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Getting Their Fix: Doctor's Dependency on Big Pharma

*Larissa Tiller**

ABSTRACT

Section 6002 of the Affordable Care Act, also known as the “Sunshine Act,” was intended to stop corrupt practices within the medical community by requiring pharmaceutical and medical device manufacturers to disclose all transfers of value of a certain amount made between them and physicians. This article suggests that the better solution to stopping corrupt practices is to ban some transfers all together.

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I. INTRODUCTION

“Though the doctors treated him, let his blood, and gave him medications to drink, he nevertheless recovered.”¹

Much has changed in the medical world since Leo Tolstoy made his wry comment concerning 19th century doctors’ attempts to treat their patients. One aspect that has remained the same, however, is the patient’s reliance on doctors to heal them. Their reliance is understandable, not only because doctors undergo years of strenuous training to acquire a degree of expertise unavailable to the general public, but also because people visit doctors in stressful situations when they are physically sick and in a vulnerable emotional state.² Patients rely on medical professionals to cure whatever ails them in a manner that puts the patient’s needs first.³ A patient’s faith is often rewarded as doctors are able to make urgent decisions without the need for constant consultations with their patient; however, allowing doctors to make unilateral decisions also leaves patients open to exploitation.

When a doctor is faced with deciding between two options, one of which will benefit the patient and one which will benefit themselves, many doctors choose the latter.⁴ Financial conflicts of interest can have the “greatest potential to create tension” with the patient’s care, as the conflict can create a “harmful influence” on the doctor’s professional judgment.⁵ For instance, imagine that in Tolstoy’s scenario, whoever made the medication also paid for the doctor’s lunch while pitching the drug to him. In addition, what if there was an equally effective and much cheaper medication available, but because that other manufacturer did not pay for the doctor’s lunch, the physician chose the more expensive medicine instead? Sadly, this scenario is not a work of fiction; this is the state of the medical world today.⁶

Despite the passage of recent regulatory laws, such as the Patient Protection and Affordable Care Act of 2010 (“Act”),⁷ the relationship between doctors, patients, pharmaceutical companies, and medical device manufacturers (“Big Pharma”), remains open to abuse. Doctors are incentivized to use certain rugs over others and to order various tests and methods of treatment—even when they are not medically necessary.⁸ Enabling this unprincipled practice is the fact that doctors are neither required to disclose potential conflicts of interest to their patients, nor to the federal government. Instead, under the section of the Act that governs this issue—

1. LEO TOLSTOY, *WAR AND PEACE* 1102 (Richard Pevear & Larissa Volokhonsky trans., Vintage Classics 2005) (1869).

2. Alexandros Stamatoglou, *The Physician Payment Sunshine Act: An Important First Step in Mitigating Financial Conflicts of Interest in Medical and Clinical Practice*, 45 J. MARSHALL L. REV. 963, 967 (2012).

3. *Id.*

4. Roy H. Perlis & Clifford S. Perlis, *Physician Payments from Industry Are Associated with Greater Medicare Part D Prescribing Costs*, 11(5) PLoS ONE 1 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4868346/>.

5. Kevin W. Williams, *Managing Physician Financial Conflicts of Interest in Clinical Trials Conducted in the Private Practice Setting*, 59 FOOD & DRUG L. J. 45, 56 (2004).

6. See generally Stephanie Saul, *Drug Makers Pay for Lunch as they Pitch*, N.Y. TIMES (July 28, 2006), <http://www.nytimes.com/2006/07/28/business/28lunch.html>.

7. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119.

8. Blake Ellis & Melanie Hicken, *The Little Red Pill Being Pushed on the Elderly: CNN Investigation Exposes Inappropriate Use of Drug in Nursing Homes*, CNN, <http://www.cnn.com/2017/10/12/health/nuedexta-nursing-homes-invs/index.html> (last updated Oct. 12, 2017, 5:51 PM).

§ 6002, often called the Sunshine provision—the government only requires “certain” pharmaceutical companies and medical device manufacturers to report certain payments of value that they make to doctors, including the names of any doctors that have invested in their companies.⁹ These reports are later published in the online database, Open Payments, where patients can search to determine whether there is a possible conflict of interest between their doctors and the medications they prescribe to their patients.¹⁰

Furthermore, the Act only requires disclosure if the products and devices are covered by Medicare, Medicaid, or the Children’s Health Insurance Program (“CHIP”).¹¹ There are other federal laws that regulate certain aspects of physician behavior, such as the Stark law, which “[p]rohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship.”¹² But Stark is narrow in focus and contains several exceptions,¹³ leaving it open to exploitation as well. Indeed, when the Act was first introduced, it was considered to “break new ground” because it both “supplements and goes far beyond existing law in terms of which payment information will get collected and publicly reported,”¹⁴ although it also has several loopholes. Moreover, Big Pharma is not the only player ferreting ways to game the system; smaller players in the medical industry have also exploited the loopholes present in medical regulations.¹⁵

Conflicts of interest between doctors and patients are not a problem unique to America. Some countries have imitated the United States’ solution by enacting their own “Sunshine” laws.¹⁶ Other countries have dealt with the problem in their own way, such as requiring doctors to disclose to their respective governments any payments they receive, and then releasing that information to the public.¹⁷ These disclosure laws are relatively new, however, and determining their effects is difficult at this time. Yet, disclosure laws alone, as they currently stand, are not enough to encourage doctors to place their patients’ needs ahead of their own. Until now, legislation has focused on regulating Big Pharma, but focus should shift to the other party in the relationship—the physician. This article puts forth the proposal that the United States Federal Government must ban certain transactions between physicians and those involved in the medical industry entirely in the hopes of finally putting the patient’s interests first.

9. Patient Protection and Affordable Care Act of 2010 § 6002 (codified as amended at 42 U.S.C. § 1320a-7h (2013)).

10. *Id.*

11. *Id.*

12. *Physician Self Referral*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html> (last updated Jan. 5, 2015, 10:59 AM); *see also* 42 U.S.C. § 1395nn (2018).

13. 42 U.S.C. § 1395nn(b).

14. Richard S. Saver, *Shadows Amid Sunshine: Regulating Financial Conflicts in Medical Research*, 145 CHEST 379, 380–81 (2014).

15. Ellis & Hicken, *supra* note 8.

16. Moya Ball, *Shining the Light on Fundamental Flaws in Global Healthcare Sunshine Laws, and a Proposal for Patient-Focused Transparency*, 28(5) HEALTH LAW. 1, 7 (2016).

17. *Id.*

II. THE SYMPTOMS

In the latter half of the 20th century and into the 21st, the relationship between Big Pharma and physicians grew increasingly intertwined.¹⁸ Pharmaceutical companies developed drugs to treat various illnesses and injuries,¹⁹ which doctors then prescribed to their sick patients. But, with several companies making similar products to compete for the same patients,²⁰ each company needed to develop a strategy to get doctors to prescribe their drugs—and only their drugs. To do that, they tried to seduce doctors by giving them “gifts” in the hope of turning their heads.²¹ As each company tried to outdo the other, the gifts grew in value until they included everything from “pens, notepads and pizza to watches, golf trips and five star dining [experiences].”²²

In the late 1980s, alarming information about the relationship between Big Pharma and physicians began to surface that revealed “kickbacks, fraud, and otherwise shady dealings” between the two parties.²³ Physicians engaged in “self-referrals,” which is a type of kickback where the physician owns a stake in whatever medical service he or she refers to a patient.²⁴ This development generated a great deal of concern over possible corruption and bribery, prompting many legislators to enact regulations, like the Stark Law, to rein in some of the more heavy-handed practices.²⁵ But, once these particular “shady dealings” were curtailed, others took their place.

As competition increased within the industry, pharmaceutical companies began sponsoring continuing medical education courses (“CME”),²⁶ that provided doctors with rebates for each dose of the company’s drug they prescribed,²⁷ and funding for their research projects.²⁸ As fears of corruption mounted across the nation, regulations were passed on a state by state basis. Vermont, one such state, was the first to

18. Steven D. Wales, *The Stark Law: Boon or Boondoggle - An Analysis of the Prohibition on Physician Self-Referrals*, 27 L. & PSYCHOL. REV. 1, 2 (2003).

19. Franco Malerba & Luigi Orsenigo, *Innovation and Market Structure in the Dynamics of the Pharmaceutical Industry and Biotechnology: Towards a History Friendly Model*, 11(4) INDUS. & CORP. CHANGE 667, 674–75 (2002).

20. *Id.* at 675.

21. Scott Velasquez, *There Ain't No Such Thing as a Free Lunch: A Look at State Gift Disclosure Laws and the Effect on Pharmaceutical Company Marketing*, 41 J. MARSHALL L. REV. 563, 563–64 (2008).

22. Emily Clayton, *'Tis Always the Season for Giving: A White Paper on the Practice and Problems of Pharmaceutical Detailing*, CALPIRG 3 (2004), <https://calpirg.org/sites/pirg/files/reports/TistheSeasonForGiving04.pdf>.

23. Wales, *supra* note 18.

24. *Id.*

25. *Id.*

26. Sheldon Krinsky, *Combating the Funding Effect in Science: What's Beyond Transparency?*, 21 STAN. L. & POL'Y REV. 101, 112 (2010).

27. Alex Berenson & Andrew Pollack, *Doctors Reap Millions for Anemia Drugs*, N.Y. TIMES (May 9, 2007) (noting that the doctors were working around the federal ban on pharmaceutical companies paying doctors to prescribe certain drugs by having them administer the intravenous drugs in the hospital). See generally Gardiner Harris & Janet Roberts, *Doctors' Ties to Drug Makers on Close View*, N.Y. TIMES (Mar. 21, 2007), <https://www.nytimes.com/2007/03/21/us/21drug.html> (“Research shows that doctors who have close relationships with drug makers tend to prescribe more, newer and pricier drugs.”).

28. Krinsky, *supra* note 26, at 119.

require pharmaceutical companies to disclose gifts over \$25 in value.²⁹ When these measures were not enough, Congress enacted the federal Sunshine Act as § 6002 of The Affordable Care Act.³⁰ The supposed purpose of this provision was to make the relationship between Big Pharma and physicians more transparent so that patients could make informed decisions about their healthcare.³¹ The Act did not prohibit Big Pharma from having any contact or association with physicians, but it did seek to give their relationship some boundaries, and for good cause.³²

A study conducted by York University in 2008 revealed that Big Pharma spent an estimated \$57.5 billion on marketing drugs in 2004, almost twice what it spent on research and development (\$31.5 billion).³³ The medical industry spends a great deal on marketing to physicians directly, with the majority of the “physician-focused marketing budget” spent on “detailing.”³⁴ Detailing is when “pharmaceutical representatives talk directly to physicians to ‘promote and market their companies’ drugs.”³⁵ Yet, despite this emphasis on targeted marketing, many doctors still claim to be “immune” from any influences on their prescription habits.³⁶ Interestingly enough, these same physicians believe that their colleagues are not immune from the influential effect of similar gifts.³⁷

Several studies have shown that even a relatively small gift can influence the recipient’s behavior. One such study, released in the *Journal of the American Medical Association* (“JAMA”), used both industry payment data from the federal Open Payments Program and prescribing data for individual physicians from Medicare Part D to determine what influences doctors’ prescription habits.³⁸ The study found that there was an association between industry-sponsored meals and an “increased rate of prescribing the promoted brand-name medication relative to alternatives within the drug class.”³⁹ In addition, it revealed that the meals did not need to be lavish affairs, and concluded that “even payments of less than \$20 are associated with different prescribing patterns.”⁴⁰ Those responsible for conducting the study were careful to note however, that this conclusion only proves association, not causation.⁴¹ But, as Dr. Peter Lurie, deputy director of Public Citizen’s Health Research Group, stated in his testimony during a Congressional hearing on the issue, “it seems unlikely that pharmaceutical companies would be catering to the culinary

29. Erin Mansfield, *Vermont to Become First State to Require Drug Price Transparency*, VTDIGGER (June 3, 2016), <https://vtdigger.org/2016/06/03/vermont-to-become-first-state-to-require-drug-price-transparency/#.WhjxZFWnHIU>.

30. Stamatoglou, *supra* note 2, at 976.

31. *Id.* at 977.

32. *Id.*

33. YORK UNIV., *Big Pharma Spends More on Advertising Than Research and Development, Study Finds*, SCIENCE DAILY (Jan. 7, 2008), www.sciencedaily.com/releases/2008/01/080105140107.htm.

34. Stamatoglou, *supra* note 2, at 970.

35. *Id.*

36. Edward C. Halperin, Paul Hutchinson & Robert C. Barrier, Jr., *A Population-Based Study of The Prevalence and Influence of Gifts to Radiation Oncologists from Pharmaceutical Companies and Medical Equipment Manufacturers*, 59 INT’L J. RADIATION ONCOLOGY BIOLOGY PHYSICS 1477, 1482 (2004).

37. *Id.*

38. Colette DeJong et al., *Pharmaceutical Industry–Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, 176 JAMA INTERNAL MED. 1114, 1115 (2016).

39. *Id.* at 1121.

40. *Id.*

41. *Id.*

and travel preferences of doctors if they didn't think that they were getting some bang for the buck."⁴²

Indeed, the "detailing" that pharmaceutical representatives do is far more targeted than many physicians may know or understand. For instance, in addition to training representatives in marketing skills and techniques, Big Pharma spends over \$20 million a year "purchasing data on individual physicians' prescription habits to ensure that detailers can tailor their techniques to physicians' specific prescription habits."⁴³ In 2012 alone, Big Pharma spent \$89.5 billion on detailing,⁴⁴ which accounted for "60% of the global sales and marketing spending" that year.⁴⁵ Therefore, pharmaceutical representatives are well-trained in how to pitch their drugs to both physicians in general, and specific physicians. Being the subject of targeted marketing could influence almost anyone, and the data from various studies supports the conclusion that physicians are not immune to these effects.

The New England Journal of Medicine conducted a national survey in 2007 where researchers found that out of 3,167 physicians, 94% reported some type of "relationship" with the pharmaceutical industry.⁴⁶ Broken down, most of the interactions between physicians and Big Pharma involved either receiving drug samples from Big Pharma representatives (78%),⁴⁷ or receiving free food while at work (83%).⁴⁸ Others involved reimbursements for the costs of attending continuing medical education meetings (26%),⁴⁹ and some received payments for consulting, giving lectures, or enrolling patients in clinical trials (28% total).⁵⁰ Individually, these figures may not appear substantial, but the effect of this "relationship" on a physician's prescribing habits does create a cause for concern.

One of the tactics Big Pharma uses to promote their drugs is to provide free samples to physicians for their patients. This tactic is wildly successful, which is why drug manufacturers spent \$16.4 billion on doling out drug samples in 2003 alone.⁵¹ It allows representatives to "influence physicians to dispense or prescribe drugs that differ from their preferred drug choice."⁵² Although the drugs are initially free to use, patients tend to stay with a particular brand even after their samples run out.⁵³ In addition, these drugs cost the patient more than if they had started off with the equally effective generic option from the beginning. One study found that the out-of-pocket expenses for a patient who never received a drug sample were \$178

42. *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the Spec. Comm. On Aging*, 110th Cong. 19 (2007) (statement of Dr. Peter Lurie).

43. Stamatoglou, *supra* note 2, at 971.

44. George A. Chressanthis et al., *Determinants of Pharmaceutical Sales Representative Access Limits to Physicians*, 14 J. MED. MKT. 220, 224 (2014).

45. *Id.*

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

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.*

51. *Prescription Drug Trends*, HENRY J. KAISER FAM. FOUND. (Oct. 2004), https://faculty.missouri.edu/~glaserr/current_news/Prescription-Drug-Trends.pdf.

52. Lisa D. Chew et al., *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, 15 J. GEN. INTERNAL MED. 478, 482 (2000).

53. *Id.*

over a 180-day period,⁵⁴ while a patient who did receive samples was out \$212 after receiving them.⁵⁵ Those who argue in favor of samples claim that it allows lower income patients to have access to better-quality drugs. Despite this assertion, the data shows that people from a higher-income bracket, or those with insurance, are more likely to receive free drug samples.⁵⁶

Rebates are another incentivizing tactic used to entice physicians to prescribe a manufacturer's brand-name drugs over their competitors'. In 2007, the New York Times reported in a series of articles that the largest pharmaceutical companies were paying hundreds of millions of dollars through rebates to doctors across the nation every year in return for them giving their patients the company's products instead of their competitors'.⁵⁷ By reimbursing the doctors for the amount of drugs they prescribed, the doctors were incentivized to prescribe more expensive drugs—and in higher doses—than what was actually considered safe for their patients.⁵⁸ But, by doing so, these doctors took advantage of their patients and the trust they placed in them to look out for their best interests.

III. THE DISEASE

The inherent power imbalance between the physician and patient means that when a conflict of interest arises, the physician controls which interest takes precedent. Additionally, some government programs further provide opportunities for conflicts to occur. For example, under current managed health care programs, like Medicare, doctors are encouraged to prescribe name-brand drugs rather than cheaper generic alternatives and to overtreat their patients by ordering unnecessary tests and procedures. These practices highlight the disparate power balance between the parties and shows how patients themselves are viewed as a commodity.

Recently, one researcher discovered the preference for physicians to prescribe Lucentis, a drug used to treat age-related macular degeneration, over Avastin, a far cheaper, equally effective drug that has not been equally prescribed.⁵⁹ The reason for this preference, the researcher claims, lies in the incentive Medicare Part B creates by reimbursing the prescribing-physicians for the average price of the drug.⁶⁰ If a physician prescribes Lucentis, they receive \$2,000 per dose, whereas Avastin will only give them \$50 per dose.⁶¹ In addition to the flat rate rebate, the physicians also receive an additional 6% every time they use either drug when treating a patient for the disease.⁶² This is all part of the reimbursement plan contained within the

54. G. Caleb Alexander, James Zhang & Anirban Basu, *Characteristics of Patients Receiving Pharmaceutical Samples and Association Between Sample Receipt and Out-of-Pocket Prescription Costs*, 46 MED. CARE 394, 397 (2008).

55. *Id.* at 397.

56. *Id.* at 396–97.

57. Berenson & Pollack, *supra* note 27 (noting that the doctors were working around the federal ban on pharmaceutical companies paying doctors to prescribe certain drugs by having them administer the intravenous drugs in the hospital); Harris & Roberts, *supra* note 27 (“Research shows that doctors who have close relationships with drug makers tend to prescribe more, newer and pricier drugs.”).

58. Berenson & Pollack, *supra* note 27.

59. Isaac D. Buck, *Furthering the Fiduciary Metaphor: The Duty of Providers to the Payers of Medicare*, 104 CALIF. L. REV. 1043, 1054 (2016).

60. *Id.*

61. *Id.* at 1055–56 (noting that Lucentis profits the doctors \$120 per dose versus Avastin at \$3 per dose).

62. *Id.* at 1056.

federally-funded Medicare, but because “participating providers exclusively decide which drugs are appropriate for their patients,” not even the Department of Justice can “argue that these highly expensive clinical decisions are illegal, or even abusive.”⁶³

A recent scandal in Philadelphia reveals how it is not just the Big Pharmacist-physician relationship that exploits the loopholes in the current system. Investigative journalists for *The Philadelphia Inquirer* discovered that a local law firm specializing in workers’ compensation cases, Pond Lehoccky Stern Giordano, sends clients to “preferred doctors and asks them to send those new patients to the law firm’s pharmacy, Workers First.”⁶⁴ In turn, the Workers First pharmacy then charges employers or their insurance companies for the workers’ pain medicine, which is often “unproven and exorbitantly priced pain creams,” with some creams costing well over \$4,000 per tube.⁶⁵ In addition, some of the doctors referred to by Pond Lehoccky are part-owners of Workers First, the pharmacy where patients are directed to pick up their prescriptions.⁶⁶ This means that the physicians make money from both treating their patients and prescribing the prescriptions,⁶⁷ all without disclosing their interest in the pharmacy or their arrangement with the attorneys. Likewise, the attorneys are not required to report their relationship with the doctors either, as they are not “applicable manufacturers” under the Act because they do not manufacture products covered by Medicare, Medicaid, or CHIP.⁶⁸

Liberty Mutual Insurance filed a suit against several of the doctors involved in the Pond Lehoccky case, claiming that their relationship with the law firm was illegal and that they had grossly overcharged their patients for medication.⁶⁹ But, while the physicians’ actions are likely illegal under the federal Stark Law, those same actions may qualify for an exception, such as fair market value compensation.⁷⁰ Therefore, not only could it be perfectly legal for the attorneys to pay the physicians to send their patients to the pharmacy, but neither party would have to inform patients of the potential conflict of interest. Patients should be privy to this information; Francis Elliot, a client of Pond Lehoccky, found out about the situation and stated, “I don’t know what’s going on,” but “I don’t want to be a part of something unethical.”⁷¹

The symptoms of a compromised medical industry were supposed to be cured by the Sunshine Act,⁷² but there are still lingering signs of the disease. Big Pharma is not alone in taking advantage of the loopholes left by the Act and other laws; doctors and other interested parties have too, as seen in the Philadelphia physicians’

63. *Id.* at 1059.

64. William Bender, ‘Talk About an Unholy Alliance’: Lawyers, Doctors and Pharmacies, PHILA. INQUIRER (Sept. 22, 2017), <http://www.philly.com/philly/business/workers-comp-insurance-pennsylvania-pond-lehoccky-referrals-20170922.html> [hereinafter *Talk About an Unholy Alliance*].

65. *Id.*

66. *Id.*

67. *Id.*

68. 42 U.S.C. § 1320a-7h(e)(2), (4) (2010).

69. William Bender, *Philly-Area Doctors, Pharmacists Named in \$4.7 Million Pain Cream Lawsuit*, PHILA. INQUIRER (Sept. 29, 2017), <http://www.philly.com/philly/business/doctors-pharmacists-compound-pain-cream-costly-lawsuit-20170929.html>.

70. 42 C.F.R. § 411.357(l) (2017).

71. *Talk About an Unholy Alliance*, *supra* note 64.

72. Paul D. Thacker, *Don’t Rewrite History: ‘Sunshine’ Law was Meant to Protect Docs from Undue Influence*, STAT (Aug. 10, 2016), <https://www.statnews.com/2016/08/10/sunshine-act-revise-history/>.

case. Moreover, not only are physicians exempt from reporting any conflicts of interest, but they can contest inaccuracies in the published data, and delay reporting of potential conflicts.⁷³ Requiring physicians to disclose such information themselves through the Open Payments database could be one method of treatment for the problem. Further measures are warranted, however, to cure the disease. One such cure would be the direct disclosure of potential conflicts of interest to the patient to ensure that the patient's interests are put first, as they should be. Nevertheless, the best solution to limit exposure is to ban these transfers of value between physicians and the pharmaceutical companies.

IV. TREATMENT

A. Federal Acts

Big Pharma's ever-increasing influence over the prescribing habits of physicians prompted the enactment of several so-called "Sunshine" laws to force the details of the relationship out into the light. The hope was that by doing so, patients could make informed decisions, and the medical industry would be cleansed of any improprieties within the relatively unregulated physician-pharma relationship.⁷⁴ While ideal in theory, in practice it all depends on whether the patients are aware that there is a website that publishes the disclosures. It further depends on their willingness to look up their doctors and hospitals, and then on the ability of the patients to fully understand the implications of the disclosed information.

In many respects, the Act has been an abject failure. Even assuming that patients are aware that the website exists and take the time to research their physicians, the website does not provide context surrounding the reported transactions.⁷⁵ In addition, the effectiveness of the Act also depends on the Open Payments website being able to publish the information in the first place. As mentioned before, physicians can contest the information to be published, and a large portion (one-third) of the information released in the first yearly report was withheld because of such contestations.⁷⁶ This is not to say that those responsible for reporting (Centers for Medicare and Medicaid Services ("CMS")), should not correct improperly reported data, but it does highlight one difficulty in providing patients access to necessary information. That is, the database is supposed to be searchable, "clear[,] and understandable,"⁷⁷ but a series of handicaps has plagued it since its conception.

The first issue with the government database is that while it reports the names of the parties, the types of payments, and the amounts paid, it does not report the context surrounding the payment.⁷⁸ For instance, a search for "Dr. Patrick Morgan"

73. 42 U.S.C. § 1320a-7h(c)(C)(ix).

74. Letter from Sen. Charles "Chuck" E. Grassley, Ranking Member, Comm. on the Judiciary, to Jacob Lew, Chief of Staff to the President of the U.S. (Jan. 22, 2013), <http://www.medicalimaging.org/wp-content/uploads/2013/02/2013-01-22-CEG-to-J-Lew-Sunshine.pdf>.

75. Jon Tripp, *4 Things to Think About When Reviewing Open Payments Data (Hint: Context is Key)*, MEDCITY NEWS (June 25, 2015, 3:30 PM), <https://medcitynews.com/2015/06/open-payments-data/>.

76. Charles Ornstein, *Feds Withholding Data on Physician Open Payment System*, J. MED. (Aug. 15, 2014), <https://www.ncnp.org/journal-of-medicine/1429-feds-withholding-data-on-physician-open-payment-system.html>.

77. 42 U.S.C. § 1320a-7h(c)(C)(i).

78. Tripp, *supra* note 75.

reveals that a physician in Tennessee received a “gift” of \$18.00 from Intuitive Surgical Inc.⁷⁹ The database describes “gift” as a “general category, which will often include anything provided to a physician or teaching hospital that does not fit into another category.”⁸⁰ Although many people might not consider a single ambiguous payment of \$18.00 as warranting concern, the use of such basic categories makes it difficult for patients to fully understand the true nature of the physician’s relationship with the disclosing companies. Additionally, as the study published in JAMA noted, even small gifts of \$20 can influence a physician’s prescription habits.⁸¹ Thus, patients are unable to make informed decisions even if they do take the time to look up the data.

In addition, CMS officials have issued warnings about how to interpret the information released through Open Payments. Shantanu Agrawal, the former deputy administrator for CMS, stated that the government would not “draw conclusions about the disclosed payments,” and “cautioned” the public not to do so either because “[f]inancial ties and relationships between medical manufacturers and health care providers do not necessarily signal wrongdoing.”⁸² Moreover, the “[O]pen [P]ayments program does not identify which financial relationships are beneficial and which could cause conflicts of interest.”⁸³ Therefore, if those in charge of the disclosure database are uncertain as to the true value of the information, it is understandable that patients would be as well. Whether or not this information has been correctly utilized, however, does not mean that it can never be used for its intended purpose. It only requires some additional steps be taken.

Even still, the forced direct disclosure of all possible conflicts of interest to a physician’s patients may not solve the problem of financial conflicts completely. The disclosure of this information will have little to no effect if the patients themselves refuse to act on it or fail to realize its true significance. Some conflicts, of course, once revealed, would likely prompt patients to refuse a service or drug (such as the Philadelphia law firm/physician/pharmacy ring), but others may not be viewed as problematic. Some studies have shown that when conflict of interest information is disclosed—such as in clinical trial testing—the participants fail to perceive a conflict.⁸⁴ They may even believe that if a physician has invested in the company, it signals his or her confidence in the product or device, thus lending the study or drug some credibility in the participants’ and patients’ eyes.⁸⁵

After two years of disclosures, it appears that patients might not benefit a great deal from the data released by CMS. Many patients simply may not want to take the time to research their doctors, a reaction that is supported by a study released in 2006 that investigated research participants’ views on the financial interests of medical researchers.⁸⁶ Out of the surveyed pool of participants, the majority “wanted to

79. Patrick L. Morgan, OPENPAYMENTS.DATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/192349/payment-information> (last visited Nov. 19, 2018).

80. *Id.*

81. DeJong, *supra* note 38, at 1114–22.

82. Peter Frost et al., *Obamacare Sunshine Act Sheds Light on \$3.5B Paid to Doctors*, CHI. TRIB. (Oct. 1, 2014), <http://www.chicagotribune.com/business/ct-sunshine-act-1001-biz-20141001-story.html>.

83. *Id.*

84. Kevin P. Weinfurt, Ph.D., et al., *Disclosure of Financial Relationships to Participants in Clinical Research*, 361 NEW ENG. J. MED. 916, 917 (2009).

85. *Id.*

86. Christine Grady et al., *The Limits of Disclosure: What Research Subjects Want to Know about Investigator Financial Interests*, 34 J. L. MED. & ETHICS 592, 597 (2006).

receive information about investigator financial interests.”⁸⁷ However, “while recognizing the value of transparency and having ‘all the cards on the table,’ only a minority thought such financial information would influence their decisions about research participation.”⁸⁸ Moreover, the participants indicated that even if medical researchers did disclose their financial interests, it would not affect the participants’ decision to take part in the study either “because it did not matter to them or was perceived as a burden that they did not want to have to deal with.”⁸⁹

The forced disclosure of conflict of interest information may not prompt the hoped-for response from all patients, but that does not mean that the information should not be disclosed in the first place. Allowing some physicians to hide their questionable activities behind the blanket of protection provided by the Act inhibits patients’ abilities to make informed decisions. If transparency is the goal, then it should not matter if every patient uses the information to make more informed decisions, so long as the opportunity to do so exists.

B. State Acts

Although the federal Sunshine Act applies throughout the country, a few states have joined the cause and passed their own medical industry transparency laws. In Missouri, a bill was introduced in February 2017 which “proposed that it become unlawful for any drug (not device) manufacturer or distributor to offer or give any gift of value to a practitioner.”⁹⁰ The Bill has not gained much traction since it was proposed,⁹¹ but its proposal warrants attention because it indicates the federal Act is not satisfactory.

In fact, Missouri is not the only state that seems to feel the federal Sunshine Act is insufficient. Maine also introduced legislation that would “curtail gifts, free food, and speaking/consulting payments from drug companies to Maine physicians.”⁹² The Bill was introduced by state representative Scott Hamann, who was prompted by the recent problems in Maine with opioid addiction and the increase in pharmaceutical companies’ influence over the doctors who prescribe them.⁹³ The Bill passed the Legislature, with some amendments to include various exemptions (like meals, education materials, and prescription drug samples),⁹⁴ and was enacted without the Governor’s signature on June 28, 2017.⁹⁵ Two other state legislatures, New Jersey and California, proposed limitations on promotional payments in 2018, but they are also subject to exemptions, which includes honoraria as well as meals—

87. *Id.*

88. *Id.*

89. *Id.*

90. Thomas Sullivan, *Maine and Missouri Propose Legislation Restricting Industry and Physician Interactions*, POL’Y & MED., <http://www.policymed.com/2017/06/maine-and-missouri-propose-legislation-restricting-industry-and-physician-interactions.html> (last updated May 4, 2018).

91. *Id.*

92. *Id.*

93. Joe Lawlor, *Even Amid Crisis, Opioid Makers Plied Doctors with Perks*, PORTLAND PRESS HERALD, <http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/> (last updated Jan. 20, 2017).

94. ME. REV. STAT. ANN. tit. 32, § 13759.2(A) (2017).

95. *Summary of LD 911*, STATE OF ME. LEG., <http://legislature.maine.gov/LawMakerWeb/summary.asp?ID=280063851> (last visited Nov. 19, 2018).

as long as they do not exceed \$250 per person annually.⁹⁶ It is clear from these legislative proposals that the states are not completely confident in the ability of the federal Act to deal with conflicts of interest in the medical field. It is also clear, however, that the state provisions, as they currently stand, may not be an effective cure either.

One glaring example of how little effect the federal Act, or any state-enacted “Sunshine” provision, has had is in a recent exposé by CNN concerning Nuedexta, a “drug approved to treat a disorder marked by sudden and uncontrollable laughing or crying—known as pseudobulbar affect, or PBA.”⁹⁷ Instead, prescriptions of this one pill alone generated Avanir Pharmaceuticals hundreds of millions of dollars a year by directly marketing the drug to physicians and psychiatrists whose patients are nursing home residents with dementia or Alzheimer’s, even if the drug was “unnecessary or even unsafe” for them.⁹⁸ The drug has not been extensively studied in elderly patients (some have called it an “uncontrolled experiment”), but the one study conducted revealed that patients who took the drug suffered from falls at double the rate than patients not taking the drug.⁹⁹

It is not Big Pharma alone that should be blamed for dangerous prescriptions; the doctors receiving payments from companies in exchange for prescribing drugs or inducing others to do so should shoulder their portion of the blame as well. Using information gathered through the Open Payments website, CNN reported that “[b]etween 2013 and 2016, Avanir and its parent company, Otsuka, paid doctors nearly \$14 million for Nuedexta-related consulting, promotional speaking and other services.”¹⁰⁰ In addition, CNN found that of the claims filed through Medicare in 2015, almost half “came from doctors who had received money or other perks from the company (ranging from a few dollars’ worth of food or drink to hundreds of thousands of dollars in direct payments).”¹⁰¹ One doctor highlighted in the article, Dr. Romeo Isidro, prescribed the drug to his patients with dementia in nursing homes while receiving money from Avanir as a speaker—which amounted to more than \$500,000 in payments, travel, and meals over the course of three years.¹⁰² Once the daughter of one of his patients found out Dr. Isidro was receiving money from the drug manufacturer, she cut ties with both him and the nursing home.¹⁰³

While the CNN exposé was made possible through data gathered from the Open Payments website, it makes it clear that the loopholes created by the Act and various other laws are still open to exploitation. Had Dr. Isidro been compelled to disclose his connection to the drug company before he made the prescription, he, and doctors like him, might not have been able to dispense drugs to people who do not need them, and may even be harmed by them. The patients, or their loved ones, could make more informed decisions for their care and not be subjected to the whims of doctors who diagnose based on the interests of their pocket book, rather than the interests of their patient.

96. Marc Iskovitz, *Limits on Pharma Payments to Doctors Back on Policy Menu*, MED. MARKETING & MEDIA (Nov. 8, 2017), <http://www.mmm-online.com/legalregulatory/limits-on-pharma-payments-to-doctors-back-on-policy-menu/article/706001/>.

97. Ellis & Hicken, *supra* note 8.

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

V. FOREIGN TREATMENTS

One, possibly unintended, effect of the federal Sunshine Act was to prompt other countries to pass physician payment disclosure laws of their own. Of course, independent forces may have prompted these laws, but several of the foreign acts were not implemented until after the United States passed the Act.¹⁰⁴ While many countries already regulated interactions between physicians and pharmaceutical companies, those regulations appeared ineffective, perhaps because the industry-wide measures were often voluntary and had little to no adverse consequences should the companies not adhere to the guidelines.¹⁰⁵ The new regulatory measures warrant inspection, but their long-term effectiveness has yet to be proven.

European countries developed their own regulations for handling the Big Pharma-physician industry relationship. For instance, in 2010, Denmark passed a law requiring healthcare providers (called HPC's, i.e. physicians) to report transactions, ownership interests, or other "affiliations" with drug or medical device companies to the Danish Health Protection Agency or National Board of Health.¹⁰⁶ In addition to physicians reporting their interactions with Big Pharma, the pharmaceutical companies must also make their own reports detailing the entities or individuals with whom they associate.¹⁰⁷

France added a provision to its own disclosure law—the Loi Bertrand Act—to prohibit gifts and require Big Pharma companies to report "agreements with and benefits provided to physicians, nurses, healthcare facilities, and even students of health professions."¹⁰⁸ That data is later published on a free public-access website.¹⁰⁹ "Benefits" that must be reported are those worth \$10 or more, as well as anything related to "clinical trials, scientific or medical seminars, travel and hospitality costs, and consultant and speaking agreements."¹¹⁰ Physicians are not required to report, and detailed product information is also not required.¹¹¹ One interesting component of the provision is that all contracts between drug companies and doctors must be approved in advance by a professional supervisory body for doctors and pharmacists.¹¹² The French Act has been subject to criticism, with some claiming that the burden of reporting this information is too high,¹¹³ and others stating that the Loi Bertrand Act itself is open to interpretation, making enforcement difficult.¹¹⁴ Regardless, it is a step in the right direction.

104. Moya, *supra* note 16, at 7 (discussing the French efforts at reform); Aditi Tandon, *Pharmas 'Bribing' Docs to Face Drug Sale Ban*, INDIA TRIB., <http://www.tribuneindia.com/news/nation/pharmas-bribing-docs-to-face-drug-sale-ban/441207.html> (last updated July 24, 2017, 1:42 AM) (focusing on India's efforts to regulate the Big Pharm-physician relationship).

105. Molly Brennan, *How Regulatory Changes in Europe are Affecting Medical Meetings*, CONVENE (Jan. 1, 2015), <http://www.pemaconvene.org/features/cmp-series-how-regulatory-changes-in-europe-are-affecting-medical-meetings/>.

106. Moya, *supra* note 16, at 7.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. Barbara Casassus, *French Scorn Sunshine*, 31 NATURE BIOTECHNOLOGY 666 (2013).

113. *Id.*

114. Daniel Kadar, *The French Sunshine Act Continues to be a Challenge*, EHEALTH L. & POL'Y 6 (Apr. 2015), <https://www.lifescienceslegalupdate.com/wp-content/uploads/sites/8/2015/05/The-French-Sunshine-Act-Continues-to-Be-a-Challenge.pdf>.

As for an industry-wide European regulation, there have been some new requirements implemented, but they are limited in scope. For instance, the European Federation of Pharmaceutical Industries and Associations (“EFPIA”) recently established a new “Disclosure Code.”¹¹⁵ The code requires each of the EFPIA’s 34 national member associations, such as the Association of the British Pharmaceutical Industry, as well as its 40 member companies to report all “Transfers of Value to healthcare professionals (HCPs) and healthcare organizations (HCOs).”¹¹⁶ The code does not require, however, the disclosure of “[m]eals and drinks, Medical Samples, Transfers of Value that are part of the ordinary course purchase and sales of medicinal products,”¹¹⁷ or “Transfers of Value related to over-the-counter medicines.”¹¹⁸ There are then some transfers of value that will go unreported that can still influence prescription patterns, which are left for individual countries to cover in their own regulations.

Beyond Europe, many countries have yet to implement a plan to address issues related to conflicts of interest. For instance, Canada does not have a national Sunshine Act equivalent, but recent issues with opioid prescriptions within the country’s medical community prompted a general plea for the creation of something like the United States Act.¹¹⁹ In May 2017, when the new national standards for prescribing opioids were published in Canada, it came to light that one-third of the people involved in drafting the guidelines had financial ties to the pharmaceutical industry.¹²⁰ The conflicts were only revealed because the university in charge of the new guidelines released a conflicts-of-interest disclosure on its website after they were published, prompting the Canadian federal government to launch an investigation into the guidelines.¹²¹ Sensing the direction the healthcare disclosure movement is headed, ten Big Pharma companies voluntarily released information about their dealings with Canadian doctors on their own websites.¹²²

India’s Department of Pharmaceuticals recently drafted the Essential Commodities (Control of Unethical Practices in Marketing of Drugs) Order 2017, which was meant to inhibit bribery of physicians by pharmaceutical companies.¹²³ Another code, previously passed in 2015, was voluntary, and therefore did little to curb corruption.¹²⁴ As V.K. Subburaj, Secretary of the Department of Pharmaceuticals for India, stated, “we found it very difficult to enforce it as a voluntary code. Hence,

115. European Federation of Pharmaceutical Industries & Associations, *EFPIA HCP/HCO Disclosure Code*, (June 6, 2014), <https://efpia.eu/media/25837/efpia-disclosure-code.pdf>

116. *Id.*

117. *Id.*

118. *Id.*

119. Karen Howlett, *Doctors Should Have to Publicly Disclose Ties to Drug Industry: Experts*, GLOBE & MAIL, <https://www.theglobeandmail.com/news/national/doctors-should-have-to-publicly-disclose-ties-to-drug-industry-experts/article35145979/> (last updated May 30, 2017).

120. *Id.*

121. *Id.*

122. Angela Mulholland, *Drug Companies Reveal info on Gifts to Doctors*, CTV NEWS, <http://www.ctvnews.ca/canada/drug-companies-reveal-info-on-gifts-to-doctors-1.3467928> (last updated June 20, 2017, 2:07 PM).

123. Tandon, *supra* note 104.

124. Rajdutt S. Singh & Pratiksha Chaturvedi, *India: Uniform Code of Pharmaceuticals Marketing Practices*, SINGH & ASSOCIATES, <http://www.mondaq.com/india/x/383754/food+drugs+law/Uniform+Code+Of+Pharmaceuticals+Marketing+Practices> (last updated Mar. 25, 2015).

the government is planning to make it compulsory.”¹²⁵ The new code, however, has faced significant opposition from the pharmaceutical company industry and was blocked by the country’s Law Ministry, who asserted that it could not be “passed under the current legal framework.”¹²⁶

While the exact effect these bills and acts will have on the industry remains unclear, they warrant attention. Despite the seeming ineffectiveness of some of these measures (perhaps because of their voluntary nature and lack of adverse consequences should the companies not adhere to the guidelines), other countries’ attempts to establish regulatory oversight over Big Pharma and physicians are worth monitoring. This highlights the fact that this is not a U.S. specific disease but one infecting a large portion of the world, and by keeping track of which treatments turn out to be the most effective, a cure might be found.

VI. THE CURE

While various solutions, like medical journals and professional societies sponsoring CME events instead of Big Pharma, have been recommended to deal with some of the problems,¹²⁷ the only real “cure” is enacting a complete ban on certain transfers of value between physicians and pharmaceutical and device manufacturers. A limited ban on certain items or transfers of value might provide a temporary solution, but it will not cure the disease. Providing federal funding for research facilities and studies could be a legitimate solution if not for the fact that each pharmaceutical company already funds their own studies and hires researchers who undoubtedly feel pressured to slant their findings favorably towards the sponsoring company. But, banning select items will not eliminate a physician’s incentive to prescribe one drug or device over the others. Big Pharma, and even “Little Pharma,” can find ways around such restrictions, as it has been shown. Therefore, a total ban on some transactions is the only solution strong enough to ensure that all symptoms of the disease are eradicated.

One other possible solution would be to require that all physicians disclose any interest that relates to the treatment they prescribe directly to the patient. This would allow the patient to make an informed decision concerning their healthcare and could deter physicians from forming relationships with Big Pharma if mandatory disclosure is required. The downside is that not all patients would view the relationship as problematic or a sign of a conflict of interest.¹²⁸ In addition, the form of the disclosure itself would have to be regulated since the physician would be the one relaying the information. If left up to each individual physician, the disclosure might take many forms, and the conflict of interest could lead them to downplay the amount or level of their involvement.

125. Sanjay Dhawan, *Uniform Code of Pharmaceuticals Marketing Practices*, PRICE WATERHOUSE COOPER (Jan. 2015), http://businessdocbox.com/Human_Resources/72123724-Uniform-code-of-pharmaceuticals-marketing-practices.html.

126. Aesha Datta, *Govt Refuses to Divulge Details of Wrangle over Pharma Ethics Rules*, BUSINESSLINE (Sept. 27, 2017), <http://www.thehindubusinessline.com/companies/govt-refuses-to-divulge-details-of-wrangle-over-pharma-ethics-rules/article9876351.ece>.

127. Halperin, Hutchinson & Barrier, *supra* note 36, at 1482.

128. Weinfurt et al., *supra* note 84.

Total bans on some items—like gifts, trips, and meals—makes sense, as they have no legitimate alternative purpose, especially in the quantities currently dispensed. Physicians are more than capable of purchasing their own lunch and dinner every day, as well as any expenses incurred for CME seminars. Items that directly benefit the patient seem to cloud the issue, and free drug samples are meant to entice. This is simply a way Big Pharma can incentivize physicians to prescribe new and expensive drugs in the hopes of getting the patients familiar with them, which will hopefully increase sales. That is hardly a compelling reason to continue the practice, and patients will be better off overall if their physicians make decisions based on whether the drug is in the best interest of the patient, rather than if it is free. Patients have enough concerns to deal with; they do not need the additional concern of if they will recover in spite of their physician's treatment.