The Role of Physician Education and Incentives in Physician Decision Making

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science
University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science, School of Engineering

Alexa Pass

Spring 2022

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Advisor

Sean M. Ferguson, Department of Engineering and Society

Introduction

With the growth of medical drug and device companies within the last one hundred years, it is common practice for representatives of these companies to meet with physicians to educate them on the company's products. The main goal of this exchange is to educate physicians with an added benefit of the physicians being more likely to prescribe their product as a result of the education.

The issue with this education is that it historically entails paying for outings (meals, golf, etc.) with physicians to get an uninterrupted hour. The notion of physician education is a highly contentious one, as it becomes difficult to draw the line between what is simply education versus what is overcompensation. While direct monetary payment for the purpose of convincing physicians to prescribe is relatively rare and agreed upon to be unethical, it is harder to make the distinction for meetings of smaller monetary cost.

The Physician Payments Sunshine Act (PPSA) as part of the Affordable Care Act of 2010 attempted to mitigate inappropriate payments that directly influence prescribing. Centers for Medicare and Medicaid (CMS) payments, an official website of the United States Government, was set up as part of the 2010 Affordable Care Act. It is a public database that houses records of payments that drug and medical device companies make to physicians in order to promote a more transparent and accessible healthcare system.

Physician education, whether a transfer of money is associated or not, *will* impact a physician's decision making. I will be investigating the roles among CMS Payments and the 2010 Affordable Care Act, physicians, pharmacists, and pharmaceutical and medical device companies in physician education and medical decisions. Angèle Bilodeau's exploratory piece in Health

Promotion International utilizes Actor Network Theory to focus on the effectiveness of public health interventions. Her exploratory paper makes an important point of how Actor Network Theory is meant to function; while the actors in the network are identified, it is actually the connections between them through which they act. Thus, the connections among the actors are the most vital piece to dissect (Bilodeau & Potvin, 2018) . In the case of physician payoffs, the connections among the actors are highlighted, as they have been altered following the implementation of the Physician Payments Sunshine. Similar to Bilodeau's piece, I will be utilizing Actor Network Theory to look at the effect of the public health intervention of legislation concerning the Affordable Care Act of 2010 on this network. The goal is to represent the interconnectedness of physician education and examine exactly how the network's connections were severed and changed as a result of the Affordable Care Act of 2010. The paper will end with a commentary on some possible solutions to shrink the public health knowledge gap concerning how patients, physicians, pharmacists, and pharmaceutical companies interact.

Methods

For a greater understanding of how this network functions, I synthesized a variety of sources to help illustrate the physician education landscape pre- and post-implementation of the Affordable Care Act of 2010. The utilization of the specific wording of the government websites and legislation was necessary to provide a concrete background with commentary rooted in fact. I also conducted four interviews, with pharmacists Dr. David Pass, Dr. Lisa Pass, and Mr. Michael Pass RPh, as well as physician Dr. Eddie Papish. These interviews give personal insight into how both physicians and pharmacists are involved in the network and have seen it fractured

in response to the Physician Payments Sunshine Act. These testimonials enrich understanding as they are from lived experiences of professionals who have worked in the medical sector during this time period. Finally, I conducted a survey of adults aged 18-65 to gauge understanding of physician education and to influence possible solutions to increase public awareness.

Pre-2010 Landscape

Even prior to the 2010 Affordable Care Act, it was illegal for physicians to receive unlawful payments for prescribing certain products through the Medicare/Medicaid Anti-Kickback Statute (Sorenson, 2003). This statute, enacted in 1991, made it illegal for a physician to receive monetary payment for referring a patient for a service/prescription/recommendation of purchase that will be paid in part/whole by a federal health care program. The violation of this statute will result in a felony. This illegal payment can include kickbacks, cash, rebates and discounts, and even alcohol (*Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions*, n.d.).

The AMA Journal of Ethics looked at this pre-2010 legislation and instances where the law has been broken. One such instance occurred in 1994, where Dr. David Brown was the one of the largest prescribers of Protropin, a genetically engineered human growth hormone made by Genentech and distributed by Caremark, a home healthcare company. Over 8 years, Dr. Brown was paid over $1.1 million dollars: over $500,000 in research grants, over $100,000 for a marketing agreement, and over $200,000 that was paid to the office and staff and additionally labeled as “consulting” fees. Dr. Brown, Genentech, Caremark, and Caremark executives were then prosecuted for violating the Medicare/Medicaid Anti-Kickback Statute. A vital part of the

plea agreement for Caremark, including $161 million in fines and restitutions, required Caremark to stipulate that it made payments to Dr. Brown to encourage him to increase Protropin referrals and resultant written prescriptions (Sorenson, 2003). While this may seem far off from the dinners and golf outings that the Physician Sunshine Act addresses, the situations are not dissimilar. The events paid for by medical device and pharmaceutical companies are simply indirect methods of payment during these educational meetings which have the possibility to encourage physicians to write more prescriptions.

I interviewed retired physician Dr. Eddie Papish for his take on physician education and incentives. Dr. Papish practiced medicine for over 30 years in a private practice setting, and then moved to clinical teaching for 10 years. Eddie was aware of other physicians receiving more expensive gifts, but said that a dinner or conference was the extent of any education he received, and was never in the form of direct monetary payment (*Interview with Dr. Edward H Papish DO, 6 October 2021.*, personal communication, n.d.).

I also interviewed David Pass, PharmD, regarding his views on physician education and how it's evolved over the past 30 years. Dr. Pass worked in marketing for multiple big pharmaceutical companies as well as a clinical pharmacist on the weekends early in his career. David's role was in marketing, but he was aware of the education that took place between the company and physicians. He states that the notion of taking physicians out to dinner was never a form of payment; physicians in private practice have very little free time during the day, so taking them out to dinner is a way to have their full attention for an hour to educate them (*Interview with Dr. David Pass PharmD, 6 October 2021*, personal communication, n.d.).

For a more robust understanding of pharmacists' views on physician education, I interviewed Michael Pass, a retired Pharmacist and business owner in Sarasota, Florida. Mr. Pass practiced pharmacy for 55 years at his small business, Family Pharmacy, before retiring in the early 2000s. Mr. Pass' view on physician payment is a unique perspective because he occasionally took physicians out to dinner. Though he was a pharmacist, he was acting in a similar manner to the pharmaceutical and medical device companies with a purpose of educating physicians. This was viewed as common practice at the time, and was very much legal. Reiterating what David Pass stated, Michael Pass wanted an uninterrupted moment with physicians to educate them on the compounded products he made. The benefit of this dedicated time is that the physicians were more likely to suggest Family Pharmacy to their patients to get specific products he compounded (*Interview with Michael Pass*, personal communication, October 6, 2021).

While it may seem that pharmacists are not involved in this network, they are actually an important player. PharmDs have a more complete understanding of the medications that are being prescribed and how these drugs or devices affect the human body. Lisa Pass PharmD worked at multiple hospitals as a clinical pharmacist for five years before retiring in 2000. Though she had no prescribing power, her role was to interact with physicians and consult on medications and dosages. Drug company representatives would often come and speak with her to provide education on their available drugs. This was similar to the interactions between physicians and pharmaceutical or device companies. She acted as a gatekeeper to the hospital formulary by evaluating proposed medications and discussing with appropriate medical staff. Dr. Lisa Pass never felt manipulated by these representatives because she was confident in her knowledge base more than marketing material (*Interview with Dr. Lisa Pass, PharmD*, personal communication, April 20, 2022).

The illegal payments that occurred before 2010 were clearer unethical situations than the situations that the Physician Payments Sunshine Act (PPSA) was trying to thwart. It is generally accepted that direct payment compensation to physicians, as is addressed by the Medicare/Medicaid Anti-Kickback Statute, is unethical. Once the Medicare/Medicaid Anti-Kickback Statute passed, pharmaceutical and med device companies had to pivot in terms of how they approach physician education and incentives. As a result, these direct payments turned into educational meetings with nice dinners, golf outings, etc. so that companies were not violating the statute. This evolution and dilution over time of education/incentives is vital to understand, as it lays the foundation of how the network came to be and what has had an impact on those connections. The network prior to 2010 can be seen in the figure below.

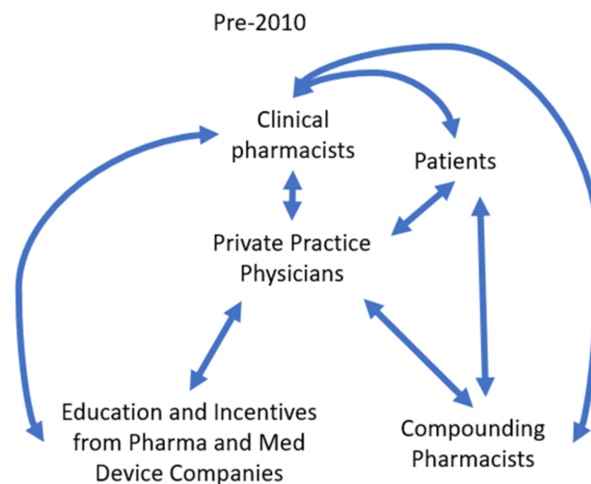

Figure 1: The Interconnected Network of Players Affected by the Physician Payments Sunshine Act Prior to 2010

2010: A Turning Point

010 was a critical turning point for medical device and pharmaceutical companies. Actor Network theory focuses on disturbances in a network (Bilodeau & Potvin, 2018) – the "disturbance" of 2010 irrevocably changed the landscape of patient care in relation to physician education by pharmaceutical and medical device companies.

The Affordable Care act of 2010 added an act specifically pointed at drug and medical device companies giving money or gifts to physicians (*The Physician Payments Sunshine Act | Health Affairs*, n.d.). The act, named the Physician Payments Sunshine Act (PPSA), requires medical product manufacturers to disclose any financial compensations made to physicians or teaching hospitals to the Centers for Medicare and Medicaid services (CMS). Additionally, it requires certain manufacturers and groups purchasing organizations (GPOs) to disclose any physician ownership or investment interests held in those companies.

The result of the Sunshine Act was the rollout of the CMS payments system, an online website dedicated to providing transparency with physician payoffs. Manufacturers of drugs, medical devices, biologics, and medical supplies and group purchasing organizations (GPOs) are responsible for reporting their physician payments into the system – a *publicly* available database[LP7] (*Open Payments Data - CMS*, n.d.).

Post-2010 Landscape

Following the implementation of the Physician Payment Sunshine Act, not only could med device and pharmaceutical companies not directly pay physicians to advocate and prescribe their drug, now they were legally required to be transparent about indirect monetary incentives as well. The PPSA threw a wrench in medical device and pharmaceutical company's plans to incentivize their physicians legally without having to report what they were doing. With all eyes on these companies *and* the physicians they meet with for educational purposes, many of these lavish dinners and trips to conferences were halted (Santhakumar & Adashi, 2015). All of a sudden for these companies and providers, it was a deer-in-headlights situation. On the med device and pharmaceutical side, it's a bad look for these companies to be spending hundreds or even thousands of dollars on dinners and sending physicians and their families to Disney world. On the physician side, these providers are put in a bad light if patients decide to view this public database and see that their physician was provided a $300 dinner and a paid trip to a conference in Bermuda by one company.

While pharmacists were not the direct target of the PPSA, they were affected. When the PPSA was enacted, Michael Pass, a member of the business sector of pharmacists, immediately stopped taking physicians out to dinner to educate them on his compounded products. He states, though, that this had very little effect on his relationship with physicians. He felt that he had a very strong and respectful connection to the physicians who sent their patients to his compounding pharmacy, and this connection was not severed when he could not longer take them out to educational dinners. While when most people think of pharmacists, they assume that they are just the people who dose and fill your medications. As a pharmacist running his own compounding pharmacy, Mike regularly interacted with patients – advising them on the medications they were

taking, instructions for usage, and overall friendly conversation. Mike understood that pharmacists, just like physicians, were professionals that patients trusted to help them get better.

Although it is not common, there have been multiple instances of a clear undue pharmaceutical influence in inappropriate prescribing. One such instance is Avenir Pharmaceuticals targeting the elderly at long term care (LTC) facilities, knowing that their drug Nuedexta was not appropriate for the needs of all of the patients. It was reported in 2019 that one physician, a paid speaker for Nuedexta, had entire units of patients on the drug in the LTC where he worked (*Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations*, 2019). It's important to highlight instances such as this one to emphasize that though they are rare, these payoffs do occur – and they have direct consequences on patients.

Despite the main sentiment of transparency, there are multiple loopholes in the CMS reporting system. One main loophole involves catering large meals, where buffets can be reported differently than individual paid meals for physicians. A second loophole is with "indirect" payments to physicians who serve as faculty for "certified" and "accredited" continuing medical education (CME) programs. It allows for money, as long as it is not directly given to the speaker/faculty member, to be unreported in the CMS system. These funds of unknown amounts can quickly add up to hundreds, thousands, even millions of dollars (Lichter, 2015).

As can be seen in the figure below, compared to the pre-2010 network, medical device and pharmaceutical companies as well as compounding pharmacists were forced to distance themselves, in a way, from physicians following the implementation of the 2010 Affordable Care Act. The connection between physicians and medical device companies was visibly strained.

Each of these actors had to watch their own back and be more careful about the implications of the education they were receiving.

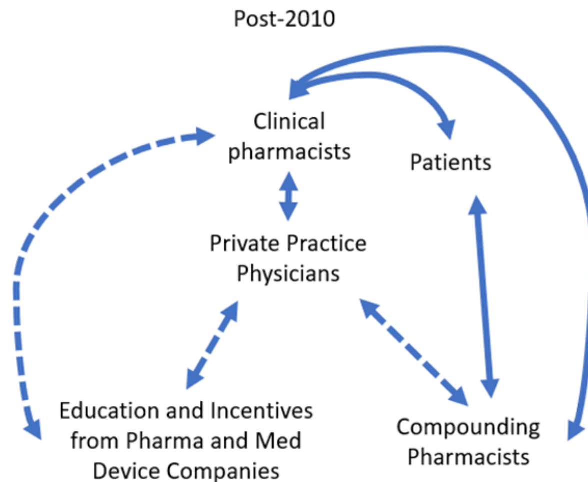

Figure 2: The Interconnected Network of Players Affected by the Physician Payments Sunshine Act Post-2010

Before creating my own survey for patients, I dug into the literature to see what has already been done to assess patient understanding of the relationship between pharmaceutical/medical device companies and physicians. One survey from 2009, prior to the implementation of the PPSA, looked at patient awareness and concern regarding pharmaceutical manufacturer interactions with doctors. The statistic from this survey that I was most interested in was that 38.8% of respondents would choose a doctor who did not see pharmaceutical representatives over one that did (Edwards & Ballantyne, 2009). While it is unclear the background of each of these respondents, it is definitely a point of interest how many patients who would rather a physician who doesn't meet with reps; as Dr. David Pass and Michael Pass both stated, this physician education is actually incredibly important as it informs providers how

to better prescribe and treat their patients. This reflects the general misunderstanding of the network and the importance that reps actually *do* play in the overall improved care of patients, which is why education hasn't been banned completely.

Like most solutions, no proposed change in the system will make physician education perfectly "ethical", smoothly run, and approved by all. When considering which changes I think would benefit the system from a patient's point of view, I wanted to include a more comprehensive view from patients regarding physician education. I created a survey and sent it to over 50 people – I got 35 responses in the google form. My "participants", those who filled out the form, were a mix of all ages (18-65, with a heavier focus on the college student 18–22-year-old age range). Though it was short, I believe the two questions below are vital in understanding how patients understand the network:

1. Are you aware that physicians can legally receive incentives/education (dinner, paid trips to conferences, golf outings, etc.) paid for by a pharma/med device company that intentionally or unintentionally sways them to write more prescriptions of a drug/medical device product?
    a. If yes, how did you know about this system?
2. What would be the most credible/useful way to send this information to increase awareness?
    a. Answer choices (multiple choice)
        i. Paid promotions on social media
        ii. Newspaper ad/promotion
        iii. Commercial/TV presence
        iv. Other (please specify)

As was expected, 27 out of the 35 participants in the survey answered no to question 1; they were not aware of the extent of the interaction between medical device and pharmaceutical companies. For those that answered yes, all 8 said that they were either directly involved in the clinical side of the medical field or had family members who were. This small-scale research indicates that this network is widely unknown to the majority of patients. 25 out of the 35 participants selected "paid promotions on social media" for number two, suggesting that this may be the best way to increase awareness in our social media-dominated society.

The overall goal for this promotional "solution" is for a wider educational understanding of how this network functions for the general public. Additionally, the promotion should be very clear in the reason behind physician education and its benefit in addressing the concerns of representatives from the 2009 survey discussed above.

Discussion

It's hard to pin down the *right* and *wrong* sides of ethical questions concerning *if* and *to what extent* should physician education be allowed. How different is a golf outing than a dinner? What exact price per meal given to each physician is too much? These questions, like most ethical questions, are very subjective. As I've seen in my personal research, most people simply do not know enough about the specifics of this physician education to even have an opinion. Instead of trying to answer the question "how unethical is physician education" I think that it's much more beneficial to understand *how* the network works and what players are involved in order to see what exactly and to what extent is influencing these final physician prescribing decisions. Once the network and connections are more fully understood, only then can the

network be critiqued for ways to improve it. Utilizing the actor network theory, I found it crucial to combine legal documents, government-run websites, personal narratives, and a representative survey as evidence to fill out the network and critically understand each player's role and the connection between each player. Ultimately, I was able to map which connections were strained following the passing of the PPSA and suggest a solution to increase public knowledge about this widely misunderstood network to allow patients to make more informed decisions about their care.

Conclusion

Physician incentives have the power to corrupt a physician's sound judgment, but Michael Pass put it best when he stated "There are good and bad people in every profession". This sentiment holds true, as the majority of physicians agree to be educated by drug and medical device companies but do not let the money, dinners, or gifts make the prescribing decisions for them. The interconnected network of physicians, pharmacists, and education and incentives was altered by the passing of the Affordable Care Act of 2010; it stopped *some* unethical physician incentives by pharmaceutical and med device companies. This act requiring transparency of payments to physicians is a partial step in the right direction; there is still work to be done to increase awareness of this system and curb unjust incentives for physicians affecting their clear decision making of thoughtful, fact-based care for patients.

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