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A REVIEW OF THE SUNSHINE ACT'S OPEN PAYMENTS PROGRAM: ARE PATIENTS STILL IN THE DARK?

Shirley Chen¹

I. INTRODUCTION

In recent years, many consumers have become more actively involved in making socially conscientious decisions through their consumption of products or services.² As consumers become more aware of the link between the goods that they buy and the practices of businesses that provide those goods, transparency has become an important factor in consumer decisions.³ However, consumers are not necessarily willing to investigate further than what is reported in the news headlines and often rely on government standards and regulations to hold companies accountable.⁴ Therefore, the federal government has been more actively involved in improving transparency in the health care industry, given that transparency is a helpful tool for “improving health care quality, lowering health care

¹ J.D./M.B.A. Candidate, May 2015, Loyola University Chicago School of Law and Quinlan School of Business

² Anne Field, *Consumers Like Social Responsibility—But They Aren't Sure What a Social Enterprise Is*, FORBES, Apr. 5, 2015, available at <http://www.forbes.com/sites/annefield/2013/04/05/consumers-like-social-responsibility-but-they-arent-sure-what-a-social-enterprise-is/>; Timothy M. Devinney, *What is Consumer Social Responsibility?*, VIMEO (Mar. 15, 2010), <https://vimeo.com/10169286>.

³ Sarah LaBrecque, *How Much Do Consumers Really Care About Transparency?*, GUARDIAN, Mar. 12, 2014, <http://www.theguardian.com/sustainable-business/transparency-consumers-care-livechat-roundup>.

⁴ *Id.*

costs, and engaging consumers in decision making about their health care choices.”⁵

In particular, large pharmaceutical companies have been increasingly scrutinized under a magnifying glass. For instance, BBC recently published a study, which found that out of the world’s ten largest pharmaceutical companies, nine of them spent more on sales and marketing than they did on research and development in 2013 (in some cases more than twice as much).⁶ Furthermore, most of the pharmaceutical’s marketing is directed at physicians: in 2012, while \$3 billion was spent in the United States marketing to consumers directly, a whopping \$24 billion was targeted at physicians.⁷ Naturally, questions have emerged regarding whether funds that pharmaceutical companies spent on advertising and gift-giving to physicians unduly influences the recipients’ decisions in prescribing medications, creating a conflict of interest.⁸

The federal government addressed this pervasive conflict of interest in the health care system as a result of the relationship between physicians and pharmaceutical companies by passing the Physician Payment Sunshine Act (Sunshine Act) as a component of

⁵ Ruth E. Granfors, *The Open Payments Program: Enforcing Transparency Under the Sunshine Law*, in HEALTH CARE LAW ENFORCEMENT AND COMPLIANCE: LEADING LAWYERS ON UNDERSTANDING RECENT TRENDS IN HEALTH CARE ENFORCEMENT, UPDATING COMPLIANCE PROGRAMS, AND DEVELOPING CLIENT STRATEGIES 23, 26 (2014 ed. 2014).

⁶ Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS, Nov. 6, 2014, available at <http://www.bbc.com/news/business-28212223>; Ana Swanson, *Big Pharmaceutical Companies Are Spending Far More on Marketing Than Research*, WASH. POST, Feb. 11, 2015, available at <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>; *Gilead Sciences Doubles Its Profits to \$12.1 Billion on Strength of \$1,000 Per Pill Hepatitis Drug*, CBS, Feb. 11, 2014, <http://sanfrancisco.cbslocal.com/2015/02/11/gilead-sciences-doubles-its-profit-in-2014-to-12-1-billion-on-strength-of-1000-per-pill-hepatitis-drug/> [hereinafter *Gilead*].

⁷ Swanson, *supra* note 6.

⁸ Shena T. Wheeler, *Under the Influence: An Examination of the Tactics Pharmaceutical Companies Use to Manipulate Physicians*, 7 IND. HEALTH L. REV. 89, 90 (2010); Joshua E. Perry, et al., *Trust and Transparency: Patient Perceptions of Physicians’ Financial Relationships with Pharmaceutical Companies*, 42 J.L. MED. & ETHICS 475, 477 (Winter 2014).

the Affordable Care Act.⁹ The program, officially rebranded the Open Payments Program, was launched last fall to disclose information on financial transactions in 2013 between physicians and drug manufacturers.¹⁰ Specifically, the program is accessible through the Centers for Medicare & Medicaid Services (CMS) website.¹¹ This article will discuss the general purpose behind the Sunshine Act, the scope of the Open Payments Program, and finally, a review of the program's success and shortcomings since its launch in September 2014.

II. BACKGROUND: THE NEED FOR TRANSPARENCY

A. An Inherent Conflict of Interest

Marketing in the pharmaceutical industry does not consist of solely magazine advertisements, billboards, and television commercials. Drug manufacturers exercise creative and non-traditional forms of incentive-based marketing through developing relationships with physicians that often involve gift-giving.¹² This can include free meals or drug samples, trinkets, compensation for speaking engagements, consulting fees, entertainment and reimbursement for travel expenses.¹³ On the one hand, forming these bonds can prove to be beneficial to the medical community as physicians and drug manufacturers collaborate more to improve public health and patient care.¹⁴ For example, free drug samples can allow physicians to begin treatment early and determine whether the drug is effective prior to a patient purchasing it.¹⁵

⁹ Granfors, *supra* note 5, at 24; *see* Patient Protection and Affordable Care Act, 42 U.S.C. § 1320a-7h (2010).

¹⁰ *Physician Financial Transparency Reports (Sunshine Act)*, AM. MED. ASS'N., <http://www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page?> (last visited Feb. 15, 2015).

¹¹ *See Open Payments*, CMS.GOV, <http://www.cms.gov/OpenPayments/index.html> (last visited Feb. 25, 2015).

¹² Wheeler, *supra* note 8, at 90.

¹³ *Id.* at 90-91; Perry, et al., *supra* note 8, at 476.

¹⁴ Perry, et al., *supra* note 8, at 475; BERNARD LO & MARILYN J. FIELD, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 2 (2009).

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

However, financial ties between the two parties create the risk that physicians will be unduly influenced by large pharmaceutical companies, compromising physicians' objective judgment in prescribing medication.¹⁶ In fact, studies show that gifts often have more of an effect on physicians' subsequent prescribing habits than they would care to admit. For instance, those that accepted free meals from drug companies were more likely to request that the companies' drugs be added to a hospital formulary.¹⁷ With respect to free drug samples, some researchers stated in their findings that drug samples might influence physicians to dispense or prescribe drugs that differed from their preferred drug choice.¹⁸

The risk of harm to individual patients is not the only concern when it comes to the pharmaceutical companies' influence over physicians. These financially incentivized relationships may even contribute to the overall affordability of prescription drugs when physicians prescribe brand name drugs over equally effective generic versions.¹⁹ For example, in the United Kingdom, it is estimated that the National Health Service could save up to £1 billion a year by switching from branded to generic drugs.²⁰ By reducing the influence that pharmaceutical companies have on physicians, there may be a reduction in overall costs of prescription drugs across the market.

B. Pharmaceutical Practices and Profits Beg the Question

In 2013, United States pharmaceutical company, Pfizer, made a 42% profit margin on its revenue. In early 2015, Gilead Sciences, a pharmaceutical firm based in the Bay Area, California, announced that it had more than doubled its revenue in 2014.²¹ As the pharmaceutical industry is an integral part of the modern health care system, the news of increased profits is consistent with the overall trend of "pharmaceutical companies report[ing] the largest profit margin of any industry worldwide."²² These profits are also in line

¹⁶ Perry, et al., *supra* note 8, at 475.

¹⁷ Wheeler, *supra* note 8, at 105.

¹⁸ *Id.* at 110; Chew, *supra* note 15, at 482.

¹⁹ See Anderson, *supra* note 6.

²⁰ *Id.*

²¹ Gilead, *supra* note 6.

²² Michael Callam, *Who Can Afford It?: The Patient Protection and Affordable Care Act's Failure to Regulate Excessive Cost-Sharing of Prescription Biologic Drugs*, CLEV. ST. J. L. & HEALTH 99, 105 (2014).

with the cost structure of many brand name drugs. For instance, cancer drugs like Gleevec are among the most expensive drugs that pharmaceutical companies have to offer with some “costing upwards of \$100,000 for a full course.”²³ Some of the costs can be attributed to patents which all eventually expire, encouraging companies to produce as much profit as possible during the roughly ten years that the drug is actually and exclusively on the market.²⁴

Moreover, drug manufacturers’ marketing techniques have likewise contributed to large profit margins and have become a point of controversy in the past few years. For instance, Johnson & Johnson was accused of practices in violation of federal anti-kickback statutes from 1999 to 2004.²⁵ During that time period, the “pharmacy’s annual purchase of Johnson & Johnson medications nearly tripled to more than \$280 million, from about \$100 million.”²⁶ Physicians and pharmacies were allegedly paid incentives to promote three of the firm’s medicines while the firm promoted the drugs for uses not approved by the Food and Drug Administration.²⁷ Johnson & Johnson eventually settled the cases for \$2.2 billion, constituting the third-largest settlement involving a pharmaceutical company in the history of the United States.²⁸

One of the United Kingdom’s giant pharmaceutical companies, GlaxoSmithKline, has also come under fire. In May 2014, Chinese authorities accused the company of bribery to government authorities and hospital officials to promote an asthma drug.²⁹ Furthermore, in the United States, the same company settled with forty-four different states in June 2014 on allegations of illegal

²³ Anderson, *supra* note 6.

²⁴ *Id.*

²⁵ Natasha Singer, *Johnson & Johnson Accused of Drug Kickbacks*, N.Y. TIMES, Jan. 15, 2010, available at http://www.nytimes.com/2010/01/16/business/16drug.html?_r=0.

²⁶ *Id.*

²⁷ *Id.*; *Johnson & Johnson Fined \$2.2bn to Settle Drug Cases*, BBC NEWS, Nov. 4, 2015 [hereinafter *Johnson & Johnson*], available at <http://www.bbc.co.uk/news/business-24811664>.

²⁸ *Johnson & Johnson*, *supra* note 27.

²⁹ *GlaxoSmithKline to be Investigated by UK Fraud Body*, BBC NEWS, May 27, 2014, available at <http://www.bbc.com/news/business-27597312>.

promotion of its drugs, which may have related to its previous federal government settlement in 2012 in the amount of \$3 billion.³⁰

The coverage in the media over the exorbitant profits that pharmaceutical companies make in conjunction with the investigation into their marketing practices reflect an overall desire for transparency in the industry, especially in regards to their interactions with physicians. This is precisely the goal of the Sunshine Act. In particular, the Sunshine Act aims to “distinguish legitimate financial relationships from improper ones” and “inform patients about the relationships so that, as health care consumers, they might make better-educated decisions about where to seek care and whom to trust.”³¹

III. THE PROGRAM’S SCOPE

As a whole, the program seeks to help make financial relationships clearer by providing a central location for financial interactions to be reported and monitored.³² Furthermore, it is meant to discourage “dishonest influence on research, education, and clinical decision-making.”³³

Unlike other state and federal laws governing the health care industry, the Open Payments Program depends on self-reporting instead of relying on whistleblowers and government investigators.³⁴ In particular, the program requires “applicable manufacturers” and “applicable GPOs,” collectively deemed “Reporting Entities,” to report to CMS any payment or transfers of value made to physicians and teaching hospitals.³⁵ Pharmaceutical companies qualifying as

³⁰ *GlaxoSmithKline in \$105m (£63m) Settlement with 44 US States*, BBC NEWS, June 4, 2014, available at <http://www.bbc.com/news/business-27706037>; see also Anderson, *supra* note 6.

³¹ Perry, et al., *supra* note 8, at 477.

³² See *Fact Sheet for Physicians*, CMS, 1, available at <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf>, (last visited Feb. 24, 2015) [hereinafter *Fact Sheet*].

³³ *Id.*

³⁴ Perry, et al., *supra* note 8, at 475.

³⁵ *Fact Sheet*, *supra* note 32, at 1; see Granfors, *supra* note 5, at 27–28 (discussing the particular characteristics to qualify as applicable manufacturers and applicable GPOs).

applicable manufacturers are required to report all payments falling into the following categories:

consulting fees, compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program, [h]onoraria, [g]ifts, [e]ntertainment, [f]ood and beverage, [t]ravel and lodging, [e]ducation, [r]esearch, [c]haritable contributions, [r]oyalty or [l]icense, [c]urrent or prospective ownership or investment interest, [c]ompensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program, [c]ompensation for serving as faculty or as a speaker for an accredited or certified continuing education program, [g]rants, [and] [s]pace rental or facility fees (teaching hospital only).³⁶

Physicians, on the other hand, are not required to disclose any information to CMS.³⁷ However, they are encouraged to register on the site, given that the success of the program is arguably dependent on the participation of physicians to keep records of all transfers of value and verify the accuracy of reported information.³⁸ Prior to publicly revealing the information, physicians have the opportunity to dispute any inaccurate information.³⁹

VI. CONCLUSION: THE RESULTS ARE IN

Reminiscent of the botched launch of the Healthcare.gov website in the fall of 2013,⁴⁰ the Open Payments Program likewise experienced some technological difficulties leading up to the September 30, 2014

³⁶ *Fact Sheet*, *supra* note 32, at 3.

³⁷ *Id.* at 1–2; Granfors, *supra* note 5, at 34.

³⁸ *Fact Sheet*, *supra* note 32, at 2.

³⁹ Granfors, *supra* note 5, at 34.

⁴⁰ See Paul Ford, *The Obamacare Website Didn't Have to Fail. How to Do Better Next Time*, BLOOMBERG BUSINESS, Oct. 16, 2013, available at <http://www.bloomberg.com/bw/articles/2013-10-16/open-source-everything-the-moral-of-the-healthcare-dot-gov-debacle>; see also Christi Parsons & Noam Levey, *Obama on Healthcare Sign-up Glitches: 'It's going to get fixed'*, LA TIMES, October 21, 2013, available at <http://www.latimes.com/nation/politics/politicsnow/la-obama-healthcare-obamacare-signup-fix-20131021-story.html>.

release date. The physician registration process was lengthy and complex; physicians that were able to register had problems navigating the portal, and the site was even taken offline for about a week and a half at the beginning of August.⁴¹ By the end of August, one month prior to the launch, physicians who had completed registration with the system had less than two weeks to review and dispute data reported regarding their financial interactions with the Reporting Entities. Nearly 62% of those registered found inaccuracies.⁴²

When the site went public at the end of September, nearly 300,000 records were withheld because they had not been verified.⁴³ In addition, 40% of reported payments had problems with the data and were subsequently stripped.⁴⁴ Since the public unveiling of the website, the Open Payments Program continues to suffer from errors including: misspelling, recording of payments for a single drug under multiple names, and payments recorded without connecting them to specific products.⁴⁵ In addition, some subsidiaries recorded payments made by its parent company for the same drugs.⁴⁶ These mishaps make it difficult for patients to get a true sense of the financial relationships.⁴⁷ According to CMS, most of the reporting errors are on the part of Reporting Entities, and CMS is committed to not

⁴¹ *Troubles with Sunshine Act Website? We're Taking Them to CMS*, AMA WIRE, Aug. 13, 2014, available at <http://www.ama-assn.org/ama/pub/ama-wire/ama-wire/post/troubles-sunshine-act-website-were-taking-cms> (last visited Jan. 28, 2015).

⁴² *Time Running Out to Review Sunshine Data—And It Isn't Very Accurate*, AMA WIRE, Aug. 28, 2014, available at <http://www.ama-assn.org/ama/pub/ama-wire/ama-wire/post/time-running-out-review-sunshine-data-isnt-very-accurate> (last visited Jan. 28, 2015).

⁴³ Jason Millman, *John Oliver Attacked Big Pharma Last Night. Here's One Important Thing He Left Out.*, WASH. POST, Feb. 9, 2015, available at <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/02/09/john-oliver-attacked-big-pharma-last-night-heres-one-important-thing-he-left-out/>.

⁴⁴ *Id.*

⁴⁵ Katie Wike, *Open Payments Continue to be Problematic*, HEALTH IT OUTCOMES, Feb. 4, 2015, available at <http://www.healthitoutcomes.com/doc/open-payments-continue-to-be-problematic-0001>.

⁴⁶ *Id.*

⁴⁷ Charles Ornstein, et al., *Data on Payments from Drugmakers to Doctors is Marred by Error*, N.Y. TIMES, Jan. 22, 2015, available at <http://www.nytimes.com/2015/01/23/upshot/data-on-payments-from-drugmakers-to-doctors-is-marred-by-error.html?abt=0002&abg=1>.

altering any of the data provided.⁴⁸ However, because the pharmaceutical industry faced tight deadlines, and given the fact that this is the first year that companies experimented with public disclosure on such a scale, the accuracy of the information is expected to improve in future years.⁴⁹

Furthermore, notwithstanding the technological complications and the reporting system's complexity, to what degree has the Open Payments Program been effective on perceptions? Since the launch in September 2014, a market research firm surveyed 461 physicians to determine their participation in the program in February 2015.⁵⁰ Of the total number of physicians surveyed, a little over half were either familiar or somewhat familiar with the Sunshine Act itself, which created the database program.⁵¹ Moreover, 46% of those surveyed visited the CMS website to either check it out or verify the accuracy of the reported information.⁵² Of that 46%, 54% stated that they did not find any issues with the information reported despite the fact that they believed some activities that should have been reported were not.⁵³ Of the 54% that did *not* visit the site, a little over half did not care if any payments had been reported.⁵⁴

Overall, 76% of physicians participating in the survey believed that their activities with the pharmaceutical company had not changed since the launch of the program and the disclosure of their 2013 activities.⁵⁵ This is, however, no indication of the future success of the program. For instance, 21% of participants did report a decrease in activity.⁵⁶ And although the Open Payments Program began with a rocky start, there is still hope in the program to achieve its original goals of bringing transparency in the health care industry to consumers and patients. As the program develops and participating entities begin learning to effectively and accurately report

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ Ed Silverman, *What Money? Many Docs Haven't Visited the Open Payments Database*, WALL STREET JOURNAL, Feb. 20, 2015, available at <http://blogs.wsj.com/pharmalot/2015/02/20/what-money-most-docs-havent-visited-the-open-payments-database/>.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

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transactions, consumers will have the tools to make informed decisions regarding their health care providers and medication. In the long run, disclosures that better characterize physician relationships with drug manufacturers may discourage unfair marketing practices and ultimately reduce the price of prescription drugs across industry.