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The Physician Payments Sunshine Act and the Problem of Pharmaceutical Companies' Influence Over Prescribing Physicians

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Abstract

Recently, concerns over physicians' conflict of interest have increased as the details of some doctors' consulting relationships with pharmaceutical companies surface. In an effort to cleanse medicine of egregiously conflicted doctors, Senator Grassley proposed the Physician Payments Sunshine Act ("PPSA") in the Senate last year. The Act mandates reporting of uncommonly large payments by drug companies to doctors, but does not confront the panoply of more subtle yet more powerful methods the drug industry uses to influence prescriber behavior. This paper argues that industry-sponsored CME, small gifts, drug samples and drug detailers unconsciously influence physician prescribing behavior, and that the PPSA and reporting requirements in general are a particularly poor way to deal with physician conflict of interest. This paper also examines the probable failure of professional codes of ethics and criminal statutes to limit conflicts of interest, and concludes that the only real solution to the problem is to prohibit gifts and direct pharmaceutical company sponsorship of physicians' activities.

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I. Introduction

Between 1993 and 2002, there was an approximately six-fold increase in the number of outpatient office visits by children and adolescents that included the prescription of one or more antipsychotic medications.\(^1\) Newer antipsychotics, known as “second-generation” or “atypical” antipsychotics, comprised over 92% of the antipsychotics prescribed to youth between 2000 and 2002,\(^2\) despite the fact that the only antipsychotic medications approved by the Food and Drug Administration ("FDA") for use with children are haloperidol (Haldol), thioridazine hydrochloride (thorazine), and pimozide, all older antipsychotics approved for certain limited diagnoses.\(^3\)

By 2006, public attention focused on the possible side effects of using atypical antipsychotics on children. In that year alone, the FDA received reports of at least 29 children dying and at least 165 more suffering serious side effects where antipsychotics were the primary suspects.\(^4\) The New York Times reported that antipsychotics could cause rapid weight gain and might put children at risk for diabetes.\(^5\) Yet, at the same time, physicians like Dr. Melissa DelBello, associate professor of psychiatry at the University of Cincinnati, were telling parents that they felt atypicals were “effective in children with bipolar [disorder] and [we] have some data to show that.”\(^6\) Dr. DelBello studied children who took both Depakote, a medication approved for the treatment of bipolar disorder in adults, and Seroquel, an atypical antipsychotic,

\(^2\) Id.
\(^3\) Id. at 680.
\(^6\) Id.
and reported that Depakote “is more effective for the treatment of adolescent bipolar mania” when used in combination with Seroquel. Dr. DelBello’s results were then reviewed by a committee of prominent experts, from whom they received the highest possible rating for scientific rigor.

The fine print, however, tells an entirely different tale. Dr. DelBello and Dr. Kowatch, the head of the committee that approved DelBello’s study, were sponsored to give talks by AstraZeneca, the maker of Seroquel. When asked about the amount of financial support she received, Dr. DelBello lied and said she “didn’t make very much”: disclosures to the University of Cincinnati showed that AstraZeneca paid her $100,000 in 2003, $80,000 in 2004, and $100,000 from 2005 to 2007. This is an example of the recruitment and sponsorship of physicians by drug companies, whether through “speakers bureaus” or “consulting” arrangements, which is easily accomplished and may be quite common. An even more dramatic example of industry sponsorship is that of Dr. Joseph R. Biederman, perhaps the most influential doctor when it comes to determining whether children are mentally ill. Dr. Biederman helped win his institution over $287 million worth of research grants from the

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7 Industry’s Role, supra note 4.
8 Id.
9 Id. In fact, DelBello received payments from the makers of all five atypical antipsychotics. Id.
National Institute of Health, which mandates reporting of consulting, yet Biederman failed to report at least $1.6 million worth of such fees.\textsuperscript{14}

The personal financial ties of doctors involved in medical research to drug companies suggest potential conflicts of interest ("COI"). COIs occur when physicians have motives or are in situations from which reasonable observers could conclude that the moral requirements of the physician’s roles are or will be compromised.\textsuperscript{15} The examples of Dr. DelBello and Dr. Biederman involve areas of research which are novel and therefore have a high potential for influence over the medical community; they also involve a great deal of money. Both of these factors should lead a reasonable observer to conclude that these physicians compromised their moral requirements in some way, and therefore had a conflict of interest worth knowing about.

In fact, these cases, along with several other similarly egregious examples, led Senator Charles Grassley and Herb Kohl to propose the Physician Payments Sunshine Act ("PPSA") of 2007,\textsuperscript{16} which would mandate the reporting of certain payments to physicians by drug and medical device manufacturers.\textsuperscript{17} The PPSA’s co-sponsors observed that “the lack of transparency [of payments] is undermining the public’s confidence in the integrity of their physicians,” and, “[t]ransparency will help make the pharmaceutical and medical device industry more accountable to the public and that’s good for public safety and public confidence.”\textsuperscript{18}

Transparency of large payments itself, while noble and needed step in the right direction, is no panacea to the problem of physicians’ COIs. There are several links in the chain between


\textsuperscript{16} S. 2029, 110th Cong. (2007).

\textsuperscript{17} \textit{Drug Pay}, supra note 14.

Dr. DelBello and an actual prescription, and the drug industry pours much of its resources into convincing everyday doctors in clinics and offices to prescribe its drugs. This paper argues that the drug industry’s influence over physicians is much more pervasive than multi-million-dollar consulting arrangements and research grants: it involves the use of drug company representatives, drug samples, industry-sponsored Continuing Medical Education (“CME”), and smaller gifts to influence the behavior of prescribing physicians. The PPSA may shed light on flagrant corruption, but is written to leave the most common influential practices undisturbed. This calls into question whether or not reporting on more subtle influences is an effective strategy toward eliminating COI, and this paper takes the position that reporting, by itself, does not work to eliminate COI and has little practical benefit. Reporting requirements should be used in conjunction with stronger legal and policy-based tactics in the fight against conflict of interest.

Part II of this paper examines the marketing strategies drug companies use to influence prescribers and demonstrates that physicians are unconsciously biased by numerous forms of drug company promotion. Part III explains the development of the PPSA and details how it fails to achieve transparency in several important areas. Part IV looks at reporting requirements under similar state laws and at public attitudes toward disclosed conflict-of-interest information in order to demonstrate how reporting requirements generally fail to eliminate conflicts of interest. Lastly, Part V considers two alternatives to reporting laws: professional COI policies and applying existing legal frameworks, and concludes that the only real solution is to curtail certain practices entirely.
II. The Landscape of Drug Industry Influence Over Prescribing Physicians

In 2004, the pharmaceutical industry spent $21 billion in promotions, which averages out to approximately $30,000 per physician in the country, with 94% of physicians reporting having some financial involvement with the industry. Advertising a product to physicians is different that any other type of marketing: it involves a combination of direct-to-physician advertisements, direct visits to physicians by pharmaceutical sales representatives (so-called “detailing”), and gifts to physicians and their institutions, as well as sampling (the provision of drugs without cost) and sponsorship of physicians meetings and events, including Continuing Medical Education ("CME"). Of the drug industry’s annual budget, the largest chunk of change is devoted to detailing and samples.

A typical doctor's office is visited by several drug detailers every week. Detailers are trained to befriend a physician, learn as much as possible about his or her prescribing habits, and use that information to drive home a message: that the drug is beneficial, safe, and should be

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19 Dr. Joseph R. Lex, *The Physician-Pharmaceutical Industry Relationship*, 18 J. L. & Health 323, 326 (2005); but see Marcia Angell, *The Truth About the Drug Companies* 139 (2004) (arguing that the GAO numbers often relied upon for these figures do not account for educational activities and are therefore far lower than what the industry actually spends on promotions). Dr. Angell puts the figure around $35 million. *Id* at 140.

20 See Allison T. Burtka, *Drug Companies Go Too Far to Influence Doctors, Critics Say*, 43 TRIAL 14 (October 2007).


23 Angell, *supra* note 19, at 139.


25 Angell, *supra* note 19, at 121.

26 *Id.* at 128.
prescribed. An experienced detailer can identify the personality-type of the physicians he is
dealing with, as well as the physician’s importance (i.e. volume of prescriptions written), and
utilize approaches that coordinate with that physician’s needs and preferences. Despite the
detailer’s sophistication, a survey of studies by Manchanda and Honka found that physicians’
attitudes towards drug detailers was either negative or neutral, and physicians seem to understand
that they can be unduly influenced by detailing. One study concluded that more than 90% of
physicians surveyed understood that detailers’ goal was drug promotion, while only 37% of
physicians saw physician education as their goal. However, physicians tend to believe that
they can extract the information about a drug that they need from a detailer, even though most
studies show a positive correlation between detailing efforts and prescribing behavior, and
physicians tend to confuse the inaccurate statements of drug detailers with the accurate ones.

Verbal exchanges, presentations, and doling out scientific findings are not the only
weapons in the drug detailer’s arsenal: skeptical doctors must be plied in other ways. Gift-giving
is one such avenue. Gifts that health care professionals receive may range from items of
negligible value, like pens and notepads, to large gifts such as luggage or even vacations.

27 Adriane Fugh-Berman & Shahram Ahari, Following the Script: How Drug Reps Make Friends and
Influence Doctors, 4 PLOS MEDICINE 621, 621-23 (2007).
28 Id.
29 Manchanda & Honka, supra note 22, at 787-91, 809; see Ned Lurie et al., Pharmaceutical Representatives
in Academic Medical Centers, 5 J. GEN. INTERN. MED. 240 (1990).
30 See David Strang et al., National Survey on the Attitudes of Canadian Physicians Toward Drug-Detailing
31 Manchanda & Honka, supra note 22, at 808-10.
32 M.G. Ziegler et al., The Accuracy of Drug Information from Pharmaceutical Sales Representatives, 273 J.
AMER. MED. ASS’N 1296, 1296-98 (1995) (finding that drug representatives made 11% inaccurate statements at one
conference, which were remembered by doctors later as being accurate 26% of the time); see also Lex, supra note
19, at 331.
33 Dana Katz et al., All Gifts Large and Small: Towards an Understanding of the Ethics of Pharmaceutical
Larger gifts are considered by physicians to be ethically problematic, either because they fear that expensive gifts create the appearance of impropriety, or because they do not want to pass on gift’s expense to their patients, and are banned or restricted in a number of ways. Smaller gifts, however, are more likely to be considered appropriate than larger gifts, and are therefore thought of by physicians as having little or no effect on their judgment.

Detailers, though, see small gifts as part of an overall strategy in the fight to win over physicians. Small items are a form of “carefully calculated generosity” meant to create a sense of shared generosity and obligation in the recipient physician. For example, fine food, combined with flattering behavior, is one of the most common tools detailers use to foster cozier working relationships with physicians, by giving the detailer a captive audience to whom they can chat or even lecture. A physician at a conference may be given a bag with the insignia of one drug maker, which he uses to collect promotional items from a host of other companies, all the while wearing lanyards, hats, and backpacks emblazoned with brand names, and perhaps even personalized in some way. The point of such “reminder items” is not to win over a physician based on his or her rational judgment; rather, it is to attack his or her subconscious with constant promotions that bribe the doctor without being perceived as a bribe.

34 W. Paul McKinney et al., Attitudes of Internal Medicine Faculty and Residents Toward Professional Interaction with Pharmaceutical Sales Representatives, 264 J. AM. MED. ASS’N 1693, 1695 (1990) (finding that 50% of faculty and 42% of residents thought gifts over $100 to be likely to influence a physician’s behavior).
36 See Part V.A., infra.
37 Steinman et al., supra note 35, at 555.
38 Katz et al, supra note 33, at 40.
39 Fugh-Berman & Ahari, supra note 27, at 621.
40 Katz et al, supra note 33, at 41.
41 Kassirer, supra note 12, at 10.
42 See id. at 2-4.
43 Fugh-Berman & Ahari, supra note 27, at 623.
Social science data confirms what the drug reps already know: that physicians are, in fact, quite susceptible to influence by the use of smaller gifts. Receiving gifts is associated with positive physician attitudes towards pharmaceutical representatives. In fact, the receipt of a gift, the number of gifts received, and the relevance of such gifts to the physician's practice have a positive correlation with physicians' belief that they cannot be influenced by such gifts. Thus, the receipt of a number of tote-bags containing note-pads, stethoscopes, and timers can work to break down a physician's critical reasoning skills, especially those physicians who believe themselves immune to such influences. Perhaps the most interesting finding about physicians is how many believe themselves to be “above the influence,” yet consider their colleagues more susceptible. Steinman et al. found that while only 16% of the respondents in their study said that other physicians were unaffected by pharmaceutical representatives, 61% said their own behavior was immune. This finding reinforces the conclusion that physicians experience a severe méconnaissance, or misapprehension of their own limitations when it comes to susceptibility from minor sources.

Similar to small gifts, drug sampling is the "most important gift[]" used by detailers to “gain entry into doctor’s offices, and to habituate physicians to prescribing targeted drugs,” and

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44 See Jason Dana & George Loewenstein, A Social Science Perspective on Gifts to Physicians From Industry, 290 J. AMER. MED. ASS’N 252, 254 (2003) (“The sheer ubiquity of trinkets given by pharmaceutical companies is evidence of their effectiveness; why else would profit-minded companies continue to provide them?”).
45 Brennan & Rothman, supra note 15, at 431.
47 See Katz et al., supra note 33, at 42-43.
48 Steinman et al., supra note 35, at 554.
49 Angell, supra note 19, at 129.
studies consistently show that sampling can influence prescriber choice. Sampling has multiple benefits to a detailer: it ingratiates the detailer with the physician, who can prescribe the drug and use samples as charity, but also ingratiates the physician with the patient, who receives a medication under patent free of charge. Samples can be used by the doctor personally or for his family's use, even if such use is not intended. Also akin to a gift is pharmaceutical industry sponsorship of CME, usually via private medical education and communication companies (MECCs), who plan the meetings, prepare teaching materials, and procure speakers. The MECC industry resulted from physicians' growing responsibility under state and local law to continue their educations, and the drug industry's eagerness to provide CME as a marketing platform. CME sponsorship, as well as the travel and lodging that so often accompany physicians' attendance at educational symposia, have been shown to lead to increased prescription of the sponsor's drug.

Assuming that physicians (perhaps excluding interns) are, indeed, wealthy enough that small gifts, meals or even samples would not be enough to make them feel a conscious moral obligation strong enough to overcome professional judgment, we have yet to name another dynamic at play that can explain the data. Dana and Loewenstein attribute physicians' behavior to “self-serving bias” in perceptions of fairness, a form of unconscious self-interest that falls

50 Fugh-Berman & Ahari, supra note 27, at 624; Wazana, supra note 46, at 376 (“Accepting samples was associated with awareness, preference and rapid prescription of a new drug, and a positive attitude toward the pharmaceutical representative.”) (internal citations omitted)).
52 Angell, supra note 19, at 139.
54 See Arnold S. Relman, Separating Continuing Medical Education From Pharmaceutical Marketing, 285 J. AMER. MED. ASS'N 2009, 2009 (2001) (“Regardless of their technical pedagogic quality, most [CME] presentations are characterized by their friendly treatment of the company's drug. The company's mission is to sell its products, and it uses its participation in CME to further that end.”).
55 Wazana, supra note 46, at 376-77.
56 Relman bluntly states that most physicians could afford CME as well. Relman, supra note 54, at 2011.
short of real impropriety. They argue that conflicts of interest arise not because physicians seek out rewards, but because the rewards at issue “chang[e] the way physicians seek out and weigh information on which they later base their choices when they have a stake in the outcome.” If this “stake” is not financial, it may be the stake a physician has in his or her own sense of self-worth, the idea that he or she is both important and above the fray, that allows him or her to tolerate constant marketing.

Other authors look to the social dynamic at play, suggesting influenced physicians are obeying an unconscious “reciprocity rule” that anthropologists have long recognized in other contexts. As described above, it is the jovial atmosphere that detailers create in which gifts are given, and it is the number, just as much as the size, of the gifts, that count. Katz et al. use the example of the Hare Krishna's “benefactor-before-beggar” strategy to influencing donors to demonstrate how gifts, even small ones, attain a social/symbolic dimension. Samples fit well here, because the detailer entrusts the physician with them: the physician could sell the samples, use the samples personally or for his or her family's medical needs. If he or she does use samples illicitly, this creates a perhaps more powerful obligation still.

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57 Dana & Loewenstein, supra note 46, at 253-254.
58 Id. at 253.
59 For example, one study of medical students' attitudes found the following: “Most students perceive they are entitled to gifts. Many simultaneously think that sponsored educational events are likely to be biased, but are helpful. Most think that their prescribing is not likely to be influenced by these interactions and that their colleagues are more likely to be influenced. This combination of perceptions, along with the high exposure to these interactions . . . suggests that as a group they are at risk for unrecognized influence by marketing teams.” Fredrick Sierles, Medical Students' Exposure to and Attitudes About Drug Company Interactions, 294 J. AMER. MED. ASS'N 1034, 1040 (2005) (using the term “cognitive dissonance” to explain this phenomenon).
60 Brennan & Rothman et al., supra note 15, at 431; Katz et al., supra note 33, at 43-44; see also Kassirer, supra note 12, at 69-70.
61 Katz et al., supra note 33, at 44.
62 See Berger, supra note 51, at 56.
III. The Development and Inadequacy of the Physician Payments Sunshine Act

Originally introduced in the Senate on September 6, 2007, the PPSA’s stated purpose is to “amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.” The bill mandates that manufacturers of drugs or devices covered by under title XI report any “transfer of value, directly, indirectly, or through an agent . . . to a physician, or to an entity that a physician is employed by” to the Social Security Administration. A company must report the physician’s name, address, and the facility the physician is affiliated with, as well as the value of the transfer and its type: honorarium, medical education, gift, or food, to name a few. Reporting is done quarterly, and each covered company must also submit an electronic “Annual Summary Report,” which the agency must make publicly available and downloadable via a website. The summary reports, along with a report of any enforcement actions taken by the agency, are also submitted to Congress annually. The penalties for noncompliance are stiff, with fines ranging from $10,000 to $100,000 for each failure to report.

The version of the bill introduced in House of Representatives in 2008 overall expanded the PPSA’s coverage and gave it additional teeth. The 2007 PPSA defines of “payment or transfer of value” to include “anything of value that exceeds $25 . . . .” This section of the 2007 bill specifically excludes three categories of transfers from the PPSA’s requirements:

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64 Id. § 2.
65 Id.
66 Id.
67 Id.
68 Id.
70 S. 2029, 110th Cong. § 2.
product samples, “payment[s] or transfers of value made for the general funding of a clinical trial,” and a “transfer of . . . value to a physician when the physician is a patient . . . .”71 The House PPSA adds as an exception compensation to a physician solely employed by a drug company.72 The House version also adds to the definition of “transfer of value” a “dividend, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in a manufacturer . . . .”73 Most importantly, the House PPSA makes any drug company penalized for non-compliance ineligible for tax deductions relating to advertising during the year they were found to be in non-compliance, without reducing the amount of the civil penalty.74

A severely limited version of the PPSA reappeared in the Senate in 2008, though, this time with the imprimatur of the drug companies.75 First, the newest version reduces the penalty for non-compliance to $1,000 to $5,000 per failure to report, and $5,000 to $50,000 per knowing failure to report, with annual caps of $50,000 and $250,000, respectively.76 Second, although the $25 transfer-of-value reporting rule is still in effect, no reporting is required where the aggregate amount transferred to a physician is less than $500 per year, and “certain educational materials” are now excluded from coverage entirely.77 Third, the PPSA would now expressly preempt

71 Id.
72 H.R. 2056, 110th Cong. § 2.
73 Id. (excluding, however, a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c))).
74 Id. § 3.
77 Id.
similar state reporting requirements. The newest PPSA’s preemption provision establishes a uniform national reporting requirement, and led some of the largest drug manufacturers, including Eli Lilly & Co., Merck, AstraZeneca, and Johnson & Johnson, as well as several professional organizations, to support the bill.

Over time, the PPSA has been whittled down from an instrument adequate to accomplish its original mission, which was to achieve near-transparency of doctor-industry relationships, to a tool to collect information on multi-million-dollar consulting and other major financial relationships. Pharmaceutical companies' support of the bill is therefore unsurprising, given the continuing need for the industry to appear morally solvent following the revelations about Biederman and others, and the stake these companies have in their continued ability to market their products to most physicians. By specifically excluding samples, gifts under $25, and especially total gift-giving under $500 from its coverage, the PPSA gives in to the “common sense” notion that only high-value items have an influence on physicians that might be of concern to the public. Because it does not mandate reporting of funding for clinical trials or when the physician is solely employed by a drug company, the bill does not allow prescribing physicians interested in the validity of a study to research the connections of the study's authors to the drug industry. CME sponsorship may not technically be a “transfer of value” and does not require inclusion in a report. Most importantly, it is not difficult for companies to flout this law

78 Id.
79 Arvantes, supra note 75.
80 The recent uncovering of a consulting relationship between NPR medical radio show host Dr. Frederick K. Goodwin and GlaxoSmithKline prompted a Glaxo spokeswoman to comment: “We continue to believe that healthcare professionals are responsible for making disclosures to their employers and other entities, in this case National Public Radio and its listeners.” Gardiner Harris, Radio Host Has Drug Company Ties, NYTIMES.COM, November 21, 2008, http://www.nytimes.com/2008/11/22/health/22radio.html.
openly, because the overall cap in the newest PPSA limits fines to amounts that a major drug manufacturer can easily afford to pay.

IV. The Problems with Disclosure Strategies and the Need for Alternatives

The PPSA is riddled with exceptions and conditions that lead it to require less-than-full disclosure of the relationships between physicians and industry. In theory, a bill could emerge which would provide for more thorough disclosure of all of a drug companies' ties to physicians. It would ask drug companies to provide all of the detail that one could want about how they fund and influence the everyday practice of medicine. A question remains, however: are reporting laws an effective strategy by which combat physician conflict of interest? This section examines public attitudes toward conflict of interest, along with state laws mandating public disclosure, in order to make the argument that disclosure is generally an ineffective strategy.

A. Public Attitudes Toward Disclosed Information

While patients find gifts to be more inappropriate and influential than their physicians, and tend to be aware that physicians in general accept gifts, patients are largely unaware that their own physicians accept gifts.81 When actually confronted with a questionnaire describing a range of hypothetical gifts, patients found larger gifts more objectionable, just as physicians did.82 The difficulty here is that in the real world, information about physician practices must be acquired. In order for a patient to become aware of their physician's influences under a reporting law, they or someone they interact with must go on a website or read a report. If the patient does not suspect their physician of such an influence, they will never have a reason to inquire about

82 Id.
potential conflicts of interest. Patients do not have the expertise to determine whether or not their physician's opinions are biased,\textsuperscript{83} and do not subscribe to the idea that their physician can be influenced by unconscious bias.\textsuperscript{84} Thus, patients are in a particularly poor position to benefit from disclosure laws.

Even where there is knowledge of a disclosure, three additional factors make that disclosure ineffective. First, disclosures can have a sanitizing effect: they diminish both parties' moral obligation to eliminate the conflict of interest. Practitioners feel that they are absolved of responsibility under the principle of \textit{caveat emptor}.\textsuperscript{85} The disclosure itself gives an appearance of "good faith" on the part of the physician that itself suggests no ill will from the disclosed relationship.\textsuperscript{86}

Second, and more surprisingly, a study by Cain et al. revealed that disclosure of bias actually leads to a greater distortion of advice.\textsuperscript{87} Individuals were randomly assigned the role of either estimator or advisor. Estimators made money by accurately estimating the value of a jar of coins they viewed from a distance. Advisors saw the jar up close, and suggested values to the estimators, but were paid according to how high, not how accurate, the estimator's guess was. Half of the advisors were required to disclose their bias. Advisors who disclosed their bias to the estimators suggested far higher dollar values than non-disclosers. Although estimators who knew of their advisors' bias did tend to discount their advisors more often than the estimators who did not perceive any bias, the estimators' discounting was insufficient to offset the

\begin{footnotesize}
\item[83] Brennan & Rothman, \textit{supra} note 15, at 431.
\item[84] Dana & Loewenstein, \textit{supra} note 46, at 254.
\item[85] Daylian M. Cain et al., \textit{The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest}, 34 J. LEGAL STUDIES 1, 3 (2005).
\item[86] Brennan & Rothman, \textit{supra} note 15, at 431.
\item[87] Cain et al., \textit{supra} note 85, at 13.
\end{footnotesize}
additional bias caused by the fact of disclosure. The advisors (doctors) literally ended up making more, and the estimators (patients) less, when disclosure was part of the game. Thus, a patient to whom conflicts of interest are disclosed may feel that he can trust his physician more, even though the physician is still biased.

Third, the desire to obtain acceptable treatment may overcome the knowledge that one's prescriber is conflicted. A recent study by Hampton et al. reported that cancer patients were largely uninterested in learning about the conflicts of interest of the physicians conducting clinical trials for drugs they received. Patients in the study were relatively affluent, yet less than 15% would not have enrolled in the clinical trials if they had known of financial ties. Although most scenarios involving prescribers are less dire than experimental cancer drug trials, less affluent patients may experience a similar lack of choice in medical service. Indeed, given its pervasive nature, patients may see COI the "cost of doing business" and prefer to ignore it.

B. Experience with State-Level Reporting Laws

By 2007, five jurisdictions, the District of Columbia, Maine, Minnesota, Vermont, and West Virginia, have laws mandating reporting of pharmaceutical company payments to physicians. Only Vermont and Minnesota made payment information available to the public. These laws vary widely in thoroughness: West Virginia's law requires only a summary report of the total number of prescribers who have received an aggregate amount within specific dollar ranges which is delivered to a legislative committee, while Vermont's law requires

88 Id. at 17.
90 Id. at 2336.
reporting of “any gift, fee, payment, subsidy, or other economic benefit provided in connection with marketing activities” over $25, with specific exclusions. 93 Each of these laws excluded payments under $25 and free samples for patients, and most excluded medical conferences and clinical trials and research. 94

Even the Vermont and Minnesota laws, which have had by far the most impact, fail to provide the public with easy access to information about physician payments. 95 For example, the Minnesota law did not provide for easy access to payment information over a website, while the Vermont law had a “trade secrets” exception, allowing data designated as such to be masked from the public view, under which nearly 62% of total payments were cloaked. 96 The authors of the first study on state reporting laws concluded that while “legislation requiring disclosure of payments remains a reasonable policy initiative . . . given the significant problems we encountered attempting to gain access to and analyze Vermont and Minnesota disclosure data, requiring disclosure of payments may not be the singular and most effective means of minimizing the undue influence of companies over the medical profession.” 97 Therefore, the PPSA's proposed preemption of these laws is a major concession to the pharmaceutical industry only prospectively.

Theoretically, the PPSA actually eliminates these specific problems, as it could any number of other deficiencies in reporting or enforcement. However, there are some problems that can never be eliminated, such as the issue of payment categorization, which was an issue for the above study. So long as payments must be strictly kept within any pre-selected category of

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93 Lurie et al., supra note 91.
94 Id.
95 Ross et al., supra note 92, at 1220.
96 Id. at 1220-21.
97 Id. at 1222.
payment type, it may be impossible to differentiate the real purpose of the payment.98 For example, under the PPSA, a payment may be listed as “compensation” - but compensation for what? Is a payment listed as “food” part of an attempt to persuade a doctor to prescribe a new drug or lunch provided during a hard day of work?

The real problem with reporting requirements, however, is more basic: the information provided could be accurate or wildly inaccurate. Other than a third-party whistleblower, there is almost no way to check the accuracy of the reported information, as the authors of the study on state laws acknowledged. Companies in that study reported millions one year, and next to nothing the next, despite the presence of enforcement mechanisms.99 Physicians, most of whom believe that sponsorship cannot conflict them, have an active disincentive - the potential loss of sponsorship or exclusion from professional activities - to report COIs when their sponsors fail to report.100 The most extreme option, examining the tax returns of individual physicians, poses serious invasion-of-privacy concerns.101 Under the guise of a complete picture, reporting laws

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98 See id. at 1221.
99 See id. at 1222.
100 For example, the enforcement of heightened financial disclosure requirements for members of the FDA Drug Advisory Committee, which approves 25-30 new chemical entities a year, had no apparent impact on the rate at which Committee members reported COIs, merely upon the detail with which reported conflicts were described. Peter Lurie et al., Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings, 296 J. AMER. MED. ASSN 1921, 1924. Another area in which COI disclosure is crucial is medical and scientific journals, and it appears that here, too, disclosure of funding sources is considered voluntary. See Lisa Bero et al., Factors Associated with Findings of Published Trials of Drug-Drug Comparisons: Why Some Statins Appear More Efficacious than Others, 4 PLOS MED. 1001(2007) (finding that 50% of statin drug trials were funded by industry, yet 37% of total trials studied reported no funding source).
101 The President of the American Psychiatric Association, Nada Stotland, recently wrote of disclosure accuracy:

If pharmaceutical companies publish information about all payments to physicians, that would be one source, but how would we know it is accurate? . . . Is it reasonable to ask APA to go through the tax returns of every DSM participant and every member of every committee? Would the tax returns even be sufficient? Arline Kaplan, Senate Investigations Spread to APA and ACCME, PSYCHIATRIC TIMES, September 1, 2008, available at http://www.psychiatrictimes.com/display/article/10168/1290674.
will almost certainly lead a citizen to see what he or she wants to see when he or she actually logs on to check out his or her doctor's activities.

V. Alternative Strategies Toward Minimizing Physician Conflicts of Interest

Once potential conflicts of interest have been identified, there are three strategies one can pursue to curb them: legal restrictions (prohibiting the conflict), policy restrictions (managing the conflict), and disclosure (reporting the conflict).102 Policy-based solutions in the form of ethics codes have been pursued and often renewed, while few legally-based solutions have been tried. This section examines the problems with modifying existing legal and policy frameworks to combat industry's influence on prescribers, and proposes a more comprehensive plan.

A. Policy-Based Solutions and the Problems With Physician Self-Regulation

In 1990, the American Medical Association ("AMA") adopted guidelines regarding gifts from industry and published them in the *Journal of the American Medical Association*. 103 The Pharmaceutical Manufacturers Association, now the Pharmaceutical Research and Manufacturers of America ("PhRMA"), as well as number of other professional associations, endorsed these guidelines,104 and PhRMA published similar guidelines in 2002. The Accreditation Council for Continuing Medical Education ("ACCME") is responsible for ensuring

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the "content, quality, and scientific integrity" of all CME activities for which physicians can receive credit.105

Established policy guidelines generally reflect the attitude that the size (type, monetary value) of a gift determines its acceptability.106 The AMA guidelines list items of "minimal value" and items relating to the physician's practice as acceptable, and excludes gifts over $100. The guidelines are hardly more exact throughout - the acceptance of gift certificates is a "grey area" where "[i]t is up to the individual physician to make the final judgment."107 The AMA guidelines preclude physicians from seeking reimbursement or honoraria for attending a conference, yet allow industry sponsorship of a professional society's charity golf tournament or the payment of lodging for a consultant's spouse.108 PhRMA guidelines specify that items of modest value may be offered if they have a legitimate connection to healthcare, and allow meals and receptions to be paid for during legitimate CME.109

Industry justifies its support of these guidelines on a number of levels. Defenders of current ethical standards argue that physicians will self-regulate: they assess information from detailers and make informed choices based on competing considerations and, the distribution of AMA guidelines means physicians have more access to ethical standards than ever before.110 Funding for professional education is increasingly uncertain, and industry provides over $1

107 American Medical Association, Addendum II, supra note 103 (Guidelines 1 and 2).
108 Id. (Guideline 5).
110 Morin & Morse, supra note 104, at 54-57.
Physicians need the information drug companies help provide in order to keep up with scientific developments. Small gifts are merely a "courtesy" that do not cause influence, and can be seen as compensation for the valuable information that drug companies provide physicians.

It appears that the AMA guidelines had a dramatic initial impact following their 1990 debut, with many companies cancelling lavish dinners and direct cash payments to physicians. Yet there is evidence that the guidelines are still flaunted. Data from the Vermont and Minnesota reporting laws reveals that payments in excess of $100 for food and other purposes, all of which clearly violate the guidelines, were not uncommon. It is unlikely that a physician who feels he or she cannot be influenced by gifts of a certain size will look to an ethical code to determine whether or not he or she should accept a gift; conversely, a physician who puts his or her patients first will likely eschew overt influence. Current PhRMA and AMA guidelines reflect, rather than shape, physicians' notions about the acceptability of gifts and industry sponsorship. As we have seen, prevailing views on COI are simply unjustified.

Professional organizations are slowly changing, and in some cases these changes are less than willing. The newest version of the PhRMA guidelines, effective in 2009, offer more detailed advice and stringent standards. In response to Sen. Grassley's investigation,

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111 Holmer, supra note 105, at 2012.
112 Id. at 2013.
113 Morin & Morse, supra note 104, at 55.
114 Katz et al., supra note 33, at 46.
116 Ross et al., supra note 92, at 1221-22.
ACCME has announced plans to scrutinize more closely COI in CME and report commercial support of COI in real-time through a website. Pfizer and Glaxo are cutting sales forces, suggesting a rethinking of marketing strategy, but most likely in response to market conditions. The history of incremental and reactionary change, combined with the material support that industry provides professional organizations, lead to the conclusion that these organizations are fundamentally incapable of providing leadership in the fight against COI.

The AMA's 2001 campaign to promulgate its ethical standards, for example, was funded to the tune of $645,000 by numerous pharmaceutical companies, which suggests COI. The development of the PPSA is itself a response to the question, "Who is minding the minders?" Another problem is enforcement: although the AMA and other local professional organizations have the ability to sanction physicians, my research revealed no cases in which a physician was sanctioned. This could be because AMA rules are often less than bright-line, or because AMA membership has declined sharply in recent years (the latter change in response to the AMA's increased commercialization).

Short of a dramatic cultural shift within the medical community, policy-based solutions hold little promise.

B. Existing Legal Mechanisms: Informed Consent and Anti-Kickback Laws

1. Informed Consent

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118 Kaplan, supra note 101.
119 Brennan & Mello, supra note 21, at 1256
121 See Kassirer, supra note 12, at 103-106.
122 Id. at 128.
123 Orentlicher, supra note 115, at 592.
124 Kassirer, supra note 12, at 127.
There are two dominant approaches to informed consent law: the medical-custom standard and the reasonable patient standard. In an example of the former, the Kansas Supreme Court wrote in 1960 that "Anglo-American law starts with the premise of thorough-going self determination," and that doctors have a duty to make "those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."125 The latter approach was adopted in Canterbury v. Spence: the doctor has a duty to disclose any "material risks" of treatment that a reasonable patient would consider significant.126 The idea that the risks of treatment could include COI was actually adopted by the California Supreme Court in Moore v. Regents of the University of California, holding that doctors had a duty to disclose their research interest in developing a cell line from the patient's spleen cells and their financial interest in patenting the cell line.127 Under the Spence theory of informed consent, the court in Moore reasoned that external incentive a physician receives for prescribing a treatment, even if the treatment is appropriate, is a factor the reasonable patient would want to consider.128

The difficulty with applying the Moore analysis to prescribers' COI is that is a redux of reporting strategies, perhaps with some advantages, but also with additional pitfalls. Informed consent disclosures may be feasible for consultancies or stock ownership, but it would be almost impossible for a physician to recount to a patient the extent to which drug companies market to him or her, if he or she is even conscious of marketing as an influence. As argued above, disclosures of any kind are unlikely to diminish either COI or harm to the patient. The major advantage of broadening informed consent law to include COI is that it provides for redress

126 464 F.2d 772, 786-87 (D.C. Cir. 1972).
128 Id. at 483-84.
when a failure to disclose is material and leads to injury. Direct disclosure to patients is also more efficient than reporting: the patient need not first suspect the physician of conflict. The major problem with the tort solution is that common-sense notion that the size or value of the influence is proportional to its influence is likely to influence a trier of fact; thus, the subtle influences this paper argues are pervasive cannot be redressed in tort.

2. **Anti-Kickback Law**

The purpose of the Medicare anti-kickback statute is to make unlawful the payment or receipt of any "remuneration" in exchange for purchasing, prescribing, or recommending any item or service, or referring any patient for treatment, for which payment may be made under Medicare or Medicaid.\(^{129}\) Technically, anti-kickback laws may be triggered whenever one material purpose, even if it is not the dominant purpose, of a payment is to cause a physician to prescribe, or to reward a physician for prescribing, any drug Medicare covers.\(^{130}\) Applied liberally, such statutes would cut a wide swath through COI practices, because almost any gift or sample (and perhaps samples especially) could at least be seen as inducing a physician to prescribe a certain drug. However, there are a few reasons that the anti-kickback law has been applied only in limited circumstances.

The administrative body that oversees the application of these laws has ruled that some benefits accorded to physicians are too *de minimus* to be likely to influence a physician's judgment, and therefore could not be intended to do so.\(^{131}\) This line of reasoning does not

\(^{129}\) 42 U.S.C. § 1320a-7(b).

\(^{130}\) See, e.g., *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1984); *United States v. Katz*, 871 F.2d 105, 108 (9th Cir. 1989).

withstand scrutiny: if the compound effect of a series of small influences is to shift a physician's prescribing habits, or the prescribing habits of a class of physicians, then such influences could well be intended to have a material effect. Another problem with anti-kickback laws is that they are rarely applied, and when a case is prosecuted, it is likely to be a flagrant abuse where the clear or exclusive intent to induce is masked only by a sham relationship.132 Proving the intent to induce in more common situations could be tricky, and prosecutions must be cost-effective due to limited resources with which to fight industry corruption. Ultimately, anti-kickback laws may be too blunt an instrument with which to combat COI, given the substantial civil and criminal penalties that follow prosecution (and can even be imposed administratively in the absence of a conviction).133

C. Conclusion: A Unified Proposal to End the Current System

Gift-giving is central to business and to our way of life. Yet, there are professionals who are not permitted to accept gifts: sports referees, judges, prosecutors, journalists, and others in whom we place a great deal of trust to make objective decisions.134 Doctors do not sell us drugs or medical devices: they prescribe them to us. Accordingly, a series of proposals should be enacted into law, or adopted by the industry and combined with strict enforcement, in order to end the common practices that lead to COI.

- Small gifts and free meals should be prohibited.135 This will eliminate the influence gifts have, as well as the "grey areas" that trouble physicians.

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132 See Angell, supra note 19, at 130-32.
133 Bulleit & Krause, supra note 131, at 284.
134 Katz et al., supra note 33, at 47.
135 Katz et al. argue for an exception based on physicians who have longstanding personal relationships with drug or sales representatives. Id. However, such exceptions are not allowed when referees and judges are concerned, and muddy the waters when it comes to perception of fairness and application in individual cases: "longstanding personal relationship" is at best a malleable phrase.
• Pharmaceutical samples should be pooled and distributed to the neediest patients.

• Drug manufacturer sponsorship of CME should be prohibited; in its place, companies wishing to support CME should pool their money and give it directly to ACCME, which would distribute it according to the needs of its members. This could include physicians travel costs.136

• Ethics trainings should be made part of the medical school curriculum.137

• Drug detailers' access to doctors offices should be limited to once a month, so that they can still provide information on their company's drug to the physician.

The virtue of such a system is its simplicity. It balances the need of the industry to appear as the benefactor of medicine and the need for physician education with COI concerns. This paper has attempted to document COI-creating influences other than consultancies and research grants. A more effective proposal to deal with those influences would include stricter monitoring: consultancies might be legitimate and research must take place. Gifts to physicians and incessant dogging by detailers need not exist. When doctors are seen as arbiters, and unconscious influences are understood to be real, a proposal of this type may well succeed.

137 See Sierles et al., supra note 59, at 1040 (finding that medical students attitudes towards outside influences are currently framed by older physicians' behavior). This proposal is meant to cause a "break" with practices that were accepted by the previous generation of physicians.