Health Law Outlook

The Health Law Forum ("HLF") is a student organization that connects Seton Hall Law students who are interested in health law with other students, faculty, health care organizations, and health law attorneys. HLF created Health Law Outlook to give its members an opportunity to research and write about health law and share their work outside of the classroom. Health Law Outlook also posts work that students prepared for classes or for other research and writing requirements.

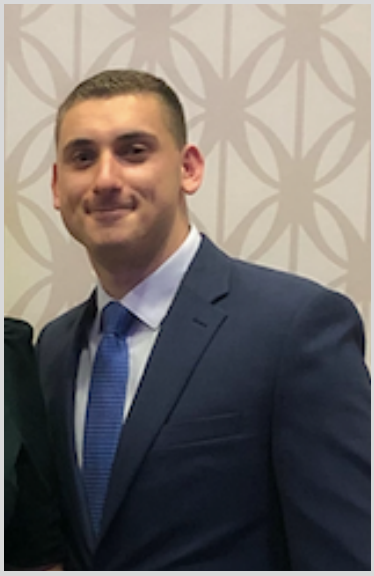
Health Law Outlook encourages students to develop their knowledge of health law, practice research and writing skills, and develop interests in specific areas of health law.

Health Law Outlook is not a journal publication, and it does not engage in a student or external submissions process. Any student who chooses a health law topic and meets the deadlines with completed work product will have their work shared through this medium.

Health Law Forum is grateful to its E-Board, Faculty Advisors, students who share their work through Health Law Outlook, and all student members for their continuing dedication to HLF and the health law field.

ADDITIONAL WORKS available at:
https://scholarship.shu.edu/health-law-outlook/

HEALTH LAW FORUM



John DeFuria

3L

Class of 2021

John grew up in Caldwell, New Jersey and graduated from The University of Delaware in 2018 with a B.S. in Finance. After his first year at Seton Hall Law, John worked as a Legal Intern at Bayer Pharmaceuticals in Whippany, New Jersey where he was first exposed to a variety of legal issues in healthcare.

During his 2L year, John continued to pursue in-house experience working as a remote Legal Extern at Genentech, Inc., headquartered in San Francisco, California. In this role, he conducted research pertaining to the evolution of U.S. privacy rights related to patient health and genetic data. This research was conducted as part of an effort to navigate the complex legal and regulatory landscape as Genentech works towards developing an integrated personalized healthcare system.

Following those experiences, John spent his 2L summer working as a Summer Associate at Brach Eichler in Roseland, New Jersey where he focused primarily on healthcare-related matters.

All of these experiences have cultivated John's ever-growing interest in healthcare law. During his 3L year, John has been working part-time as a law clerk at Mandelbaum Salsburg in Roseland, New Jersey where he has been assisting with healthcare issues as well as white-collar criminal matters and government investigations. After graduation, John will be joining Mandelbaum Salsburg as an Associate in their Healthcare
Department.

Outside of academics, John is the President of the Rodino Society at Seton Hall Law. He enjoys spending time with his family and is proud to have co-founded an annual toy drive to benefit the children of Colombia Presbyterian Children's Hospital n New York, New York where his younger brother received three open-heart surgeries.

The Patient Assistance Problem

John DeFuria*

Introduction

Prescription drug prices and rising healthcare costs in the United States continue to be a topic of controversy as drug manufacturers, governments, insurance companies and patients battle over who to blame for high drug prices.[1] Due to increasingly high healthcare costs, the reality of how insurance companies cover the cost of prescription medicines has left many Americans "functionally uninsured" meaning that their health insurance either does not cover certain medications or requires them to pay out-of-pocket costs that they simply cannot afford.[2] Patient Assistance Programs ("PAPs") serve as an important safety net for the many Americans who do not have insurance or whose insurance does not sufficiently cover the costs of their medications.[3] PAPs come in various forms and facilitate patient access to prescription drugs by providing financially needy patients with cash subsidies and co-pay assistance.[4] At first glance, relieving the financial burdens that would otherwise keep patients from accessing life-saving medications appears to be a reasonable solution.[5] However, from a broader perspective, it might not do anything to address the underlying reasons why these financial burdens exist in the first place, and a flood of recent enforcement actions by the Department of Justice targeting PAPs have led to increased scrutiny in the area.[6] Many question the long-term sustainability of the current patient financial assistance model, and wonder if PAPs are merely a Band-Aid trying to fix a much larger problem.[7]

---

* J.D. Candidate, 2021, Seton Hall University School of Law; B.S., The University of Delaware.

[1] *See List of Pharmaceutical Companies in the United States of America*, PHARMAAPROACH, https://www.pharmapproach.com/list-of-pharmaceutical-companies-in-united-states-of-america (last updated Dec. 21, 2020) (listing pharmaceutical companies in the U.S.); *10 Government Health Care and Assistance Programs,* HOFSTRA UNIV. SCH. OF LAW BLOG, https://onlinelaw.hofstra.edu/blog/10-government-health-care-insurance-and-assistance-programs (last visited Apr. 20, 2020) (listing U.S. government sponsored health insurance programs); Alex Flitton, *Top 25 Health Insurance Companies in the U.S.*, PEOPLEKEEP (Jan. 13, 2020, 4:09 PM), https://www.peoplekeep.com/blog/top-25-health-insurance-companies-in-the-u.s (listing examples of private health insurance companies in the U.S.).

[2] *The Need for Patient Assistance and Access Programs*, PATIENTS RISING NOW, https://patientsrisingnow.org/the-need-for-patient-assistance-and-access-programs/ (last visited Aug. 6, 2019).

[3] *Id.*

[4] *Id.*

[5] Rishi Sachdev & Yousuf Zafar, *Patient Assistance Programs: Do They Help or Hurt?*, NAT'L COAL. FOR CANCER SURVIVORSHIP: CANCER POLICY BLOG (Mar. 26, 2018), https://www.canceradvocacy.org/blog/patient-assistance-programs-do-they-help-or-hurt/.

[6] *See id.*

[7] Trevis Gleason, *Who Really Benefits From Pharma Patient Assistance Programs?*, EVERYDAY HEALTH: LIFE WITH MULTIPLE SCLEROSIS (Mar. 22, 2017), https://www.everydayhealth.com/columns/trevis-gleason-life-with-multiple-sclerosis/who-benefits-from-patient-assistance-programs/.

In order to begin analyzing the potential issues, it is important to take a closer look at the pharmaceutical industry as a whole. The United States biopharmaceutical industry is the largest in the world, and U.S. firms conduct over half of the world's pharmaceutical research and development spending.[8] The pharmaceutical industry often appears on lists of the most profitable industries;" the massive profits often associated with pharmaceutical companies are made possible, however, because of the patent protection granted to new drug discoveries.[9] The pharmaceutical industry is research and development-driven with manufacturers investing millions of dollars and incurring significant expenses with hopes of developing a "blockbuster" drug.[10] A successful drug discovery can generate exponential profits, but the high upfront costs and level of uncertainty create a risky investment, leaving investors seeking high potential returns to offset the risk.[11] Once a drug is developed, marginal manufacturing costs are relatively low, which makes patent protection necessary to justify the research and development costs.[12] Without patents, manufacturers would be able to produce drugs at minimal prices; there would be no incentive, however, for pharmaceutical companies to take the risk and invest in the creation of new drugs if there was no prospect of high returns.[13] This would create a potentially devastating impact on future medical progress as research and development investing would be left to public funding.[14]

This comment will provide a comprehensive overview of the pharmaceutical industry and illustrate the role that PAPs play in the prescription drug pricing crisis. Part I will look at the economic factors that drive the prescription drug market, provide a basic overview of the pharmaceutical supply chain as drugs move from manufacturer to patient, and the financial relationship between different key players. Part II will introduce the various types of PAPs and explain how they play a role in facilitating patient's access to prescription drugs. Part III will describe the potential for fraud presented by PAPs, address guidance provided by the Office of the Inspector General and summarize recent enforcement actions related to PAPs. Next, Part IV will briefly cover recent government enforcement action related to PAPs. Part V will utilize data to illustrate the problem created by PAPs, how they affect prescription drug spending, and who is hurt by the cost-implications of this system. Part VI will summarize recent state legislation regarding limiting PAPs in order to lower prescription drug prices, and why these laws fell short. Finally, Part VII will use an example of a recent federal legislative proposal to analyze the challenges presented in creating federal healthcare legislation.

I. The Pharmaceutical Industry at a Glance

The United States pharmaceutical industry is extremely complex and includes many more market participants beyond simply manufacturers and consumers.[15] The United States

---

[8] *Biopharmaceutical Spotlight: The Biopharmaceutical Industry in the United States*, SELECTUSA, https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states (last visited Apr. 29, 2020).

[9] *U.S. Pharmaceutical Pricing: An Overview*, AXENE HEALTH PARTNERS, https://axenehp.com/us-pharmaceutical-pricing-overview/ (last visited Apr. 29, 2020) [hereinafter *U.S. Pharmaceutical Pricing*].

[10] *Id.* (defining a blockbuster drug as "an innovative drug that treats a serious condition with a large number of patients in economically advanced countries").

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *U.S. Pharmaceutical Pricing*, *supra* note 9.

[15] *See generally Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, THE KAISER FAMILY FOUND. (2005), http://avalere.com/research/docs/Follow_the_Pill.pdf [hereinafter *Follow the Pill*].

pharmaceutical supply chain is "multi-faceted" and the process in which drugs travel to patients includes a number of "stakeholders."[16] The key players in the U.S. pharmaceutical supply chain include pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").[17] The complex chain from manufacturer to consumer in conjunction with heavy government regulation leads to a complicated market, which is difficult for most people to comprehend.[18]

As long as there are patients with life-threatening illnesses, there is going to be a demand for prescription drugs.[19] The market for pharmaceutical drugs is "highly inelastic" and regardless of how high drug prices rise, there will be a constant demand for life-saving drugs.[20] Consequently, when a family member or loved one is diagnosed with a life threatening disease, often there is no time to waste and people are unlikely to sacrifice time shopping around for the best deal, nor are they likely to sacrifice quality for a lower price.[21] Financial considerations take a back-seat and raw human emotions take control when individuals are tasked with making life or death decisions for their loved ones.[22] Everything that economics textbooks tell us about the ordinary forces that drive product markets, like supply and demand[23] suddenly become irrelevant and all that matters is keeping someone alive or improving their quality of life, no matter what the cost.[24] The tough reality is that at the end of the day, despite being part of a market that represents an economic anomaly, pharmaceutical companies are businesses and as the centuries old decision in *Dodge v. Ford Motor Co.* made clear: the foremost objective of a business is to generate profits for its shareholders.[25]

Despite a unique market boasting near-inelastic demands, in the world of pharmaceuticals, nothing happens fast, and nothing comes cheap. Developing a new drug can take ten to fifteen years.[26] Estimates suggest "that only one out of every 5,000-10,000 drugs make it to" clinical trials,[27] and only 11.83% of those drugs that make it to the clinical trial phase make it to the market.[28] Odds like these seem better suited for a Las Vegas casino, maybe suggesting why

---

[16] Lisa Ellis, *Snapshot of the American Pharmaceutical Industry*, HARV. SCH. PUB. HEALTH (Jul. 14, 2016), https://www.hsph.harvard.edu/ecpe/snapshot-of-the-american-pharmaceutical-industry/.
[17] *Id.*
[18] *See id.*
[19] *See Follow the Pill*, *supra* note 15, at 4 (explaining how "consumer demand in this market is expressed through the medium of a prescribing physician or other licensed health care provider").
[20] Cami R. Schiel, *Leveraging Pharma to Lower Premiums: Medical Loss Ratio Regulation in the Pharmaceutical Industry*, 2018 B.Y.U. L. REV. 205, 222 (2018).
[21] *Id.*
[22] *See id.*
[23] *See* N. GREGORY MANKIW, PRINCIPLES OF ECONOMICS 77 (8th ed. 2018) (explaining that the principles of market equilibrium suggest that when the price of a good increases past the equilibrium price, demand for the product will decrease); THOMAS SOWELL, BASIC ECONOMICS: A COMMON SENSE GUIDE TO THE ECONOMY 47 (5th ed. 2015) ("There is perhaps no more basic or more obvious principle of economics than the fact that people tend to buy more at a lower price and less at a higher price.").
[24] *See* Schiel, *supra* note 20 ("In a way, it is a collective sense of humanity – an unwillingness to begrudge the funds needed in order to save a life or prolong suffering – that throws normal market forces out the window. The normal market is not designed for life-or-death situations. Drugs are.").
[25] Dodge v. Ford Motor Co., 170 N.W. 668, 684 (Mich. 1919) (holding that "[a] business corporation is organized and carried on primarily for the profit of the stockholders").
[26] Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 324 (2010).
[27] *Id.*
[28] *See* Joseph A. Dimasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 25 (2016).

companies are willing to gamble their money with hopes of hitting a jackpot. A recent study by Tufts University Center for the Study of Drug Development estimated the pre-approval cost of developing a new prescription drug at nearly $2.6 billion[29] and that estimated post-approval research and development costs can increase that number by over $400 million.[30] The level of risk involved in developing a new drug in conjunction with the astronomical costs of research and development justifies companies charging high prices in order to maintain profitable returns for their investors.[31]

With low marginal costs after a drug is developed, why would pharmaceutical companies be incentivized to bear the costs necessary to develop a drug only for the rest of the market to produce it inexpensively and drive the price down?[32] This is why patent[33] and intellectual property laws[34] are critical to the pharmaceutical industry, as they provide the incentive for companies to invest in innovation by providing patent protection.[35] In practical effect, patent protection grants the inventor or patent holder a "limited monopoly" for the duration of the patent and with that, deference to the judgement of manufacturers in pricing their drugs how they see fit.[36] Because of patent law, regardless of whether or not the general public views the prices manufacturers charge as "morally repugnant," they are legal.[37] Another unfortunate consequence of the for-profit prescription drug industry is the lack of incentive for companies to invest in the development of drugs for less common "neglected conditions"[38] with small patient populations, as they would not provide the high returns sought by drug manufacturers. Despite both federal[39] and state[40] initiatives to help make prescription drugs more affordable, many Americans are still underinsured and unable to afford the cost-sharing expenses[41] imposed by their health plans.[42]

---

[29] *See id.*
[30] *See id.* at 26.
[31] *See* Schiel, *supra* note 20, at 239–42.
[32] *See U.S. Pharmaceutical Pricing*, *supra* note 9.
[33] U.S. Patent Act, 35 U.S.C. §§ 1-376 (2012).
[34] *See* U.S. CONST. art. I, § 8, cl. 8. Often referred to as "The Copyright Clause" this section of the U.S Constitution has been interpreted to authorize Congress's power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."
[35] *See* Alexander Walsdorf, Note, *I Get by with A Little Help from My 750-Dollar-Per-Tablet Friends: A Model Act for States to Prevent Dramatic Pharmaceutical Price Increases*, 102 MINN. L. REV. 2497–98 (2018).
[36] *Id.* at 2498.
[37] *Id.*
[38] Schiel, *supra* note 20, at 241–42. The term "neglected conditions" is used to describe conditions that are in need of cures or treatments but, because of the lack of a sizeable patient population due to the rarity of the condition, the subsequent demand is too low to justify the cost of developing treatment as it is unlikely that the product will be profitable.
[39] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (2003). *See generally* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355 (1984)).
[40] *See infra* notes 147 and 151 and accompanying text.
[41] *See Deductible*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/deductible/ (last visited Apr. 21, 2020). Insured patient's out-of-pocket costs typically consist of deductibles, and either co-payments or co-insurance. A deductible is the amount you pay for covered health care services before your insurance plan kicks in and starts to pay. After you have reached your deductible, you typically pay either a co-pay or co-insurance for covered services and your insurance company provides the rest. Co-payments are a fixed amount you pay for covered health care services after you have paid your deductible. For example, a co-payment may be $20 per prescription. Alternatively, co-insurance is based on a percentage of the costs of covered health care services after the deductible is met. For example, a co-insurance payment may be 20% of total prescription cost.
[42] Tironi, *supra* note 26, at 311–12.

To understand the forces that drive prescription drug prices and the cost-sharing structure wherein PAPs fit, it is important to "demystify"[43] the United States Pharmaceutical Supply Chain and to have a general understanding of the different entities and the financial relationships that connect them.[44] Pharmaceutical manufacturers invest in the research and development necessary to develop new drugs, produce important safety guidelines, and are the source of drugs in the pharmaceutical supply chain.[45] Manufacturers typically distribute the drugs to wholesalers, specialty pharmacies, government purchasers and other bulk purchasers, rarely ever selling straight to customers.[46] Aside from spending for research and development, drug manufacturers also spend significant amounts of money on direct-to-consumer advertising.[47] Such significant spending on this consumer-targeted advertising is often purported to be "deceptive" because it allegedly takes advantage of patients who lack the requisite knowledge to know any better than to show up at their physician's office and demand brand-name drugs based on testimonials from commercials.[48]

Wholesale distributors purchase drugs in bulk from manufacturers, store them in warehouses and manage distributing them to a variety of customers such as pharmacies and hospitals.[49] Over the years, the drug wholesale industry has consolidated considerably, leaving several companies in control of the market.[50] To increase efficiency, the drug wholesale business has adapted to provide its customers with a variety of services in addition to traditional distribution such as handling electronic data, reimbursements and other specialized services.[51] The final step in the pharmaceutical supply chain before drugs reach patients are pharmacies, which purchase drugs from wholesalers and store them until they are dispensed to patients when they fill a prescription.[52] Throughout this process, PBMs work alongside the other parties to negotiate manufacturer discounts on behalf of health plans (private insurance, employer health plans, government health plans, etc.) and decide which drugs will be included in the insurer's formularies—the list of drugs they will cover.[53]

Even more complex than the physical supply chain for prescription drugs is the financial flow between different parties. Wholesalers purchase drugs from manufacturers at wholesale acquisition cost ("WAC"), which is often further discounted for things such as prompt-pay or high-volume purchases.[54] Pharmacies negotiate prices with manufacturers based on the pharmacy's ability to sell certain volumes, and even though wholesalers distribute the drugs, the payment flows from the pharmacy to the manufacturer.[55] If the negotiated price between the pharmacy and manufacturer is lower than the WAC price paid by wholesalers, the wholesaler will utilize a pricing mechanism known as a "chargeback" and the manufacturer will reimburse the wholesale distributor for the difference in the price paid by the consumer and the WAC price paid by

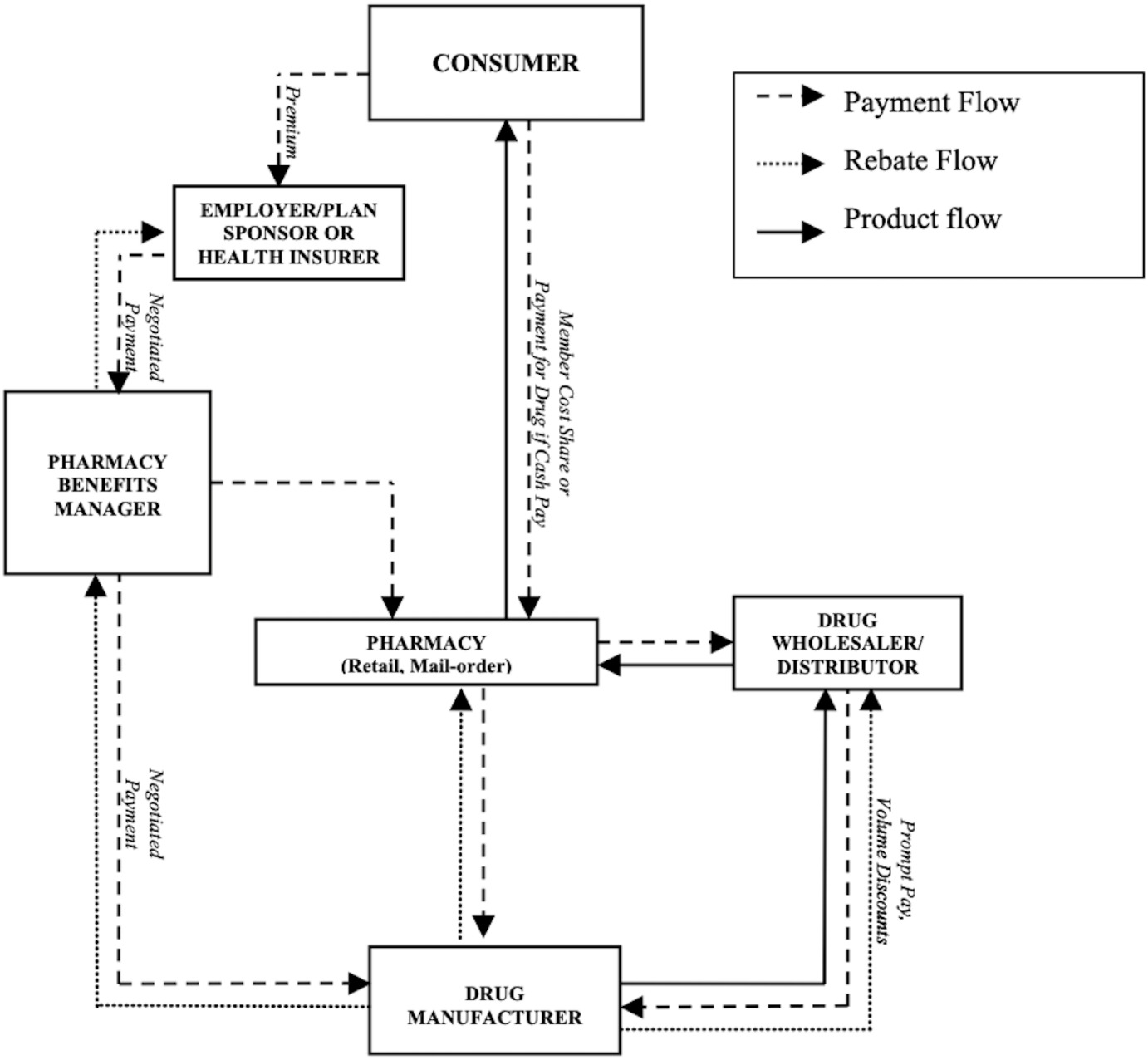
[43] *Follow the Pill*, *supra* note 15, at 1.
[44] *Id.*
[45] *See id.* at 4.
[46] *Id.*
[47] *See* Ellis, *supra* note 16.
[48] *But see Follow the Pill*, *supra* note 15, at 18.
[49] *Follow the Pill*, *supra* note 15, at 8.
[50] *See* Matan C. Dabora et al., *Financing and Distribution of Pharmaceuticals in the United States*, 318 JAMA 21 (2017) ("The US distributor market is highly consolidated, with 3 companies accounting for more than 85% of market share: AmerisourceBergen, Cardinal Health, and McKesson.").
[51] *Follow the Pill*, *supra* note 15, at 9.
[52] *Id.*
[53] *Id.* at 1–2.
[54] *Id.* at 1.
[55] *Follow the Pill*, *supra* note 15, at 19.

wholesalers.[56] Somewhere in this complex chain is the PBM who contracts with health plans to manage drug costs by negotiating discounts and rebates with manufacturers in exchange for their drugs being included on the health plan's formularies.[57]

At the end of the day, after each of these parties has had their say in the different negotiations, there is a price tag for the drug that needs to be paid before the consumer can ultimately access their drugs. Health insurance plays a huge role in facilitating this process by utilizing cost-sharing methods to mitigate individual loss and "limit a consumer's exposure to healthcare costs."[58] In order for the health insurance system to work, customers (patients) are responsible for their proportionate share of the cost in the form of co-pays, deductibles, etc. With healthcare costs increasing every year,[59] what happens when patients are unable to even afford their out-of-pocket expenses? Enter: Patient Assistance Programs ("PAPs").

[56] *See id.*
[57] *Id.* at 22.
[58] Schiel, *supra* note 20, at 223–24.
[59] Schiel, *supra* note 20, at 208.

Exhibit 1: Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain[60]



II. Patient Assistance Programs

[60] *Follow the Pill*, *supra* note 15, at 3.

PAPs have been considered an important "safety net" for low-income patients who do not have health insurance or are otherwise unable to afford their medication.[61] PAPs can be structured in different ways such as direct manufacturer PAPs[62] or Independent Charity PAPs.[63] Direct PAPs are affiliated with pharmaceutical manufacturers and typically provide assistance in the form of free or discounted drugs as well as cash subsidies directly to the patients.[64] PAPs that are offered directly through pharmaceutical manufacturers provide patients that meet the eligibility requirements with access to their brand name drugs at little or no out-of-pocket costs.[65]

Indirect Patient Assistance is offered through Independent Charitable PAPs, 501(c)(3) non-profit organizations such as Patient Advocacy or Patient Support Groups, that provide co-pay assistance to patients of a specific disease state.[66] 501 (c)(3) organizations receive federal tax-exempt status, and in order to qualify the organization must be "organized and operated exclusively" for one of the purposes specified by the statute—which includes "charitable" purposes.[67] "Independent charities operate PAPs that offer aid such as financial assistance to uninsured consumers or underinsured consumers who cannot meet their health plans' premiums or cost sharing, such as co- payments, coinsurance, and deductibles."[68] Pharmaceutical manufacturers make cash donations to third party independent bona fide charities, which are charities that support patient groups that are in line with the manufacturer's business and products.[69] For example, a company that manufactures a drug for prostate cancer may donate to organizations with programs that support prostate cancer patients. If properly structured, these programs use the donations they receive to award assistance to financially needy patients in a uniform and independent manner. The goal is to increase patient's access to drugs in a truly charitable manner that "severs any link between the pharmaceutical manufacturer's funding and the beneficiary,"[70] in other words, making sure that the assistance provided cannot be directly attributed to the manufacturers who made the donations.[71]

---

[61] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623–24 (Nov. 22, 2005).

[62] *Pharmaceutical Manufacturer Patient Assistance Program Information*, CTR.S FOR MEDICARE & MEDICAID SERV., https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html (last updated July 23, 2018). The United States Centers for Medicare and Medicaid Services (CMS) describes Manufacturer Patient Assistance Programs as: "Pharmaceutical manufacturers may sponsor patient assistance programs (PAPs) that provide financial assistance or drug free product (through in-kind product donations) to low income individuals to augment any existing prescription drug coverage." *Id.*

[63] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,626.

[64] *See id.* at 70,624.

[65] *See Pharmaceutical Manufacturer Patient Assistance Program Information*, *supra* note 62.

[66] The primary eligibility requirement for most Patient Assistance Programs is financial need, which is usually based on some percentage of the federal poverty level. *See generally The Need for Patient Assistance and Access Programs*, *supra* note 2.

[67] 26 U.S.C. § 501(c)(3) (2018).

[68] CONG. RESEARCH SERV., R44264, PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAMS 15 (2017), https://www.everycrsreport.com/files/20170615_R44264_1620b32a24a5e7e0bd6150be54c139fc134c4ab2.pdf (quoting from HHS OIG).

[69] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,626.

[70] *Id.*

[71] *Id.*

III. Potential Corrupt Payments and the OIG

In recent years, the United States has seen a sharp increase in pharmaceutical spending which has led the government to more closely scrutinize drug prices as well as the relationships between different actors in the pharmaceutical market.[72] Under the Federal Anti-Kickback Statute ("AKS") pharmaceutical manufacturers cannot provide patients with any direct or indirect financial assistance that would subsidize their co-pays or expenses for drugs that are reimbursed by a government insurance program such as Medicare.[73] Pursuant to the 2010 amendment to AKS,[74] violations of AKS that result in a federal health care payments are per se violations of the False Claims Act[75] ("FCA").[76] The FCA has proven to be an effective tool for fighting healthcare-related fraud by creating a public-private partnership by which "whistleblowers" can recover civil damages on behalf of the United States government.[77]

The AKS prohibits manufacturers from offering or paying, directly or indirectly, any remuneration that would induce Medicare patients to purchase the company's product.[78] Co-pay requirements were included in Medicare programs partially to serve as a check on health care costs such as the prices that pharmaceutical manufacturers can demand for their drugs.[79] The law is clear that waving co-pays can constitute a violation of the AKS and thus the FCA.[80]

The Office of the Inspector General ("OIG") of the Department of Health and Human Services periodically develops and issues guidance to alert and inform the healthcare industry about potential issues as well as areas of special interest and legal significance. Before the Medicare Part D program[81] was even enacted, the OIG recognized the potential for fraud and published a Special Advisory Bulletin in 2005 assessing the potential for fraud and abuse if pharmaceutical manufacturers offered patient assistance to Medicare Part D beneficiaries.[82] Although the OIG's statements were based primarily on speculation at the time they were made, they highlight the fact that years ago, the OIG was already aware of the potential for fraud.[83] In the 2005 Special Advisory Bulletin, the OIG clearly explained that pharmaceutical manufacturer affiliated PAPs that provided cost-sharing subsidies to Medicare Part D beneficiaries would implicate the anti-kickback statute and "pose a heightened risk of fraud and abuse."[84] As a "less-abusive" alternative to direct manufacturer PAPs, the OIG made it clear that pharmaceutical manufacturers are still

---

[72] *Follow the Pill*, *supra* note 15, at 24.
[73] 42 U.S.C. § 1320a-7b (2018).
[74] 42 U.S.C. § 1320a-7b(g).
[75] 31 U.S.C. §§ 3729, 3733 (2018).
[76] *See, e.g.*, Guilfoile v. Shields, 913 F.3d 178, 182 (1st Cir. 2019).
[77] Andrew E. Brashier, *The Federal Government's Chief Weapon in Combatting Fraud: The False Claims Act*, 34 ALA. ASS'N JUST. J. 60 (2014).
[78] *Id*.
[79] Press Release, DOJ, Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks (Dec. 20, 2017), https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability [hereinafter United Therapeutics Agrees to Pay $210 Million].
[80] 42 U.S.C. § 1320a-7b(g).
[81] *See* SCOTT BECKER ET AL., HEALTH CARE LAW: A PRACTICAL GUIDE §7.02 (2d ed. 2012). Medicare Part D is an outpatient prescription drug benefit program created to offer optional coverage to Medicare beneficiaries. *See id.*
[82] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,624–25.
[83] *See id.*
[84] *Id.* at 70,624.

able to contribute to patient assistance through donations to independent charitable PAPs, as long as the programs were properly structured.[85]

In defining what would be a "properly structured" program, the OIG provided five points of focus for which safeguards can be employed to minimize the risk of manufacturers using independent charity assistance programs as a vehicle to indirectly fund patients' co-pays for their drugs.[86] First, "neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) [should] exert[] any direct or indirect influence or control over the charity or the subsidy program."[87] Second, the charity should award "assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (i.e., the assistance provided cannot be attributed to the donating pharmaceutical manufacturer)."[88] Third, the charity should award "assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D plan."[89] The OIG did, however, recognize that some independent patient assistance charities focus their programs on specific disease states in order to benefit patients suffering from that type of condition (i.e. prostate cancer or hemophilia) and have allowed donors to contribute to charities that support patients with diseases that the company manufactures drugs to treat.[90] The OIG further noted that the fact that a pharmaceutical manufacturer's donations are earmarked for a specific disease should not significantly raise the risk of abuse as long as the disease categories are not so narrowly defined to allow the donations to effectively subsidize the manufacturer's product.[91] Fourth, the charity should provide "assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner."[92] Fifth, the pharmaceutical manufacturer should not "solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products."[93]

In 2014, after years of being able to experience the implementation of Medicare Part D and the problematic features of PAPs, the OIG issued a Supplemental Special Advisory Bulletin focused specifically on Independent Charity PAPs.[94] The OIG stated that the 2014 Supplement was not meant to replace the 2005 Special Advisory Board but instead was intended to provide additional guidance regarding independent charity PAPs in light of new risks that had been identified in recent years.[95] The 2014 Supplement expanded on the previous guidance in three

---

[85] *Id.*
[86] *See id.* at 70,626.
[87] *Id.*
[88] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,626.
[89] *Id.*
[90] *Id.* at 70,627.
[91] *Id.*
[92] *Id.* at 70,626.
[93] *Id.*
[94] Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120 (May 30, 2014).
[95] *Id*.

specific areas: disease funds, eligible recipients, and donor conduct.[96] The OIG called for increased scrutiny of charity-specific disease funds in an effort to ensure they are not defined so narrowly as to allow a donor to essentially subsidize their own products (i.e., specific stages of a disease, specific methods of treatment or rare diseases with only one available drug).[97] The supplement noted that disease funds "should be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products,"[98] and eligibility should be determined "according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner."[99] The OIG used this supplement as an opportunity to clarify that PAPs may be limited to federal healthcare beneficiaries as long as the appropriate eligibility criteria is met. The OIG emphasized that the cost of a particular drug, in isolation, is not an appropriate factor for determining financial need. Generally, overly broad financial need criteria in conjunction with narrowly defined disease funds may be evidence of the intent to cover the co-pays of a specific drug instead of focusing on the goal of helping to fund treatment for financially struggling patients with a specific disease.

IV. Recent Enforcement Actions

The main concern for AKS implications lies in the potential for manufacturer donors to use the charity PAPs as a vehicle to essentially subsidize the cost of co-payments for their own products.[100] Conduct on behalf of donors that attempts to correlate their contributions to the support for their products actually received by patients would raise a red flag of the intent to commit such fraud.[101] In recent years, the U.S. Department of Justice (DOJ), one of the agencies tasked with enforcing the AKS, has entered into numerous settlements with pharmaceutical companies in regard to anti-kickback violations due to alleged use independent patient assistance charities as "conduits" to pay for patient's co-pays of their drugs.[102] United Therapeutics Corporation (hereinafter "UT") agreed to a $210 million settlement for allegedly using an independent patient assistance foundation to pay Medicare patient's co-pays for their hypertension drug by not permitting Medicare beneficiaries from participating in UT's direct free drug program and instead referring them to the foundation.[103] Similarly, Jazz Pharmaceuticals (hereinafter "Jazz"), manufacturer of narcolepsy drug Xyrem, agreed to pay $57 million to settle allegations that they made Medicare patients ineligible for the company's free drug program and instead

[96] *Id*. at 31,121; *see also* Thomas Sullivan, *HHS-OIG Releases Updated Advisory on Independent Charity Patient Assistance Programs*, POLICY & MED., https://www.policymed.com/2014/05/hhs-oig-releases-updated-advisory-on-independent-charity-patient-assistance-programs.html (last updated May 6, 2018) (breaking down the 2014 OIG Supplement and highlighting the key takeaways from each of the three sections).
[97] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. at 31,121.
[98] *Id.* at 31,122.
[99] *Id.*
[100] *Id.* at 31,121.
[101] *Id.*
[102] *See* Press Release, DOJ, Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations (Apr. 4, 2019), https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid.
[103] United Therapeutics Agrees to Pay $210 Million, *supra* note 79.

referred them to a narcolepsy-focused patient assistance foundation that almost exclusively supported Xyrem patients and was solely funded by Jazz.[104]

UT and Jazz are just two examples of contributors to the over $800 million that has been paid by pharmaceutical companies in recent years in order to resolve FCA and AKS investigations related to patient assistance charities.[105] Increased government scrutiny of the independent PAP structure has shown that the compliance risks involved in donating to these charities make it a high-risk activity for drug companies.[106] The surge of federal government investigations along with nearly $1 billion in settlements suggests that something is not right with this system.

V. Defining the Problem: How PAPs Affect Drug Spending and Who is Hurt

The pharmaceutical industry is unique in the sense that unlike many other markets, the end consumer (the patient) rarely pays anywhere near the actual cost of the product, instead that cost is shared with either private health insurance companies or federal healthcare programs.[107] Patients' out-of-pocket expenses are typically a fraction of the drug's total cost, and with the bulk of payment coming from insurance or other third party payers, patients become desensitized to drug prices because they do not pay the full price themselves.[108] This structure essentially incentivizes drug suppliers to charge higher prices[109] because insured patients are mainly concerned with their out-of-pocket costs and co-pays[110] rather than the total cost of the drugs, which are paid by the insurance company or other third-party payor.

Advocates of PAP-provided support make the argument that if patients are unable to afford medication to treat serious diseases, they will end up needing more expensive treatment in the future which, in the long run will increase the cost of the healthcare system as a whole.[111] This may be true for the rare disease for which there is only one single viable treatment option, however, this argument is invalid when dealing with drugs that have generic equivalents.[112] PAPs may "inhibit cost-effective medication use" and have important implications on public drug spending by allowing patients to use higher-cost medications when there are more cost-effective options available such as generics.[113]

In order to illustrate, assume there is a branded drug that costs $10,000 and a generic equivalent of the same drug costs $1,000. Patient "X" has health insurance that would make his

---

[104] Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations, *supra* note 102.

[105] *See* John Bentivoglio et al., *Inside DOJ's Recent Charitable Copay Foundation Settlements*, LAW360 (Apr. 22, 2019, 3:54 PM), https://www.law360.com/articles/1150649/inside-doj-s-recent-charitable-copay-foundation-settlements.

[106] Brett. R. Friedman et al., *Emerging Enforcement Trends for Patient Support Programs*, LAW360 (May 15, 2018, 12:43 PM), https://www.law360.com/articles/1042623/emerging-enforcement-trends-for-patient-support-programs.

[107] *U.S. Pharmaceutical Pricing*, *supra* note 9.

[108] *See U.S. Pharmaceutical Pricing*, *supra* note 9.

[109] Patricia M. Danzon, *Economics of the Pharmaceutical Industry*, 2006 THE NAT'L BUREAU OF ECON. RES. REP. 15 , https://www.nber.org/reporter/fall06/danzon.html.

[110] *Deductible*, *supra* note 41.

[111] *See* Lisa Schencker, *Lifesavers or Kickbacks? Critics Say Patient-Assistance Programs Help Keep Drug Prices High*, MODERN HEALTHCARE (Mar. 7, 2015, 12:00 AM), https://www.modernhealthcare.com/article/20150307/MAGAZINE/303079980/lifesavers-or-kickbacks-critics-say-patient-assistance-programs-help-keep-drug-prices-high.

[112] *See* Niteesh K. Choudhry et al., *Drug Company-Sponsored Patient Assistance Programs: A Viable Safety Net?* 28 HEALTH AFFAIRS 827, 833 (2009).

[113] *Id*.

out-of-pocket cost for the branded drug $500, and his out-of-pocket cost for the generic version $5. Patient X is unable to afford the branded drug but finds an independent PAP that covers most of his out-of-pocket costs for the branded drug. With patient X's out-of-pocket costs for the branded and generic drug now roughly the same, he decides to go with the branded drug. Now, the insurance company is paying the remainder of the cost for the $10,000 branded drug, when there was a generic alternative available for one tenth of the cost.

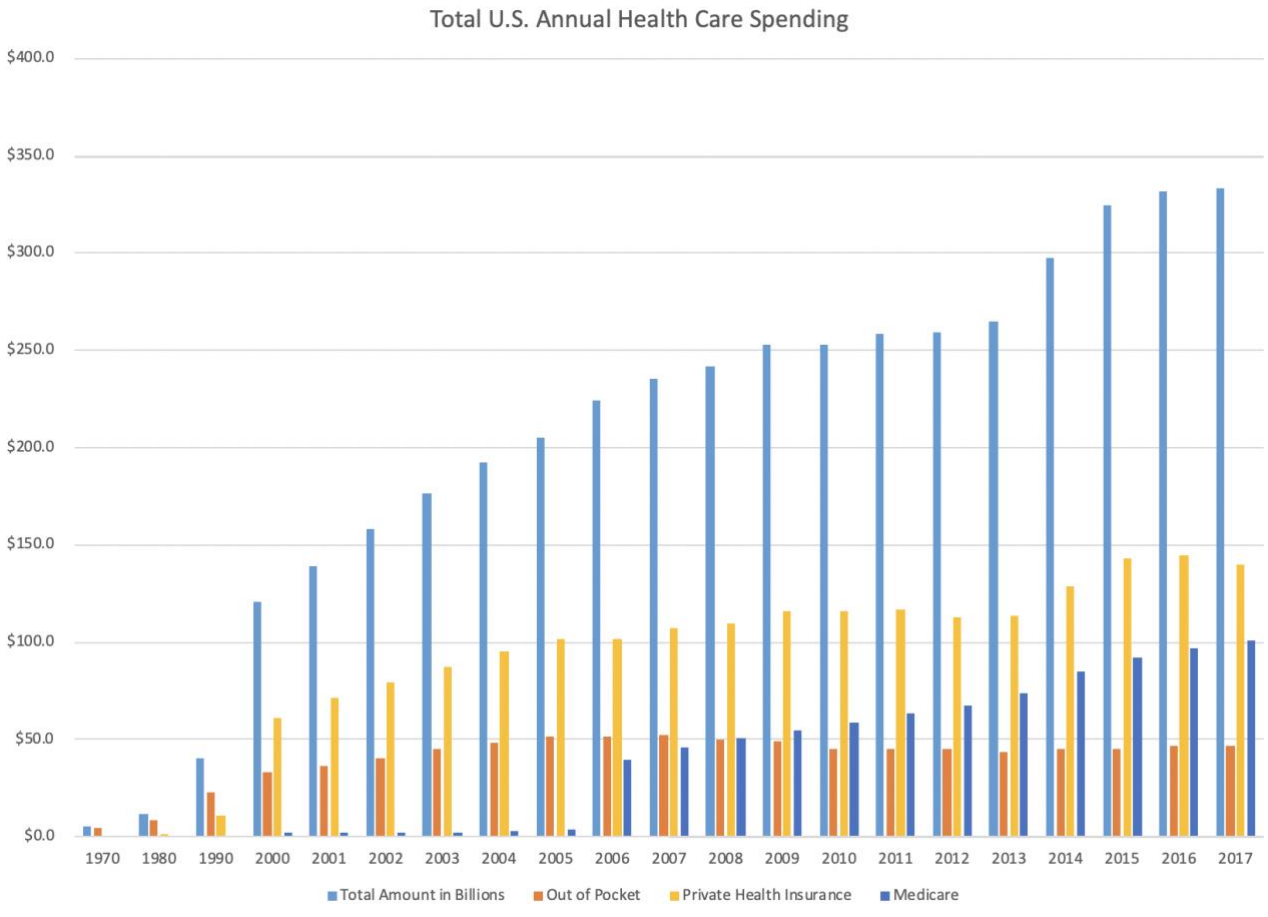
The Federal AKS[114] exists in part to protect Medicare and the taxpayers who fund it from overpaying for drugs and essentially "'holding the bag for the costs of expensive drugs.'"[115] In response to recent DOJ settlements with pharmaceutical companies resolving allegations of anti-kickback violations regarding independent foundations, District of Massachusetts U.S. Attorney Andrew E. Lelling explained, "This misconduct is widespread, and enforcement will continue until pharmaceutical companies stop circumventing the anti-kickback laws to artificially bolster high drug prices, all at the expense of the American taxpayers."[116] Consider Medicare beneficiaries who are unable to afford the out-of-pocket costs for expensive drugs. Instead of pharmaceutical companies being pressured to lower drug prices, independent PAPs allow these individuals to purchase the expensive drugs at little to no out-of-pocket cost, and Medicare is left to pay the remainder of the drug price.[117] By contributing money to independent charity PAPs in the disease areas of their products, manufacturers allow for federal healthcare beneficiaries to minimize their out-of-pocket costs and keep receiving the brand name drugs, ensuring the rest of the drug costs will be reimbursed by the government. At the end of the day, American taxpayers are the ones being affected because millions of tax dollars are potentially wasted every year by overpaying for drugs that could be less expensive.[118] When drug manufacturers support privately insured patients with direct patient assistance and co-pay coverage, private insurance companies are left to pick up the rest of the expensive drug costs.[119] Therefore, privately-insured patients who would otherwise not even be able to afford their co-pays are able to get the drugs, and once again the drug manufacturers get paid.[120] This creates further cost implications in the private insurance market because as more patients receive assistance to obtain high priced brand-named drugs when lower-cost alternatives are available, gross expenses increase for the insurance companies.[121] The most likely response from insurance companies is then to implement cost-sharing measures by raising the coverage rates for all patients, effectively passing on the increase in expenses they endure from covering higher-cost drugs when less expensive generic alternatives are available.[122] PAPs can be critical for patients who need expensive life-saving drugs with no generic substitutes.[123] When commercially insured patients utilize co-pay assistance in order to choose higher-cost branded drugs over available generics, the short-term out-of-pocket savings they enjoy may come at the cost of higher long-term expenses for themselves and society as a whole.[124] Exhibit 2 below

---

[114] 42 U.S.C. § 1320a-7b.
[115] United Therapeutics Agrees to Pay $210 Million, *supra* note 79 (quoting Acting U.S. Attorney Weinreb).
[116] Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations, *supra* note 102.
[117] *See id.*
[118] United Therapeutics Agrees to Pay $210 Million, *supra* note 79.
[119] *Lifesavers or Kickbacks?*, *supra* note111.
[120] *See* United Therapeutics Agrees to Pay $210 Million, *supra* note 79.
[121] Joseph S. Ross & Aaron S. Kesselheim, *Prescription-Drug Coupons - No Such Thing as a Free Lunch*, 369 NEW ENG. J. MED. 1188, 1189 (2013).
[122] *Id.*
[123] *Id.*
[124] *Id.*

illustrates that since the early 2000s, total annual healthcare spending in the U.S. has increased drastically, reflecting steady increases in both private health insurance as well as Medicare spending. Meanwhile, out-of-pocket costs paid by individuals remain stagnant, failing to increase proportionately with the increases in spending.

Exhibit 2: Annual U.S. Health Care Spending 1970-2017[125]



One of the most puzzling aspects of the PAP "system" as a whole is that despite the argument that they help manufacturers keep drug prices high, multiple parties in this field benefit from the current system and there is thus little motivation to advocate for change. PAPs act as effective public relations programs for pharmaceutical companies because when patients complain about high drug prices, manufacturers can respond by claiming they will help out anyone who cannot afford the drugs or point them in the direction of a charity PAP.[126] Pharmaceutical manufacturers have no reason to advocate for change because supporting PAPs gives the

[125] Created with National Health Expenditure data compiled by the Center for Medicare and Medicaid Services. *National Health Expenditure Data*, CTR. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData (page last updated Dec. 16, 2020).

[126] Schencker, *supra* note 111.

appearance that they are helping make drugs more affordable to patients, but in reality, they are making sure that they get paid.[127]

For example, Mechanic Andre Rucker was diagnosed with a rare blood cancer and struggled to afford his $500 per month co-pay for the treatment with an annual cost of $142,000, explaining "it was a choice between covering his mortgage and paying for his cancer drug."[128] Rucker received co-pay assistance from the Patient Access Network Foundation, an independent PAP funded largely by drug manufacturers that has previously been investigated by the Department of Justice for alleged fraud.[129] When discussing the criticism of PAPs, like the one that allowed him afford his cancer medication, Rucker admitted that he has a hard time questioning the program that helped save his life and explained that "I know it's drug [company]-funded . . . [B]ut without that, I wouldn't be sitting here talking to you right now."[130] This simple yet powerful statement accurately illustrates the issue that despite their knowledge of the highly-criticized relationship between drug manufacturers and PAPs, patients who accessed life-saving medication because of these organizations are highly unlikely to turn around and accuse them of any wrongdoing, let alone advocate for change to a system that has only benefitted them.[131] The challenge lies in finding a way to make people understand that making drugs more affordable for a certain group of individuals does nothing to address the bigger issues of high drug prices and increased healthcare costs.[132]

Recently, the Journal of the American Medical Association ("JAMA") published a study that analyzed the characteristics of independent PAPs. The study focused on six of the largest patient charity organizations in the United States and the sub-group of 274 PAPs they maintained, analyzing their contributions for the fiscal year 2018.[133]

Based on the analysis of this sub-group, drugs were covered by at least one PAP for 36% of generic drugs "costing less than $7,200, 52% of drugs costing between $7,200 and $10,000, 73% of specialty drugs costing between $10,000 and $30,000, and 83% of specialty drugs costing more than $30,000."[134] PAPs were more likely to cover higher-priced specialty drugs and brand-name drugs than less-expensive brand-name drugs and generic equivalents.[135] "The exclusion of uninsured patients from the eligibility criteria was a uniform pattern across PAPs."[136] For PAPs, the cost of providing support to an insured patient is cheaper than covering an uninsured patient who needs the same drug. Why? Because the insured patient likely only needs assistance with

---

[127] *Id.*
[128] *Id.*
[129] *Id.*; United Therapeutics Agrees to Pay $210 Million, *supra* note 79.
[130] Schencker, *supra* note 111.
[131] *See id.*
[132] *See id.*
[133] *See* So-Yeon Kang et al., *Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs*, 322 JAMA 422 (2019).
[134] *Id.* at 425.
[135] *Id.* at 427.
[136] *Id.* Of the 274 patient assistance programs offered by the 6 charities in this study, 97% of the programs did not provide financial assistance to uninsured patients based on disclosed patient eligibility requirements. *See id. See generally* 2017 Annual Report, PAN FOUND. (2017), https://panfoundation.org/index.php/en/about-us/reports-financials. To qualify for Patient Access Network (PAN) assistance, the patient must have health insurance that covers his or her qualifying medication or product. *See also Patients*, HEALTHWELL FOUND., https://www.healthwellfoundation.org/patients/ (last visited Apr. 29, 2020) ("To qualify for assistance, you must have some form of health insurance — such as private insurance, Medicare, Medicaid or Tricare — that covers part of the cost of your treatment.")

out-of-pocket expenses and will have the rest of the drug cost covered by Medicare or private insurance.[137] The most likely justification for excluding uninsured patients, is that this allows programs to use their limited amount of funding to help the largest number of patients.[138] A primary focus of the OIG's 2014 Supplementary Advisory Bulletin was to reiterate that the donor should not be able to access any information that would enable them to "correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP."[139] A PAP's eligibility requirement that patients have some form of health insurance does not directly give donors any information regarding assistance provided for their specific product, however, the statistics published by PAPs in their annual reports disclose exactly what percentage of funds are used to cover patient co-pays.[140]

For PAPs that give out almost 100% of their funds in the form of co-pay assistance, this indirectly lets manufacturers know that nearly all of the PAP's contributions will be used to pay co-pays for patients whose drug costs will be covered by insurance, and also provides data that, depending on the specific PAP, could be utilized to make rough estimates of which products patients receive assistance.[141] The findings that show a higher percentage of PAP coverage of specialty or brand-name drugs as opposed to generics, supports the argument that PAPs encourage physicians and patients to choose specialty or brand-name treatments.[142] Even though these treatment options are likely to be much more expensive in total cost, despite the availability of lower cost generics, the higher likelihood of available co-pay assistance from PAPs means that the specialty and brand-name drugs may have the lowest out-of-pocket costs for patients.[143]

In an editorial accompanying the JAMA study, Katherine Kraschel, JD, of Yale Law School, and Gregory Curfman, MD, of JAMA, claimed that the findings questioned the role of PAPs as charitable organizations and further noted that:

> By preferring patients with insurance (which must cover the patient's specific drug), the nonprofit [PAPs] maximize payments to the for-profit pharmaceutical companies that fund them. The findings also illustrate the way PAPs drive up health care costs by providing support for more expensive specialty drugs in lieu of less expensive alternatives. In sum, these new results show that PAPs provide assistance to a narrow, insured patient population to the benefit of the pharmaceutical companies.[144]

This analysis highlights that the relationship between PAPs and pharmaceutical manufacturers may not be as straightforward and altruistic as it appears. The complexity of this relationship can potentially allow a seemingly charitable arrangement to advance the underlying financial motives of the pharmaceutical companies that fund them.

---

[137] Kang, *supra* note 133, at 427.
[138] *Id.*
[139] Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. at 31,123.
[140] Kang, *supra* note 133, at 425.
[141] *Id.*
[142] *See id.* at 426.
[143] *Id.* at 427.
[144] Erin Michael, *Just 3% of Charity Patient Assistance Programs Accept Uninsured Patients*, HEALIO PRIMARY CARE (Aug. 16, 2019), https://www.healio.com/primary-care/practice-management/news/online/%7B28f39b5c-8d65-43d2-9afc-350f4a89e406%7D/just-3-of-charity-patient-assistance-programs-accept-uninsured-patients.

VI. Recent State Legislation Attempts and Why They Fell Short

Although no federal regulation expressly prohibits direct manufacture patient assistance to federal health care beneficiaries, the OIG guidance made it clear that such support would be subject to strict scrutiny, leading manufacturers to exclude Medicare beneficiaries from their assistance programs.[145] Despite shying away from supporting federal healthcare beneficiaries, manufacturers continue to offer co-pay assistance to privately insured patients.[146] In efforts to lower drug costs by promoting the use of generics, California enacted legislation in 2018 which prohibits manufacturers of brand name drugs from providing co-pay assistance to patients for drugs that fall into one of two categories.[147] The first category is drugs for which a lower cost generic drug that has been designated as a therapeutic equivalent by the Food and Drug Administration (FDA) is available and is covered under the patient's health insurance plan.[148] The second category is drugs that have active ingredients that are contained in products that are approved by the FDA and available without prescription at a lower cost and are not otherwise contraindicated for the treatment of the condition for which the prescription drug is approved.[149] Yet, the California law "does not prohibit or limit assistance to a patient provided by an independent charity PAP."[150]

Similarly, Massachusetts anti-kickback law includes provisions that limit drug manufacturer co-pay assistance stating, "[p]harmaceutical manufacturing companies shall be prohibited from offering any discount, rebate, product voucher or other reduction in an individual's out-of-pocket expenses, including co-payments and deductibles, for any prescription drug that has an AB rated generic equivalent as determined by the United States Food and Drug Administration."[151] Unlike the California Law, the Massachusetts statute applies not only to drugs paid for by government healthcare programs but extends to drugs paid for by any insurer which includes private health insurance.[152] The Massachusetts statute only applies to direct patient assistance and does not extend to restrict the provision of co-pay assistance through independent PAPs.[153]

Neither of these laws include any restrictions on contributions to independent patient assistance foundations.[154] Manufacturers already stay away from providing direct patient assistance to Medicare beneficiaries for fear of anti-kickback violations and creating laws to limit direct patient assistance to privately insured patients is unlikely to fix this problem.[155] With statutes like these in effect, rather than cut off all patient assistance spending, it is more likely that manufacturers

---

[145] Andrew Furlow, *Recent Developments Raise Difficult Questions About Balancing Patient Access to Medication with Efforts to Limit Prescription Drug Costs*, 20(1) J. HEALTH CARE COMPLIANCE 21, 22 (2018).
[146] *Id.*
[147] Cal. Health & Safety Code §§ 132000-132008 (2018).
[148] Cal. Health & Safety Code § 132000(a).
[149] Cal. Health & Safety Code § 132002.
[150] Cal. Health & Safety Code § 132008(b)(1).
[151] Mass. Ann. Laws ch. 175H, § 3(b)(2) (2018).
[152] Furlow, *supra* note 145, at 26.
[153] *See* Richard P. Church et al., *Increased Scrutiny of Patient Assistance Programs: Enforcement Overview and Considerations*, K&L GATES (Mar. 20, 2018), http://m.klgates.com/increased-scrutiny-of-patient-assistance-programs-enforcement-overview-and-considerations-03-20-2018/.
[154] *See* Cal. Health & Safety Code §§ 132000-132008; Mass. Ann. Laws Ch. 175H, § 3.
[155] *See* Gary Giampetruzzi et al., *Life Sciences Cos. Should Assess Charitable Donations Programs*, LAW360 (June 20, 2018, 3:27 PM), https://www.law360.com/articles/1055390/life-sciences-cos-should-assess-charitable-donations-programs.

will instead redirect their financial assistance in the form of support to charitable patient assistance foundations that are consistent with federal and state requirements.[156]

VII. Possible Federal Legislative Approaches

One of the challenges with using state legislation to tackle rising drug prices is that different laws must be enacted over time by each individual state. Not only could this be time consuming given that any proposed laws would have to pass through each state's legislative process, but it could potentially present issues in consistency, as each state's laws would likely be different. Perhaps most pertinent is the fact that any change in drug prices due to state legislation would lack the immediate and large-scale effects that would come with federal legislation. Although greater in scope, designing federal legislation to lower drug prices presents its own challenges.

For example, in 2019, House Speaker Nancy Pelosi introduced the "Lower Drug Costs Now Act," a proposed federal approach to lowering drug prices that was met with fierce opposition by drug manufacturers and industry experts.[157] Among other things, the Act would force drug manufacturers who raised prices in excess of "inflation since 2016 to either reverse the price or rebate the amount of the increase to the federal government."[158] Manufacturers of the limited group of drugs chosen for the program would essentially be forced to accept a "maximum fair price" determined by the Secretary of Health and Human Services, or be subjected to up to a 95% sales tax.[159] The act does not expressly make reference to PAPs, but it does explain that the maximum fair price would be the exact price patients pay at the pharmacy, making it unlikely that any further discounts would be allowed for those drugs.[160] Although a federal legislative approach to drug pricing might be a step in the right direction, the fact that this proposed law would apply only to a select group of drugs fails to provide consistency, as the benefits are limited to those patients who need the drugs chosen to be included in the program. As highlighted earlier, making specific drugs more affordable for specific groups of people is merely a crutch and fails to address the bigger issue why the drug prices are as high as they are.[161] With regard to the drugs not included in the proposed law, patients, health insurers and the government are left to deal with the patient assistance problem.

The issue that is drawing the most opposition and will likely cause this bill to fail illustrates perhaps the greatest challenge in designing a federal law to lower drug prices: maintaining balance between lowering prices and still encouraging medical innovation.[162] By putting manufacturers in a gun-to-the-head situation to either accept the governments price or pay unrealistic tax penalties, a rigid structure like this is likely to decrease research and development spending and result in less life-saving drugs from reaching the market.[163] In fact, the Council of Economic Advisors estimates

---

[156] *See* Furlow, *supra* note 145, at 24–25.
[157] Elijah E. Cummings Lower Drug Costs Now Act of 2019, H.R. 3, 116th Cong. (2019).
[158] Shefali Luthra, *Pharma's Take on the Pelosi Drug-Pricing Bill: Fair Warning or Fearmongering?,* CAL. HEALTHLINE (Dec. 5, 2019), https://californiahealthline.org/news/pharmas-take-on-the-pelosi-drug-pricing-bill-fair-warning-or-fearmongering/.
[159] Lower Drug Costs Now Act of 2019, H.R. 3, 116th Cong. (2019).
[160] *Id.*
[161] *See generally* Shencker, *supra* note 111.
[162] Council of Economic Advisors, House Drug Pricing Bill Could Keep 100 Lifesaving Drugs from American Patients (Dec, 3, 2019), https://www.whitehouse.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients/.
[163] *See id.*

that if passed, the Lower Drug Costs Now Act could lead to as many as one hundred fewer drugs entering the U.S. market over the next decade and a decrease in national life expectancy.[164]

Perhaps a better solution would be a federal law that makes it illegal for any drug manufacturer PAP or independent charity PAP to provide co-pay assistance towards drugs for which there is an FDA approved generic equivalent. If the prices for these drugs remained so economically discriminatory to the extent that patients are unable to afford the co-pays for the drug without assistance, it is likely that more generics would be utilized and the healthcare system as a whole would see a decrease in spending. What becomes of the manufacturers and their high drug prices? With patients having to choose medication based on more realistic financial considerations, lower-cost alternatives will hopefully begin to push the overpriced branded drugs out of the market. Ideally this would allow normal economic factors[165] to come into play and force the prices to lower naturally over time, as opposed to a drastic and artificial decrease like what was proposed in the Lower Drug Costs Now Act.[166]

VIII. Conclusion

The drug pricing crisis in the United States is real; health care costs are continuing to rise and show no sign of slowing down anytime soon.[167] As this paper hopefully reflected, there are a great deal of moving parts in the U.S. prescription drug market and the economics behind drug prices are truly enigmatic. If nothing is done to fix this crisis, drug prices and healthcare spending will continue to keep rising until what . . . ? For now, that ending remains unknown. One thing, however, we can know for sure—there is a patient assistance problem.

[164] *Id.*
[165] MANKIW, *supra* note 23.
[166] Lower Drug Costs Now Act of 2019, H.R. 3, 116th Cong. (2019).
[167] *See supra* Exhibit 2 and note 125.

Recommended Citation for this Post:

John DeFuria, *The Patience Assistance Problem*, HEALTH LAW OUTLOOK (Mar. 16, 2021), https://scholarship.shu.edu/health-law-outlook/.

HEALTH LAW FORUM