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THE PHYSICIAN PAYMENT SUNSHINE ACT: AN IMPORTANT FIRST STEP IN MITIGATING FINANCIAL CONFLICTS OF INTEREST IN MEDICAL AND CLINICAL PRACTICE

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I. INTRODUCTION

"Sunlight is said to be the best of disinfectants; electric light the most efficient policeman."1

After six months of trying to pull her twenty-six-year-old son, Dan Markingson, out of a clinical trial testing antipsychotic drugs sponsored by pharmaceutical company AstraZeneca, Mary Weiss left a voicemail for the trial coordinator, asking “[do we have to wait until he kills himself or someone else before anyone does anything?]”2 Less than two weeks later, her son committed suicide.3 After being diagnosed with schizophrenia and suffering from delusions for over a year,4 Markingson gruesomely killed himself in a halfway house shower.5 Making Markingson’s death even

* Thank you to my family for your constant support, and thank you Sarah for everything, you are a saint. I love you.

1. See Louis D. Brandeis, Other People’s Money, HARPER’S WEEKLY, Dec. 20, 1913, available at http://www.law.louisville.edu/library/collections/brandeis/node/196 (supporting the supposition that publicity is a remedy for “social and industrial diseases”).


3. Elliott, supra note 2; Olson and Tosto, supra note 2.

4. See Olson and Tosto, supra note 2 (explaining that Weiss was surprised and somewhat skeptical of her son’s diagnosis, given their family history of bipolar disorder).

5. Elliott, supra note 2. “Dan had stabbed himself to death with a box cutter, ripping open his abdomen and nearly decapitating himself. His body was discovered in the early hours of the morning by a halfway-house worker, along with a note on the nightstand that said, ‘I left this experience smiling!’” Id. See also Second Aff. of Harrison G. Pope, MD., mph at ¶ 17, Weiss v. Bd. of Regents for the Univ. of Minn. (Minn. Dist. Ct. Nov. 30, 2007) (No. 27CV07-1679), 2007 WL 5465856 (describing Markingson’s death as a “psychotic,
more shocking is the fact that that his caring physician's medical judgment may have been compromised by his own financial and professional self-interest.8

After an uneventful childhood and early adulthood,7 Dan's behavior grew increasingly bizarre and destructive.8 When Dan threatened to kill his mother, she took Markingson to the hospital for treatment, a decision that ultimately led to his enrollment in the clinical trial and his suicide.9 His treating physician and psychiatrist at Fairview University Medical Center,10 Dr. Stephen C. Olson, also served as a professor with the University of Minnesota's psychiatry department.11 After obtaining a court order to have Markingson involuntarily committed to a state treatment center due to his inability to make decisions about his own care,12 Dr. Olson stayed the commitment on the condition that

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6. See Elliott, supra note 2 (intimating that the primacy of the clinical research system has been subverted by market forces).

7. Elliott, supra note 2. Dan and his family were natives of the Minneapolis-St. Paul area. Id. Dan graduated high school, earned a perfect score on the verbal portion of the SAT, and graduated from University of Michigan in 2000 with a degree in English. Id. Dan then moved to Southern California in the hopes of starting a career as a screenwriter. Id.

8. Elliott, supra note 2. When Mary visited Dan in California, she discovered that Dan had encircled his bed with wooden posts, salt, candles and money in order to protect himself from evil spirits. Id. He then showed his mother a burn spot on his apartment's carpeting, claiming that aliens had done the damage. Id. Dan then became convinced that the Illuminati were orchestrating "an event" in Duluth, Minnesota. Id. At this "event," Dan was convinced that he would be called upon to murder many people. Id. Desperate for her son to return to Minnesota, she sent him emails pretending to be the guardian angel spirit of his dead grandmother, and suggested that the storm would begin soon in Minnesota. Id.

9. See Elliott, supra note 2 (stating that on November 12, Mary called the police and took Dan to the hospital after Dan said he would kill her if he was called upon to do so).

10. Olson and Tosto, supra note 2. Dr. Olson and Dr. Charles Schulz, head of the University's psychiatry department, helped launch Station 12, a unit within Fairview Hospital that was created in order to both treat psychotic patients and to screen them for research studies conducted at the University. Id. Prior to the creation of Station 12, Dr. Olson had only managed to recruit one research subject in six months, and was pressured by Quintiles, the Clinical Research Organization that managed the study at the University, by placing the program on probation. Elliott, supra note 2. But then, over the first nine months of Station 12's existence, Dr. Olson had recruited twelve patients. Id. Dr. Olson's recruiting was then held out as an example by Quintiles of how an under-performing program could turn around their recruitment numbers. Id.

11. Elliott, supra note 2.

12. Olson and Tosto, supra note 2. Three days after Dr. Olson recommended involuntarily commitment, a clinical psychologist also recommended commitment, noting that Dan had threatened to "slit his mother's throat." Elliott, supra note 2.
Markingson agree to follow the doctor’s treatment plan, Dr. Olson’s plan was to enroll Markingson in the Comparison of Atypicals in First Episode study (“CAFE”), a clinical trial sponsored by drug maker AstraZeneca at the University of Minnesota. The purpose of the CAFE study was to compare the effectiveness of AstraZeneca’s popular antipsychotic drug Seroquel with two competing antipsychotic drugs. Markingson consented to the treatment plan, despite the fact that just days earlier, a court had ruled that he was unable to make decisions about his own care.

Markingson’s participation in the study left him with fewer treatment alternatives, since he was required to adhere to the trial’s drug regimen. Markingson’s condition deteriorated during his six months enrolled in the study. Despite Ms. Weiss pleading for Dr. Olson to change his treatment or withdraw Markingson from the CAFE study altogether, Dr. Olson requested an additional six-month stay of commitment. Shortly after Dr. Olson’s request, Dan committed suicide.

AstraZeneca compensated Dr. Olson and the University of Minnesota psychiatry department for each new recruit brought

13. MINN. STAT. ANN. § 253B.095(a) (West 2009). In Minnesota, involuntarily committed persons may have their commitment stayed if they agree to comply with their psychiatrist’s treatment plan. Id. After a hearing and before a commitment order has been issued, the court may release a proposed patient to the custody of an individual or agency upon conditions that guarantee the care and treatment of the patient. Id.

14. Olson and Tosto, supra note 2. According to Ms. Weiss, “discussions about research started right away at the hospital.” Id.

15. Elliott, supra note 2.

16. Id. Mary was shocked that Dan was enrolled in the study on the basis of his consent, given that, just days before, he was ruled to not have capacity to make decisions about his own care. Id. She subsequently made numerous attempts to withdraw him from the CAFE Study. Id.

17. Id. The CAFE Study tested the effects of antipsychotic drugs Seroquel, Zyprexa, and Risperdal in subjects experiencing their first psychotic episode. Id. The study called for the test subjects to take only one of the three drugs for a year. Id. It barred subjects from being taken off their assigned drug. Id. It prohibited switching to another drug studied in the trial. Id. It restricted which supplemental drugs subjects could take in order to manage the symptoms of side effects, such as depression. Id. The combined effect of all the restrictions on test subjects meant that they had fewer therapeutic options available to them as a result of taking part in the study than if they were not in the study. Id.

18. Id. Four months after Dan’s entry into the study, notes from workers charged with caring for Dan at the halfway house described how his thoughts were still “delusional and grandiose.” Id. In addition, his appearance was disheveled, isolated and withdrawn, and lacked insight and self-awareness. Id.

19. Id. Dr. Olson noted that Dan would be in danger if treatment were to end. Id.

20. Supra note 5 and accompanying text.
into the study to the tune of over $15,000 per recruit. Dr. Olson’s financial ties with AstraZeneca ran deeper; he was paid $240,045 by the company between 2002 and 2008 for speaking engagements, consulting, and research grants. Regardless of whether Dr. Olson’s medical judgment was actually impaired with respect to Dan Markingson’s medical care, his financial stake in the CAFE study raises questions over physicians’ commitment to their patients in the face of outside financial interests.

The steadily stronger ties between physicians and the pharmaceutical industry have roused the public’s attention. As a result, in March of 2010, Congress passed the Physician Payment Sunshine Act (“Sunshine Act” or “Act”), mandating that physicians report to the Secretary of Health and Human Services (“Secretary”) all payments over $100 from pharmaceutical companies. The Secretary must then aggregate and post this data to an easily searchable and downloadable public website. In a word, Congress mandated transparency.

This Comment will evaluate whether the Sunshine Act’s transparency measures will negate the deleterious impact that physician-pharmaceutical financial relationships have on patients’ trust in physicians. Part II of this Comment will review the relevant duties that a doctor owes to his or her patient, and the extent to which the pharmaceutical industry potentially undermines those duties by influencing that doctor’s actions and judgments. Part III will survey the relevant provisions of the Sunshine Act and evaluate their likely effect on the doctor-patient relationship, as well as the industry-physician relationship. Part IV will propose additional duties on pharmaceutical companies and physicians that more effectively protect patients’ interests.

II. BACKGROUND

A. Physicians’ Duties Owed to Patients—Primary and Secondary Interests

The physician-patient relationship is characterized by trust, service, and an imbalance of power. It is considered a fiduciary

22. Id. While fees for speaking engagements and consulting are paid directly to the physician, money for research grants is paid to the university. Id.
23. 42 U.S.C. § 1320a-7h(a) (2010).
24. Id.
25. Id.
26. ARTHUR B. LAFRANCE, BIOETHICS: HEALTH CARE, HUMAN RIGHTS, AND THE LAW 691 (2d ed. 2006). Trust is a critical aspect of the therapeutic relationship between physician and patient. Id. Under traditional healing theory, patients must bare themselves both physically and emotionally in order for the physician to properly diagnose an illness. Id. Analysts consider
relationship, defined by the duties owed by the physician to the patient.  

27 Physicians are entrusted with power that must be used for the benefit of his or her patient.  

28 To that end, physicians rely on their specialized medical knowledge and expertise in caring for and advising their patients.  

29 But they also retain substantial control over patients' access to medical resources.  

30 Because patients are usually ill and vulnerable when seeking a physician's advice and care, patients are highly dependent on the physician's judgment.  

31 Patients rely on their physicians to provide advice and judgment that is wholly loyal to the patient's therapeutic needs and unaffected by any other interests.  

Conflicts of interest arise when a secondary interest creates a

the therapeutic effect of this trust not just effective, but necessary. Frances H.  


See also Karine Morin and Jacqueline M. Darrah, What You Should Know About Gifts to Physicians from Industry: Module 1: Overview of Ethical, Professional, and Legal Issues, 23, AMR. MED. ASS'N (July 2003), available at http://www.ama-assn.org/ama1/pub/upload/mm/384/july03umppt.ppt  

(explaining that as a result of the fiduciary nature of the physician-patient relationship, physicians are generally expected to avoid conflicts of interest that may undermine patient care).

27. See LAFRANCE, supra note 26, at 691 (referring to the relationship between patient and health care provider as a fiduciary relationship).  

The fiduciary concept claims its origins in the law of trusts and agency. Marc A.  

Rodwin, Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System, 21 AM. J.L. & MED. 241, 243 (1995). The trustee, or fiduciary is "entrusted with power or property," and is under a duty to manage it for the benefit of the beneficiary. Id. The fiduciary's actions are subject to the control of beneficiaries, who direct the fiduciaries to act for their benefit. Id. at 243-44. While performing their fiduciary duties, fiduciaries are prohibited from furthering their own personal interests while performing work or service for the benefit of the beneficiary. Id. at 244. See also Miller, supra note 26, at 427 (stating that because of the inherent imbalance of power in the physician-patient relationship, the law has imposed fiduciary duties in order to provide balance and protect the patient from potential overreaching by the physician).  

But see Rodwin, supra note 27, at 242 (stating that although doctors perform fiduciary-like roles and hold themselves out as fiduciaries in their ethical codes, the law only holds physicians accountable as fiduciaries in restricted situations).

28. See LAFRANCE, supra note 26, at 691 (explaining that the physician's primary responsibility is to his or her patient). See also Rodwin, supra note 27, at 243 (stating that "the law defines a fiduciary as a person entrusted with power or property to be used for the benefit of another and legally held to the highest standard of conduct.").

29. Rodwin, supra note 27, at 245.  

30. Id. at 246.  

31. Id.  

32. See LAFRANCE, supra note 26, at 692 (stating that a physician's primary responsibility is to his or her patient, and that all personal interests of the physician, including financial, professional or research goals are not to affect a physician's judgment when dispensing with a patient's care).
risk that a physician's professional judgment will be unduly influenced.\textsuperscript{33} A physician's primary interest includes promoting the patient's welfare by using his or her judgment and discretion in advising the patient.\textsuperscript{34} For a physician, a secondary interest is one that does not factor in the care of the patient.\textsuperscript{35} While certainly not the only secondary interest that may affect a physician, financial interests have garnered the most attention from scholars and commentators.\textsuperscript{36} While many secondary interests are legitimate,\textsuperscript{37} they may become problematic for the patient when they begin to affect, or have the appearance of affecting, a physician's professional judgment.\textsuperscript{38}

Despite the fact that physicians are held out as fiduciaries, in general, the conflicts between physicians' primary and secondary interests are not regulated by the courts as they are in other fiduciary contexts.\textsuperscript{39} The exception to that is Moore v. The Regents of the University of California, where the California Supreme Court held that a university's financial interests could affect the professional judgment of a physician who was a faculty member of the university.\textsuperscript{40} The court held that the university's financial interests were not sufficiently removed from the professional judgment of the physician to allow the university to avoid the duty of loyalty to the patient.\textsuperscript{41}

\textsuperscript{33} CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 46 (Bernard Lo and Marilyn J. Field eds., The National Academies Press 2009) (hereinafter CONFLICT).

\textsuperscript{34} Id. See also Kevin W. Williams, Article: Managing Physician Financial Conflicts of Interest in Clinical Trials Conducted in the Private Practice Setting, 59 FOOD DRUG L.J. 45, 56 (2004) (defining a conflict of interest as "a set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).".

\textsuperscript{35} See id. at 47 (noting that conflict of interest policies typically focus on financial gain because they are more objective, fungible and quantifiable, and therefore thought to be more effectively regulated as compared to other secondary interests). See also Williams, supra note 34, at 56 (noting that scholars focus on the financial conflicts that affect physicians and medical researchers because (1) they are the most recognizable types of secondary interests, (2) they are likely to create the most tension with physicians' primary interests with harmful consequences on the physicians and researchers, and (3) financial conflicts may lead to decisions that lead to injury or death in patients or research subjects).

\textsuperscript{36} See CONFLICT, supra note 33, at 46 (describing how secondary interests of a physician are those that are separate from the patient's care).

\textsuperscript{37} See CONFLICT, supra note 33, at 47 (noting how most secondary interests, including pecuniary interests, are legitimate and desirable goals for physicians; see also Williams, supra note 34, at 56 (observing that secondary interests are not necessarily illegitimate in and of themselves).

\textsuperscript{38} CONFLICT, supra note 33, at 47. The authors explain that secondary interests are objectionable only when they affect professional decision making. Id. See also Williams, supra note 34, at 56 (stating that the danger in secondary interests in patient care arise when they are in tension with the physician's primary interest as caregiver, and that this conflict may adversely affect the physician's professional judgment).

\textsuperscript{39} See Rodwin, supra note 27, at 246 (explaining that while physicians are held accountable by courts and the law for several categories of misconduct, with the exception of Moore v. Regents of the Univ. of Cal., 51 Cal. 3d 120 (1990), physicians are not held accountable by law regarding financial conflicts of interest).
Court held that a physician owed a fiduciary duty to his patient, and that the physician breached that duty by not disclosing his financial interests to the patient when the doctor used the patient's white blood cells for research and his own pecuniary gain.\(^{40}\)

While physicians' conflicts of interests are generally not regulated by law or by courts, medical practitioners are still held to a high ethical standard.\(^{41}\) Professional organizations such as the American Medical Association have set forth strong ethical guidelines which strongly urge physicians to avoid conflicts of interest.\(^{42}\) Despite these strong exhortations, conflicts remain pervasive, and continue to impact patients' care.

B. Substantial Secondary Interests—Big Pharma's\(^{43}\) Deep Pockets

Big Pharma spends a substantial amount of money marketing directly to physicians.\(^{44}\) Roughly $12 billion is spent on marketing

\(^{40}\) Moore v. Regents of the Univ. of Cal., 51 Cal. 3d 120, 125 (1990). In Moore, the plaintiff, Mr. Moore, had hairy cell leukemia. Id. He visited Dr. Golde, the defendant, at UCLA Medical Center in 1976 for treatment. Id. On Dr. Golde's recommendation and after Moore gave informed consent for the procedure, Moore underwent a splenectomy. Id. at 126. However, Dr. Golde failed to disclose his intent to use Moore's removed spleen for research purposes, which had no bearing on Moore's care. Id. After the procedure, Dr. Golde advised Moore to continue returning to UCLA Medical Center for ongoing care. Id. During the visits, Dr. Golde would extract blood and other fluids from Moore. Id. The continuing withdrawal of Moore's fluids had nothing to do with his care, but was conducted solely for purposes of Dr. Golde's research. Id. This went on for several years. Id. As a result of the research, Dr. Golde patented a cell line from Moore's white blood cells. Id. at 127. Dr. Golde and UCLA went on to profit substantially from the patent. Id. at 127-28. Moore sued Dr. Golde for, inter alia, breach of fiduciary duty. Id. at 128. See also Williams, supra note 34, at 53 (describing Moore as “the most significant U.S. case to date dealing directly with informed consent and financial conflicts of interest.”). But see Rodwin, supra note 27, at 248 n.48 (pointing out that Moore is the exception to the general rule that physicians are not held to fiduciary standards with respect to financial conflicts of interest).


\(^{42}\) See id. (stating in the Preamble that “a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self . . . . A physician shall, while caring for a patient, regard responsibility to the patient as paramount.”).

\(^{43}\) "Big Pharma" refers generally to the pharmaceutical industry.

\(^{44}\) See Amanda L. Connors, Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics, 73 ALB. L. REV. 243, 243 (2009) (stating that by "distribut[ing] free drug samples, skewed marketing materials, meals and more, the [pharmaceutical] industry engages
drugs annually.45 While marketing to physicians has gone on for over half a century, pharmaceutical companies’ outsized profits, coupled with their increasingly intense efforts to market their new and often expensive drugs, have brought increasing scrutiny on the effect that these efforts have on patient care.46 While commentators mostly agree that partnerships between the pharmaceutical industry and physicians are essential to the development of new therapies,47 the exorbitant amount of dollars at play between Big Pharma, physicians, and medical researchers raise concerns over whether medical decisions are being unduly affected by secondary financial considerations outside of the physician-patient relationship.

1. Big Pharma Marketing to Physicians

The majority of Big Pharma’s physician-focused marketing budget is spent on “detailing,” whereby pharmaceutical representatives engage are sent directly to physicians to promote and market their companies’ drugs.48 Promotion is done in several ways, such as giving small gifts, drug samples, and meals.49 In a recent study, nearly all physicians surveyed reported that they had some kind of contact with a Big Pharma representative in the previous year.50 Four out of five physicians reported that they had in deception hidden by a veil of flattery and free gifts.”). See also Sheldon Krimsky, Symposium: Academic Integrity: Combating the Funding Effect in Science: What’s Beyond Transparency?, 21 STAN. L. & POL’Y REV. 81, 92 (2010) (discussing Big Pharma’s “symbiotic” relationship with physicians and research scientists, which encompasses the hiring of academics to conduct clinical trials, to recruit human test subjects, to test drugs, and directly engage with physicians through office visits and paying for continuing education, gift vacations and lucrative honoraria for speaking at Big Pharma-funded conferences).

45. Thomas L. Hafemeister & Sarah P. Bryan, Beware Those Bearing Gifts: Physicians’ Fiduciary Duty to Avoid Pharmaceutical Marketing, 57 U. KAN. L. REV. 491, 492 (2009). The author notes that while there is no precise data on the amount of money invested by Big Pharma in marketing, credible estimates put the figure around $12 billion annually. Id.

46. Id. at 491-492. Another possible explanation for the increased level of scrutiny of financial relationships between physicians and pharmaceutical companies is the contention that physicians are more susceptible to outside payments as a result of physicians’ average real income declining over the last several years. CONFLICT, supra note 33, at 167-69. To wit, the real income of physicians decreased by 7 percent between 1995 and 2003. Id.

47. CONFLICT, supra note 33, at 97-99.


49. Id. See also Connors, supra note 44, at 256 (noting that the pharmaceutical industry uses several techniques to market to physicians; including targeting groups vulnerable to marketing, such as medical students and residents; personalizing sales pitches for individual physicians, and tracking physicians’ individual prescription habits).

50. CONFLICT, supra note 33, at 172. Studies show that 94 percent of physicians reported having some kind of relationship with industry over the
received a free meal in the last year and received free drug samples from industry representatives.\textsuperscript{51} Another study showed that nearly two thirds of physicians reported receiving meals, travel, or entertainment on Big Pharma’s dime.\textsuperscript{52}

The number of Big Pharma representatives has skyrocketed since the mid-1990s, both in numerical terms as well as relative to the number of physician targets.\textsuperscript{53} These representatives are well-trained, well-educated professionals who are extremely adept at marketing their products.\textsuperscript{54} In addition to employing a highly skilled marketing force, Big Pharma companies spend over $20 million purchasing data on individual physicians’ prescription habits to ensure that detailers can tailor their techniques to physicians’ specific prescription habits.\textsuperscript{55}

While physicians generally maintain that these marketing techniques have no effect on their judgment, evidence suggests otherwise.\textsuperscript{56} Big Pharma’s marketing techniques have been shown to effectively sway physicians’ prescribing decisions.\textsuperscript{57} A survey of physicians’ prescribing habits found that physicians were significantly more likely to prescribe a drug after attending an all-

\begin{itemize}
\item \textsuperscript{51} Id.
\item \textsuperscript{52} Id.
\item \textsuperscript{53} See Rikin S. Mehta, Why Self-Regulation Does Not Work: Resolving Prescription Corruption Caused by Excessive Gift-Giving by Pharmaceutical Manufacturers, 63 FOOD & DRUG L.J. 799, 801 (2008) (noting that the number of pharmaceutical sales representatives more than doubled from 1996 to 2000, from 41,800 to 83,000, and grew to 100,000 by 2005, making about one rep for every six physicians); but see Hafemeister & Bryan, supra note 45, at 494-95 (stating that as of 2007, there were 100,000 pharmaceutical reps marketing to only 200,000 physicians).
\item \textsuperscript{54} Connors, supra note 44, at 256-258. The “always good-looking, overly-friendly, and stylish” sales representatives who are dispatched to market directly to physicians are well-trained in the use of both verbal and non-verbal cues in order to better persuade their targets. Id. See also CONFLICT, supra note 33, at 171 (stating that Big Pharma representatives use a variety of “interpersonal techniques to establish relationships with physicians to promote their [approach to their] products and may calibrate their assessments of the physician’s personality and intellectual style.”).
\item \textsuperscript{55} Hafemeister & Bryan, supra note 45, at 494-95. The number of detailer visits to physicians is determined by how often a physician prescribes drugs, with the most active prescribers receiving the most visits. Id. An AMA study found that physicians who prescribe 1 to 10 prescriptions per week are visited on average 2.33 times per week, while those who prescribe over 150 times per week are visited 8 times per week. Id.
\item \textsuperscript{56} Connors, supra note 44, at 265-66. While many physicians claim that they are immune to the marketing techniques of pharmaceutical companies, they are nevertheless suspicious of the effect of these techniques on their colleagues. Id.
\item \textsuperscript{57} See Mehta, supra note 53, at 804 (citing a study which concluded that “physicians exhibited a ‘significant increase’ in prescribing a company’s drugs after attending an expense paid trip to a drug company’s symposium”).
\end{itemize}
expense-paid trip to attend the donor company's symposium. But big-ticket trips are not the only way to influence prescribing habits. Gifts of any size or expense have been shown to subtly influence doctors' behavior.

2. Big Pharma-Sponsored Clinical Trials

Big Pharma's funding of clinical research trials has received less public scrutiny than the industry's relationship with physicians. Despite the lack of attention, industry relationship with research universities and individual researchers nevertheless present issues that are important to the safety of human test subjects, as well as for the integrity of the professional practice itself.

Big Pharma's relationship with the research community is relatively new compared with the relationship between Big Pharma and physicians growing out of drug marketing. The passage of the Bayh-Dole Act in 1980 is regarded as the catalyst for the current relational framework between Big Pharma and the medical research community, because it allowed researchers and universities to receive automatic patents for inventions and research sponsored by the university. Big Pharma is now the

58. Id.
59. Connors, supra note 44, at 264-65. Gifts can create a feeling of reciprocity and obligation in physicians, even if on a subconscious level. Id.
61. See generally Elliott, supra note 2 (describing the circumstances under which Dan Markingson enrolled in a clinical trial funded by AstraZeneca, designed to test the side effects of three antipsychotic medications in schizophrenic test subjects); see generally Robin Fretwell Wilson, The Death of Jesse Gelsinger: New Evidence of the Influence of Money and Prestige in Human Research, 36 AM. J.L. & MED. 295 (2010) (telling of the circumstances of Jesse Gelsinger's death while enrolled in a clinical trial testing the effects of a gene therapy designed to treat ornithine transcarbamylase deficiency, a rare liver disease).
62. See Robert Freedman, et al., Commentary, Conflict of Interest - An Issue for Every Psychiatrist, AM. J. PSYCHIATRY, March 2009, available at http://ajp.psychiatryonline.org/cgi/content/full/166/3/274 (noting that the profession of psychiatry as a whole suffers from examples of pharmaceutical companies failing to report negative information about drugs critical to their safe use).
63. See Williams, supra note 34, at 57 (observing that private industry currently funds the majority of clinical research in universities, which is in stark contrast to before 1980, when the federal government funded most university-based clinical research).
65. See Williams, supra note 34, at 56-57 (noting that the passage of the Bayh-Dole Act is responsible for a substantial increase in revenue generated for universities, as well as for private laboratories). The Act resulted in
largest source of funding for biomedical research.\textsuperscript{66} The growth of the pharmaceutical industry-research relationship has led to an increasing number of researchers who own a financial stake in their research, as well as a proprietary stake in the company funding the research.\textsuperscript{67} Aside from benefitting the individual researchers and research institutions, society has benefitted from this collaboration by having access to new and effective drugs.\textsuperscript{68} Notwithstanding these benefits, this relationship threatens to create situations that can cause researchers to overlook their duties to their human test subjects in favor of the research results themselves.\textsuperscript{69}

The growing custom of using clinical trial results as a marketing tool rather than for scientific gain has been described as a shift from "evidence-based medicine" to "marketing-based medicine."\textsuperscript{70} One practice lending credence to this theory is the manipulation of clinical trials' results in order to make drugs manufactured by the trials' sponsors appear more efficacious than they really are.\textsuperscript{71} Data shows that, when compared to trials funded
by neutral sponsors, clinical trial studies sponsored by pharmaceutical companies overwhelmingly yield more favorable results for the sponsoring company's drug. The funding effect of clinical trials has engendered widespread suspicion of trial results published under Big Pharma sponsorship. Despite these trials' dubious credibility, the results are then published in journals and

The study was supposed to demonstrate the advantage of its antipsychotic drug, Seroquel, over an older and cheaper drug, Haloperidol. But the Study 15 results painted a different picture, indicating that Seroquel actually was less effective than the older drug and that it caused significant weight gain. Subsequent internal emails among AstraZeneca personnel speak of how to put a "positive spin" on the test results. Another email mentions how an AstraZeneca doctor had done a "great 'smoke and mirrors' job!" with the results. Yet two years after the emails, AstraZeneca officials presented different data to an American Psychiatric Association conference and a European meeting, showing that Seroquel had fared better in the clinical trials than Haloperidol. 72

Several reviews and studies have shown that industry-funded clinical trials are more likely to come out in favor of the trial sponsor. One study found that clinical trials sponsored by the drug manufacturer or where the trial investigator has financial ties to the manufacturer are 3.6 times more likely to find that the drug tested was effective, as compared with clinical trials not sponsored by a manufacturer. Another survey found that studies, which favored a drug were four times more likely to be funded by the drug manufacturer. Still another study found that industry-funded studies were more likely to find that a particular drug was safe, even when there was a significant increase in adverse effects for that drug.

There is also evidence that articles published in symposia with drug company support were more likely to favor the drug of the sponsor than articles published independently of drug company influence. In addition, a correlation exists between drugs recommended by clinical practice guideline authors when those authors have a relationship with the drug manufacturers.

Nevertheless, several medical professionals claimed that the study did not stand up to its scrutiny. For example, Dr. Peter Tyrer, editor of the British Journal of Psychiatry, pointed out the small sample size of the study, and commented that "[i]n scientific terms this study is of very little value." Dr. John Davis, the Gillman Professor of psychiatry at the University of Illinois-Chicago, found it troubling that the study did not elaborate on the causes of why many patients dropped out of the study. According to Dr. Davis, "[i]t does not make scientific sense to do a study and not measure one of the most important outcomes."

Finally, Dr. David Healy described the study as "a non-study of the worst kind," saying that "[i]t is designed not to pick up a difference between the three drugs. It looks like an entirely marketing-driven exercise."
used by Big Pharma to market their products to physicians.74

The manipulation of clinical trials' results clearly diminishes the integrity of the trials, and ultimately endangers the health of patients to whom these drugs are prescribed. Big Pharma's funding of clinical trials, coupled with the industry's marketing techniques toward physicians, has prompted Congress to take action to expose the underlying financial relationship to the public in order to prevent such practices.75

III. ANALYSIS

The impact of physician-Big Pharma ties on patient care has not escaped the American public's attention. In a 2008 survey conducted by the Pew Prescription Project, 64 percent of surveyed participants believed that it was important to know their physicians' financial relationship with the pharmaceutical industry.76 Sixty-eight percent of respondents supported legislation requiring pharmaceutical companies to disclose gifts to physicians.77 In general, a vast majority of those surveyed disapproved of the current relational framework between the pharmaceutical industry and physicians.78 A handful of states took

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74. Daniel Carlat, Dr. Drug Rep, N.Y. TIMES MAGAZINE, Nov. 25, 2007, available at http://www.nytimes.com/2007/11/25/magazine/25memoir-t.html. Dr. Daniel Carlat, a psychiatrist who practices in Newburyport, Massachusetts, wrote an article on his experiences as a detailer hired by Wyeth Pharmaceuticals to give talks on the benefits of using the Effexor XR for treatment of depression. Id. The talks often centered on Effexor's performance against competing drugs as shown in a Wyeth-sponsored clinical trial, namely that Effexor had a 10-percent advantage in remission rates over other comparable drugs. Id. However, Dr. Carlat acknowledges how his presentations were "highlighting Effexor's selling points and playing down its disadvantages," such as a 50 percent greater hypertension rate in Effexor users. Id. Dr. Carlat continued expounding Effexor's selling points even after learning of subsequent clinical trials, which showed results that Effexor's remission rates were not as positive as originally reported. Id. Reflecting on his talks, Dr. Carlat realized that he "had spun the results of the [Wyeth-sponsored] study in the most positive way possible," and "had not talked about the limitations of the data" by "tweaking and pruning the truth in order to stay positive about the product." Id. Dr. Carlat's internal ethical dilemma about fudging the study results reflected in less enthusiastic endorsement for the drug in his talks. Id. He resigned from his position as a Wyeth detailer, noting that, "I was paid to enthusiastically endorse their product . . . [o]nce I stopped doing that, I was of little value to them, no matter how much 'medical education' I provided." Id.

75. See infra Part III.A (describing the Sunshine Act's stated purpose and substantive provisions).


77. Id.

78. Id. Respondents to the survey disapproved of even small gifts to physicians. Id. For example, 86 percent of respondents thought free dinners
notice and passed legislation mandating disclosure of industry payments to physicians. Congress joined the fight by enacting the Physician Payment Sunshine Provision in March of 2010 as part of the Patient Protection and Affordable Care Act. While the Sunshine Act allows for far more transparency in the currently opaque world of the industry-physician financial relationship, the question still remains whether greater transparency will lead to better patient care and enhance trust in physicians’ decisions.

A. The Physician Payment Sunshine Act—Shedding Light on Industry-Physician Financial Relationship

1. Intent Behind the Sunshine Act

The Sunshine Act was first introduced in 2007 by Senator Charles “Chuck” Grassley (R-IA) and Senator Herbert “Herb” Kohl (D-WI) to create transparency in the financial relationship between the pharmaceutical industry and physicians. According to Senator Grassley, an “intricate network of financial ties” between Big Pharma and physicians, combined with a lack of transparency surrounding those relationships, obscure what was best for the patient. To prove the lack of transparency under the then-current regulatory framework, Senator Grassley spoke of several academia-affiliated physicians who accepted, but did not disclose, millions of dollars from pharmaceutical companies while also conducting government-funded research on the drugs manufactured by those same companies.

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79. See Krimsky, supra note 44, at 93 (noting that Minnesota, Vermont, Massachusetts, Maine, West Virginia, and the District of Columbia have each enacted statutes which mandate that pharmaceutical companies disclose payments to physicians).
81. 153 CONG. REC. 11,217-18 (2007). In his speech from the Senate floor, Senator Grassley described the need for transparency as “an important issue affecting all Americans who take prescription drugs or use medical devices.”
82. 155 CONG. REC. 787-88 (2009). Senator Grassley cited speaking honoraria, consulting fees, free travel to exotic locations, and funding for research as examples of these financial relationships.
83. See 154 CONG. REC. 2,320 (2008) (explaining how industry payments to physicians influence medical practice). Senator Grassley reported that the Federal Government paid billions of dollars under various programs for the drug Seroquel, manufactured by AstraZeneca. Id. In doing so, the government relied in part on a published study which concluded that Seroquel was effective in treating bipolar disorder in children. Id. However, as Senator Grassley noted, the panel responsible for publishing the results of the study...
The Sunshine Act's sponsors refuted the notion that the mandatory disclosures are meant to regulate the business of drug companies, or the amount that they spend to market their products.\textsuperscript{84} They argued instead that the Act was necessary to deter against any improper industry-physician relationship since, as Senator Grassley observed, pharmaceutical companies would not spend billions of dollars marketing to physicians unless such action directly affected what drugs physicians prescribed.\textsuperscript{85} Indeed, the aim of the Act is two-pronged: (1) to help distinguish legitimate financial relationships from those that are improper, and (2) to notify patients of these relationships so that they can make better-informed decisions about their care.\textsuperscript{86}

2. Sunshine Act's Substance

The substantive provisions of the Sunshine Act will take effect on March 31, 2013.\textsuperscript{87} On this date, and on the ninetieth day based its recommendation on a single inconclusive study in which the half of tested subjects dropped out of the study. \textit{Id}. Senator Grassley then discovered that Dr. Melissa DelBello, the lead author of the study and professor at the University of Cincinnati, had been paid $238,000 by AstraZeneca between 2005 and 2007. \textit{Id}. Dr. DelBello only reported $100,000 of those earnings to the University, which was charged with the duty to monitor any potential conflicts of interests among its faculty. \textit{Id}.

Another notable example pointed out by Senator Grassley was that of Dr. Karen Wagner, professor at the University of Texas-Galveston and author of Study 329 on the effectiveness of GlaxoSmithKline drug Paxil. \textit{154 CONG. REC.} 8,166 (2008). Study 329 was later cited in a lawsuit against the company where positive results were promoted, but unfavorable results were not. \textit{Id}. GlaxoSmithKline paid Dr. Wagner cumulatively over $70,000 in 2000 and 2001, when Study 329 was published. \textit{Id}. The irony was that Dr. Wagner later served on the University’s Conflict of Interest Committee from 2003 to 2004. \textit{Id}.

\textsuperscript{84} 155 CONG. REC. 788 (2009). The Act does not seek to “outlaw” industry-physician relationships because many of them are appropriate and beneficial. \textit{Id}. In his speech in support of the Sunshine Act, Senator Kohl begins by stating that “industry payments to physicians for research purposes or products they have helped develop are completely legitimate.” \textit{Id}. “Medical breakthroughs as a result of research have saved countless lives and could not have been achieved without the diligence of these [medical] professionals.” \textit{Id}. Senator Kohl also recognized that pharmaceutical companies have the right to spend as much as they want, without limit, on marketing their products. \textit{Id}.

\textsuperscript{85} 153 CONG. REC. 11,218 (2007). In a later speech, Senator Grassley refers to the improper influence that industry payments to physicians may have, motivating physicians to modify treatment practices. \textit{154 CONG. REC.} 2,319-20 (2008).

\textsuperscript{86} 155 CONG. REC. 788-89. While conceding that most industry-physician relationships are proper, Senator Kohl states that “[t]ransparency will help to illuminate the difference between legitimate [relationships] and those that are questionable.” \textit{Id}. Senator Kohl also expressed his hope that the transparency provided by the Act will encourage patients to discuss concerns about any financial relationships in which their physician is involved. \textit{Id}.

\textsuperscript{87} The Social Security Act, 42 U.S.C. § 1320a-7h(a)(1)(A) (2010). The
of each subsequent year, all drug and medical device companies operating in the United States will have to disclose to the Secretary the amounts paid, items provided, and value given to any physician or teaching hospital during the prior year. Submissions will have to include the name and address of the recipient, dates of payment, payment amounts, and whether the payment was in money, stock or ownership in the donor company, or something else of value. The disclosing companies will also have to describe the purpose behind the payment. If the disclosed payment is related to marketing, education or research in regards to a specific drug or medical product, the company will be obligated to specify the name of that drug or product. Companies may delay disclosing payments for research associated with new drugs or medical products until the drug or product is approved by the Food and Drug Administration, or four calendar years after the date of the payment, whichever comes first.

By September 30, 2013 and by June 30 of each subsequent year, the Secretary will be obligated to publish all the information disclosed by medical companies on a public, user-friendly website. Companies will be subject to fines ranging from $1,000 to $10,000 for each unreported payment, up to $150,000 per year. A company that knowingly fails to report payments will be subject to fines ranging from $10,000 to $100,000, up to $1 million a year.

B. Consequences of the Sunshine Act

1. Beneficial Consequences

The Sunshine Act’s transparency provisions will allow patients to peer into the previously obscured financial

Sunshine Act provision in the Patient Protection and Affordable Care Act was an amendment to the Social Security Act. Id.

88. 155 CONG. REC. 788.
89. Id. But despite the broad disclosures required by the Sunshine Act, some payments are exempt from disclosure. See § 1320a-7h(e)(10)(B) (stating that payments or transfers of value less that $10 are not subject to the disclosure requirements, as long as the total amount of such payments do not exceed $100). Pharmaceutical companies also are not required to disclose the value of free drug samples which are not intended to be sold. Id.
90. Id. Examples include payments for consulting fees, compensation for services besides consulting, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalties or licenses, ownership or investment interests, compensation for speaking at medical education programs, and grants. Id.
91. Id.
92. 42 U.S.C. § 1320a-7(c)(1)(E)(i).
93. Id. at (c)(1)(C).
94. Id. at (b)(1)(A)-(B).
95. Id. at (b)(2)(A)-(B).
relationships between physicians and pharmaceutical companies. Several commentators, including those within the pharmaceutical industry, recognize that the Sunshine Act will enhance the physician-patient relationship by increasing the level of trust that patients have in their physicians. The Act will allow patients access to data pertaining to their physicians’ ties with Big Pharma. The Act will also lend greater credibility to clinical trial results, since anyone can look to see if trial investigators maintain ties with drug companies whose drugs are being tested. Finally, it will give patients a bona fide opportunity to discover their physicians’ financial relationships with the pharmaceutical industry without having to confront their physicians directly.

96. See supra text accompanying notes 76-81.
97. Johnson & Johnson Announces Support for Kohl-Grassley Physician Payments Sunshine Act of 2009, Johnson & Johnson (May 7, 2009), http://www.jnj.com/connect/news/all/20090507_130000. In voicing his support for the Sunshine Act, Johnson & Johnson CEO William C. Weldon, in a company press release, stated: “Greater transparency will enhance trust and recognition that collaborations between pharmaceutical and device manufacturers and physicians lead to important medical advances that save lives.” Id. Weldon’s statement echoes Senator Kohl’s contention that the Act will augment trust within the physician-patient relationship: “Patients want to know that they can fully trust the relationship they have with their doctor.” Id.

98. See Donald Brown, Provision of Health Care Reform Requires Drug Companies to Report Payments to Doctors, First Amendment Coalition (Mar. 25, 2010), http://www.firstamendmentcoalition.org/2010/03/provision-of-health-care-reform-requires-drug-companies-payments-to-doctors/ (stating that because patients will have access to industry payments their physicians receive from pharmaceutical companies, patients will be able to make more informed decisions about the advice from their physicians).

99. John Fauber, Surgeons Routinely Fail to Disclose Financial Ties, JSOnline (Sept. 13, 2010), http://www.jsonline.com/features/health/102811174.html. A 2007 study of ninety-five articles authored by thirty-two surgeons found that only 46 percent of the authors disclosed major payments from industry. Id. The lack of disclosure substantially discounts the credibility of these studies. Id. Noting the exceeding difficulty of journals to identify industry payments to authors, the mandatory disclosures made pursuant to the Sunshine Act mean that such journals no longer need to rely solely on self disclosures from authors. Id. Rather, journals can independently discover whether such authors are recipients of large payments from industry companies, and therefore subject to skewing data in favor of those donors. Id.

100. Ibby Caputo, Probing Doctors’ Ties to Industry, The Wash. Post, Aug. 18, 2009, available at http://www.washingtonpost.com/wp-dyn/content/article/2009/08/17/AR2009081702090.html. While most patients do believe that it is important to know the extent of their physician’s ties to industry, confronting one’s physician about such ties is “a genuinely difficult and awkward conversation to have,” according to Allan Coukell, director of the Pew Prescription Project. Id. Patients fear that challenging their physicians could lead to an antagonistic relationship. Id. For this reason, patients are not likely to broach the subject with their physicians, according to Steve Nissen, chairman of the Department of Cardiovascular Medicine at the Cleveland
The easily searchable and downloadable format of the data offers a marked improvement over the recent voluntary disclosures of some pharmaceutical companies. While voluntary disclosures by individual companies demonstrate a willingness to be open about their relationships with physicians, they have also been derided as being of limited value. Companies publish their disclosures in PDF format, making viewing and organizing the data unduly onerous. Furthermore, voluntary disclosures do not provide the purpose behind the payments. Because voluntary disclosures often show payment amounts that appear lower than expected, some find them untrustworthy. An impartial national database that allows users to easily search, aggregate, and download data on industry payments to physicians would remedy

Clinic. Id. Citing this reticence, Nissen notes that greater transparency would benefit patients the most. Id. 101. 42 U.S.C. § 1320a-7(h)(1)(C). 102. Duff Wilson, Data on Fees to Doctors Is Called Hard to Parse, N.Y. TIMES, Apr. 12, 2010, available at http://www.nytimes.com/2010/04/13/business/13docpay.html?fta=y. In evaluating the disclosures on industry companies' websites, John Mack, editor or the Pharma Marketing blog, noted that they are "[m]ore translucent than transparent." Id. 103. Id. An Eli Lilly spokesperson has stated that the data was published in such a way in order to protect the data's integrity. Id. However, the format of the disclosures makes it nearly impossible to aggregate the money paid to a doctor from several sources, identify the biggest recipients, or list recipients by hospital or city. Id. 104. See Daniel Carlat, The Physician Sunshine Act: Time for Hired Guns to Scatter, THE CARLAT PSYCHIATRY BLOG (Mar. 26, 2010), http://carlatpsychiatry.blogspot.com/2010/03/physician-sunshine-act-time-for-hired.html (noting that voluntary disclosures made by pharmaceutical companies do not adequately categorize payments to physicians, but merely list the physician donee and the amount given). Dr. Daniel Carlat illustrates the strength of the Sunshine Act as compared to voluntary disclosures by explaining how Eli Lilly's registry allows one to discover that a recipient physician "made $50,000 in 2009 performing healthcare professional education programs." Id. But under the Sunshine Act, the website will give greater detail by publishing that the physician was paid "$50,000 for marketing Zyprexa in 2009." Id. Dr. Carlat also notes that payments will be broken down by date, so that a patient can see not only how much his or her physician was paid to market the drug that the physician prescribed, but also how soon before or after the payment was made. Id. 105. Duff Wilson, Pfizer Gives Details on Payments to Doctors, N.Y. TIMES (Apr. 1, 2010), http://www.nytimes.com/2010/04/01/business/01payments.html. While expressing surprised approval of Big Pharma's disclosure efforts, Dr. Marcia Angell, former editor of the New England Journal of Medicine, noted what seemed to be low payment numbers on Pfizer's registry, saying that "I can't help but think something has escaped." Id. Eric G. Campbell, lead author of a 2007 study of physician-industry relationships published in the New England Journal of Medicine, stated that he puts "absolutely no trust in what drug companies voluntarily disclose to the public when those things are unaudited." Id.
the shortcomings of companies' voluntary efforts.

There is evidence that mandatory disclosures will diminish the amount of money that Big Pharma spends on physicians. Both Minnesota and Vermont have enacted their own transparency measures, resulting in declining payments from Big Pharma to physicians and researchers. For example, Dr. S. Charles Schulz, the chairman of University of Minnesota's psychiatry department who also oversaw the AstraZeneca clinical trial that led to Dan Markingson's suicide, only received $9,546 in 2008 from Eli Lilly. This amount is dwarfed by the $500,000 that Dr. Schulz received from 2003 to 2007. The data, as well Dr. Schulz's example, underscores the underlying goal of the Sunshine Act: to deter these financial relationships when there is an appearance of improper influence.

2. Negative Consequences

Predictably, some within the medical and pharmaceutical communities have criticized the Act's transparency provisions. There are those that believe that the mandatory disclosures are overly broad, and the result of just a handful of "bad apples" when compared to the vast number of industry-physician and researcher relationships which yield beneficial medical results. Some even

106. See Jeremy Olson, Pharmaceutical Companies Spending Less on Minnesota Doctors, NALRX (June 15, 2009), http://www.twincities.com/ci_12573822?IADID=Search-www.twincities.com-www.twincities.com&nclick_check=1 (stating that Minnesota physicians received millions less in payments from pharmaceutical companies in 2008 than in each of the five previous years). Public scrutiny on such payments increased after publication of these payments by watchdog groups and journalists. Id. See also Arlene Weintraub, New Health Law Will Require Industry to Disclose Payments to Physicians, KAISER HEALTH NEWS (Apr. 26, 2010), http://www.kaiserhealthnews.org/Stories/2010/April26/physician-payment-disclosures.aspx (noting that industry payments to Vermont physicians dropped 13 percent in 2009 from the time reporting of such payments became mandatory in 2002).

107. Olson, supra note 106.

108. Id.

109. Reed Miller, Let the Sunshine in: TCT Docs Debate Purifying Physician Relationships with Industry, THE HEART.ORG (Oct. 1, 2010), http://www.theheart.org/article/1130139.do. Dr. Richard Popp, professor at Stanford University, approves of the deterrent effect of the Sunshine Act, noting that "[a]ll of this 'sunshine' is good because if you're embarrassed by the relationship you have with industry, you shouldn't be having it." Id.

110. Thomas Sullivan, Physician Payment Sunshine Act: Nature's Unintended Consequences, POLICY AND MEDICINE (July 16, 2010), http://www.policymed.com/physician-payment-sunshine-act/. While Senator Grassley's investigations have uncovered some cases where disclosure discrepancies and conflicts existed, those examples are the exception. Id. Dr. Mininder Kocher, associate professor of orthopedic surgery at Harvard Medical School, believes that "there probably is only a minority of surgeons who intentionally did not disclose" payments to their university employers. Id.
suggest that publication of financial information will only inflame negative public sentiment regarding these partnerships while ignoring the benefits. There are still others who fear that the cost of compliance and the stigma of physicians being viewed as "conflicted" will lead to recruitment problems for clinical trial studies. This could ultimately lead Big Pharma companies to conduct their research and clinical trials in other countries, thus avoiding the Sunshine Act's compliance measures.

In addition to the grumblings from the pharmaceutical and medical communities, there are those on the other side of the coin that contend that the provisions of the Sunshine Act do not go far enough. For example, some argue that the monetary penalties levied on uncooperative companies are inadequate. Several of the pharmaceutical companies whose payments inspired the Act reap billions of dollars in profits per year, and are accustomed to paying large court settlements as a cost of doing business. The

111. Id. Some in industry believe that disclosure only perpetuates the myth that all industry-physician relationships have negative consequences for the patient. Id. Michael Gonzalez-Campoy, CEO for Minnesota Center for Obesity, Metabolism and Endocrinology, believes that "a lot of harm comes from the implication that doctors are corruptible, that they don't do what they think or know is best for their patients." Id. 112. Oriana Schwindt, Sunshine Laws Stump Compliance Departments, PHARMEXEC.COM (Apr. 28, 2010), http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=667301. A survey of persons working in compliance departments in pharmaceutical, biomedical and medical device companies anticipate that their employers will farm out the compliance requirements to third party companies, which they believe will increase the overall cost of compliance. Id. 113. Sullivan, supra note 110. Joel Martin, President and CEO of Altair Therapeutics, a medical device manufacturer, fears that disclosures could lead to "a strong backlash against pharma, which will cause more academics to bow out of industry relationships." Id. Along the same lines, Dr. Antonio Hardan, associate professor of psychiatry at Stanford University, believes that "academia will be losing more and more smart people, because of its growing anti-industry sentiment." Id. A study of 200 active physician research investigators found that 24 percent are less likely to continue to do so if their income is publicly disclosed. William Sharbaugh, Implications of Physician Payment Act, APPLIED CLINICAL TRIALS (Oct. 1, 2010), http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/CRO%2FSponsor/Implications-of-Physician-Payment-Act/ArticleStandard/Article/detail/690489. 114. See Sullivan, supra note 110 (noting that the anti-industry culture is causing research, development and commercialization of medical products to move to other places outside of the United States). 115. See supra notes 90-91 and accompanying text. 116. See Nathaniel Whittemore, Here Comes the Sun?: Sunshine Act Attempts to Improve Transparency in Doctor-Pharma Relationships, CHANGE.ORG (June 24, 2010), http://socialentrepreneurship.change.org/blog/view/here_comes_the_sun_sunshine_act_attempts_to_improve_transparency_in_doctor-pharma_relations
lack of a substantial deterrent effect has caused some to call for criminal penalties that entail prison time for instances of noncompliance.117

It is also notable which payments the Sunshine Act does not require industry companies to disclose. While the Act requires disclosures to physicians and teaching hospitals,118 companies are not required to disclose payments to advocacy groups and professional organizations, some of which are quite powerful and exert substantial influence over physicians.119 While one of the Sunshine Act’s purposes is to expose financial influences that may affect care, the absence of a disclosure requirement for payments to professional and advocacy groups leaves a gaping hole in the Act.

Finally, the question remains whether the Act will actually enhance patient care and trust. The physician-patient relationship is defined by the power that the physician holds over the patient by virtue of his or her expertise and knowledge and the patient’s (acknowledging that the maximum fines in the Sunshine Act do not give a convincing reason to comply in an industry that regularly pays billions of dollars in fines for engaging in illegal marketing tactics and health care fraud). See also Roy M. Poses, M.D., Deferred Prosecution Agreements End, So let the Payments Grow, HEALTH CARE RENEWAL (June 17, 2010), http://hcrenewal.blogspot.com/2010/06/deferred-prosecution-agreements-end-so.html (arguing that limiting punishments of health care organizations for misconduct to corporate fines and “deferred prosecution agreements” do not deter further misconduct).

117. Poses, supra note 116. On the lack of a deterrent effect for corporate fines levied against medical device manufacturers who have violated the law, Dr. Charles D. Rosen, president of the Association for Medical Ethics, believes that “[n]othing will change until someone goes to jail. It’s a big game.” Id.

118. See supra note 83 and accompanying text.

119. See Alison Bass, The Troubling Link Between Big Pharma and the American Psychiatric Association, THE FASTER TIMES (Mar. 30, 2010), http://thefastertimes.com/healthinvestigations/2010/03/30/the-troubling-link-between-big-pharma-and-the-american-psychiatric-association/ (noting that disclosure of payments to all medical personnel and medical organizations is a shortcoming of the Sunshine Act). Bass points out that the National Alliance for the Mentally Ill, regarded as the most powerful advocacy group representing the interests of those with mental illness, received millions of dollars in funding from pharmaceutical companies, which “no doubt spurred this group’s embrace of potent psychoactive drugs over alternative methods of treating mental illness.” Id. Another noteworthy potential conflict of interest that cries out for disclosure is that of the American Psychiatric Foundation (APF) and the American Psychiatric Institute for Research and Education (APIRE), “two of the philanthropic arms” of the American Psychiatric Association (APA). Id. The majority of the boards of APF and APIRE are comprised of pharmaceutical executives and practicing psychiatrists with financial ties to pharmaceutical companies. Id. The APA is a powerful lobbying force in Washington, D.C., and also publishes the Diagnostic and Statistical Manual of Mental Disorders (DSM), or the “diagnostic bible of psychiatry.” Id. A proposed updated version of the DSM broadens categories of various disorders, which would create new markets for drug companies. Id.
trust that the physician will care for the patient with his or her interests at heart. Only a third of people would question a physician on his or her financial ties with pharmaceutical companies. This reluctance is a by-product of the physician-patient relationship, where the patient is more accustomed to receiving and following the physician’s advice rather than questioning the physician’s motives.

Under the Sunshine Act, patients will have the option of finding a physician who does not take money from pharmaceutical companies. But the search for a physician unaffiliated with the pharmaceutical industry may carry unintended consequences. For example, pharmaceutical companies typically recruit the most distinguished physicians in their respective fields to market their drugs. At some point, a patient will have to choose between a physician at the top of his profession, but encumbered with significant financial relationship with Big Pharma, and one who is not as highly regarded, but takes no Big Pharma money. This is not meant to insinuate that only competent physicians accept payments from Big Pharma. But, at some point, a patient may be in such a position and have to make a choice between a highly regarded physician who accepts Big Pharma money, and a less highly regarded physician who does not. It is doubtful that the Sunshine Act’s proponents contemplated this predicament, yet it is a scenario that may nevertheless occur. If there is a commitment to mitigate financial conflicts of interests, more must be done to protect patients’ care.

IV. PROPOSAL

The Sunshine Act makes previously hidden financial relationships open for all to see. The Act was passed with the purpose of rebuilding physicians’ trust in physicians by encouraging frank discussions about physicians’ financial

120. See supra notes 24-30 and accompanying text.
121. See Caputo, supra note 100 (noting how only 34 percent of recent survey respondents said they would ask their physician about financial ties to pharmaceutical companies).
122. Carlat, supra note 74. Dr. Carlat notes that 25 percent of physicians are asked to speak for or are employed by pharmaceutical companies, and are flattered to have been recruited. Id. According to Dr. Popp, a physician consulting for industry is regarded as a positive, which “means that they’re considered an expert, somebody values their intellect and contributions, and usually the faculty want[s] to go work with industry . . . .” Miller, supra note 109.
123. For example, a group of health care providers have established No Free Lunch, an organization guided by the principle that pharmaceutical marketing should not dictate clinical practice. See NO FREE LUNCH, http://www.nofreelunch.org/aboutus.htm (last visited Nov. 4, 2010) (providing a short recitation of the organization’s mission and goals).
The Physician Payment Sunshine Act relationships. But this theory is undermined when one takes an honest look at the power structure in the typical physician-patient relationship. It is therefore clear that the Act will not fully achieve its goal of more effective patient care. To accomplish that, the transparency and penalty provisions must be strengthened and be better-tailored to the intricacies of the physician-patient relationship.

Three things must occur to remedy the Sunshine Act's shortcomings. First, the Act's range of covered professionals must be enlarged to include all professional medical associations and advocacy groups. Second, to encourage compliance and to punish companies for not complying, penalties for not disclosing should be raised significantly. Thirdly, and most importantly, physicians should be required to disclose their financial relationships with pharmaceutical companies to their patients when the physician reasonably believes that the patient would find such information important when deciding to take the physician's therapeutic advice.

124. See supra note 81 and accompanying text.
125. See supra notes 115-117 and accompanying text.
126. See supra Part III.B.2.
127. Id.
128. See, e.g., CONFLICT, supra note 33, at 184 (recommending that in order for clinical physicians to avoid conflicts of interest in patient care, physicians should not accept any items of value from pharmaceutical companies unless the transaction involves a payment for services at fair market value). In discussing the effect that financial conflicts of interest have on the physician-patient relationship, many members of the academia and of the public have called for severely limiting or outright banning payments from pharmaceutical companies to physicians and medical researchers. Id. See id. at 117-118 (recommending that research institutions prohibit recipients of pharmaceutical company payments from conducting clinical research testing the effects of that drug); see also Andrew L. Younkins, The Physician Payments Sunshine Act and the Problem of Pharmaceutical Companies' Influence Over Prescribing Physicians, SELECTED WORKS 2 (2008), available at http://works.bepress.com/cgilviewcontent.cgi?article=1000&context=andrew_younkins (concluding that because the Sunshine Act is a "poor way to deal with physician conflicts of interest," the "only real" solution to solve the problem is to prohibit all pharmaceutical gifts and sponsorships of physicians' activities); see also Editorial, Limit Pay Docs Can Get from Drug Firms, CHI. SUN-TIMES, Jan. 10, 2010, at A26 (acknowledging the benefits of the Sunshine Act, the editor, nevertheless, concludes that transparency is not enough to cure the ills of financial conflicts, and calls on medical schools, hospitals and professional organizations to limit the amount of profit a physician is allowed to make from a relationship with pharmaceutical companies). However, passing legislation severely limiting or prohibiting any such payment paints with an overly broad brush, when one factors the benefits that come from industry-physician relationships, such as discovering new medical innovations. See supra note 46 and accompanying text. Because severely limiting industry-physician relationships will come at the cost of such innovations, less restrictive means of regulating these relationships are appropriate.
A. Expanding the Sunshine Act to Cover Payments to Medical Organizations and Advocacy Groups

The Sunshine Act mandates the disclosure and publication of pharmaceutical payments to physicians and teaching hospitals with the aim of mitigating against the detrimental impact that Big Pharma money has on patient trust and care. To the extent that transparency of these financial relationships will deter against physicians being improperly influenced by outside interests, the Act achieves this goal. However, the absence of reporting requirements for payments to others that impact patient care—namely, medical organizations and advocacy groups—ignores the influence that these two groups hold. Indeed, some of these groups readily acknowledge these relationships with the pharmaceutical industry and advertise their role in developing new treatments. These relationships can lead to beneficial and innovative results in the development of new drugs and treatments, similar to the benefits that come from industry-physician synergy.

Pharmaceutical companies have used these relationships as a marketing tool to target specific patient groups, just as they targeted physicians. Professional organizations and advocacy groups wield significant influence over which treatments their members prescribe and purchase. The intent behind the Sunshine Act was to give patients a way to peer into the financial relationship between pharmaceutical companies and the physicians whom they trusted to dispense honest medical

129. See supra notes 80-81 and accompanying text.
130. See supra note 114 and accompanying text.
131. See Beryl Lieff Benderly, Advocacy Groups are Crucial Players in Developing New Neurotherapies, J. OF THE AM. SOC'Y FOR EXPERIMENTAL NEUROTHERAPEUTICS (Oct. 2004), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC534956/ (noting that advocacy groups play a crucial role in bringing new neurotherapeutics to market through exerting influence on the drug development process). See also Chapel Hill, Pharmaceutical Advocacy Relations: Building Strong Connections Drives Product Awareness, BUSINESS WIRE (June 1, 2004), http://findarticles.com/p/articles/mi_m0EIN/is_2004_Oct_6/ai_n6224256/?tag=content;col1 (reporting on the close links developed between pharmaceutical companies and patient advocacy and professional groups). Tactics used by pharmaceutical companies include using senior management to advance key issues with advocacy groups and professional organizations, and aligning patient advocacy relationship efforts with marketing and medical departments. Id.
132. See Evelyn Pringle, Tracking the American Epidemic of Mental Illness - Part IV, SCOOP INDEPENDENT NEWS (June 22, 2010, 3:27 PM), http://www.scoop.co.nz/stories/ HL1006/S00162.htm (claiming that pharmaceutical manufacturers spend millions of dollars a year to patient advocacy organizations, in return for their help in marketing the companies' drugs to their members).
advice. The same principle supports the position that pharmaceutical companies' payments to these organizations and groups, given their influence on their members, should be treated similarly.

B. Sunshine Act Penalties Will Not Deter Companies From Noncompliance

Selling pharmaceutical drugs is big business. In 2009, the top ten pharmaceutical companies in the world collectively turned a profit of close to $75 billion. These profits come at a price. The amount of money that Big Pharma companies routinely pay in settlements or government fines for acts arising out of their wrongdoing is staggering, sometimes reaching into the multi-billion dollar range.

In light of pharmaceutical companies' large settlements and larger profit margins, the Act's penalties are too small to encourage compliance. To encourage compliance and best effectuate the purpose of the Act, the fines for not reporting must be raised substantially from their current levels. This Comment proposes that the current penalties are raised ten-fold. For example, the penalty range for each instance of not reporting a payment should be raised to between $10,000 and $100,000, with an annual cap of $1.5 million. For knowing failures to report payments, the penalty range should be raised to between $100,000 and $1 million, with an annual cap of $10 million. While these fines are still relatively small when compared to the industry's profits, they more appropriately represent Congress's commitment to transparency and rebuilding the public's trust in their physicians. But because of the demonstrated limited effect that fines have on mitigating bad corporate behavior, this Comment proposes that egregious, continuous, and knowing failures to

133. See supra Part II.A.1-2.
135. See Big Pharma Lawsuits - Who Got Hit With the Biggest Settlement?, LAWYERSANDSETTLEMENTS.COM (Oct. 25, 2010), http://www.lawyersandsettlements.com/blog/big-pharma-lawsuits-who-got-hit-with-the-biggest-settlement-05310.html (listing some of the highest settlement amounts for various law violations). Some of the more notable settlements include: Eli Lilly was fined $1.4 billion by the U.S. Dept. of Justice, for violations arising out of marketing its drug Zyprexa in 2009; Pfizer was charged with $2.3 billion by the U.S. Dept. of Justice for off-label marketing in 2009; Allergan was fined $600 million by the U.S. Dept. of Justice in 2010 for "off-label use of Botox for headaches, pain, and cerebral palsy." Id.
report, or affirmative attempts to misrepresent disclosures should carry a criminal penalty, including possible prison time.\footnote{136} The public's need to discover industry-physician relationships is of the utmost importance to restore patients' trust.\footnote{137} Undermining that interest is worthy of a harsher penalty under the law.

C. Physicians Should Have the Duty to Disclose Financial Relationships with Pharmaceutical Companies

The Sunshine Act unquestionably provides more transparency into the financial relationship between physicians and pharmaceutical companies than ever before.\footnote{138} The intent behind the Act was to encourage conversations between patients and their physicians by allowing patients to broach the subject with their physicians.\footnote{139} But under the contours of the physician-patient relationship, it is unlikely that patients will have the courage to interrogate their physicians.\footnote{140} The Act can also help create situations where patients are left with a less than optimal choice of selecting between more qualified, but highly “conflicted” physicians, and those that are less qualified, but who take less or no pharmaceutical money.\footnote{141} The best way to resolve this imbalance would be to require physicians to disclose their financial relationship to patients when the advice or prescription given falls within the field of a secondary relationship.

Patients overwhelmingly believe that knowledge of their physicians' financial relationship with outside interests is important.\footnote{142} Evidence of the impact that such relationship has on

\footnote{136} Andrew Jack, *Drugmakers Face Rising Fines and Sentences*, FINANCIAL TIMES (Oct. 27, 2010, 8:27 PM), http://www.ft.com/cms/s/0/9fd96910-e1f9-11df-a064-00144feabdc0.html. The fine amounts imposed on pharmaceutical companies have been derided as merely “the cost of doing business,” by Neil Getnick, an attorney who won a $750 million dollar settlement from GlaxoSmithKline for marketing failures. \textit{Id.} Fines are becoming less effective in preventing pharmaceutical industry abuses; Getnick believes that criminal penalties may be appropriate. \textit{See also} Bruce Lehr, *Big Pharma Absorbs $5 billion in Fines!* “The Cost of Doing Business!”, THE BIG RED BIOTECH BLOG (Oct. 2, 2010), http://thebigredbiotechblog.typepad.com/the-big-red-biotech-blog/2010/10/pharmagossip-5-billion-in-fines-the-cost-of-doing-business.html (contending that the regulatory system which penalizes pharmaceutical companies for deceptive practices by the imposition of large fines has engendered the view among these companies that payment of these fines is a standard business practice).
\footnote{137} \textit{See supra} notes 77-81 and accompanying text.
\footnote{138} \textit{Id.}
\footnote{139} \textit{See supra} notes 80-81 and accompanying text.
\footnote{140} \textit{See supra} notes 115-16 and accompanying text.
\footnote{141} \textit{See supra} notes 117-18 and accompanying text.
\footnote{142} \textit{See supra} note 71 and accompanying text.
patient care is abundant.\textsuperscript{143} Physicians should have the duty to disclose to their patients the nature of their financial relationship when a patient’s knowledge of the physician’s relationship would be important to his or her decision-making. A patient’s knowledge of his physician’s relevant financial relationship affects the credibility of the physician’s advice and prescription habits.\textsuperscript{144} A physician’s duty to inform her patient will better ensure that the patient will make a more informed decision in electing to take the physician’s recommended course of treatment. The public regards physicians’ financial relationships as a matter of great importance.\textsuperscript{145} This affirmative duty will alleviate the anxiety that most patients feel about approaching this topic, and it will mitigate against improper physician-Big Pharma financial relationships, since physicians will engage only in financial relationships that they are comfortable enough to discuss with their patients.

V. CONCLUSION

The Physician Payment Sunshine Act is a significant legislative achievement, mandating that previously hidden payments to physicians be published for all to see. It will go a long way in deterring improper relationships between physicians and Big Pharma. It also has the potential to empower patients with information that will enhance the level of medical care they receive. But to better diminish the impact of secondary financial interests, more action must be taken.

\textsuperscript{143.} See supra notes 56-57 and accompanying text. 
\textsuperscript{144.} Canterbury v. Spence, 464 F.2d 772, 779-94 (D.C. Cir. 1972). The doctrine of informed consent in patient care was explored in Canterbury. Id. While the facts of that case involve a physician not informing his patient of a risk of paralysis from needed back surgery, some of the same principles on a physician’s duty to disclose information to his or her patient are still relevant in this context. Id. at 776. In holding that the physician did have a duty to inform his patient of the risks involving the procedure, Judge Robinson elucidated some important concepts with respect to the doctrine of informed consent. Id. at 779. The most important one is that “every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . .” Id. at 780. Because most patients have little or no medical knowledge, there is a need for physicians to reasonably inform patients to make such therapeutic decisions possible. Id. Judge Robinson also recognized that in addition to the duty to treat a patient skillfully, the physician also labors under the duty to disclose information when the “exigencies of reasonable care call for it.” Id. at 781. This includes the need to disclose the obligation to advise the patient of the need for or desirability of an alternative treatment than the one being pursued. Id. 
\textsuperscript{145.} See supra notes 72-4 and accompanying text.
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