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ABSTRACT

Transparency has become one of the primary themes in health care reform efforts in the United States and across the world. In the face of exorbitant drug prices, high levels of patient cost-sharing, and pharmaceutical expenditures that consume a growing proportion of public sector budgets, much attention has been drawn to the pharmaceutical industry. Congressional investigations, academic publications, and news articles have endeavored to reveal the extent of drug and device industry influence on health care actors. In response, several nations, including the United States, have passed legislation mandating disclosure of drug company payments to physicians. In the United States, there are currently no legal requirements for disclosure of pharmaceutical industry sponsorship to patient-advocacy organizations by either party to the transaction. An ongoing concern is that drug industry payments could interfere with the objectivity of patient-advocacy groups and may induce them to take public positions favorable to the drug industry but at odds

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with the interests of patients. This article provides a comparative analysis of industry codes of practice and regulation that govern relationships between pharmaceutical companies and patient-advocacy organizations in the United States, the United Kingdom, Germany, France, Australia and Canada, with an emphasis on disclosure policies for industry sponsorship. The article draws upon the practices of other nations and the Physician Payments Sunshine Act to make a case for an expansion of the Sunshine Act to patient-advocacy groups.

Keywords: Sunshine Act; patient-advocacy organizations; disclosure; pharmaceutical industry; conflict of interest

I. INTRODUCTION

Research has identified concerns about the connection between funding and decision-making in medical research and practice. For example, a meta-analysis of studies demonstrated that industry-sponsored research trials were 3.6 times more likely to reach conclusions favorable to industry than those without industry sponsorship.[7] Another study found that physicians who received pharmaceutical industry gifts subsequently shifted their prescribing patterns: they tended to write more prescriptions and prescribed brand drugs more heavily.[8] Likewise, concerns have been raised about industry relationships with patient-advocacy organizations; these groups that have faced criticism for accepting funding from the drug industry and seemingly prioritizing industry interests above those of patients. [9, 10, 11]

While funding from industry plays an important role in ensuring financial viability for patient-advocacy organizations, it may compromise the independence of these organizations and create conflicts of interest. For instance, under pressure from a Congressional investigation led by

7. Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 454-465 (2003).

8. Susan F. Wood et al., *Influence of Pharmaceutical Marketing on Medicare Prescriptions in the District of Columbia,* 12(10) PLOS ONE, e0186060 (2017).

9. Emily Kopp & Rachel Bluth, *Nonprofit Linked to PhRMA Rolls out Campaign to Block Drug Imports*, KAISER HEALTH NEWS (April 19, 2017), https://khn.org/news/non-profit-linked-to-phrma-rolls-out-campaign-to-block-drug-imports/ (last visited June 3, 2018).

10. Ray Moynihan & Lisa Bero, *Toward a Healthier Patient-advocacy Voice: More Independence, Less Industry Funding*, 177 JAMA INTERN. MED. 350-51 (2017).

11. GARDINER HARRIS, *Drug Makers are Advocacy Groups' Biggest Donors*, N.Y. TIMES, Oct. 21, 2009, https://www.nytimes.com/2009/10/22/health/22nami.html (last visited June 4, 2018).

Senator Charles Grassley, the National Alliance on Mental Illness ("NAMI") revealed that it receives nearly two-thirds of its donations from pharmaceutical companies.[12] NAMI adopted a pro-industry stance toward FDA's black-box warning on antidepressants, which alerts patients and prescribers to the risk of suicide in children and adolescents, by arguing that the warning deters treatment and that the label omits the risk of suicide from untreated mental illness.[13] A Congressional investigation led by former Senator Claire McCaskill exposed donations by opioid manufacturers to patient-advocacy groups such as the American Pain Foundation; this group and others were accused of downplaying the risks of opioid drugs and promoting opioid usage.[14]

A spokesperson for the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the trade association for U.S. biopharmaceutical and biotechnology companies, has been quoted as saying that "patient groups and biopharmaceutical companies share the same goal of improving patient access to innovative therapies and ensuring the continued development of new treatments and cures."[15] However, the primary goal of any company is, and should be, to create value for its shareholders, while the primary goal of a patient-advocacy organization is to serve its patients. Although in many circumstances these goals are aligned, in other cases they may be in conflict. Policymakers and the public must be able to discern when conflicts exist.

There have been calls for increased scrutiny and transparency of pharmaceutical industry funding to patient-advocacy organizations in the U.S. [16, 17, 18]; yet, there is currently no publicly available record, nor any

12. *Grassley works for disclosure of drug company payments to medical groups*, CHUCK GRASSLEY: UNITED STATES SENATOR FOR IOWA (Dec. 8, 2009), https://www.grassley.senate.gov/news/news-releases/grassley-works-disclosure-drug-company-payme nts-medical-groups (last visited June 4, 2018).

13. *FDA Announcement on Black Box Warning Label for Antidepressants Used With Children*, THE NATIONAL ALLIANCE ON MENTAL ILLNESS (Oct. 15, 2004), https://www.nami.org/Press-Media/Press-Releases/2004/FDA-Announcement-on-Black-Box-Warning-Label-for-An (last visited June 3, 2018).

14. *BREAKING: Millions in Payments Among Findings of McCaskill Opioid Investigation into Ties Between Manufacturers and Third Party Advocacy Groups*, WEBSITE OF UNITED STATES SENATOR CLAIRE MCCASKILL (Feb. 12, 2018), https://www.mccaskill.senate.gov/media-center/news-releases/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups- (last visited June 3, 2018).

15. Jayne O'Donnell, *Patient-advocacy Groups Funded by Drug Companies are Largely Mum on High Drug Prices*, USA TODAY, Jan. 21, 2016, https://www.usatoday.com/story/news/nation/2016/01/21/patient-advocacy-groups-drug-makers-high-drug-prices/79001722 (last visited Apr. 28, 2018).

16. Matthew S. McCoy et al., *Conflicts of Interest for Patient-Advocacy Organizations*,

standardized disclosure required by either side of these financial exchanges. Instead, news sources and Congressional investigations attempt to fill the gap. In a recent report, Kaiser Health News ("KHN") identified over 1,200 patient-advocacy organizations in the U.S., of which nearly half received funding from pharmaceutical companies: KHN found that 14 pharmaceutical companies gave over $116 million dollars to 594 patient-advocacy groups in 2015.[19]

The Physician Payments Sunshine Act requires disclosure of payments and transfers of value from drug, device, biologic, and medical supply manufacturers to physicians and teaching hospitals in the U.S. As legal academic Marc Rodwin has written, "at the core of doctoring lies tension between self-interest and faithful service to patients and the public."[20] The same tension exists with not-for-profit organizations that represent patients in the collective, yet must also secure income adequate to sustain their efforts and ensure their continued existence. The Physician Payments Sunshine Act and disclosure of contributions to patient-advocacy organizations are based on the same principle: transparency would allow the public and policymakers to understand the potential for conflicts of interest and act so as to mitigate potential harm to patients and the public.

Though standardized disclosure of industry contributions to patient-advocacy organizations is absent in the U.S., this is not the case in many other countries. Drug industry trade associations in many nations have instituted codes of practice that establish guidelines for the interactions between pharmaceutical companies and patient-advocacy organizations, including disclosure policies, and several nations have enacted legislation to mandate disclosure. Both laws and codes of practice routinely place the reporting burden on drug and device companies. While laws require disclosure, codes of practice are voluntary; they rely on a company's willingness to comply, and enforcement of the terms of these codes for failure to comply is not guaranteed.

This article proceeds in six sections. Section I introduces the issue of disclosure of pharmaceutical industry funding to patient-advocacy groups.

376 NEW ENG. J. MED, 880-885 (2017).

17. Susannah L. Rose et al., *Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest*, 177 JAMA INTERN. MED. 344-350 (2017).

18. Norman R. Augustine et al., *Making Medicines Affordable: A National Imperative*, NAT'L ACADEMIES OF SCI. ENG'G & MED. 93-94 (2017).

19. Emily Kopp et al., *Patient Advocacy Groups Take in Millions from Drugmakers. Is There a Payback?*, KAISER HEALTH NEWS, https://khn.org/news/patient-advocacy-groups-take-in-millions-from-drugmakers-is-there-a-payback/ (last visited Dec. 21, 2018).

20. Marc A. Rodwin, *The Heart of the Matter*, *in* CONFLICTS OF INT. AND THE FUTURE OF MED.: THE U.S., FR, AND JAPAN, Oxford U. Press, 20-37 (2011).

Section II provides a cross-national comparison of the laws and industry codes of practice that govern disclosure of pharmaceutical industry payments to patient-advocacy organizations in the United States, the United Kingdom, Germany, France, Australia, and Canada. Section III compares government-mandated disclosure to voluntary self-regulation by the drug industry and reaches the conclusion that a combination of both mechanisms may be most fitting to address industry sponsorship of patient-advocacy organizations. Section IV draws lessons from the Physician Payments Sunshine Act to make recommendations for disclosure policy relating to payments and transfers of value to patient-advocacy organizations in the U.S. Section V extends the discussion to professional medical associations, and the final section offers concluding remarks.

II. A CROSS-NATIONAL COMPARISON OF DISCLOSURE CODES AND REGULATION

We conducted a qualitative comparison of the pharmaceutical trade association codes of practice and government regulations guiding industry relationships with patient-advocacy groups in the United States, the United Kingdom, Germany, France, Australia, and Canada. The nations were purposively chosen to be illustrative of the advancements of pertinent national industry codes and regulations. The European supranational code put forth by the European Federation of Pharmaceutical Industries and Associations ("EFPIA") was also examined for provisions applicable to relationships with patient-advocacy organizations. Based on the content of the codes, we established a 17-point checklist of common principles relating to financial and non-financial disclosure and other governing principles of interactions with patient-advocacy organizations, and subsequently scored each code according to the presence or absence of these principles (Table 1). The discussion that follows provides greater detail on the substance of each code, as well as relevant national law and regulation relating to disclosure of industry support to patient-advocacy organizations. This article does not consider industry sponsorship of patient assistance programs, which provide financial assistance to qualifying patients for the purchase of pharmaceutical drugs.

A. United States

There is currently no federal legislation mandating disclosure of drug

company funding to patient-advocacy organizations, other than regulations related to filing a citizen petition at the FDA[21] (that regulation only requires disclosure of a party who directly funds the particular petition filed). The Physician Payments Sunshine Act, passed in 2010 as part of the Patient Protection and Affordable Care Act, requires disclosure of payments and transfers of value from drug, device, biologic, and medical supply manufacturers to physicians and teaching hospitals ("Covered Recipients"), but not to patient-advocacy organizations. Beginning in 2014, manufacturers that have at least one product reimbursed by Medicare or Medicaid must disclose these payments on a public website — the Open Payments database.[22]

Senators Herb Kohl and Chuck Grassley first introduced the Physician Payments Sunshine Act in 2007[23] after Senate investigations revealed that researchers at major universities failed to disclose millions of dollars of pharmaceutical industry payments, sometimes while holding investments in the companies they were funded to study.[24] Physicians were frequent recipients of sponsorship from the drug and device industry, which took various forms including monetary payments for consultation services, paid speaking arrangements, grants, gifts, free meals, paid travel expenses and other perks.[25, 26] A study published in the *New England Journal of Medicine* in 2007 found that 94 percent of physicians accepted some form of financial or non-financial "benefits" from industry.[27]

The Physician Payments Sunshine Act sought to cast a public light on payments and inducements to physicians, which could compromise their

21. Robin Feldman & Rabiah Oral, Comments, *FDA Public Meeting on Hatch Waxman Amendments: Ensuring a Balance Between Innovation and Access* (Sept. 18, 2017).

22. Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 27 (to be codified at 42 C.F.R. pts. 402, 403).

23. Physician Payments Sunshine Act of 2007, S. 2029, 110th Cong. (2007).

24. *Let the Sunshine in: Implementing the Physician Payments Sunshine Act: Roundtable before the S. Special Committee on Aging*, 112th Congress, Second Session (2012).

25. *Grassley works to disclose financial ties between drug companies and doctors*, CHUCK GRASSLEY, UNITED STATES SENATOR FOR IOWA (Jan. 22, 2009), https://www.grassley.senate.gov/news/news-releases/grassley-works-disclose-financial-ties-between-drug-companies-and-doctors (last visited Mar. 16, 2018).

26. *Paid to Prescribe?: Exploring the Relationship between Doctors and the Drug Industry: Hearing before the S. Special Comm. on Aging*, 110th Cong. (2007), https://www.aging.senate.gov/hearings/paid-to-prescribe-exploring-the-relationship-betwe en-doctors-and-the-drug-industry (last visited Mar. 16, 2018).

27. Eric G. Campbell et al., *A National Survey of Physician-industry Relationships*, 356 NEW ENG. J. MED. 1742-50 (2007).

independence and could influence prescribing practices in favor of more expensive brand drugs. The Act mandates disclosure of the amount and form of the payment or transfer of value, the date it is provided, the name and address of the recipient, and a description of the nature of the payment.[28] The Act also contains a requirement for disclosure of ownership or investment interests held by physicians or their immediate family members in a covered manufacturer or group purchasing organization ("GPO").

Corporate integrity agreements ("CIAs") between pharmaceutical companies and the U.S. Office of Inspector General often mandate a level of reporting that exceeds that required by the Physician Payments Sunshine Act. For example, a CIA may obligate a pharmaceutical company to disclose the monetary value and recipients of philanthropic grants, fundraising contributions, or other sponsorship provided to non-profit organizations, including patient-advocacy groups and professional societies.[29] The reporting obligations under CIAs may explain disclosure of funding to patient-advocacy groups by some U.S. pharmaceutical companies, rather than voluntary rigor in transparency practices. The durability of disclosure reporting prompted by a CIA is questionable, as the agreement typically lasts for five years, after which a company may choose to discontinue disclosure practices not required by law.

Recently, proposed legislation has sought to place payments to patient groups within the scope of required reporting under the Physician Payments Sunshine Act. Following an investigation led by Senator McCaskill's office which revealed that opioid manufacturers, including Purdue Pharma, gave over eight million dollars from 2012 to 2017 to fourteen "outside working groups" on opioid-related issues,[30] Senator McCaskill introduced the "Patient Advocacy Transparency Act" (S.3000, 115th Cong.) in June of 2018. This bill would amend the Physician Payments Sunshine Act to require reporting of certain forms of industry

28. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119, 689 (2010) (codified as amended at 42 U.S.C. § 1320(a)).

29. Corporate Integrity Agreement between the Off. of Inspector Gen. of the Dep't of Health and Human Services & Novartis Pharmaceuticals Corporation, Off. of Inspector Gen., Corporate Integrity Agreement Documents (effective Sept. 29, 2010, updated Mar. 15, 2018), https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp#n (last visited July 5, 2018).

30. *Fueling an Epidemic, Report Two, Exposing the Financial Ties between Opioid Manufacturers and Third Party Advocacy Groups, U.S. Senate Comm. on Homeland Security & Governmental Affairs* (Ranking member's office), https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mcc askill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-gr oups- (last visited Dec. 22, 2018).

sponsorship to patient groups, professional societies, and providers of continuing medical education. No further Congressional action has been taken on S.3000, and it remains to be seen whether it will face headwinds from industry or funding recipients.

In response to the Physician Payments Sunshine Act, some warned of a dampening effect on innovation resulting from fewer physician-industry relationships[31] [32] - it was argued that physicians who received payments would be unfairly stigmatized and would avoid engaging with drug and device companies. Since the benefits resulting from physician-industry collaboration would not be concomitantly measured and presented, the Open Payments database could present a picture of industry influence that is unfairly skewed. From this response, we anticipate that the reaction to mandatory reporting of payments to patient-advocacy groups may highlight the many benefits and synergies resulting from their partnerships with industry. Disclosure of funding, however, need not lead to a decrease in funding, and transparency will encourage greater emphasis on ethical boundaries.

In the U.S., PhRMA has established a code entitled "Principles on Interactions with Patient Organizations." It states that pharmaceutical companies must respect the independence of patient-advocacy organizations and may provide financial support for activities that are primarily "professional, educational, or scientific in nature."[33] There is no requirement or recommendation for public disclosure of industry funding to these organizations.[34] As will be shown below, this stands in contrast to the codes of practice that pharmaceutical trade associations of many other developed nations have established.

With respect to disclosure by patient-advocacy organizations themselves, no mandatory reporting of company-level funding exists in the United States. While dual disclosure may seem redundant, it can

31. Thomas Sullivan, *Physician Payment Sunshine Act: Radiologists Concerned with Potential Mischaracterizations of Relationships with Industry*. POL'Y & MED. (May 6, 2018), https://www.policymed.com/2013/10/physician-payment-sunshine-act-radiologists-concerned-with-potential-mischaracterizations-of-relationships-with-industry.html (last visited Dec. 26, 2018).

32. Thomas Sullivan, *Physician Payment Sunshine: Media Missing the Mark – This Could be Sunset for Innovation*, POL'Y & MED. (May 6, 2018), https://www.policymed.com/ 2012/01/physician-payment-sunshine-media-missing-the-mark-this-could-be-sunset-for-innovation.html (last visited Dec. 26, 2018).

33. PhRMA Principles on Interactions with Patient Organizations, PHRMA WEBSITE, http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_principles_paper_20120919_ final.pdf (last visited July 3, 2018).

34. *Id*.

accomplish different purposes and have different effects. It is the view of the authors that both forms of disclosure are necessary to properly address the conflict of interest inherent in the exchange between the two parties. The National Health Council ("NHC"), an umbrella organization for U.S. "health-related organizations," has over fifty member patient-advocacy organizations (also referred to as voluntary health agencies).[35] The NHC recently implemented a Standards of Excellence Certification Program consisting of thirty-eight standards that deal with "governance, human resources, programs, fundraising, finance, accounting and reporting, and evaluation." Standard 31, which pertains to corporate relationships, requires:

> disclosure of the name of the individual corporation identified on Schedule B of its Form 990 (more than the greater of $5,000 or 2% of the total amount of contributions reported on line 1H of Part VIII of Form 990) and the aggregate amount of support provided by each corporation *OR* the total amount of corporate support from pharmaceutical, biotechnology, and medical device companies as a percentage of total *organizational revenue* [emphasis added].[36]

This standard permits a patient-advocacy organization to circumvent disclosure of company-specific support, and indeed many US patient-advocacy organizations do not disclose the specific amounts provided to them from particular pharmaceutical companies; rather, they provide an aggregate value for total corporate sponsorship. While individual patient-advocacy organizations can choose to address the issue of disclosure of corporate sponsorship through internal policies, such policies are not common; in a survey based on a random sample of patient-advocacy organizations, only one-quarter (73 of 284 patient-advocacy organizations surveyed) reported having disclosure policies for public reporting of industry financial relationships.[37] A study of disclosure information featured on national and international patient-advocacy organization websites found that only a fraction (7 of 37) of the patient-advocacy organizations with annual reports included corporate donations, and of those, none provided the level of detail necessary to ascertain

35. NAT'L HEALTH COUNCIL: MEMBERSHIP DIRECTORY, http://www.nationalhealthcouncil.org/about-nhc/membership-directory (last visited July 3, 2018).

36. NAT'L HEALTH COUNCIL: *Standards of Excellence Certification Program for Voluntary Health Agencies* (January 2017), http://www.nationalhealthcouncil.org/sites/default/files/NHC_Files/Governance/Full_Standards_of_Excellence.pdf (last visited July 3, 2018).

37. *See supra* note 17.

pharmaceutical company-level funding.[38] Website disclosures were not always consistent with annual reports, and none of the websites examined in the study indicated the proportion of a patient-advocacy group's total income obtained from pharmaceutical companies.[39]

B. Europe

The European Federation of Pharmaceutical Industries and Associations ("EFPIA"), which consists of national pharmaceutical industry trade associations from thirty-three European countries[40] and forty member pharmaceutical companies (both full members and member affiliates),[41] has put forth codes that govern relationships with health care entities. The Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations, hereafter referred to as the EFPIA Patient Organization Code, contains provisions that apply specifically to interactions with patient-advocacy groups,[42] including a prohibition on the requirement of single-company funding of a patient-advocacy organization (Article 7) and the requirement of a written agreement for financial support and significant non-financial support to patient-advocacy organizations (Article 2). It also requires annual disclosure of a list of all patient-advocacy organizations to which a company provides support, the monetary value of the support and invoiced costs, and an account of the nature of the support "that is sufficiently complete to enable the average reader to form an understanding of the significance of the support" (Article 5).[43]

The EFPIA Patient Organization Code requires written approval for a pharmaceutical company's use of a patient-advocacy organization's logo or proprietary material (Article 3) and prohibits companies from shaping a

38. Douglas E. Ball, Klara Tisocki, & Andrew Herxheimer, *Advertising and Disclosure of Funding on Patient-advocacy Organisation Websites: A Cross-sectional Survey*, 6 BMC PUB. HEALTH 201 (2006).

39. *Id*.

40. *EFPIA Disclosure Code: Frequently asked questions*, WEBSITE OF EFPIA (Eur.), http://www.esmo.org/Policy/EFPIA-Disclosure-Code/Frequently-Asked-Questions#eztoc9 58298_0_1_6 (last visited May 14, 2018).

41. *EFPIA Corporate Members*, WEBSITE OF EFPIA (Eur.), https://www.efpia.eu/about-us/membership (last visited May 14, 2018).

42. *EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations*, WEBSITE OF EFPIA (Eur.), https://www.efpia.eu/media/24310/3c_efpia-code-of-practice-on-relationships-pharmapluspt-orgs.pdf (last visited Apr. 9, 2018).

43. *Id.*

patient-advocacy organization's written materials to further their commercial interests (Article 4).

The EFPIA Patient Organization Code, along with the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (hereafter referred to as the "EFPIA Disclosure Code"),[44] establish minimum standards for disclosure. However, they do not exempt companies from abiding by more rigorous national laws or codes. National EFPIA member associations, not EFPIA itself, retain the responsibility to impose sanctions on member companies that violate relevant code or law.[45] The EFPIA Patient Organization Code requires that member trade associations establish a complaint procedure and a national body to manage complaints.[46]

1. United Kingdom

The Association of the British Pharmaceutical Industry ("ABPI") issued the most recent version of its Code of Practice for the Pharmaceutical Industry in 2016. The ABPI Code of Practice is a comprehensive set of guidelines and standards outlining appropriate relationships between pharmaceutical companies and other groups, including patient-advocacy organizations. Clause 27.7 of the ABPI Code echoes the EFPIA Patient Organization Code: all member companies must disclose annually to the public a listing of patient-advocacy organizations to which they provide "financial support and/or significant indirect/non-financial support," along with a "description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support," and disclosure of the monetary or non-monetary value of the support.[47] The Code allows for optional reporting of the patient-advocacy organization's total income and the percentage of total income attributable to pharmaceutical company donation. Companies must report a listing of patient-advocacy

44. *EFPIA HCP/HCO Disclosure Code*, WEBSITE OF EFPIA (Eur.), https://www.efpia.eu/media/25837/efpia-disclosure-code.pdf (last visited May 14, 2018).

45. *See supra* note 40.

46. *EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient-advocacy Organizations, Annex II: Implementation and Procedure Rules*, WEBSITE OF EFPIA, (Eur.), https://www.efpia.eu/media/24310/3c_efpia-code-of-practice-on-relation ships-pharmaluspt-orgs.pdf (last visited May 14, 2018).

47. ABPI Code of Practice for the Pharmaceutical Industry (2016) (U.K.), http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf (last visited Apr. 4, 2018).

organizations that they have engaged for contracted services, such as speaking arrangements, consulting services, or involvement in advisory board meetings (Clause 27.8), including the total amount paid to each patient-advocacy organization over the reporting period.[48]

The ABPI Code of Practice also requires that pharmaceutical companies establish written agreements with patient-advocacy organizations, including provisions governing engagements for consulting or other services, but does not require that such agreements be made public. Other provisions prohibit a company from requiring that it serve as the singular source of financial support for a patient-advocacy organization (Clause 27.4); require written agreements for public use of a patient-advocacy organization's logo or other proprietary materials (Clause 27.5); and prohibit the utilization of a patient-advocacy organization's materials to advance a pharmaceutical company's commercial interests (Clause 27.6).[49] ABPI currently has over 60 full members,[50] which supply ninety percent of the pharmaceuticals consumed by the National Health Service.[51] The organization maintains a centralized database, Disclosure UK,[52] accessible from its website, which provides a listing of charitable donations searchable by health care organization and pharmaceutical company.

The ABPI Code of Practice does not impose monetary fines or penalties for non-disclosure. Rather, companies must demonstrate that they are taking steps to correct a breach and comply with the code. "Serious cases" may result in sanctions, including but not limited to an audit of company procedures, submission of a corrective statement, public reprimand, and suspension or exclusion from membership in ABPI.[53]

2. Germany

The German regulatory body for pharmaceutical companies, FSA ("Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.," or "Voluntary Self-regulation for the Pharmaceutical Industry") has fifty-five

48. *Id.*

49. *Id*.

50. *ABPI Members List*, WEBSITE OF ABPI (U.K.), https://www.abpi.org.uk/membership/abpi-members-list/ (last visited Apr. 4, 2018).

51. *See supra* note 47.

52. *Disclosure UK*, ABPI WEBSITE (U.K.), https://abp-euags.emea.crm.cegedim.com/AggregateSpend360/Posting/ExpenseReport.aspx?postedreporttype=pCctRQJCLQc%3D&reportID=fzQi4WVhSqKCaerpJbCgxg%3D%3D&Language=NyRIIBaAuMY9s3bTmUSGXQW6yEjsGDHz&DataValue=qWE1R12&LCID=2057 (last visited Apr. 4, 2018).

53. *See supra* note 47.

member companies[54] that control roughly seventy-five percent of the pharmaceutical market in Germany.[55] FSA promulgates a "Code of Conduct on the Collaboration with Patient Organizations" and a "Transparency Code" that detail requirements for disclosure of pharmaceutical company sponsorship to health care entities, including physicians, patient-advocacy organizations, and medical institutions. The FSA Board of Arbitration may impose monetary fines for code violations.[56]

The FSA Code of Conduct on the Collaboration with Patient Organizations contains many principles in common with other codes, including the need to respect the "neutrality and independence" of patient-advocacy organizations (Section 6) and a ban on member companies from serving as the exclusive supporter of a patient-advocacy organization or any of its activities (Section 16).[57] The involvement of pharmaceutical companies in patient-advocacy organization-sponsored events must be carried out in a "balanced and objective" manner that allows for competing or alternative information to be presented (Section 6). Written agreements are required for collaboration between member companies and patient-advocacy organizations (Section 11) and for contracted services, which are restricted to health care-related services only (Section 12). The promotion or recommendation of specific prescription-only pharmaceuticals is prohibited (Section 9).

The FSA Code contains several notable provisions absent from other codes; one is the prohibition on member companies from establishing patient-advocacy organizations (Section 7), and a prohibition on employees or representatives of member companies from acting "in any capacity" for patient-advocacy organizations and specifically, exclusion of company representatives and employees from serving on executive bodies of patient-advocacy organizations, other than scientific advisory boards (Section 7). Another provision unique to the code is the prohibition of websites operated jointly by patient-advocacy organizations and pharmaceutical companies, and a ban on links to member company websites from the

54. *FSA Members: At a Glance*, WEBSITE OF FSA (2016) (Ger.), https://www.fsa-pharma.de/der-fsa/auf-einen-blick/ (last visited May 6, 2018).

55. *Transparency Code: The Second Year*, WEBSITE OF FSA (June 21, 2017) (Ger.), https://www.pharma-transparenz.de/service/aktuelles/mitteilung/?tx_ttnews%5Btt_news%5D=157&cHash=212e1799fad23b65080cdeeb14d64756 (last visited May 6, 2018).

56. *Ten Facts about the Transparency Code*, WEBSITE OF FSA (Ger.), https://www.pharma-transparenz.de/fachkreisangehoerige/zehn-fakten-zum-transparenzkodex/ (last visited May 6, 2018)

57. *FSA Code of Conduct on the Collaboration with Patient-Advocacy Organizations*, WEBSITE OF FSA (Ger.), https://www.fsa-pharma.de/fileadmin/Downloads/Pdf_s/Kodizes__Empfehlungen/Code_of_Conduct_PORG.pdf. (last visited May 21, 2018).

websites of patient-advocacy organizations (Section 9).

With respect to public disclosures, the FSA Code requires annual reporting to the public of all patient-advocacy organizations that a member company supports through financial or "significant indirect or non-financial benefits," including a requirement to report the "total amount of monetary benefits and donations in kind per calendar year and patient-advocacy organization," or a description of benefits if non-monetary (Section 15). FSA maintains a public database of such sponsorship, searchable by pharmaceutical company and by patient organization.[58]

The umbrella organization for patient-advocacy groups in Germany, BAG SELBSTHILFE, promotes disclosure by patient-advocacy organizations. In 2016, it established an online listing of member groups that have dedicated a portion of their homepage to transparency of the group's sponsorship (the "Transparency List").[59]

3. France

In 2009, the diabetes drug and off-label weight loss agent Benfluorex (trade name "Mediator") was removed from the market in France after resulting in the death of an estimated 2,000 persons due to cardiac complications.[60, 61] The drug's maker, Servier, was alleged to have concealed Mediator's safety risks from the French health regulator while promoting the drug's off-label use for weight-loss.[62] Servier was also alleged to have made payments to individuals with ties to the French authorities, including a former French health minister, in order to keep Mediator on the market well after other nations had removed it. In May of 2013, France signed into law the historic "Loi Bertrand" (also referred to as

58. *Benefits of Member Companies to Patient Organizations for the Year 2017*, WEBSITE OF FSA (Ger.), https://www.fsa-pharma.de/bezugsgruppen/patientenorganisation/zuwendungen-intern/ (last visited July 5, 2018).

59. *Grants from Business Enterprises (Transparency List)*, BAG SELBSTHILFE (Ger.), https://www.bag-selbsthilfe.de/informationsportal-selbsthilfe-aktive/unabhaengigkeit-der-selbsthilfe/zuwendungen-von-wirtschaftsunternehmen-transparenzliste/ (last visited Dec. 21, 2018).

60. *France's Servier to Face Trial over Mediator Weight-loss Drug*, REUTERS (Sept. 5, 2017), https://www.reuters.com/article/us-france-drugs-mediator/frances-servier-to-face-trial-over-mediator-weight-loss-drug-idUSKCN1BG2G2 (last visited Dec. 22, 2018).

61. Scott Sayare, *Scandal over Mediator, a French Weight-loss Drug, Prompts Call for Wide Changes*, N.Y. TIMES, Dec. 11, 2011, https://www.nytimes.com/2011/12/12/health/scandal-widens-over-french-weight-loss-drug-mediator.html (last visited Dec. 22, 2018).

62. Owen Dyer, *France to prosecute its drug regulator and Servier in scandal over diabetes drug*, j4231 BMJ 358 (2017).

the French Sunshine Act) in the spirit of the Physician Payments Sunshine Act and as a response to the Mediator scandal.

A wider range of companies are responsible for disclosure under the French Sunshine Act than under U.S. law, including not only manufacturers of drugs, devices, biologics, and medical supplies, but also makers of cosmetics, contact lenses, health software, and biomaterials. The French Sunshine Act requires disclosure of benefits to a much more expansive set of stakeholders, including medical students and trainees, nurses, midwives, pharmacists, and dieticians, as well as professional medical societies, "associations of users of the health system" (including patient-advocacy organizations), media publishing companies, and prescription and dispensing software companies.[63, 64, 65]

France maintains an online database (La base de données publique transparence – Santé), updated biannually and searchable by company, that contains information on direct and indirect benefits, the date the exchange was made, and the monetary value (with a minimum threshold for disclosure of ten euros).[66] A 2016 decree expanded the scope to include the monetary value of contracted services.[67] Knowing failure to comply may result in fines, and disclosure must conform with French data privacy laws.

Les Entreprises du Médicament ("LEEM"), the French pharmaceutical trade association and an EFPIA member, issued a code, Dispositions Déontologiques Professionnelles,[68] that includes a section concerning relationships with patient-advocacy organizations. The code contains many of the same provisions as the EFPIA Patient Organization Code.

LEEM has over 260 member companies.[69] CODEEM (le Comité de déontovigilance) enforces the LEEM Code through its Litigation and

63. Quinn Grundy et al., *Decoding disclosure: Comparing conflict of interest policy among the United States, France, and Australia*, 122 HEALTH POL'Y 509-518 (2018).

64. Cristiana Spontoni, Françoise Labrousse & Armelle Sandrin-Deforge, *French Sunshine Obligations Clarified and Extended*, Jones Day, LEXOLOGY, Jan. 25, 2017, https://www.lexology.com/library/detail.aspx?g=54ec76ab-51f6-4a66-b4cd-a86fa765c418 (last visited May 22, 2018).

65. Loi N° 2011-2012 Du 29 Décembre 2011 Relative Au Renforcement De La Sécurité Sanitaire Du Médicament Et Des Produits De Santé. 2011, Légifrance: Paris, France.

66. *Base Transparence Santé*, https://www.transparence.sante.gouv.fr/flow/main?execution=e1s1 (last visited May 22, 2018).

67. *See supra* note 63.

68. *Dispositions Deontologiques Professionnelles*, LES ENTREPRISES DU MÉDICAMENT (Jan. 12, 2016) (Fr.), https://www.leem.org/sites/default/files/DDP%20ApplicablesAu-12%20janv%202016_0.pdf (last visited May 22, 2018).

69. *Who is LEEM?* LES ENTREPRISES DU MÉDICAMENT (Fr.), https://www.leem.org/sites/default/files/Who%20is%20LeemtradLeem.org__0.pdf (last visited May 22, 2018).

Sanctions Commission,[70] which may institute sanctions on member companies for noncompliance, including a warning with or without a request for corrective measure, publicized warnings if corrective measures are not implemented, and suspension or cancellation of membership in LEEM "in case of serious breach or repeated failure."[71] The LEEM code also contains a complaint procedure.

C. Australia

Medicines Australia, the trade association that represents pharmaceutical companies in Australia, promulgates a Code of Conduct that contains guidelines for interactions with patient-advocacy organizations, as well as transparency reporting requirements relating to patient-advocacy organization funding from industry. [72] The Medicines Australia Code of Conduct very closely resembles the language of the EFPIA Patient Organization Code, though Medicines Australia is not within the jurisdiction of EFPIA.

Every member pharmaceutical company must provide a list of patient-advocacy organizations to which it provides "financial support and/or significant direct / indirect non-financial support." [73] The major difference as compared to the EFPIA reporting practice is the use of a standardized tabular format for reporting.[74] Rather than allowing each company to report on its own website, Medicines Australia maintains a centralized listing[75] of the reports of all member pharmaceutical companies, which is updated annually.

The Medicines Australia Code contains the stipulation common to many other codes that "no company may request that it be the sole funder of a health consumer organization or any of its major programs."[76] The

70. *CODEEM*, LES ENTREPRISES DU MÉDICAMENT (Fr.), https://www.leem.org/codeem-le-comite-de-deontovigilance (last visited May 22, 2018).

71. *Dispositions Deontologiques Professionnelles*, LES ENTREPRISES DU MÉDICAMENT, (January 12, 2016) (Fr), https://www.leem.org/sites/default/files/DDP%20ApplicablesAu-12%20janv%202016_0.pdf (last visited May 22, 2018).

72. *Med.'s Austl. Code of Conduct Edition 18*, WEBSITE OF MED.'S AUSTL. (2014), https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/ (last visited May 22, 2018).

73. *Id.*

74. *Id.*

75. *Member Company Reports*, WEBSITE OF MED'S. AUSTL., https://medicinesaustralia.com.au/code-of-conduct/transparency-reporting/health-consumer-organisation-support-reports/member-company-reports/ (last visited July 5, 2018).

76. *See supra* note 72.

code proceeds to clarify that "this would not preclude a company who is the only supplier of a prescription product for a specific condition or disease from sponsoring a health consumer organization or any of its programs (14.1)."[77]

Medicines Australia currently has over forty member companies in various categories of membership.[78] The Code of Conduct Committee may impose sanctions for breaches of the code, which may include an order to terminate improper conduct, issuance of a corrective action, and imposition of a monetary fine according to a detailed schedule.[79]

D. Canada

Innovative Medicines Canada (formerly Canada's Research-based Pharmaceutical Companies), a pharmaceutical trade association with over 45 member companies,[80] first issued "Guidelines for Transparency in Stakeholder Funding" in 2009 as an annex to its Code of Ethical Practices. "Guidelines for Transparency in Stakeholder Funding" enumerates seven principles and eight guidelines to manage relationships with various stakeholders, including patient-advocacy organizations.[81] Contained within the principles are statements promoting the independence and integrity of stakeholders and the need for "transparent funding relationships."[82] The guidelines articulated in the document prohibit the use of stakeholder relationships to promote prescription medicines; require a written agreement with details of direct funding to stakeholders; and require member companies to report "a list of all stakeholders to which they provide direct funding" at regular intervals on their websites or annual reports.[83] However, there is no requirement or recommendation that member companies disclose the *value* of financial payments or non-financial transfers to individual stakeholders such as patient-advocacy

77. *Id*.

78. *Our Members*, MED'S AUSTL WEBSITE, https://medicinesaustralia.com.au/about-us/our-members/ (last visited May 22, 2018).

79. *See supra* note 72.

80. *Member Companies*, INNOVATIVE MED'S CAN., http://innovativemedicines.ca/about/member-companies/ (last visited July 5, 2018).

81. *Our History*, INNOVATIVE MED'S CAN., http://innovativemedicines.ca/about/our-history/ (last visited July 5, 2018).

82. *Guidelines for Transparency in Stakeholder Funding, Annex A to the Code of Ethical Practices* (2018) INNOVATIVE MED'S CAN., http://innovativemedicines.ca/wp-content/uploads/2018/06/Code-Formatted_Regular_EN-2.pdf (last visited July 5, 2018).

83. *Id*.

organizations. Innovative Medicines Canada maintains a complaint process and imposes monetary penalties, as well as public reporting on its website, in cases of violations of the Code of Ethical Practices.[84]

In June 2017, ten member companies of Innovative Medicines Canada agreed to voluntarily disclose an *aggregate* value for three categories of payments: (1) payments for the services of Canadian health care professionals; (2) payments made to health care organizations; and (3) payments to Canadian health care professionals to cover the cost of travel to meetings.[85] These aggregate disclosures do not include details of organization-specific or provider-specific funding.

In December 2017, Ontario passed the Health Sector Payment Transparency Act that mandates annual reporting of transfers of value to health care professionals and a wide array of parties within the health care sector, including patient-advocacy organizations, foundations, and charitable groups.[86, 87, 88] The parties responsible for reporting ("payors") include not only drug and device manufacturers, but also wholesalers, distributors, marketing firms, and organizers of continuing medical education.[89] According to the draft regulations, payors are obligated to report value transfers made to a lengthy list of recipients, including common recipients (hospitals and health care providers), as well as many other allied health employees and organizations (advocacy groups, long-term care providers, colleges and universities, researchers, students, immediate family members of these recipients, and any person who is employed as a "board member, director, trustee, officer, appointee, employee, or agent of the above," among others).[90]

84. *Id*.

85. *Voluntary Disclosure of Payments*, INNOVATIVE MED'S CAN., http://innovativemedicines.ca/ethics/voluntary-disclosure-of-payments/ (last visited July 5, 2018).

86. Thomas Sullivan, *Ontario Open Payments: Proposed Rule for the Health Sector Payment Transparency Act*, POL'Y MED. (Updated May 4, 2018), http://www.policymed.com/2018/03/ontario-open-payments-proposed-rule-for-the-health-sector-payment-transparency-act.html (last visited July 5, 2018).

87. Health Sector Payment Transparency Act, S.O. 2017, c. 25, Sched. 4, s. 2 (Can.). https://www.ontario.ca/laws/statute/17h25?_ga=2.265956687.1189033580.1524957522-1335467172.1524957522#BK1 (last visited July 5, 2018).

88. Ministry of Health and Long-Term Care, Proposed new regulation made under the Health Sector Payment Transparency Act, 2017, (Can.), http://www.ontariocanada.com/registry/showAttachment.do?postingId=26846&attachmentId=37128 (last visited April 28, 2018).

89. Health Sector Payment Transparency Act, 2017, S.O. 2017, c. 25, Sched. 4, s. 3 (Can.).

90. Health Sector Payment Transparency Act, 2017, Consultation Draft (Can.), http://www.ontariocanada.com/registry/showAttachment.do?postingId=26846&attachmentI

Under the Ontario law, companies are required to report the dollar value of the transfer, the nature of the transfer (cash or cash-equivalent, in-kind item or service, etc.) and the category to which a transfer belongs (charitable donation, research, travel and accommodation, operational support, etc.). Reporting will take place electronically, with public disclosure on a website operated by the Minister of Health and Long-Term Care. The Health Sector Payment Transparency Act allows for the imposition of fines on individuals and on corporations for failure to comply.[91] The legislation places no reporting obligations on recipients of pharmaceutical industry funding.

E. How do These Countries Score on the 17-point Checklist of Common Principles and Governance Rating Scale?

As presented in Table 1, the U.S. scores the lowest (3 points), Canada scores 9 points, and all other countries score greater than 10 points on the 17-point checklist of common principles. Compared to the other countries examined here, the U.S. received the lowest score due to the absence from the PhRMA "Principles on Interactions with Patient Organizations" of most principles contained in other codes. Of the seventeen common principles identified, the PhRMA code contains only three: a statement regarding the independence of patient-advocacy organizations, a statement that no company should require that it be a patient-advocacy organization's sole funder, and a requirement for written documentation of support.

A commonality among the industry codes with the exception of PhRMA's "Principles on Interactions with Patient Organizations" is the prohibition on advertising prescription pharmaceutical drugs to the public. Direct-to-consumer advertising, legally permissible in the U.S., is a key factor that distinguishes the U.S. from the other nations considered in our analysis. Direct-to-consumer advertising may contribute to industry reluctance to reveal payments to patient organizations in the U.S., since payments may help support direct-to-consumer marketing tactics that walk a fine line between promotional and non-promotional messaging to patients. The potential influence of patient-advocacy organizations' industry funding on direct-to-consumer advertising to patient-members is beyond the scope of our analysis here but represents an important area for further research.

d=37129 (last visited July 5, 2018).

91. Health Sector Payment Transparency Act, 2017, S.O. 2017, c. 25, Sched. 4, s. 17 (Can.).

Each country's code of conduct and relevant law were examined for the presence of three governance principles: (1) whether code or law requires public disclosure of industry funding to patient-advocacy organizations; (2) whether code or law requires disclosure on a centralized website; and (3) whether code or law imposes monetary penalties for non-disclosure. (Only monetary penalties were considered here since they represent a more stringent repercussion for non-compliance than non-monetary penalties.) Table 2 presents the findings. A country receives a 0, 1, 2, or 3 depending on the number of governance principles present. Australia, Germany, France, and Canada (taking into account the recently passed Health Sector Payment Transparency Act in Ontario) all achieved a 3 out of 3 rating, signifying intensive disclosure governance. Of note, France and Canada have legislative requirements for disclosure. The United Kingdom achieved a 2 out of 3 rating, in light of the fact that financial penalties are not imposed for non-disclosure. The United States earned a 0 out of 3 rating, given that no mandatory disclosure is in place, there is no centralized disclosure venue, and there are no monetary penalties for non-compliance established in code or law. Taking the results from Tables 1 and 2 together, the U.S. lacks rigorous principles guiding pharmaceutical company interactions with patient-advocacy organizations, including disclosure policies for drug industry funding to these organizations, a feature that stands in contrast to the other industrialized nations considered here.

III. MANDATORY REGULATION VS. VOLUNTARY INDUSTRY SELF-REGULATION

The chief obstacle to the effectiveness of a voluntary code of conduct, and thus the main justification for a legislative solution, is compliance. For example, a company could claim to conform with a trade association code of practice while not actually revealing every payment made to a patient-advocacy organization. A trade association that promulgates a code may not actually impose the sanctions set out in the code for failure to comply. Even if sanctions are imposed, they may not be severe enough to deter unethical behavior, or companies that desire to conceal payments may simply accept a sanction as a cost of doing business.

Voluntary codes, as opposed to law, are typically not administered by an independent agency that can ensure accountability and verify the accuracy of reported data through independent audits. Self-government creates disincentives to expose noncompliance or wrongdoing of members. The disinclination of governing bodies to enforce their own ethical codes

has been referred to as "the conflict within conflict of interest laws."[92] The unwillingness of a trade association to expose its own members' violations could render the codes impotent. Independent audits of pharmaceutical company disclosures conducted at regular intervals may serve as a check on misleading or incomplete reporting.

There is a risk that companies will employ voluntary reporting for public relations purposes,[93, 94] limiting the usefulness of the reports as a mechanism for accountability. The implementation of a standardized national disclosure regime according to law or regulation would reduce the ability of corporations to fashion their disclosures for a public relations advantage.

Other sectors have wrestled with the issue of mandatory regulation versus voluntary corporate self-regulation, especially vis-à-vis policies pertaining to safety and the natural environment. A study of U.S. chemical companies that adopted a voluntary environmental, health, and safety code — the Responsible Care program — noted that the code established "metastandards" that outlined broad goals while placing the process or mechanism to achieve those goals at the discretion of each company. This strategy allowed for flexibility but also led to heterogeneity in implementation practices, which was more prominent for internal practices than for external, public-facing practices.[95] In keeping with this example, public-facing disclosure practices may be more likely to converge on uniform standards, which largely corresponds to what has occurred among the international codes of practice for interactions with patient-advocacy organizations, with the notable exception of the United States where disclosure is not recommended or required. Notwithstanding a tendency toward convergence of standards, discrepancies in disclosure practices across nations and the complete absence of a disclosure policy in the United States give way to inconsistency and obfuscation.

Of course, government regulation and industry self-regulation are not mutually exclusive. A combination of both mechanisms may be most effective in achieving both disclosure and conflict of interest management.

92. R.M. Rhodes, *Enforcement of Legislative Ethics: Conflict within the Conflict of Interest Laws*, 3 HARVARD J. ON LEGIS. 373-406 (1973).

93. Deborah Doane, *Market Failure: The Case for Mandatory Social and Environmental Reporting*, NEW ECON. FOUND. (March 2002), http://thomas.reverdy.free.fr/Envt%20Reporting.pdf.

94. Dara O'Rourke, *Opportunities and Obstacles for Social Responsibility Reporting in Developing Countries*, THE WORLD BANK (March 2004), https://nature.berkeley.edu/orourke/PDF/CSR-Reporting.pdf.

95. Jennifer Howard, Jennifer Nash, & John Ehrenfeld, *Standard or Smokescreen? Implementation of a Voluntary Environmental Code*, 42 CA MGMT. REV. 63-82 (2000).

Industry codes of conduct go far beyond disclosure, as was illustrated in Section II, and include many other broad principles to guide ethical interactions with patient-advocacy organizations. Disclosure, and enforcement of disclosure, may be best accomplished through law or government regulation, while industry codes of conduct and patient-advocacy organization codes of ethics may provide the necessary scaffolding for conflict of interest management once enforceable disclosure policy is in place.

IV. LESSONS FROM THE SUNSHINE ACT FOR PATIENT-ADVOCACY ORGANIZATIONS

In this section, we use the Physician Payments Sunshine Act as a guide to make suggestions for key features of transparency legislation that could be designed to regulate the disclosure of industry funding to patient-advocacy organizations in the U.S.

A. Who Should Report?

The Physician Payments Sunshine Act places reporting obligations and penalties for non-disclosure unilaterally on drug, device, biologic, or medical supply companies.[96] However, it is unclear if industry is the most fitting party to disclose funding to patient-advocacy organizations. On one hand, legal systems may choose to place burdens on the party most likely to have the relevant information and the ability to comply. "Applicable manufacturers," the term that defines the companies covered by the Physician Payments Sunshine Act's reporting requirements, currently have the infrastructure to meet data collection and reporting requirements.[97] There may be minimal added burden on companies to utilize this infrastructure to report payments to patient-advocacy organizations. On the other hand, since patient-advocacy organizations stand to benefit substantially from these payments, as a matter of fairness, one could argue that they should share accountability for proper reporting. Unlike individual physicians, patient organizations are entities that have boards of directors and already have record-keeping and reporting obligations related to maintaining their status as tax-exempt organizations under Section 501(c)(3) of the Federal Tax Code.

96. Physician Payments Sunshine Act, 42 C.F.R. § 403.904(a-b) 2010.

97. *Id*. § 403.902.

Moreover, unless a patient-advocacy organization is required to provide data on its sources of income from industry, policymakers will not know the extent of their dependency on industry. As noted by the Physician Payments Sunshine Act's prime sponsor, Senator Chuck Grassley (R-IA), "[t]ransparency fosters accountability, and the public has a right to know about financial relationships. . . The goal of our legislation is to lay it all out, make the information available for everyone to see, and let people make their own judgments about what the relationships mean or don't mean."[98] By analogy, disclosure of payments to patient-advocacy organizations would allow the public to weigh any potential bias on the part of those receiving the funds. From that perspective, the information should be available directly from the organization receiving the funds, based on the theory that someone examining the organization would look at the organization itself.

Either legislative or regulatory changes could provide the legal mechanism to achieve transparency of drug company funding to patient-advocacy groups. As one of the authors has noted in public comments to the FDA, the Physician Payments Sunshine Act could be amended to include patient-advocacy groups in the definition of "Covered Recipients" — as the Patient Advocacy Transparency bill proposes — and to require reporting by patient groups as well as by drug companies.[99] Alternatively, the FDA could require that every patient-advocacy group participating in a public forum meet certain disclosure requirements. The FDA citizen petition regulations already require disclosure of value transfers related to writing the petition and penalize non-disclosure with civil money penalties. These regulations could be expanded to include identification of all third-parties that fund a patient-advocacy group in general, not just those who sponsor a particular petition.

B. What Should be Reported?

It is useful to report the monetary value of charitable donations and payments to a patient-advocacy organization, but a more instructive metric is the payment amount relative to the total income of the organization. Disclosure of this metric is best accomplished through mandatory reporting by patient-advocacy organizations. Although it is inappropriate to require public disclosure of a physician's income, public disclosure of a patient-advocacy organization's income is already required within 990 forms

98. *See supra* note 25.

99. *See supra* note 21.

submitted to the Internal Revenue Service. Additional reporting requirements for company-specific funding and the accompanying proportion of a patient-advocacy organization's total income derived from each company could be added to the existing forms, along with a requirement to provide the same information on a central website.

C. Accessibility to the Public

A public database, analogous to Open Payments, that is easily searchable by pharmaceutical company *and* by patient-advocacy organization, would provide the fullest picture of industry support. A single company's donations could be viewed through the database, as well as a patient-advocacy organization's sources of pharmaceutical industry funding. This would fulfill two of the key purposes of disclosure: achievement of the public's right to know, and creation of a tool for informed decision-making.

D. Sanctions for Inaccurate Reporting and Failure to Comply

The full extent to which pharmaceutical trade associations in other nations impose sanctions on companies that fail to report, in accordance with the terms of their codes of practice, is unknown. In the U.S., the Physician Payments Sunshine Act allows for civil monetary penalties on manufacturers and GPOs "that fail to timely, accurately or completely report the information required" by the Act, and imposes greater penalties for intentional failure to report.[100] It is reasonable that manufacturers would face similar penalties for failure to report funding to patient-advocacy organizations. As with trade association codes, however, sanctions have power only to the extent that they are enforced, and governing bodies must have the will to carry out the sanctions set out in the regulation.

E. Disclosure as a Starting Point for Conflict of Interest Management

The existence of a financial relationship between industry and a patient-advocacy organization does not imply wrongdoing, and we do not

100. Physician Payment Sunshine Act, Penalties for Failure to Report, 42 C.F.R. §403.912.

espouse putting an end to financial contributions. Standardized national reporting will help foster public trust between patients and the organizations that serve them.

Similar to the Physician Payments Sunshine Act, other financial disclosure laws in the United States have been passed in the aftermath of scandals and government investigations that attracted public attention and aroused public ire. For example, the Ethics in Government Act of 1978 was passed after the Watergate scandal and the Sarbanes-Oxley Act of 2002 was enacted following prominent accounting scandals involving WorldCom, Enron, and other companies. For both of these landmark pieces of legislation, financial disclosure was viewed as a necessary step toward repairing public trust. Academic papers and news articles placing a spotlight on payments to patient-advocacy groups have contributed to declining public confidence in the independence of these organizations. In this climate, financial disclosure can bolster public trust in patient-advocacy groups, but it runs the risk of having a trivial impact without concurrent efforts to address conflicts of interest.

Disclosure should fit within a larger strategy of conflict of interest management that includes elements such as exclusion of pharmaceutical company employees from participation in the boards of patient-advocacy organizations, in the vein of the German FSA Code of Conduct; strict prohibition on pharmaceutical company marketing, including the posting of logos, specific drug names, or other drug advertisements, at patient-advocacy organization events or in an organization's materials; and a prohibition on involvement of pharmaceutical companies in the development or editing of a patient-advocacy organization's educational materials (a provision that is present in the majority of the trade association codes considered here, but not in that of PhRMA). Patients and family members who belong to patient-advocacy groups should be informed of the existence of online funding disclosure reports and should be encouraged to review them. Maintaining the independence and integrity of patient-advocacy groups by ensuring separation from the drug company and its interests should be the principal aim of conflict of interest management.

V. THE NEXT FRONTIER: PHARMACEUTICAL INDUSTRY FUNDING TO PROFESSIONAL MEDICAL ASSOCIATIONS

Similar to patient-advocacy organizations, professional medical associations have no legal obligation to disclose corporate funding sources in the U.S. Industry funding to these associations is common, yet organizational policies to manage conflicts of interest are inconsistent, and

in some cases, inadequate.[101, 102] For example, the American Academy of Family Physicians ("AAFP"), the main professional organization in the United States for family medicine doctors, attracted criticism and lost physician members after it established a "Consumer Alliance" with the Coca-Cola Company to fund a joint obesity education program and consumer education website. [103, 104, 105] According to the AAFP, the alliance with Coca-Cola offered "evidence-based information on sugary beverages, sweeteners, and healthy living benefits,"[106] but many rebuked the professional body for accepting money from a company that has a vested interest in the sale of sugary beverages and for sending a dangerous message that sugary beverages should be part of a healthy diet.

Industry funding to professional medical associations has the potential to imperil the fiduciary duty that those organizations and their physician-members owe patients. Some have called upon professional medical associations to divest themselves of corporate financial ties.[107] Other recommendations include capping the percentage of a professional medical association's operating budget that may be derived from industry donation, disqualifying those who receive industry support from participating in the development of clinical practice guidelines, and requiring physician leadership of professional societies to have no financial connections to industry.[108] Some have suggested a "central repository" for industry donations to professional medical associations and to academic medical centers for continuing medical education,[109, 110] from which funds could be

101. David J. Rothman et al., *Professional Medical Associations and Their Relationships with Industry: A Proposal for Controlling Conflict of Interest,* 301 JAMA 1367-1372 (2009).

102. Howard Brody, *Professional Medical Organizations and Commercial Conflicts of Interest: Ethical Issues,* 8 ANNALS FAM. MED. 354-358 (2010).

103. *Id.*

104. John G. Spangler, *Family Medicine's Sweet Tooth – for Money*, ABC NEWS (Nov. 16, 2009), https://abcnews.go.com/Health/Wellness/coke-partnership-aafp-angers-doctors/story?id=9079376 (last visited May 16, 2018).

105. Marion Nestle, *Family Doctors Resign from AAFP over Coke Partnership,* FOOD POL. (Oct. 29, 2009), https://www.foodpolitics.com/2009/10/family-doctors-resign-from-aafp-over-coke-partnership/ (last visited May 16, 2018).

106. *AAFP, Coca-Cola End Consumer Alliance Agreement*, WEBSITE OF AAFP (June 26, 2015), https://www.aafp.org/news/inside-aafp/20150626tccc.html (last visited May 16, 2018).

107. *See supra* note 102.

108. David J. Rothman, *Professional Medical Associations and Divestiture from Industry: An Ethical Imperative for Pain Society Leadership*, 17 PAIN MED. 218-219 (2016).

109. *See supra* note 101.

110. Troyen A. Brennan et al., *Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 JAMA 429-433 (2006).

doled out without attribution to any particular donor company. While these strategies place distance between industry sponsors and particular activities, they do not eliminate the potential for influence and may not provide the recipients with the degree of autonomy they promise.

A professional medical association is essentially an aggregate of individual physicians. Since industry payments to physicians must be disclosed publicly pursuant to the Physician Payments Sunshine Act, so should payments provided to a collective of physicians. This is especially important since a collective organization wields more influence over prescribing patterns than any individual doctor ever could. Furthermore, the inclusion of teaching hospitals within the statutorily defined "Covered Recipients" sets a precedent for disclosure by entities, not just by individuals, which paves the way for an expansion of the Physician Payments Sunshine Act to professional medical associations and patient-advocacy organizations.

VI. CONCLUSION

No standardized disclosure exists in the United States for financial exchanges between pharmaceutical companies and patient-advocacy organizations, while trade association codes in other nations obligate such disclosure. The lack of transparency in the United States introduces doubt and mistrust in the public mind and leaves room for malfeasance. To address the gap, the U.S. could expand the scope of the Physician Payments Sunshine Act, and it may be prudent to place reporting obligations on patient groups as well as pharmaceutical companies. Standardized and vigilantly enforced disclosure policies along with rigorous conflict of interest management can help these entities remain faithful to their purposes.

Table 1. Principles contained in pharmaceutical trade association codes governing relationships with patient organizations. (X indicates the presence of that principle in the code.)

	United States PhRMA Principles on Interactions with Patient Organizations	United Kingdom ABPI Code of Practice for the Pharmaceutical Industry	Europe EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations	Australia Medicines Australia Code of Conduct	Germany FSA Code of Conduct on the Collaboration with Patient Organizations	France LEEM (Les Entreprises du Médicament) Dispositions Déontologiques Professionnelles	Canada Innovative Medicines Canada Guidelines for Transparency in Stakeholder Funding (Annex A to the Code of Ethical Practices)
(1) Statement regarding respecting or assuring the independence of patient organizations	X	X	X	X	X	X	X
(2) Prohibition on requesting or requiring that a company be the patient organization's exclusive source of funding	X	X	X	X	X	No[1]	X[2]
(3) The need for a written agreement or written documentation of support	X	X	X	No	X	X	X
(4) Enumerated criteria or template for the written documentation or agreement in (3)	No	X	X	No	No	X	No
(5) Requirement for companies to publicly disclose support (financial support and	No	X	X	X	X	X	No
significant indirect/non-financial support) to patient groups							
(6) Requirement for annual (or more frequent) updates of public disclosures	No	X	X	X	X	X	No
(7) Requirement for disclosure of a patient organization's total income or the company's support as a percentage of the patient organization's total income	No	Optional	No	No	No	No	No
(8) Existence of a centralized website for disclosure reporting	No	X	No[3]	X	X	X	No
(9) Monetary fines or penalties for failure to comply	No	No	No[3]	X	X	X[4]	X
(10) Non-monetary sanctions for failure to comply	No	X	X	X	X	X	X
(11) Prohibition on advertising or promoting prescription-only pharmaceuticals to the public	No	X	X	X[5]	X	X	X
(12) Prohibition on using a patient organization's logo or proprietary material without a written agreement	No	X	X	X	X	X	No

(13) Prohibition on influencing or editing a patient organization's materials in a manner favorable to the commercial interests of the company	No	X	X	X	X	X	No
(14) Prohibition on engaging or contracting with a patient organization as an inducement to recommend a particular medicine	No	X	X	No[6]	X	X	X
(15) Existence of a complaint procedure	No	X	X	X	X[7]	X	X
(16) Prohibition on companies from establishing patient organizations	No	No	No	No	X	No	X[8]
(17) Prohibition on employees or representatives of companies from serving on the executive bodies of patient organizations	No	No	No	No	X[9]	No	No
Total score (of 17)	3	13	12	11	15	13	9

Notes:

1: "The pharmaceutical industry is in favor of patient associations being funded by multiple sources."
2. "To the greatest extent practicable, a Member should not be the exclusive funder of a stakeholder organization."
3. Left to the discretion of member associations.
4. As per the Bertrand Act.
5. As per the Commonwealth Therapeutic Goods Legislation.
6. Not specifically for patient organizations; only stated for healthcare providers (HCPs) or administrative staff.
7. A complaint form is accessible from the FSA website.
8. "Members should refrain from creating patient groups whose sole purpose is to further market access in an area of therapeutic interest."
9. Exception for participation in scientific advisory boards.

Table 2. A comparison of key features of transparency reporting.

Country	National or supranational pharmaceutical trade association	Code of conduct relating to patient organizations and relevant legislation	Does the code or law require public disclosure of industry funding to patient organizations?	Does the code or law require disclosure on a centralized website?	Does the code or law impose monetary penalties for non-disclosure?	Governance rating
United States	Pharmaceutical Research and Manufacturers of America (PhRMA)	Principles on Interactions with Patient Organizations	No	No	No	0/3
Europe	European Federation of Pharmaceutical Industries and Associations (EFPIA)[1]	Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations	Yes	No; national law or industry code dictates the site of disclosure	Yes; EFPIA defers sanction authority to member associations. However, there is the potential for a financial penalty (amount unspecified)[2]	2/3
United Kingdom	Association of the British Pharmaceutical Industry (ABPI)	Code of Practice for the Pharmaceutical Industry	Yes	Yes; Database: Disclosure UK[3]	No	2/3
Australia	Medicines Australia	Code of Conduct (Edition 18)	Yes	Yes; Database: Medicines Australia website, Transparency Reporting tab[4]	Yes	3/3
Germany	Freiwillige Selbstkontrolle für die Arzneimittelindustrie" (FSA) ("Voluntary Self-regulation for the Pharmaceutical Industry")	FSA Code of Conduct on the Collaboration with Patient Organisations	Yes	Yes Database: Transparency List[5]; Searchable database[6]	Yes	3/3
France	Les Entreprises du Médicament (LEEM)	Dispositions Déontologiques Professionnelles Loi Bertrand (French Sunshine Act)	Yes	Yes Database: La base de données publique Transparence – Santé ("The Transparency-Health Public Database")[7]	Yes	3/3
Canada	Innovative Medicines Canada	Code of Ethical Practices (2018) Health Sector Payment Transparency Act (Ontario)	Yes	Yes; Database: planned but not yet launched	Yes	3/3

Notes:

1. Includes national pharmaceutical industry associations from 33 European countries.
2. *EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations*, WEBSITE OF EFPIA, http://www.efpia-e4ethics.eu/usd/e4ethics.nsf/_/65E5C4055CA73D5BC125806E004713C6/%24File/FARMA_129399.pdf.
3. *Disclosure UK*, ABPI WEBSITE, (Fr.), https://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk/.
4. *Member Company Reports*, WEBSITE OF MED'S AUSTRL, https://medicinesaustralia.com.au/code-of-conduct/transparency-reporting/health-consumer-organisation-support-reports/member-company-reports/.
5. *Transparency List*, WEBSITE OF FSA (Ger.) https://www.fsa-pharma.de/bezugsgruppen/patientenorganisation/transparenzliste-2017/.
6. *Benefits of Member Companies to Patient Organizations for the Year 2017*, WEBSITE OF FSA WEBSITE (Ger.), https://www.fsa-pharma.de/bezugsgruppen/patientenorganisation/zuwendungen-intern/.

7. *La base de données publique Transparence – Santé, Ministère des Solidarités et de la Santé* (Fr.), *https://www.transparence.sante.gouv.fr/*.

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