stronger interest in wielding financial influence with physicians who are in the best position to order their drugs and devices and these clinicians tend to work in more interventional fields. The Sunshine Act data reveals that, roughly, and with some exceptions, medical specialties at the higher end of the interventionist spectrum, such as cardiology, neurosurgery, and gastroenterology, have higher prevalence rates of clinicians receiving any form of industry payment than the low intervention fields such as pediatrics and internal medicine.<sup>105</sup> This information can help guide regulators develop targeted audits and educational efforts within certain specialty fields to facilitate more efficient enforcement of the Anti-Kickback Statute,<sup>106</sup> False Claims Act,<sup>107</sup> Physician Self-Referral Law (aka "Stark Law"),<sup>108</sup> and other healthcare fraud and abuse laws that may be triggered by the industry-medicine financial relationships.

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102. Kesselheim et al., *supra* note 86, at 2051.

103. See, Gregory L. Cvetanovich et al., *Industry Financial Relationships in Orthopaedic Surgery: Analysis of the Sunshine Act Open Payments Database and Comparison with Other Surgical Specialties*, 97 J. BONE JOINT SURGERY 1288 (2015), <https://www.ncbi.nlm.nih.gov/pubmed/26246264> [<https://perma.cc/Y6TY-49DL>].

104. *Id.*

105. Marshall, *supra* note 87, at 88 (noting that one exception to this trend, for example, is plastic surgery, a high interventionist field where the prevalence rate (37%) of physicians having any form of reported financial ties is relatively low).

106. 42 U.S.C. § 1320a-7b (2015).

107. 31 U.S.C. §§ 3729-3733 (2009).

108. 42 U.S.C. § 1395nn (2010).

### *C. Variation by Physician Gender*

Gender matters according to the Sunshine Act data. Similar to physician specialty, physician gender correlates with different frequency and dollar value of financial ties with industry. Analysis of 2015 reports in the Open Payments Database indicated that among physicians nationally, 51% of male physicians but only 42.7% of female physicians had a reportable financial relationship with industry.<sup>109</sup> Female physicians nationally also had a lower mean value of general payments per physician than their male peers (\$1309 compared to \$5031).<sup>110</sup> These trends for physicians overall also carried over to distinct medical specialties, as within most medical fields male physicians were more likely to receive general payments from industry, and their mean per-physician payments were higher.<sup>111</sup> These results are consistent with earlier analyses. For example, analysis of 2013 Open Payments Database reports revealed that of the 300 doctors who received the most money for speaking and consulting payments, 90% were male.<sup>112</sup> Similarly, among reported general payments to oncologists, male physicians were more likely to receive industry payments and in greater amounts than female physicians.<sup>113</sup>

The gender disparity in overall general payments likely arises for several reasons. Royalty and license payments can significantly increase the overall dollar value of payments flowing to individual physicians.<sup>114</sup> But female physicians remain underrepresented in product invention and development and may therefore have less interactions with device companies and drug manufacturers.<sup>115</sup> Others speculate that female physicians tend to desire more patient-oriented care and may have different preferences than male physicians regarding dealing with industry.<sup>116</sup> It may also be that because male physicians tend to earn higher compensation in the medical labor market,<sup>117</sup> industry needs to offer more, in terms of dollar value, to attract the attention of male physicians

109. Tringale, *supra* note 3, at 1777.

110. *Id.* at 1779.

111. *Id.* at 1779, 1783.

112. Charles Ornstein, *Men Dominate List of Doctors Receiving Largest Payments from Drug Companies*, N.Y. TIMES (Oct. 9, 2014), <https://www.nytimes.com/2014/10/09/upshot/men-dominate-list-of-doctors-receiving-largest-payments-from-drug-companies.html> [<https://perma.cc/EZ66-M2C2>].

113. Deborah C. Marshall et al., *Distribution and Patterns of Industry-Related Payments to Oncologists in 2014*, 108 J. NAT'L CANCER INST. 1, 4, 9 (2016), <https://academic.oup.com/jnci/article-abstract/108/12/djw163/2706926/Distribution-and-Patterns-of-Industry-Related?redirectedFrom=fulltext> [<https://perma.cc/3VGX-248G>].

114. Tringale, *supra* note 3, at 1781.

115. Marshall, *supra* note 113.

116. Tringale, *supra* note 3, at 1781.

117. Catherine Saint Louis, *Dr. Paid-Less: An Old Title Still Fits Female Physicians*, N.Y. TIMES (July 11, 2016), <https://www.nytimes.com/2016/07/12/health/women-doctors-salaries-pay-gap.html> [<https://perma.cc/7LHW-K4D4>].

when initiating financial relationships. Moreover, the gender disparity may be self-reinforcing, as industry may prefer to target influential opinion leaders and manufacturers may view more male physicians belonging in this group precisely because of the male physicians' greater likelihood of having previous deals with manufacturers.<sup>118</sup>

The gender disparity data also has interesting ramifications for regulation and policy. Because gender is a predictor, among other factors, for potential financial conflicts, regulators might consider physician gender in developing targeted educational efforts and monitoring plans for compliance under the health care fraud and abuse laws. Moreover, the incentives female physicians face for less financial relationships with industry might be further studied and replicated on a broader scale to counter aggressive industry influence. Meanwhile, some commentators hope that the Sunshine Act's transparency about gender disparity will end up reducing gender differences.<sup>119</sup> Under this view, increased visibility of how industry payments to physicians differ by gender could lead to greater questioning of manufacturers' business practices generally, pressuring companies to adopt more gender-neutral payment practices in interacting with medicine.<sup>120</sup> Any such impact of the Sunshine Act, however, remains to be seen.

*D. Skewed Distribution: Small Number of Physicians Attracting Most Dollars*

The emerging Sunshine Act data has also revealed interesting patterns in the distribution of payments within a medical specialty. Among physicians within a particular medical field who do receive payments, the financial amounts involved are not relatively uniform. Instead, payment distribution is heavily skewed toward a small number of physicians who are top earners. For example, among orthopedic surgeons, a very small number of practitioners attract the lion share of payments in terms of dollar value. Open Payments Database reports indicates that only about 2% of orthopedic surgeons receive royalty and license payments from industry. But the aggregate dollar value of these payments is quite large, accounting for 70% of the total value of monetary payments received by all orthopedic surgeons.<sup>121</sup>

Similar skewed payment distribution patterns, with large dollar amounts flowing toward a few top-earners, have been observed in several other specialties. According to early Sunshine Act data, the top ten percent of otolaryngologists, ranked by the dollar value of industry payments they each receive, account for 87% of all the industry payments to their specialty field as a whole.<sup>122</sup> Industry

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118. *Id.*

119. Susannah L. Rose et al. *Gender Differences in Physicians' Financial Ties to Industry: A Study of National Disclosure*, PLOS ONE 1, 8 (June 11, 2015), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0129197> [<https://perma.cc/7UB4-MM85>].

120. *Id.*

121. Cvetanovich, *supra* note 103, at 1293–94.

122. Vinay Rathi et al., *Industry Ties in Otolaryngology: Initial Insights from the Physician Payment Sunshine Act*, 152 OTOLARYNGOLOGY-HEAD & NECK SURGERY 993 (2015)



payments to obstetrics-gynecologists likewise seem skewed to a small number of top earners.<sup>123</sup> Orthopedic surgery and neurosurgery have the greatest payment distribution disparity (in terms of overall dollar value flowing to each physician) between practitioners in their disciplines. However, not all medical fields have this very high degree of skewed payment distribution. Primary care fields like internal medicine and family medicine are not as heavily skewed in payment distribution.<sup>124</sup>

The skewed payment distribution patterns can be interpreted in different ways. A more benign explanation is that manufacturers target the few respected opinion leaders within each field based on academic credentials and general reputation, hoping to tap their expertise and standing in the field in a variety of legitimate collaborations, such as consulting on product development. In addition, royalty and license fees often comprise the large dollar payments to the top few earners. It should not surprise that only a few physicians in each field are able to earn such fees as successful innovators because of the long, arduous process for taking products from the invention stage to regulatory approval and regular clinical use. A more troubling explanation, however, is that this represents industry attempts to heavily leverage a few physicians through very lucrative relationships, and rely upon those physicians to influence their peers' prescribing and referral choices, which may be a more cost-effective way of driving physician prescribing in the aggregate than more equal distribution of payments.

Further, the skewed payment distribution patterns have implications for regulation and policy. In clinical fields where heavily skewed payment distributions occur, regulators might consider taking action specifically directed at the top dollar physician recipients as their financial ties may warrant more fine-tuned responses. This could include concentrated audit and enforcement actions and prophylactic monitoring of the top dollar physician recipients' prescribing. Regulators might also consider looking at the underlying payment categories driving the skewed payment distributions and consider whether additional rules are needed. For example, royalty and license payments appear to contribute significantly to the skewed distribution patterns. Additional safe harbor regulations might be considered to minimize risk of bias and undue influence within royalty and license arrangements. As an illustration, surgeons might be required to contribute more than just surgical volume with a device in order to be considered part of the device's design team and be eligible for sharing in royalty

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<http://journals.sagepub.com/doi/pdf/10.1177/0194599815573718> [https://perma.cc/Z8E7-255H].

123. See Nicole Tierney et al., *Industry Payments to Obstetrician-Gynecologists*, 127 OBSTETRICS & GYNECOLOGY 376, 379 (2016), [http://journals.lww.com/greenjournal/Abstract/2016/02000/Industry\\_Payments\\_to\\_Obstetrician\\_Gynecologists\\_.28.aspx](http://journals.lww.com/greenjournal/Abstract/2016/02000/Industry_Payments_to_Obstetrician_Gynecologists_.28.aspx) [https://perma.cc/PYA9-HEF8].

124. Andre Samuel et al., *Orthopedic Surgeons Receive the Most Industry Payments to Physicians but Large Disparities are Seen in Sunshine Act Data*, 47 CLINICAL ORTHOPAEDICS & RELATED RES. 3287, 3301 fig. 3 (2015), <https://www.ncbi.nlm.nih.gov/pubmed/26088767> [https://perma.cc/HW5B-JYG9].

and license payments from the product's commercialization.<sup>125</sup>

#### V. WHAT STILL NEEDS TO BE KNOWN

While the Sunshine Act is building up the evidence base in some key respects, a great deal remains unknown, even in this new era of sunshine, about financial conflicts regulation. This section considers several significant areas where the lack of firm evidence continues to complicate and undermine development and enforcement of optimal laws and policies.

##### *A. Correlation vs. Causation: The Actual Causal Impact of Financial Conflicts*

The Sunshine Act has made more transparent the pervasiveness and wide variety of industry-medicine financial relationships. But whether these financial ties directly create harm, and to what extent, remains far less certain. Limited data exists concerning the effects of financial conflicts in health care decision-making generally and it remains subject to conflicting interpretation.<sup>126</sup> Opponents of heightened regulation charge that proof is still lacking that financial ties sway physicians' prescribing and referral decisions in ways that actually harm patients therapeutically.<sup>127</sup> For example, while financial ties have been correlated with more expensive drug prescribing,<sup>128</sup> this does not mean patients are receiving clinically inappropriate treatments. Standards of care are rarely uniform; wide variations exist in the way clinicians practice medicine.<sup>129</sup> Many prescribing decisions are made where there is no one clear treatment pathway and reasonable clinicians may have different preferences, all within various accepted schools of thought. Thus, "it is often quite difficult to assess whether advice is biased or not, even in the presence of a conflict of interest."<sup>130</sup> The knowledge gap about the

125. Cf. Richard H. Gelberman, *Orthopedic Surgeons and the Medical Device Industry: The Threat to Scientific Integrity and the Public Trust*, 92 J. BONE & JOINT SURGERY 765, 773 (2010), [http://journals.lww.com/jbjsjournal/Citation/2010/03000/Orthopaedic\\_Surgeons\\_and\\_the\\_Medical\\_Device.30.aspx](http://journals.lww.com/jbjsjournal/Citation/2010/03000/Orthopaedic_Surgeons_and_the_Medical_Device.30.aspx) [<https://perma.cc/WG9T-XRXF>].

126. Compare Christopher Robertson et al., *Effects of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence*, 40 J. L. MED. & ETHICS 452 (2012), with Teddy D. Warner & John P. Gluck, *What Do We Really Know About Conflicts of Interest in Biomedical Research?*, 171 PSYCHOPHARMACOLOGY 36 (2003). See also RONALD BAILEY, *SCRUTINIZING INDUSTRY FUNDED SCIENCE: THE CRUSADE AGAINST CONFLICTS OF INTEREST* (American Council on Science & Health, 2008).

127. See, e.g., D. Barton et al., *After 20 Years, Industry Critics Bury Skeptics, Despite Empirical Vacuum*, 68 INT'L J. CLINICAL PRAC. 666, 666 (2014).

128. See *infra* notes 141–46 and accompanying text.

129. See, e.g., John E. Wennberg, *Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers: Is More Better?*, COMMONWEALTH FUND PUB. NO. 874 (2005); James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" as a New Role for QIOs?*, 59 VAND. L. REV. 1017, 1026–27 (2006); MARK A. HALL ET AL., *HEALTH CARE LAW AND ETHICS* 322 (8th ed. 2013).

130. Sunita Sah et al., *Effect of Physician Disclosure of Specialty Bias on Patient Trust and*

true impact of industry-medicine financial ties is particularly acute regarding medical research. Financial relationships between industry and investigators, while correlated with possible publication bias, have not been linked to increased rates of adverse events for subjects participating in clinical trials.<sup>131</sup>

Debate over the true impact of financial conflicts boils down to correlation versus causation. Much of the empirical data about financial interests is based on observational rather than conventional studies.<sup>132</sup> The studies typically report association between financial ties and problematic research behavior, as opposed to causal evidence.<sup>133</sup> Many serious risks are associated with financial conflicts, including harming patients, increasing costs, limiting choice, and biasing research.<sup>134</sup> But for all these supposed risks, virtually none have been causally linked to underlying financial conflicts through comprehensive studies employing gold standard proof and rigorous statistical techniques, such as randomization and use of controls. As opponents of stricter regulation often highlight, any number of confounding variables may be responsible for associations between financial ties and certain problematic conduct.<sup>135</sup> Moreover, design limitations make determining the effects of financial conflicts difficult. For example, observed associations may be false negatives arising from the often-small sample sizes.<sup>136</sup> Meanwhile, multiple possible sources of causation raise contamination problems. Comparison physicians, thought to be unexposed to financial ties, may be

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*Treatment Choice*, 113 PNAS 7465, 7467 (2016).

131. Thomas P. Stossel, *Regulating Academic-Industrial Research Relationships—Solving Problems or Stifling Progress?*, 353 NEW ENG. J. MED. 1060, 1061 (2005).

132. See, e.g., Josephine Johnston, *Financial Conflicts of Interest in Biomedical Research*, in *TRUST & INTEGRITY IN BIOMEDICAL RESEARCH* 11, 16–17 (Thomas H. Murray & Josephine Johnston, eds., 2010) (noting that as even the Institute of Medicine’s 2009 Conflict of Interest Report concedes, “on many topics related to conflicts of interest, no systematic studies are available...[while] for other topics, data are suggestive rather than definitive.”). IOM CONFLICT OF INTEREST REPORT, *supra* note 1, at 4.

133. See, e.g., Stanford C. Taylor et al., *Physician-Industry Interactions and Anti-Vascular Growth Factor Use Among US Ophthalmologists*, 134 JAMA OPHTHALMOLOGY 897, 897 (2016) (“[T]his analysis cannot determine whether the payments reported caused the increased use, are a result of the increased use, or are merely associated with some other factor that causes the increased use.”).

134. IOM CONFLICT OF INTEREST REPORT, *supra* note 1, at 23, 27.

135. See, e.g., Barton *supra* note 127, at 671 (“[A] 1998 study found that authors with financial ties to drug manufacturers were more likely to endorse the use of calcium channel blockers, which some believed to be unsafe, than those without such ties. This was interpreted as a case where financial ties caused physicians to endorse a product they otherwise might not have. Yet, the association is confounded since these authors’ views could also be explained by their greater seniority, prominence and experience.”).

136. 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, 17 (2010), <http://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1000352&type=printable> [<https://perma.cc/D4BT-GV32>].

influenced by their peers who do transact with industry, while physicians with financial ties may nonetheless be more strongly influenced by non-financial sources.<sup>137</sup> Further, some correlations may reflect bidirectional causation, as physicians who prescribe in larger volume or more expensively may in turn willingly expose themselves to more promotional activities and industry influence.<sup>138</sup>

The Sunshine Act has moved the ball in some respects. The information generated offers even stronger evidence of correlation and in a wide variety of contexts. Publicly available databases detail the Medicare-reimbursable services provided by individual physicians<sup>139</sup> and the prescription drugs ordered by individual physicians under the Medicare Part D prescription drug program.<sup>140</sup> Thus, it is now theoretically feasible to compare industry spending directed at an individual physician within the Open Payments Database and the prescribing and referral decisions of that same physician for Medicare patients within these latter databases. A first wave of studies making such comparisons has been published, with interesting conclusions about correlation.<sup>141</sup>

One noteworthy investigation, looking at 12 different medical specialties, indicated that physician receipt of industry payments was associated with greater prescribing costs per Medicare patient and greater likelihood of the physician prescribing more costly brand name medications instead of cheaper generics.<sup>142</sup> The study authors noted that this association persisted across all the medical specialties examined, except for general surgery, even though there was wide variation between most of the medical specialties in the distribution and amount of industry payments.<sup>143</sup> The study authors further noted that in some specialties the cost increases largely arose due to the physicians' more expensive prescribing overall, whereas in other specialties the cost increases were driven largely by the

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137. *Id.*

138. *Id.*

139. *Medicare Provider and Utilization and Payment Data: Physician and Other Supplier*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html> (last modified June 15, 2017) [<https://perma.cc/FL62-VVZC>].

140. *Medicare Provider and Utilization and Payment Data: Part D Prescriber*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html> (last modified May 25, 2017) [<https://perma.cc/X3UF-KLVY>].

141. *See, e.g.*, William Fleischman et al., *Association Between Payments from Manufacturers of Pharmaceuticals to Physicians and Regional Prescribing: Cross Sectional Ecological Study*, 354 *BMJ* 1, 4–5 (2016); Taylor, *supra* note 133, at 899–902; DeJong, *supra* note 50, at 1114.

142. Roy H. Perlis & Clifford S. Perlis, *Physician Payments from Industry Are Associated With Greater Medicare Part D Prescribing Costs*, *PLOS ONE*, 1, 1 (May 16, 2016), <http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0155474&type=printable> [<https://perma.cc/4TEU-B9Q9>].

143. *Id.* at 6.

physicians prescribing brand-name drugs over generics.<sup>144</sup>

Another such study found correlation between physician prescribing and mere receipt of meals. The investigators looked at physicians who received reported food payments from industry and their prescriptions to Medicare patients for statins, angiotensin receptor blockers, cardioselective beta-blockers, and selective serotonin reuptake inhibitors.<sup>145</sup> The researchers found a significant association between a physician receiving a single meal and higher rates of prescribing the costlier brand name medication connected to the promotional meal. This association persisted even though for the class of drugs studied there was no strong evidence that the brand name medications were any better than cheaper generic equivalents.<sup>146</sup>

The Sunshine Act has even led to correlation studies concerning physicians' use of social media. One recent investigation, using Open Payments Database reports, found that more than 70% of cancer doctors with active Twitter accounts received payments from industry unrelated to research or grants.<sup>147</sup> These ties were ordinarily not disclosed on their Twitter accounts. In some instances, the physicians might have been tweeting reviews about particular medications or clinical trials involving products made by manufacturers making payments to the physicians.<sup>148</sup>

However, as intriguing as these studies utilizing Open Payments Database information may be, they still only show correlation, not causation. For example, with the DeJong meal study, the physicians who accepted the industry meals may have already developed a preference for the brand name medications, for reasons unrelated to industry payments, and so they were more likely to attend promotion meals sponsored by the brand name manufacturers than other physicians.<sup>149</sup> Under this interpretation, it is still debatable whether the financial relationships directly swayed physician prescribing.

Unfortunately, it is unlikely that the emerging Sunshine Act data will ever be able to resolve definitively the enduring uncertainty about financial conflicts and causation. Financial conflicts of interest, risk of bias, and undue influence operate in a complex and ultimately murky environment with many levers and moving parts. Confounding factors include: the widely different types of financial transactions that arise; industry-medicine financial relationships also have non-financial dimensions; the supposed biasing effect of financial ties involves hard to measure psychological pressures and unconscious decision-making; difficulty in isolating the effect of particular financial ties on individual physicians from the impact of larger financial relationships industry may form with institutions where

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144. *Id.* at 7.

145. DeJong, *supra* note 50, at 1114.

146. *Id.*

147. Derrick L. Tao et al., *Financial Conflicts of interest Among Hematologists-Oncologists on Twitter*, 177 JAMA INTERNAL MED. 425, 426 (2017).

148. Alexandra Sifferlin, *What Your Doctor Isn't Telling You on Twitter*, TIME (Jan. 17, 2017), <http://time.com/4634502/twitter-cancer-doctors/> [<https://perma.cc/TBM7-VBW8>].

149. Dejong, *supra* note 50, at 1121.

the physicians practice; and physician behaviors can change over measurement periods for reasons unrelated to industry's financial influence, such as malpractice liability concerns, new institutional policies, and reimbursement changes from payers. Moreover, it is nearly impossible to design rigorous randomized trials with controls to study causation when investigating financial relationships already occurring, leaving much of the analysis to observational studies that inevitably can be challenged as not firm enough proof.

It should be noted that evidence of correlation, even if not causation, may still be enough to warrant stronger regulatory responses. For one, financial relationships may reinforce problematic prescribing patterns through association, even if not initially causing those prescribing choices.<sup>150</sup> Moreover, the risk of harm from certain financial relationships may be of such concern that, because of risk mitigation and the "precautionary principle,"<sup>151</sup> it may be better to regulate prophylactically even where evidence of causation is still lacking. The dangers of inaction may be so great that it is unwise to wait for definitive causation evidence to arrive, if it ever does. Further, as Robert Steinbrook has argued, it may not be necessary to prove a causal relationship between industry-medicine financial ties and changes in physician behavior. Associations between industry payments and physician prescribing of more expensive brand name medications are troubling enough because of the perceptions created of industry influence.<sup>152</sup> Also, even in the absence of causation evidence, physicians have a professional obligation to consider how these relationships with industry affect the costs imposed on patients.<sup>153</sup>

Nonetheless, the lack of firm causation evidence remains a serious challenge. It calls into question the proportionality and ultimate justification for much financial conflicts regulation. This makes it all the harder to obtain political consensus on the best policy options, including all-important buy-in from more entrepreneurial physicians. Perceptions that financial conflicts regulation inequitably burdens physicians who collaborate with industry can encourage cynicism, disregard, and noncompliance, making it much harder to implement and enforce rules addressing financial conflicts.<sup>154</sup>

### *B. Choosing Between Regulatory Options*

Transparency alone clearly is insufficient to address health care financial conflicts. Knowing this, then what? Which regulatory options, beyond

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150. Lo, *supra* note 45, at 1720.

151. Daniel Goldberg, *On Physician-Industry Relationships and Unreasonable Standards of Proof for Harm: A Population-Level Bioethics Approach*, 26 KENNEDY INST. ETHICS J. 173, 175 (2016).

152. Robert Steinbrook, *Physicians, Industry Payments for Food and Beverages, and Drug Prescribing*, 317 JAMA 1753, 1753–54 (2017).

153. *Id.*

154. Richard S. Saver, *Shadows Amid Sunshine: Regulating Financial Conflicts in Research*, 145 CHEST 379, 383 (2014).

disclosure, should also be deployed? Non-disclosure regulatory alternatives include supplying alternative sources of information to guide health care decision-making, such as mandatory second opinions from independent physicians about recommended treatment and research. Similarly, governmental and institutional policies can support academic detailing programs. Academic detailing provides neutral expert physician advice to community physicians about particular treatment options, and employs similar persuasion techniques used by pharmaceutical companies to counter industry's marketing efforts.<sup>155</sup> Regulation can also impose outright prohibitions, such as transactional bans of financial ties of certain dollar amounts or within certain payment categories (e.g., banning speaker fees) or barring physicians with apparent financial conflicts from rendering certain services such as serving on clinical practice guideline committees or conducting primary research. Regulation can also address industry influence by substituting certain industry roles with governmental action. For example, commentators have urged minimizing financial conflicts in research by requiring that independent entities, overseen by government agencies, entirely take over the design and conduct of clinical trials.<sup>156</sup>

Unfortunately, almost none of these approaches has been implemented in a way to accrue significant data. The dearth of information arises because much conflict of interest regulation, whether through law or institutional policies, has developed ad hoc in response to particular crises. As Lisa Rosenbaum observes, "conflict of interest policies have evolved not through careful data gathering and analysis but through intensification of regulations after each big scandal."<sup>157</sup>

Accordingly, questions arise whether particular regulatory options work well in the broad range of situations contemplated. Further, like mandated disclosure, will some of these alternatives have unintended effects and introduce new problems? For example, requiring patients to seek a second medical opinion from a physician who has no financial relationship seems, at first impression, a promising way to counter potential bias of conflicted physicians. But behavioral studies suggest that professional advisors with a conflict, aware that their clients will have access to a second opinion, are more likely to give more biased recommendations.<sup>158</sup> Therefore, a required second opinion policy could be

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155. See generally Jerry Avorn, *Academic Detailing: Marketing the Best Evidence to Clinicians*, 317 JAMA 361 (2017) (detailing a discussion of academic detailing modeled on the very successful practices adopted by pharmaceutical companies to create physician interest in their firms' drugs, such as the use of physician peer educators and face-to-face discussions with physicians by drug company sales representatives. Academic detailing involves one-on-one or small group visits between the targeted physicians and an expert physician spokesperson).

156. See Marc A. Rodwin, *Independent Drug Testing to Ensure Drug Safety and Efficacy*, 18 J. HEALTH CARE L. & POL'Y 45, 77–81 (2015).

157. Lisa Rosenbaum, *Beyond Moral Outrage—Weighing the Trade-Offs of COI Regulation*, 372 NEW ENG. J. MED. 2064, 2065 (2015).

158. Sah, *supra* note 130, at 7465; see also Sunita Sah & George Loewenstein, *Conflicted Advice and Second Opinions: Benefits but Unintended Consequences*, 130 ORGANIZATIONAL BEHAV. & HUM. DECISION PROCESS 89, 89 (2015).

counterproductive, increasing the degree of biased advice that patients receive from their primary physicians with financial conflicts.

Perhaps most vexing, comparative effectiveness data about the possible regulatory responses is sorely lacking. Even if interested in moving beyond transparency, policymakers lack a foundation to understand how to choose between the regulatory alternatives, as some may be more effective than others in differing contexts. Also lacking is comparative effectiveness data on whether transparency combined with one or more additional regulatory approaches is ultimately more effective than one of the alternatives alone. Heavy reliance on any one regulatory approach is unwise, because industry-medicine financial relationships are so pervasive, varied, and complex.<sup>159</sup> Each regulatory alternative may work through different channels and levers, with particular advantages that can be combined to address more comprehensively the underlying risks posed by financial conflicts. However, finding the right regulatory mix remains uncertain.

In optimally choosing between regulatory alternatives, it also remains important, but unfortunately difficult, to account properly for the costs of potential over-deterrence. For example, transactional bans limiting industry-medicine financial relationships of certain types or amounts, or barring physicians with financial ties from rendering certain opinions and services, may seem cleaner and more direct than regulation through transparency. But such aggressive approaches could also lead to slower development of important therapies and the lack of needed expertise in development of clinical practice guidelines or even publication of important study results.

These lost benefits often are less visible and salient than the risks of potential bias arising from financial conflicts. As Lisa Rosenbaum writes in the *New England Journal of Medicine*:

The invisibility of potential benefits makes rationally weighing the trade-offs we make with conflict of interest policies even harder. When we miss an appendicitis diagnosis, we usually find out that we've erred. When we prevent the dissemination of expertise, thwart productive collaborations, or dissuade patients from taking effective drugs, we get no such feedback. Meanwhile, we're incessantly reminded of the so-called risks [of financial conflicts]. . . .<sup>160</sup>

Thus, choosing between regulatory options in moving beyond transparency remains fraught with uncertainty and possible counterproductive effects.

### *C. If Disclosure, How to Do it Effectively?*

Even if policymakers continue to look to transparency as an important, if not by itself sufficient, regulatory tool for addressing financial conflicts, much still remains uncertain about the optimal way to go about disclosing. Thorny logistical issues and many possible pitfalls arise in deciding the process and format for

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159. Stead, *supra* note 48, at 1765.

160. Rosenbaum, *supra* note 157, at 2065.



disclosing information about a topic as complex and multifaceted as industry-medicine financial ties. Primary audiences may not know what to make of the disclosed financial conflict, have considerable uncertainty about how it actually affects their care, become overwhelmed by too much disclosure, or simply ignore the information.<sup>161</sup> Unfortunately, there have been few studies of the relative effectiveness of different ways to disclose financial conflicts. Indeed, “given the importance of this issue for U.S. health care, it is striking how little evidence exists to guide policies or interventions.”<sup>162</sup>

As previously discussed, the Open Payments Database has clear limitations, notably the lack of important comparative and contextual information. However, adding detailed comparative and contextual information threatens to burden and confuse end users with too much complexity. A significant unknown, and where more research is sorely needed, is determining the hard to find sweet spot between financial conflicts disclosure that is engaging, accessible, and understandable but also accurate and sufficiently detailed.

Moreover, the optimal disclosure method and parties that should be involved also remain unclear. Is transparency best done through a publicly accessible, searchable database, such as the Open Payments Database? Or by requiring providers to make their conflicts disclosures directly to patient, payers, and other stakeholders? As previously noted, the Open Payments Database may not match patient preferences for how to learn about financial conflicts. Focus group research suggest patients prefer a live discussion of the conflict with their physicians during an office visit oriented around the treatment for which the financial relationship is relevant.<sup>163</sup> Direct disclosure of this type may be preferable because it best facilitates a dialogue, immediately responsive to the disclosure, between the patient and the provider about the financial conflict where the patient can ascertain more personally relevant information about the conflict’s possible implications.<sup>164</sup> Also, having physicians more actively involved in initiating financial conflict disclosure makes the process more automatic, with patients as regular recipients of the information even when they do not ask about it.

Would requiring that providers directly disclose their conflicts to patients therefore be better? Not necessarily. Removing physicians directly from the disclosure process, as the Sunshine Act does, helps minimize concerns suggested by behavioral research that the act of disclosing can lead advisors like physicians to give more biased advice.<sup>165</sup> Also, physicians are unlikely to have as accurate information about their financial ties as the manufacturers. Many physicians typically have a wide variety of financial relationships that arise with multiple

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161. Katrina Armstrong et al., *Challenges and Opportunities in Disclosing Financial Ties to Patients*, 317 JAMA 1743, 1743–44 (2017). Ian Larkin & George Loewenstein, *Business Model-Related Conflicts of Interest in Medicine*, 317 JAMA 1745, 1746 (2017).

162. Armstrong, *supra* note 161, at 1744

163. Oaks, *supra* note 66, at 40–41

164. Armstrong, *supra* note 161, at 1744.

165. See *supra* notes 83 to 84 and accompanying text.

drug and device firms in everyday medical practice, including receipt of small items such as food, making it difficult to keep track of all the transactions. Further, removing physicians from having to make the direct disclosures also eases the regulatory burden on already time-pressed physicians and may be a more politically palatable way of ensuring some form of transparency.

In theory, decision aids could make the disclosure process more effective.<sup>166</sup> For one, decision aids could educate patients about the risk of bias arising even in small dollar transactions with industry and also the prevalence of financial ties.<sup>167</sup> But their content, and how they would best be used, is still the subject of much speculation given the limited experience with using decision aids for financial conflicts disclosures. Some commentators suggest that financial conflicts disclosure might work better if patients were generally educated about industry-medicine financial relationships well before they consider a particular treatment choice, such as during the time of enrollment with their health plans.<sup>168</sup> Again, however, given the dearth of studies, whether this would actually improve the disclosure process is mostly speculation.

#### *D. What do Patients Really Think?*

While patients may ultimately not be the best audience for financial conflicts disclosure, for reasons previously discussed,<sup>169</sup> accounting for their views remains important to designing responsive regulation as part of a patient-centered health care system.<sup>170</sup> Unfortunately, what patients really think about financial conflicts remains muddled. For example, as earlier noted, research indicates that most patients want to know whether their physician has financial ties with industry, but far fewer indicate that it would materially change their decision-making.<sup>171</sup> What should be concluded from this? Are these seemingly divergent views—wanting to know the information, but saying it would likely not sway their decision—irrational? Understandable?

One view is that such patients may respond, “the more information the better,” under a vague right-to-know imperative, even if they are not materially bothered by learning about physicians with financial ties. Such patients may correctly perceive that other constraints, such as reimbursement rules, professional norms, and tort liability, already limit the likelihood that their physicians will provide flawed, biased advice and treatment. Also, patients may be unbothered and even blasé about industry-medicine financial ties because they remain well aware of financial conflicts arising elsewhere in medicine and

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166. Sah, *supra* note 130, at 7468.

167. Cf. Chimonas, *supra* note 41, at 10.

168. Armstrong, *supra* note 161, at 1744.

169. See *supra* notes 60–74 and accompanying text.

170. Cf. INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 48 (2001); Joan H. Krause, *Can Health Law Truly Become Patient Centered?*, 45 WAKE FOREST L. REV. 1489, 1489–90 (2010).

171. See *supra* notes 71 to 74 and accompanying text.

perceive such conflicts as ingrained. Many patients recognize that, despite the lofty ideal of a physician with undivided loyalty to the patient, a physician can earn more depending on the type and volume of services recommended. Under the traditional fee-for-service reimbursement model, a physician faces financial conflicts—the more severe and long-lasting the illness, the more complex services a physician can provide, and the higher fees earned.<sup>172</sup> Thus, risk of bias arising in financial ties with industry may seem, to many patients, to simply be more of the same.

A more troubling consideration is that many patients have general awareness of industry-medicine financial relationships but underestimate how this may affect their own health care. Even with increased sunshine, patients may not know what to make of the disclosed information and how it may affect them, therapeutically and financially. Disregard is especially likely because, as previously discussed, only certain contextual factors, such as payment amount and payment category, may be salient to patients and not the many other conditions that can increase risk of bias.<sup>173</sup> Also, disclosing the data on financial relationships simply may lead to more questions with no good answers. As Abigail Zuger observes, “[t]he meaning behind the numbers still remains elusive. Are lavishly compensated physicians just shrills for the pharmaceutical industry? Or are they simply well-paid advisers...? [H]ow can patients be expected to decide?”<sup>174</sup>

It is tempting to assume that because of extensive news coverage of problematic industry-medicine relationships and the rollout of the Sunshine Act patients are at least primed to consider possible financial conflicts in their own health care decision-making. But a recent national patient survey indicated that 45% of the patients were generally aware of industry payments to physicians, but only 12% knew that this information was publicly available through programs like the Sunshine Act.<sup>175</sup> Moreover, only five percent of the patients reported knowing whether their own physician had received industry payments.<sup>176</sup> Even worse, among patients who believed that their physician did not receive an industry payment, a review of the Open Payments Database revealed that 41% were incorrect.<sup>177</sup> Thus, a fair number of patients may mistakenly assume that financial ties to industry do not impact their own personal health care.

Another possible explanation for the seemingly divergent patient responses is the stickiness of the doctor-patient relationship. Many patients, even if concerned about a disclosed financial conflict, likely find it difficult to contemplate terminating their relationships with their physicians. For the mysterious therapeutic healing process to activate in the doctor-patient relationship, the patient ordinarily must have a certain level of trust and even

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172. Zuger, *supra* note 6, at 1747.

173. See *supra* notes 47 to 56 and accompanying text.

174. Zuger, *supra* note 6, at 1748.

175. Pham-Kanter, *supra* note 4.

176. *Id.*

177. *Id.*

uncritical faith in the physician.<sup>178</sup> A financial conflicts disclosure may not be enough to jeopardize that trust and motivate the patient to seek treatment elsewhere.<sup>179</sup> Indeed, a patient may be less tolerant of financial conflicts generally than for her own physician because the personal connection formed with the physician, and the special investment in the treatment relationship, may outweigh more abstract concerns about financial conflicts.<sup>180</sup> Another reason for stickiness in the doctor-patient relationship is patient realization that search costs and insurance coverage constraints may make it hard to change physicians anyway.

Unfortunately, while these explanations of patients' seemingly divergent views seem plausible, they also are highly speculative. We just do not know enough at present about the full scope of patient expectations and attitudes about industry-medicine financial relationships. Further research is needed to get a better handle on what patients really think about financial conflicts and why.

#### *E. Role of Conflict of Interest Committees*

An important but underappreciated entity in the regulatory space concerning financial conflicts is the institutional conflict of interest committee (COIC). COICs exist at most major medical centers and health systems. Usually established pursuant to internal institutional policies, they are comprised of a mix of physician and medical center administrative staff.<sup>181</sup> Certain financial relationships between the medical center, staff physicians, and industry will be referred to and reviewed by the COIC. These committees can act as proxies for patients and research subjects, and in theory, can better assess and interpret the relevant conflicts disclosures.

Apart from internal institutional policies, federal research regulations also contemplate an active role for COICs in monitoring financial conflicts. For example, the NIH regulations require that NIH grantees disclose to their institutions "significant financial interests,"<sup>182</sup> such as consulting payments or equity interests that relate to their research-related activities.<sup>183</sup> The institution must then evaluate the disclosed financial relationship and report to the Public Health Service any interests identified as conflicting and the institution's

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178. See generally Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463 (2002).

179. Genevieve Pham-Kanter, *Act II of the Sunshine Act*, PLOS MED. (Nov. 4, 2014), <http://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001754&type=printable> [<https://perma.cc/T6CB-MVXX>].

180. Zuger, *supra* note 6, at 1748.

181. See, e.g., *Northwestern University Conflict of Interest Committee Oversight Guidelines*, NW. U. (Oct. 20, 2014), [http://www.northwestern.edu/coi/committees/COIOC\\_Final\\_Guidelines\\_FINAL.pdf](http://www.northwestern.edu/coi/committees/COIOC_Final_Guidelines_FINAL.pdf) [<https://perma.cc/4G3N-5KLJ>]; see also *Conflict of Interest (COI)*, U. MICH. RES. ETHICS & COMPLIANCE, <http://research-compliance.umich.edu/conflict-interest-coi> [<https://perma.cc/H6LN-5WHE>] (last visited Sept. 9, 2017).

182. 42 C.F.R. § 50.604(e).

183. 42 C.F.R. § 50.603.

management plan for dealing with the conflict.<sup>184</sup> COICs usually perform this important required review at the institutional level for financial relationships that trigger the NIH reporting requirement. In coming up with management plans, COICs have tremendous discretion to impose safeguards that they feel adequately address a financial relationship they have identified as conflicting. For example, COICs can choose to require the investigator to disclose the conflict in all published studies resulting from the research, move the research to another site, or ban the conflicted investigator from directly enrolling subjects for the research.<sup>185</sup> Similarly, guidance from the Department of Health and Human Services (HHS) urges medical centers where HHS funded research is conducted to make distinct use of their own COICs to monitor and address recurring issues of financial conflict of interest for both the investigators doing the clinical trial work and for the institutions as a whole.<sup>186</sup>

Thus, as the Sunshine Act generates information about industry-medicine financial ties, more questions about specific financial relationships uncovered can be expected to be referred to COICs at the applicable institutions. COICs will play a critical role on the ground in how most institutions respond to and manage newly identified financial ties that have been revealed through greater transparency.

But there is a striking dearth of information about the institutional capacity of COICs to perform this role and the best practices that they should follow. Indeed, “[d]espite . . . federal regulation and substantial debate over the appropriateness of financial ties and their management, very little is known about the actual decision-making processes of university COI committees.”<sup>187</sup> Minimal to no regulatory guidance exists on basic matters such as how COICs are to be constituted, the procedures they should follow, and the substantive criteria that should guide their reviews. This can leave COICs woefully unprepared for simply assessing the financial relationships, let alone determining appropriate oversight steps.<sup>188</sup> As a result, many important questions are left for ad hoc development by each COIC. For example, what is the optimal membership composition between committee members with scientific backgrounds and lay perspectives? How to ensure COICs have sufficient membership expertise to understand the underlying economic terms and other technical financial aspects of the business relationships they review? How significant must a conflict be for the COIC to conclude the

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184. 42 C.F.R. §§ 50.604(f), 50.605(a).

185. 42 C.F.R. § 50.605(a)(1).

186. Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, 69 Fed. Reg. 26393, 26936 (May 12, 2004).

187. Elizabeth A. Boyd & Lisa A. Bero, *Defining Financial Conflict and Managing Research Relationships: An Analysis of University Conflict of Interest Committee Decisions*, 13 SCI. & ENGINEERING ETHICS 415, 416 (2007).

188. Francesco Pelliccia et al., *Transparency in Medical Research: Time for a Paradigm Shift*, 186 INT’L J. CARDIOLOGY 259, 260 (2015) (“[N]ot surprisingly, given all these complicated dynamics at play, [COICs] reports enormous difficulties in making sense of the actual economic relationships and tracking how the money flows.”).

financial relationship must be terminated? Are COIC reviews best done by reviewing form disclosures about each deal or by having the committee talk to the physicians involved? What type of follow-up should COICs require once they institute a management plan? The unfortunate lack of guidance for COICs stands in contrast to the more detailed regulations directed at institutional review boards (IRBs) in their role in approving and monitoring proposed research studies for acceptable risk/benefit ratios and for ensuring protection of human subjects.<sup>189</sup>

Because of the minimal regulatory guidance for COICs, inconsistency between COICs in addressing similar financial relationships is a suspected problem. This parallels the well-known variability that has been identified with IRBs.<sup>190</sup> One of the only studies to examine the workings of COICs in detail, a review of the deliberations of three COICs at three public universities in California, found that the committees struggled in several respects, including consistency.<sup>191</sup> The study observed that the COICs had difficulty applying relevant policies about financial conflicts, did not work from a standardized definition of what was a conflict, and rarely ever recommended refusing research funding as a way of managing the conflict, although other less strict management plans were considered and recommended.<sup>192</sup> On the one hand, the COICs showed some flexibility in how they responded to identified financial conflicts, balancing concerns of academic freedom and professional autonomy with concerns of protecting subjects and providing accountability.<sup>193</sup> On the other hand, this rather ad hoc process, with little express guidance for COICs as to how to do their jobs, seems to have resulted in COICs underutilizing their compliance roles.<sup>194</sup>

It seems we may be expecting too much of COICs to do their important work as conflicts monitors without further study as to whether COICs are well designed to perform these tasks and without standardized guidelines for COICs to follow.<sup>195</sup> The risk is that the information uncovered by transparency programs like the Sunshine Act may end up being underutilized by COICs and inconsistently acted upon. Indeed, “disclosure without corresponding guidance [to COICs] for the practical management of particular financial relationships may not be the ultimate solution to the problem of conflict of interest in academic research.”<sup>196</sup> Further, the failure to subject conflicts oversight to rigorous assessment means that COICs operate without a strong empirical basis for

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189. See 45 C.F.R. § 46 (HHS regulations, 2017); 21 C.F.R. § 56 (FDA regulations, 2017).

190. CARL SCHNEIDER, *THE CENSOR’S HAND: THE MISREGULATION OF HUMAN-SUBJECT RESEARCH* 82–83 (2015).

191. Boyd & Bero, *supra* note 187, at 430–431.

192. *Id.* at 422–423, 431.

193. *Id.* at 416.

194. *Id.* at 433.

195. TRUST AND INTEGRITY IN BIOMEDICAL RESEARCH: THE CASE OF FINANCIAL CONFLICTS OF INTEREST 123 (Thomas H. Murray & Josephine Johnston, eds. 2010) (“There is, as yet, no comprehensive source of data on the oversight activities of universities....Without data, it is difficult for institutions to learn from themselves or from one another in this area...”).

196. Boyd & Bero, *supra* note 187, at 433.

determining which conflicts pose greater risk of bias and which management plans prove effective. In short, because there is such implicit reliance on COICs to do important financial conflicts oversight in the face of new Sunshine Act disclosures, we need to know a lot more about how to ensure COICs are up to the task.

#### *F. What About Non-Financial Interests?*

The Sunshine Act exclusively focuses on financial relationships. This does not surprise. Concern about financial conflicts has crowded out consideration of other secondary interests that can also bias health care decision-making. For example, the Institute of Medicine's Conflict of Interest Report focuses almost entirely on financial conflicts.<sup>197</sup> Likewise, many institutional policies and professional society guidelines address only financial conflicts.<sup>198</sup> But what about non-financial influences that can also negatively impact a healthcare provider's professional judgment and conduct? Nonfinancial interests of this type include prestige, professional honors, career advancement, glory seeking, political predispositions, and intellectual zeal.<sup>199</sup>

Unfortunately, the evidence base is underdeveloped concerning the prevalence and influence of non-financial interests. There is no equivalent to the Sunshine Act in terms of comprehensive reporting of non-financial interests. Public disclosure of non-financial interests has been very limited, such as with the International Committee of Medical Journal Editors (ICMJE)'s uniform disclosure rules that require medical journal authors to report certain non-financial interests in their publications.<sup>200</sup> Equally unclear is how to regulate non-financial interests, which are more intangible and amorphous compared to financial relationships.

But enough is known to suspect that nonfinancial interests warrant greater regulatory attention. For example, in the clinical research context, investigations suggest that financial conflicts and certain non-financial interests, such as allegiance to a particular treatment approach, raise comparable concerns. Both are associated with quite similar bias effects, including failure to publish negative results and selection of less effective interventions to compare against the favored approach.<sup>201</sup> Indirect and circumstantial evidence suggest that non-financial

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197. IOM CONFLICT OF INTEREST REPORT, *supra* note 1, at xii (“[W]e focus on conflicts that involve financial interests because they are at the heart of concerns and debates about conflicts of interest.”).

198. See, e.g., *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, AAMC-AAU (Feb. 2008), <https://members.aamc.org/eweb/upload/protecting%20Patients,%20Preserving%20Integrity.pdf> [<https://perma.cc/VE55-LATV>] (concentrating exclusively on financial conflicts).

199. Richard S. Saver, *Is It Really All About the Money? Reconsidering Non-Financial Interests in Medical Research*, 40 J.L. MED. ETHICS 467, 468 (2012).

200. See INT'L COMMITTEE MED. J. EDITORS, *supra* note 21, at § 5.

201. See Mario Maj, *Non-Financial Conflicts of Interest in Psychiatric Research and Practice*,

interests raise misaligned incentives problems on a regularly recurring basis. A review of scientific misconduct incidents reported on HHS' Office of Research Integrity's website concluded that many of the reported incidents of faked data and other troubling actions to alter study results rarely appeared to involve researchers with conflicting financial interests, but instead involved non-financial pressures such as academic advancement pressures.<sup>202</sup> Researchers also anecdotally report that non-financial interests are widespread and, at times, pose more risk than financial interests.<sup>203</sup>

Regulatory disregard of non-financial interests is concerning not only because of the risks they pose. Financial conflicts regulations are simply inadequate when they address problematic provider and researcher behaviors likely influenced both by financial ties and non-financial interests.<sup>204</sup> Moreover, it may be unwise, and even impossible, to treat financial conflicts as a discrete, compartmentalized area of focus, as the Sunshine Act attempts to do. Where financial ties end and non-financial interests begin is often unclear. Non-financial rewards can also result in financial gain. An investigator's enhanced academic reputation may be able to be monetized as it increases the researcher's ability to attract grants or demand a higher salary.

The boundary problems run in the other direction as well. Financial ties can facilitate relationships that ultimately warrant concern primarily because of the social, not economic, influences introduced, such as the pressures of indebtedness, unconscious gratitude, and reciprocity that are thought to arise for physicians receiving even small gifts and low dollar payments.<sup>205</sup> Non-economic interests often not only accompany but also "modify and strengthen financial incentives."<sup>206</sup> The increasingly blurred distinctions between financial and non-financial interests calls into question the exclusive regulatory focus on financial conflicts.

While the evidence base is limited regarding non-financial interests, they certainly combine with and magnify the risk of financial conflicts. Thus, to improve regulation of financial conflicts generally, a great deal more needs to be learned about non-financial influences, including further research on their prevalence and impact, how they interact with financial conflicts, and the efficacy

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193 BRIT. J. PSYCHIATRY 91, 91 (Aug. 2008); *Making Sense of Non-Financial Competing Interests*, 5 PLOS MED 1299, 1299 (Sept. 30, 2008), <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050199> [<https://perma.cc/3XFQ-UHML>].

202. JERRY MENIKOFF & ED RICHARDS, WHAT THE DOCTOR DIDN'T SAY: THE HIDDEN TRUTH ABOUT MEDICAL RESEARCH 226 (2006).

203. See, e.g., David Korn, *Conflicts of Interest in Biomedical Research*, 284 JAMA 2234, 2334 (2000).

204. Yuval Feldman et al., *Curbing Misconduct in the Pharmaceutical Industry: Insights From Behavioral Ethics and the Behavioral Approach to Law*, 41 J.L. MED. ETHICS 620, 621 (2013).

205. Lo, *supra* note 45, at 1720.

206. S.A. Magnus, *Physicians' Financial Incentives in Five Dimensions: A Conceptual Framework for HMO Managers*, 24 HEALTH CARE MGMT. REV. 57, 67 (1999).



of regulatory responses.

## VI. CONCLUSION

The new era of sunshine about financial conflicts has not been entirely radiant. Considerable implementation challenges concerning data selection and communication have hampered the Sunshine Act's rollout. These problems are likely inherent and unavoidable in transparency programs dealing with industry-medicine financial relationships. Financial conflicts are particularly unwieldy subject matter for many reasons, including the complex transactions involved, the necessary importance of contextual and comparative information, the seeming low concern and disregard about financial conflicts among patients, and the inevitable, enduring uncertainty as to the actual causal impact of financial conflicts on the health care system. Additionally, considerable doubts exist about the Sunshine Act's effect on primary audiences, such as patients and physicians. The Sunshine Act suffers from uncertainty and poor design as to intended audience and mandatory disclosure has possible counterproductive behavioral effects.

Nonetheless, because of the Sunshine Act, a great deal more has been learned about industry-medicine financial dealings. The new era of sunshine has generated valuable information about the nature and scope of financial ties between industry and medicine, such as variations by clinical specialty, type of payment, and physician gender, all of which have important implications for health law and policy and can inform future evidence-based regulation.

Unfortunately, even with this greater understanding, knowledge gaps about financial conflicts remain and are not answerable by the Sunshine Act. These significant unknowns have become even more salient and vexing as they complicate and undermine effective financial conflicts regulation. A critical need for more evidentiary support exists in several key areas, including the actual causal impact of financial conflicts, the comparative effectiveness of different regulatory approaches, the optimal way to disclose conflicts, what patients really think about financial relationships with industry, and the role of institutional conflict of interest committees in monitoring financial ties. Despite the new era of sunshine, much more work remains for developing sensible and effective financial conflicts regulation.