HOW MUCH WILL IT COST? THE "PRICE" OF PHARMACEUTICAL GAG CLAUSES AND WHY THEIR PROHIBITION MAY NOT EQUATE TO SAVINGS

Amy Faye Eng[*]

I. INTRODUCTION

Individuals often perceive pharmacists as trustworthy. A pharmacist may be responsible for a wide variety of tasks—from keeping a watchful eye for erroneous dosing to being a source of knowledge on drug interactions or side effects. Considering the potentially endless list of interactions between an individual and a pharmacist, a relationship is likely to form over time, which augments the feeling of trust. Until recently, however, there was one thing a pharmacist could not be trusted to do: let you know when you are paying "too much" for your prescription medication.

Rhode Island Representative Brian Kennedy found himself in a situation shared by many Americans: at the pharmacy picking up a prescription.[1] The pharmacist filling the prescription happened to be a friend of Representative Kennedy and discreetly disclosed to the Representative that he would be charged the drug's retail price as opposed to his copay.[2] The reason why was simple—the retail price was less than the copay.[3] The impact of making such a disclosure was more than just a friend looking out for another. In that single moment, the pharmacist committed a major transgression and simultaneously catalyzed the proposal of a new piece of Rhode Island legislation, which was later introduced by Representative Kennedy.[4] The pharmacist, whose identity could not be

[*] J.D. Candidate, 2020, Seton Hall University School of Law, concentration in Health Law; B.A., *magna cum laude*, 2017, Rutgers University. Special thanks to Professor John Jacobi for sharing his endless wisdom and helping bring this Comment to life. To the pharmacists who trusted their stories with a mere law student. And finally, for my family and friends, whose love and support has never wavered (even when I only wanted to speak about gag clauses exclusively).

[1] Elaine S. Povich, *There Might Be a Cheaper Drug, But Pharmacists Can't Tell You That*, PEW (June 4, 2018), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/06/04/there-might-be-a-cheaper-drug-but-pharmacists-cant-tell-you-that.

[2] *Id.*

[3] *Id.*

[4] *Id.*

shared due to the possibility of retaliation, had breached a "gag clause."[5]

The healthcare system in the United States is complex, and while there are many defining features that make it unlike any other, healthcare in the United States is arguably best known for being notoriously expensive.[6] Consequently, pharmaceutical spending comprises a large part.[7] To put it into perspective, "[t]he United States spends twice as much on healthcare as 10 other high-income nations," which includes countries such as the United Kingdom, Switzerland, Canada, and Japan.[8] Of all healthcare spending in the United States, the pharmaceutical sector compromises almost fifteen percent.[9] Moreover, prescription drug spending has been on the rise in the United States.[10] Needless to say, any conversation regarding healthcare automatically points to a discussion about the cost of pharmaceuticals.

The high cost of prescription drugs is a continuously raised issue, and the need for solutions is never-ending. Part of what makes the matter so pressing is the inability of many Americans to afford their medication.[11] In

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[5] *Id.*

[6] *See* Margot Sanger-Katz, *Why is U.S. Health Care So Expensive? Some of the Reasons You've Heard Turn Out to Be Myths*, N.Y. TIMES (Mar. 13, 2018), https://www.nytimes.com/2018/03/13/upshot/united-states-health-care-resembles-rest-of-world.html ("There were two areas where the United States was quite different: We pay substantially higher prices for medical services, including hospitalization, doctors' visits and prescription drugs. And our complex payment system causes us to spend far more on administrative costs.").

[7] *Id.*

[8] Jessica Glenza, *Sky-high Prices of Everything Makes US Healthcare the World's Most Expensive*, GUARDIAN (Mar. 13, 2018, 4:29 PM), https://www.theguardian.com/us-news/2018/mar/13/us-healthcare-costs-causes-drug-prices-salaries. In 2018, healthcare spending reached 3.6 trillion dollars, which comes to $11,172 per person. CMS.GOV: CTR. MEDICARE & MEDICAID SERV., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited Jan. 16, 2020); Bradley Sawyer & Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON KAISER: HEALTH SYS. TRACKER (Dec. 7, 2018), https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start. The next highest spending country was Switzerland at $8009 per person while every country after that spent roughly half, if not less, than the United States. *Id.*

[9] Nancy L. Yu et al., *Spending on Prescription Drugs in the US: Where Does All the Money Go?*, HEALTH AFF. (July 31, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180726.670593/full/.

[10] Allen Coukell & Ian Reynolds, *A Look at Drug Spending in the U.S.*, PEW (Feb. 27, 2018), http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/02/a-look-at-drug-spending-in-the-us (describing that in 2018, prescription drug spending was expected to rise more rapidly than any other part of the healthcare sector).

[11] *See* Paulina Firozi, *The Health 202: 'Gag Clauses' Mean You Might Be Paying More For Prescription Drugs Than You Need To*, WASH. POST: POWERPOST (July 5, 2018), https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2018/07/05/the-

recent discussions regarding ways to lower costs for Americans, "gag clauses" captured national attention.[12] Gag clauses are clauses found in contracts between Pharmacy Benefit Managers ("PBMs") and pharmacies.[13] These clauses are stipulations put in place by PBMs, which prohibit pharmacists from notifying consumers of the most cost-efficient way to procure their medication.[14] Generally, this impedes a pharmacist from telling a consumer that paying out-of-pocket would be cheaper than processing the payment through the consumer's insurance plan.[15]

Until recently, gag clauses were relatively unknown outside of the industry. Since making their debut in news headlines across the nation, they have captured widespread public attention and prompted lawmakers to take action at both the state and federal levels.[16] Even President Donald Trump has commented, brandishing the practice "a total rip-off" and further indicating, "[W]e are ending it."[17] Since making that statement, the Trump Administration has achieved its goal of eliminating the use of gag clauses,[18] but the elimination of gag clauses is only a surface level solution to a much deeper issue regarding the cost of drugs and the role of PBMs.

This Comment will examine PBMs, their use of gag clauses, and the lessons that can be learned post-gag clause legislation. Specifically, this Comment will address the various harms consumers face when gag clauses are permitted and utilized and further explain how these harms are not isolated incidents but issues pervasive in the PBM system. Essentially, what has changed with the removal of gag clauses and what more can be done? The analysis ultimately argues gag clauses were rightfully banned due to ethical implications and public policy concerns; however, rather than being viewed as an end, the prohibition of gag clauses should be considered the first step to amending problematic PBM practices. Gag clauses

health-202-gag-clauses-mean-you-might-be-paying-more-for-prescription-drugs-than-you-need-to/5b3a36ca1b326b3348addc4a/?utm_term=.22255ed87d1e (describing a couple who could not afford a $111 co-pay for medication).

12 *Id.*

13 *Id.*

14 Robert Pear, *Why Your Pharmacist Can't Tell You That $20 Prescription Could Only Cost $8*, N.Y. TIMES (Feb. 24, 2018), https://www.nytimes.com/2018/02/24/us/politics/pharmacy-benefit-managers-gag-clauses.html.

15 *Id.*

16 *See id.*

17 Katie Thomas, *6 Takeaways from Trump's Plan to Lower Drug Prices*, N.Y. TIMES (May 11, 2018), https://www.nytimes.com/2018/05/11/health/trump-drug-prices.html (statement from President Donald Trump commenting on the use of gag clauses during a speech addressing prescription drug prices).

18 Dartunorro Clark & Brenda Breslauer, *Trump Signs Bill Lifting Pharmacist 'Gag Clauses' on Drug Prices*, NBC NEWS (Oct. 10, 2018, 3:31 PM), https://www.nbcnews.com/politics/white-house/trump-signs-bills-lifting-pharmacist-gag-orders-drug-prices-n918721.

ultimately harmed consumers and offered little, if any, benefit. Unfortunately, this is a theme that persists despite the prohibition of gag clauses.

Part II provides a brief overview of PBMs and describes the supply chain for how medication reaches a consumer, and more importantly, how price is determined. Afterward, Part III defines gag clauses and their function. Part IV then discusses some of the issues associated with gag clauses and details how they adversely impact consumers. Part V explores the widespread attention received by gag clauses and analyzes state and federal legislation prohibiting their use.

Finally, Part VI ends with the position that while gag clauses should be prohibited and their removal is ultimately a win for lawmakers and Americans alike, nothing has significantly changed. The gag clause story reveals deeply entrenched issues in the PBM system; gag clauses are gone, yet issues regarding fiduciary duties, conflicts of interest, and transparency still remain. If lawmakers are genuinely interested in protecting Americans, they should seek to strengthen gag clause legislation and find other avenues to further reform the harmful practices of PBMs.

II. BACKGROUND: PBMS, DRUG PRICING, AND THE RISING COST OF HEALTHCARE

For a drug to reach a consumer, there are several moving parts that must align. Ideally, a patient goes to his or her doctor, the doctor makes a diagnosis, the doctor prescribes an appropriate medication, the patient goes to the pharmacy to have the prescription filled, and the patient receives the medication. In reality, however, the system may not be so streamline. Patients must consider whether their insurer covers the prescription, whether the pharmacy they frequent is in network, and so on. The entire process may spark endless questions: "who decides what drugs are included on a formulary?"; "why does a patient need to try several treatments prior to receiving the medication the physician originally wanted to prescribe?"; "what is actually the difference between a biosimilar and a bioequivalent?" While all of these are valid, the most important question for the purposes of this Comment is: "how much will it cost?"

A. *What is a PBM?*

PBMs came into existence in the 1970s to serve as "fiscal intermediaries by adjudicating prescription drug claims by paper and then, in the 1980s, electronically."[19] Historically, the role of the PBM was to

[19] Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U. L. REV. 33, 34 (2007).

process prescriptions.[20] The process began when a patient dropped his or her prescription off at the pharmacy to be filled.[21] The pharmacy would then contact the PBM to ensure the patient had coverage, whether the prescription was covered by the plan, the copay amount, and whether further authorization was required.[22] Once the prescription was filled, the pharmacy would contact the PBM with the patient's information, and the PBM would then approve or disapprove the transaction.[23] After, the PBM would seek payment from the insurer and transfer the proper payment amount to the pharmacy.[24]

Since its inception, the role of the PBM has changed greatly. From its arguably "humble" beginnings of "simply processing prescription transactions," PBMs are now tasked with "managing the pharmacy benefit for health plans."[25] Individual insurers seek to control costs yet they do not always have the necessary expertise to effectively negotiate. [26] As a result, insurers have turned to PBMs to handle drug purchasing.[27] PBMs have significant buying power and "act like giant buying networks for drugs, representing consumers from multiple employers and insurers."[28] Thus, insurers usually opt to contract with a PBM rather than internally manage drug procurement.[29] Unlike the insurer, PBMs have standing within the pharmaceutical industry and the power to negotiate.[30]

PBMs are best known as the entity that negotiates rebates and discounts with pharmaceutical manufacturers. It is argued that, through their efforts, "PBMs save consumers and third-parties that pay for

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[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] Garrett & Garis, *supra* note 19.

[26] Ruth Barber Timm, *The Intraenterprise Conspiracy Doctrine and the Pharmaceutical Benefit Management Industry: A Proposed Exception to the Copperweld Holding*, 31 VAL. U. L. REV. 309, 316 (1996).

[27] *Id.*

[28] John Arnold, *Are Pharmacy Benefit Managers the Good Guys or Bad Guys of Drug Pricing?*, STAT (Aug. 27. 2018), https://www.statnews.com/2018/08/27/pharmacy-benefit-managers-good-or-bad/.

[29] *Id.*

[30] Cole Werble, *Pharmacy Benefit Managers*, HEALTH AFF. (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/. *See also* Robert Calandra, *PBMS: New Power and Influence*, MANAGED CARE (April 5, 2015), https://www.managedcaremag.com/archives/2015/4/pbms-new-power-and-influence ("The more members a PBM represents, the bigger its buying power. The bigger its buying power, the larger its influence on the marketplace. The larger its influence . . . well, you get the idea.").

prescription drugs billions of dollars each year."[31] These savings are achieved through various means. For instance, a PBM may be in charge of crafting the formulary, which gives the PBM immense leverage in negotiations.[32] The ability to craft the formulary is powerful and can affect patient care.[33] A formulary is a list of preferred drugs a plan covers.[34] Plan participants are incentivized to use medications included on the formulary because these medications are generally cheaper.[35] This, in turn, increases consumer demand for particular products and results in significant sales for the respective drug manufacturers.[36] As a result, drug manufacturers want their products on the formulary, and since they are competing with every other manufacturer, they are willing to offer discounts and rebates to appeal to the formulary drafter, i.e. the PBM.[37] Ultimately, PBMs have immense influence over which drugs consumers have access to, the means in which consumers are able to procure them, and how much they will cost.[38]

Additionally, PBMs are powerful because they are largely under-regulated and are able to partake in conduct that can impair, rather than enhance, the value of competition in the retail drug market.[39] PBMs have amassed large patient networks, and in order for a manufacturer or

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[31] Joana Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Advisory*, 9 NW. J.L. & SOC. POL'Y 1, 2 (2013).

[32] Garrett & Garis, *supra* note 19. Being able to craft a formulary gives a PBM crucial leverage over the system because a PBM has the ability to "exclude hundreds of drugs" and show preference for a select few. David Dayen, *The Hidden Monopolies That Raise Drug Prices*, AM. PROSPECT LONGFORM (Mar. 18, 2017), http://prospect.org/article/hidden-monopolies-raise-drug-prices.

[33] *See* Mark A. Buckles, *Electronic Formulary Management and Medicaid: Maximizing Economic Efficiency and Quality of Care in the Age of Electronic Prescribing*, 11 U. FLA. J.L. & PUB. POL'Y 179, 183 (2000) ("Plans encourage physicians . . . to adhere to formularies by linking their compensation or status in the plan to their prescribing practices or simply by making it more costly for patients if physicians deviate from the formulary.").

[34] Shepherd, *supra* note 31, at 5; Michael Bihari, *Understanding Your Health Plan Drug Formulary*, VERYWELL HEALTH (June 24, 2019) ("A drug formulary is a list of prescription drugs, both generic and brand name, that are preferred by your health plan" with the intention of steering patients towards "the least costly medications that are sufficiently effective for treating [the] health condition.").

[35] Shepherd, *supra* note 31, at 5.

[36] *Id.*

[37] *Id.*

[38] *Id.* at 2 ("They [PBMs] influence how much consumers pay for drugs, which pharmacies they use, and even which drugs they take."); Jane Horvath, *Pharmacy Benefit Manager Model Legislation: Questions and Answers*, NASHP (Aug. 9, 2018), https://nashp.org/pharmacy-benefit-manager-model-legislation-questions-and-answers/ ("If a manufacturer's drug is not in a formulary, insurers won't cover the drug and physicians won't prescribe it, so PBMs have great leverage when negotiating prices.").

[39] *See generally* Garrett & Garis, *supra* note 19, at 34–35 ("Over the past decade, significant changes have occurred in the PBM industry, but regulation of the PBMs has not kept pace with those changes.").

pharmacy to have access to that network, it must contract with the PBM.[40] Alternatively, to remain attractive to manufacturers and effectively negotiate, PBMs are motivated to grow their networks.[41] As a result, PBMs have resorted to consolidation.[42] The three largest PBMs, sometimes referred to as the "Big Three," are Express Scripts, CVS Caremark, and OptumRx.[43] It is estimated that these three PBMs control roughly seventy-five to eighty percent of market share, which translates to 180 million prescription drug customers.[44] With the exception of Express Scripts being a standalone PBM, CVS Caremark is aligned with the major drug retailer CVS Health, and OptumRX partners with the insurer UnitedHealth.[45] All, however, have been parties in mergers and retain significant control of the PBM market.[46]

While PBMs should help consumers, it is unclear whether they truly achieve this goal. Given their role as masters of the formulary and the sheer volume of individuals managed, PBMs significantly impact consumers. Primarily, this impact is realized through rebates and discounts.[47] This model, utilizing rebates and discounts to raise revenue, has led to concerns regarding possible "perverse impact[s] on pharmacy costs and patient out-of-pocket costs."[48] Ultimately, when it comes to consumers, PBMs may actually be doing more harm than good.

B. *Following the Cost (and the Pill) to the Consumer*

For a consumer who obtains a prescription drug at the pharmacy (as opposed to receiving it directly from a physician in an outpatient setting),[49]

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40 Dayen, *supra* note 32.

41 Werble, *supra* note 30, at 2.

42 *Id.*

43 Garrett & Garis, *supra* note 19, at 36.

44 Garrett & Garis, *supra* note 19, at 34. Another way to look at this: "Within the United States, approximately two-thirds of all prescriptions filled pass through the hands of PBMs in one way or another." *Id.*

45 Werble, *supra* note 30, at 2.

46 Evan Sweeney, *Lawmakers Ask FTC for Retrospective Review of PBM Mergers*, FIERCEHEALTHCARE (Jul. 30, 2018, 12:00 AM), https://www.fiercehealthcare.com/payer/house-energy-and-commerce-ftc-pbm-mergers-healthcare-costs ("CVS Health bought Caremark in 2007, Express Scripts bought Medco Health Solutions in 2012 and UnitedHealth bought Catamaran in 2015."). Further, CVS is looking to acquire Aetna, and Cigna is looking to acquire Express Scripts. *Id.*

47 *See* discussion *infra* Section II.B.

48 Horvath, *supra* note 38.

49 Drugs can be obtained at a pharmacy but can also be obtained directly from a health care provider. *See A Tangled Web: An Examination of the Drug Supply and Payment Chains* (June 2018) [hereinafter *A Tangled Web*], https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf. For example, a patient may receive care from the outpatient department of a hospital, a physician's office, or an outpatient clinic and receive

that drug has traveled from the manufacturer that made the drug, all the way to the pharmacy that has the ability to dispense the drug.[50] Yet following the movement of a pill from the manufacturer to the consumer is much less complex than following the exchange of money necessary to move the drug through the supply chain.

The decision as to what a consumer will pay at the pharmacy counter depends on a complicated chain of negotiations largely influenced by the passing along of discounts and rebates.[51] A manufacturer establishes a list price, also known as the Wholesale Acquisition Cost ("WAC"), which "is intended to capture the price a manufacturer would charge a drug wholesaler or other direct purchaser before any discounts, rebates or other price reductions."[52] This is the "sticker price."[53] The sticker price, however, is virtually never paid due to various financial incentives offered by manufacturers in an effort to stimulate demand.[54] The manufacturer sells to a wholesale distributor, who pays a negotiated price, and in turn, the wholesale distributor will sell to a pharmacy, who pays a different negotiated price.[55] It is during these separate negotiations that discounts and rebates come into consideration.[56]

PBMs are the intermediary between the manufacturer and pharmacy—they negotiate price and conduct quality and utilization management screens on the drugs being purchased.[57] The price is then passed to the consumer who may use his or her insurance, whether it be public or private coverage, to help pay for the drug.[58] Every insurance plan

medication directly from the health care provider without ever stepping foot inside a pharmacy. *Id*. at vii. In this situation, the drug is made by the manufacturer, sent to a wholesale distributor, and then makes it way to the health care provider. *Id*. This practice is sometimes referred to as "direct dispensing," "point-of-care dispensing," or "in-office dispensing." This Comment will not explore the administering of pharmaceuticals through the outpatient channel.

50 *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, HEALTH STRATEGIES CONSULTANCY LLC 1 (Mar. 2005), https://avalere.com/research/docs/Follow_the_Pill.pdf.

51 Henry C. Eickelberg, *The Prescription Drug Supply Chain "Black Box" How It Works and Why You Should Care*, AM. HEALTH POL'Y INST. 9 (2015), http://www.americanhealthpolicy.org/Content/documents/resources/December%202015_AHPI%20Study_Understanding_the_Pharma_Black_Box.pdf.

52 *Id.* (emphasis omitted).

53 *Id.*

54 *Id.* This can be likened to buying a car. A sticker price exists, but more often than not, that price will not be paid by the consumer.

55 *Id.*

56 *Id.*

57 Eickelberg, *supra* note 51, at 7.

58 *See* Laura D. Hermer, *Private Health Insurance in the United States: A Proposal for a More Functional System*, 6 HOUS. J. HEALTH L. & POL'Y 1, 2 (2005) (describing various means of accessing health care).

is unique, but generally, the insurance company and/or PBM will have contracts in place to reduce the cost of drugs for plan participants.[59] This is, of course, assuming that the health coverage includes pharmacy coverage.[60] If a consumer does not have pharmacy coverage, he or she will be charged a cash price.[61]

As the middlemen, PBMs directly influence a consumer's out-of-pocket costs. Cost is contingent on how "well" the PBM is able to negotiate a rebate or discount, but more importantly, cost is ultimately decided by the price the PBM chooses to charge the consumer.[62] For instance, a manufacturer may charge $10 for a pill that costs 50¢ to produce. The PBM negotiates and pays $3, and to make a profit, the PBM will set the price at $5. The consumer and their insurer will then pay the $5, and the PBM makes a profit of $2. While $2 may seem inconsequential, it adds up in the aggregate. Moreover, the split in price is not always just $5. It can be a much larger and sometimes even shocking amount. Take for example, the 2016 situation with Mylan's EpiPen. A two-pack EpiPen costs about $2 to manufacture.[63] In 2007, Mylan was charging $100, and by 2016, the price exceeded $600 without any substantive justification for the price hike.[64] The high price resulted in significant out-of-pocket costs for families, many of which could not afford the life-saving medication.[65] On a $600 EpiPen, a PBM was estimated to receive roughly $300 per prescription.[66] PBMs faced backlash for their failure to keep costs down,

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[59] Kimberly Amadeo, *How Health Insurance Works*, BALANCE (Sept. 25, 2018), https://www.thebalance.com/how-does-health-insurance-work-3306069 ("Health insurance is necessary for Americans to pay for the high cost of healthcare. . . . Health insurance companies provide lots of choices.").

[60] *See* Steve Vernon, *Medicare Prescription Drug Coverage: You May Need a New Plan*, CBS NEWS (Sept. 26, 2018; 1:23 PM), https://www.cbsnews.com/news/medicare-prescription-drug-coverage-open-enrollment-starts-oct-1-how-a-new-plan-can-save-money/ (explaining Medicare coverage may not include prescription drug coverage, which would "potentially save hundreds or even thousands of dollars."). The same is true for private insurance, and an individual's private insurer may or may not include prescription drug coverage. For example, Blue Cross Blue Shield directs participants to check their individual plan for coverage information. *How Do I Know My Plan Covers My Prescription Drug?*, BLUE CROSS BLUE SHIELD NETWORK MICH., https://www.bcbsm.com/index/health-insurance-help/faqs/plan-types/pharmacy/know-if-plan-covers-prescription-drug.html (last visited Oct. 24, 2018).

[61] Eickelberg, *supra* note 51, at 10.

[62] *See* Jessica Wapner, *How Prescription Drugs Get Their Prices, Explained*, NEWSWEEK (Mar. 17, 2017, 8:00 AM), https://www.newsweek.com/prescription-drug-prici ng-569444.

[63] Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?*, 102 MINN. L. REV. 2273, 2274 (2018).

[64] *Id.*

[65] *Id.* at 2274–75. EpiPens treat anaphylaxis. *Id.* at 2273 n.2.

[66] David Balto, *How PBMs Make the Drug Price Problem Worse*, HILL (Aug. 31, 2016,

especially when it seemed they pursued profit at the expense of consumers—consumers they were supposed to be serving and negotiating on behalf of.[67] Undeniably, something went wrong in the EpiPen situation, and consumers paid the price.[68]

Consumers arguably have the most at stake; they use the medication, yet the system does not offer them a voice nor does it allow them an opportunity to make decisions about care—instead, consumers "wait to see what their physicians prescribe and what their insurance will pay for."[69] Because PBMs make their profit depending on the difference in cost between what they pay and what they charge, PBMs are incentivized to pass on higher costs to consumers.[70] While the PBM may be saving the consumer from paying the list price—the price that nobody ever pays—the PBM may not be passing on the negotiated savings to consumers in a meaningful way.

III. DEFINING THE "GAG CLAUSE"

Gag clauses are found in contracts between PBMs and pharmacies and constrain a pharmacist's ability to communicate price alternatives to a consumer.[71] Pharmacies contract with PBMs in order to access the patients within the PBM's network.[72] In order to make a profit, a pharmacy needs to have customers, and in order to have customers, the pharmacy must engage with a PBM who is the gatekeeper to a plan's participants. When a pharmacy dispenses medication to a consumer, the pharmacy is at a monetary loss until the PBM issues a reimbursement.[73] Thus, pharmacies

5:51 PM), https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse.

[67] *Id.*

[68] The EpiPen situation is still playing out, and the PBMs who were involved in the scandal are currently involved in litigation regarding their involvement. *In re* EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig., 336 F. Supp. 3d 1256 (D. Kan. 2018); *see also* Carmen Castro-Pagan, *CVS, UnitedHealth, Others Must Defend EpiPen Pricing Suit*, BLOOMBERG LAW (Oct. 29, 2018, 8:53 AM), https://news.bloomberglaw.com/employee-benefits/cvs-unitedhealth-others-must-defend-epipen-pricing-suit ("The insureds who last year sued the nation's largest pharmacy benefit managers—including Caremark, Express Scripts, Optum, and Prime Therapeutics LLC—over EpiPen's pricing scheme have alleged sufficient facts to establish their right to bring the lawsuit . . . .").

[69] Wapner, *supra* note 62.

[70] Balto, *supra* note 66 ("The higher the price, the higher the rebate—and [the PBM] walk[s] away with a bigger slice of the pie.").

[71] Matthew Perrone, *To Get Around Pharmacy Gag Rules, Ask About Drug Costs*, MED. XPRESS (June 6, 2018), https://medicalxpress.com/news/2018-06-pharmacy-gag-drug.html.

[72] *See supra* text accompanying note 40.

[73] *See Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines*, PHRMA 1, 4 (Nov. 2017),

rely on PBMs to access consumers and receive payment.[74] As part of the agreement allowing a pharmacy to work with the PBM's patients, a pharmacy is likely to agree to various conditions such as a gag clause, which "contractually obligate[s a pharmacist] to keep quiet regarding possible patient cost savings" or risk losing the network contract with the PBM.[75]

Often, gag clauses prevent pharmacists from notifying consumers they "could save money by paying cash for prescription drugs rather than using their health insurance."[76] This situation plays out in the following hypothetical: Jane Doe needs a prescription medication. It costs the pharmacy $10 to stock the medication, and Jane's copay is $20. If Jane opts not to process the payment through her insurance, she would pay $10 and have an immediate savings of $10. If the pharmacist is subject to a gag clause, he or she will be unable to notify Jane of the price difference. As a result, Jane will have to pay the higher price of $20 unless Jane knows to ask whether a lower price is available. One pharmacist describes this situation as: "[If] I see on my screen that if you pay the cash price it would actually be cheaper for you than if you were to pay with your insurance, I can't tell you unless you specifically ask me about it."[77]

Sometimes gag clauses are expressly stated in the contract.[78] More commonly, however, the clauses are obscured or hidden in "broad confidentiality rules" that employ "broad and nebulous confidentiality verbiage."[79] While the clauses generally bar pharmacists from initiating conversations about cheaper alternatives, a gag clause may not be a complete prohibition on the information depending on the specific contract.[80] Thus, if a consumer asks his or her pharmacist directly for a drug's cash price or asks if there is a cheaper alternative, the gag clause is unlikely to interfere with the pharmacist being able to answer.[81] Conversely, a pharmacist beholden to a gag clause will never be able to

http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf.

[74] *See* Jeffrey S. Baird, *What to Know About Working with PBMs*, PHARMACY TIMES (Feb. 20, 2018), https://www.pharmacytimes.com/news/what-to-know-about-working-with-pbms ("[T]he PBM 'possesses the pharmacy's money.'").

[75] Lynn Shapiro Snyder et al., *New Federal Laws Banning "Gag Clauses" in the Pharmacy*, EPSTEIN BECKER GREEN (Oct. 19, 2018), https://www.healthlawadvisor.com/2018/10/19/new-federal-laws-banning-gag-clauses-in-the-pharmacy/.

[76] Pear, *supra* note 14.

[77] Firozi, *supra* note 11 (Anthony Reznik, director of government affairs for the Independent Pharmacy Alliance, on gag clauses).

[78] *Id.*

[79] *Id.* (explaining it would be rare to see an over prohibition that said, "Though shall not tell the patient the true negotiated price").

[80] Perrone, *supra* note 71.

[81] *Id.*

initiate a conversation about cost.[82]

Even if consumers have the ability to initiate a conversation with their pharmacist about cost alternatives, many do not.[83] Most consumers do not think of the cost of medication as being "negotiable"—much less know about the clauses—and would never think to ask.[84] "As a consumer you would have no idea how it works . . . . Even if you were aware of the issue, it would be hard to know when the person across the counter says, 'This is $20.' They would pay the $20, because what is the option?"[85] And this makes sense. It would be counterintuitive for consumers to assume there is a cheaper option when the role of insurance is to lower costs.[86]

Gag clauses are particularly problematic for vulnerable communities like senior citizens who are more likely to take larger amounts of prescription medication due to age-related health factors.[87] The clauses also affect individuals who have plans with higher cost-sharing responsibilities because a gag clause could result in the consumer's copay being higher than the retail price of the drug.[88] Nevertheless, gag clauses have the ability to affect anyone. Anyone who goes to a pharmacy to procure medicine, whether it is once a day or once every ten years, could potentially be affected.

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[82] *Id.*

[83] Jared S. Hopkins, *Pharmacists May Soon Be Able to Tell You the Cheapest Way to Get Prescriptions*, BLOOMBERG (Sept. 25, 2018, 6:20 PM), https://www.bloomberg.com/news/articles/2018-09-25/pharmacy-gag-clause-on-cheaper-drug-prices-barred-by-congress ("Most patients never realize there's a cheaper cash price because of clauses in contracts between pharmacies and PBMs that bar the drugstore from telling people there's a cheaper way to pay.").

[84] *Id.*

[85] Povich, *supra* note 1 (Richard Cauchi, the health program director for the National Conference of State Legislatures, on gag clauses).

[86] Hopkins, *supra* note 83 ("Insurance is intended to save consumers money . . . . Who would think that using your debit card to buy your prescription drugs would be less expensive than using your insurance card? It's counterintuitive."); Sen. Susan Collins (@SenatorCollins), TWITTER (Oct. 10, 2018, 4:37 PM), https://twitter.com/senatorcollins/status/1050123175688847362?lang=en.

[87] *See* Susan Morse, *House Passes Bills Prohibiting Pharmacy Gag Clauses on Drug Price*, HEALTHCARE FIN. (Sept. 27, 2018), https://www.healthcarefinancenews.com/news/house-passes-bills-prohibiting-pharmacy-gag-clauses-drug-prices ("Nearly 60 percent of Americans, including roughly 90 percent of seniors, take prescription drugs. A study published in the Journal of the American Medical Association found that 23 percent of prescriptions filled through insurance ended up costing more for customers than if they had paid out-of-pocket.")

[88] Mary Kane, *New Laws Lift 'Gag Clauses' on Pharmacists*, KIPLINGER (Oct. 10, 2018), https://www.kiplinger.com/article/insurance/T039-C000-S009-new-laws-lift-gag-clauses-on-pharmacists.html ("[I]f you pay a hefty co-pay, it might cost less to pay for a drug yourself . . . .").

Without doubt, gag clauses are implemented to benefit PBMs, and PBMs offer several justifications for their utilization. First, PBMs argue the money collected is reallocated to help keep costs down as well as slow premium increases.[89] Second, PBMs argue they have the right to pocket excess payments because generally, consumers pay less due to the efforts of the PBM.[90] In other words, PBMs "make less than they are requesting so it's justified on the rarer occasions that they make more than the list price."[91] Third, PBMs argue there is a need to ensure consumers stay within the system. If consumers are free to choose when they will and will not use their insurance, PBMs are unable to predict expenses, and they become susceptible to only paying for high-cost medications without an opportunity to recoup funds on lower cost prescriptions.[92] Arguably, the lack of certainty would lead to higher costs for everyone in order to buffer the risk.

There is also disagreement regarding how widespread gag clauses actually are and whether or not they truly impact consumers. On the subject, a spokesman for Express Scripts indicated, "We do not engage in this anti-consumer practice and are working constructively with state and federal policymakers to ban this practice."[93] Likewise, a statement from CVS Health noted, "CVS Health's own pharmacy benefit manager, CVS Caremark, does not engage in the practice of preventing pharmacists from informing patients of the cash price of a prescription drug, known as 'gag clauses.'"[94] Conversely, there are countless accounts from pharmacists

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89 *See* Sean Dickson & Alisa Chester, *Policymakers Seek Ways to Lower Drug Costs at the Pharmacy Counter*, PEW (July 12, 2018), https://www.pewtrusts.org/en/research-and-analysis/articles/2018/07/12/policymakers-seek-ways-to-lower-drug-costs-at-the-pharmacy-counter.

90 Letters to the Editor, *How Those Pharmacy Gag Clauses Are Justified*, NJ.COM (Oct. 19, 2018), https://www.nj.com/hudson/2018/10/how_those_pharmacy_gag_clauses_are_justified_lette.html.

91 *Id.*

92 This could be compared to the Affordable Care Act's individual mandate. The individual mandate was implemented to compel Americans to purchase insurance in order to spread cost and prevent adverse selection. Alberto R. Gonzales & Donald B. Stuart, *Two Years Later and Counting: The Implications of the Supreme Court's Taxing Power Decision on the Goals of the Affordable Care Act*, 17 J. HEALTH CARE L. & POL'Y 219, 222 (2014); *see also* Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 548 (2012). The same could be said in this situation. PBMs want to ensure that individuals continue to process payments through the insurer so costs can remain lower for everyone overall.

93 Firozi, *supra* note 11 (Phil J. Blando, spokesman for Express Scripts, in a statement to Health 202).

94 *Id.* (CVS Health in a March 2018 Statement on its website); *CVS Caremark Does Not Have "Gag" Clauses*, CVSHEALTH, https://cvshealth.com/thought-leadership/cvs-caremark-facts/cvs-caremark-does-not-have-gag-clauses ("[A]t CVS Caremark, we do not and have never prevented pharmacies in our network from discussing the availability of a lower cash price with plan members." (emphasis omitted)) (last visited Jan. 7, 2020).

who indicate gag clauses are an everyday impediment to the work that they do.[95] In 2016, an industry survey found "nearly 20 percent of pharmacists were limited by gag clauses more than 50 times per month."[96] In 2013, it was estimated that there were roughly $135 million in overpayments due to gag clauses.[97] Regardless of which side of the debate is "correct," gag clauses have been prevalent enough to warrant widespread attention and were framed by lawmakers as being a significant problem.

IV. THE PROBLEM WITH GAG CLAUSES

Those who have never heard of gag clauses usually react with discomfort or disgust. When a system is supposed to help by lowering out-of-pocket costs for consumers, it is unnerving to find that the exact opposite is occurring.[98] Ultimately, gag clauses affect the way in which consumers are able to interact with pharmacists, thereby interfering with a relationship that otherwise functions on trust.[99] As a consequence, not only do gag clauses raise concerns about saving money, they also highlight ethical and public policy implications.

A. *Fiduciary Duties*

Gag clauses reveal an issue with fiduciary duties, specifically in regard to who owes them and who does not. The fiduciary duties imposed on pharmacists do not directly require any sort of disclosure related to

[95] I spoke with several pharmacists. All of them were very aware of gag clauses and could cite to instances in which a gag clause had affected the way they interacted with a consumer. Overwhelmingly, it seemed that gag clauses had a negative impact on consumer interactions.

[96] *Collins, McCaskill, Stabenow, Barrasso, Cassidy Bill to Prohibit "Gag Clauses" That Cause Consumers to Overpay for Prescriptions Clears Key Senate Hurdle*, SUSAN COLLINS: U.S. SENATOR ME. (July 25, 2018, 10:52 AM), https://www.collins.senate.gov/newsroom/collins-mccaskill-stabenow-barrasso-cassidy-bill-prohibit-%E2%80%9Cgag-clauses%E2%80%9D-cause-consumers.

[97] *Id.* Overpayments are the result of copays being more than the total cost of the medication, which means insurance does not need to contribute any payment. Karen Van Nuys et al., *Overpaying for Prescription Drugs: The Copay Clawback Phenomenon*, USC SCHAFFER 1, 1 (2018). These overpayments are pocketed by PBMs and are referred to as "clawbacks." *Id.* Clawbacks are a separate but generally interrelated issue to gag clauses.

[98] Brittany Hoffman-Eubanks, *The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1*, PHARMACY TIMES (Nov. 14, 2017), https://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1 ("To address these increases in costs related to prescription drugs, private employer groups, individual States, and the federal government[ ] have utilized the services of pharmacy benefit managers.").

[99] Ryan Marotta, *Pharmacists Remain Among Most Trusted and Ethical Professionals*, PHARMACY TIMES (Feb. 9, 2018), https://www.pharmacytimes.com/news/pharmacists-remain-among-most-trusted-and-ethical-professionals (citing a Gallup poll, which listed pharmacists as ranked amongst the most honest and ethical professionals).

methods of prescription payment; however, pharmacists do have other fiduciary duties. During their training, pharmacists are taught ethics, and there is a certain ethical norm expected of pharmacists by society as health care professionals.[100] As such, the limitation placed on pharmacists via gag clauses is counterproductive to their role as fiduciaries. "A fiduciary has 'duties involving good faith, trust, special confidence, and candor towards another,'" and the specific duties are defined by the specific relationship between the parties.[101] Arguably, the most well-known fiduciary obligation in the medical profession is the Hippocratic Oath.[102] Pharmacists are administered a similar oath called the "Oath of a Pharmacist," which is curated by the American Pharmacists Association.[103] Much like the Hippocratic Oath, the Oath of a Pharmacist describes a pharmacist's duty to help patients and hold high standards.[104]

The problem with gag clauses is that they interfere with a pharmacists' ability to help the consumer. The consumer is harmed tangibly in that he or she is unable to save money but also intangibly in that the relationship between the pharmacist and the consumer is strained.[105]

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[100] Courts have also found that pharmacists have fiduciary duties imposed by law. The Supreme Court of New York found that pharmacists are "responsible for collecting otherwise confidential medical information and providing advice to customers." Anonymous v. CVS Corp., 728 N.Y.S.2d 333, 337 (Sup. Ct. 2001). The Court ultimately outlined a duty of confidentiality, which was implicated when the defendant in this case transferred customer information without the customer's knowledge or consent. *Id.* Alternatively, the Supreme Court of Alabama affirmed that pharmacists have a duty to counsel, which may extend to a duty to warn in instances of changes in dosage. Jesse C. Vivian, *Duty to Warn With No Directions for Use*, U.S. PHARMACIST (Feb. 17, 2012), https://www.uspharmacist.com/article/duty-to-warn-with-no-directions-for-use; *see also* Nail v. Publix Super Mkts., 72 So. 3d 608, 614, 616 (Ala. 2011).

[101] Julia A. Martin & Lisa K. Bjerknes, *The Legal and Ethical Implications of Gag Clauses in Physician Contracts*, 22 AM. J. L. & MED. 433, 456 (1996).

[102] *See Greek Medicine: The Hippocratic Oath*, U.S. NAT'L LIBR. MED., https://www.nlm.nih.gov/hmd/greek/greek_oath.html. The Hippocratic Oath establishes a physician duty as a healer obligated to help the patient first and foremost while also maintain the interests of society and self. *See also* Rachel Hajar, *The Physician's Oath: Historical Perspectives*, 18 HEART VIEWS 154, 156 (2017).

[103] *Oath of a Pharmacist*, AM. PHARMACISTS ASS'N, https://www.pharmacist.com/oath-pharmacist (last accessed Jan. 7, 2020).

[104] *Id.*

[105] One pharmacist explained to me how he would decide to go against the gag clause. Depending on whether the individual was a long-term customer and could be trusted not to contact his or her insurer to ask why their price was "higher," which would ultimately get the pharmacist in trouble due to the gag clause, the pharmacist would be willing to disclose the price difference. According to the pharmacist, he did not have any "official" fiduciary obligation to the individual—in fact, the duty was contractually owed to the PBM—but he felt it was worthwhile to act based on the trust relationship and the best interest of the consumer. For those he opted against helping, it was merely business and nothing personal. He also indicated the fiduciary duty that should be owed is the one from the PBM to the consumer.

This relationship is important because there is a potentially large societal cost if citizens are unable to trust individuals who provide care.[106] "Patients are more likely to open up and disclose information if they trust their pharmacist[,]" and a better quality interaction leads to better care.[107] Gag clauses implicate a pharmacist's fiduciary obligations, but they also present another dilemma: PBMs are tasked with lowering costs for consumers yet gag clauses achieve the exact opposite. The logical follow-up question: how does this happen when PBMs have a fiduciary obligation to protect consumers? As the gag clause situation reveals, PBMs owe very few duties to consumers, which ultimately harms the consumer.[108]

B. *Conflicts of Interest*

Gag clauses also show how the PBM system is riddled with conflicts of interest. A "[c]onflict of interest describes a situation in which a person is or appears to be at risk of acting in a biased way because of personal interests."[109] Gag clauses put pharmacists in a position where they must choose between appeasing a PBM and acting in self-interest or helping the consumer by letting him or her know about a cheaper option and jeopardizing the pharmacy's contract with the PBM. One main function of PBMs is to forward money from the health plan to the pharmacy.[110] Pharmacists, especially independent pharmacists, often rely on the money from PBMs—"participation in PBM networks is the lifeblood of independent pharmacy revenue."[111] As such, there is financial pressure pushing against a pharmacist's willingness to counsel a consumer in the face of a gag clause.[112] A consumer may automatically assume the pharmacist is working on his or her behalf, unaware that the pharmacist is really allegiant to the PBM and the preservation of self due to a gag clause.

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106 *See* Maria Allison & Betty Chaar, *How to Build and Maintain Trust with Patients*, PHARMACEUTICAL J. (Nov. 15, 2016), https://www.pharmaceutical-journal.com/pharmacy-learning-centre/how-to-build-and-maintain-trust-with-patients/20201862.article?firstPass=false.

107 *Id.*

108 *See* discussion *infra* Section VI.B.1.

109 Christopher C. Muth, *Conflicts of Interest in Medicine*, 317 JAMA 1812, 1812 (2017).

110 Garrett & Garis, *supra* note 19, at 34.

111 Jonathan L. Swichar & Bradley A. Wasser, *Pharmacy Fights Back Against PBM Termination Notice*, DUANE MORRIS (Nov. 2017), https://www.duanemorris.com/articles/pharmacy_fights_back_against_pbm_termination_notice_1117.html.

112 An independent pharmacist shared with me how crippling it can be to upset a PBM. As a small pharmacy, much of the pharmacist's income could be dependent on PBM payments so from a financial standpoint, there is no benefit to helping a consumer by going against a gag clause at the expense of severing ties with the PBM. At the end of the day, the consumer does not keep the lights on—the PBM does.

Also, depending on the contract, PBMs may have the power to terminate without cause.[113] In a situation where PBMs retain so much power, it is unlikely a pharmacist will be willing to put a relationship he or she heavily relies on at risk.

The utilization of gag clauses by PBMs highlights a flaw in the system where financial incentives are misaligned with what is best for consumers. Like any business, PBMs only profit when consumers use their services, and gag clauses were a way to ensure consumers would not stray. While gag clauses are gone, the system remains, and once again, consumers are harmed.

C. *Transparency*

Finally, gag clauses display how opaque the PBM system is. Gag clauses are often coupled with broad rules regarding anti-disparagement or confidentiality, which makes it impossible for the gagged party to give any indication a gag clause is in effect.[114] For example, one pharmacist landed himself in trouble with a PBM because discussing alternative ways to purchase a prescription breached the contract for "disparaging the plan."[115] Gag clauses themselves are a form of confidentiality clause, which prohibits any kind of conversation about pricing.[116] Hence, the problem is circular—not only is a pharmacist unable to tell a consumer about a cheaper option due to a gag clause, but the pharmacist may also be unable to discuss the constraints he or she is under as it could be viewed as disparaging.[117] This is problematic because consumers are unaware of the restrictions placed on the pharmacist and are otherwise under the impression a pharmacist is loyal to them and not an unknown third-party entity. The public suffers because pharmacists are unable to discuss the agreements that bind them.

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113 *See* Swichar & Wasser, *supra* note 111.

114 Shannon Firth, *Proposed House Bill Seeks to End Drug Price 'Gag Clause*,' MEDPAGE TODAY (Sept. 5, 2018), https://www.medpagetoday.com/publichealthpolicy/healthpolicy/74942.

115 *Id.*

116 Deanna Dewberry, *NYS Exposed: Insured Patients Could be Paying Too Much for Prescriptions*, WHEC (Mar. 9, 2018, 7:07 AM), https://www.whec.com/news/insured-patients-could-be-paying-too-much-for-prescriptions/4818961/.

117 *See* Mary Caffrey & Allison Inserro, *Senate Votes 98-2 to Ban Pharmacist Gag Clauses*, AJMC (Sept. 18, 2018), https://www.ajmc.com/newsroom/senate-votes-982-to-ban-pharmacist-gag-clauses ("The PBM stated we were in violation of our contract for disparaging the plan when we discussed the cost of a drug off insurance."); *Local Pharmacist Hugh Chancy in the White House, Champions Patients*, VALDOSTATODAY.COM (Oct. 16, 2018), http://valdostatoday.com/news-2/local/2018/10/local-pharmacist-hugh-chancy-goes-to-white-house/ [hereinafter *Local Pharmacist*] ("[I]f we said anything to disparage the plan or patient [drug] pricing then we were in violation.").

The method for negotiating contracts is also suspicious and little is known the process because PBMs have the upper hand. Pharmacies, particularly independent pharmacies, generally do not have the means to compete with big business.[118] Often, a neighborhood pharmacy will be independently managed by an individual, or small group, whose responsibilities range from administering medication to reconciling budget sheets and paying to keep the lights on at the end of the month. In order to protect themselves, small pharmacies will participate in a Pharmacy Services Administration Organization ("PSAO"), which is a group of independent pharmacies that have banned together to leverage bargaining power.[119] Even so, a PBM is better situated to refuse a contract than an independent pharmacy, especially when the PBM community is so small and there is not an abundance of choice.[120] For instance, the power wielded by the Big Three is imposing—"[i]f you're outed by just one network out of these three, you could lose your entire business, and those patients lose access to a pharmacy they may have frequented for decades."[121]

In general, the contracting process with PBMs lacks transparency, which disadvantages pharmacists who do not have access to information about the party they are negotiating with or resources that would make the dealings more level.[122] One pharmacist describes the situation: "People think we [pharmacists] can negotiate the contracts," but in reality, PBMs

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[118] *See Give Independent Pharmacies Leverage Against Take-it Or-Leave-it PBM Contracts*, NCPA: NAT'L COMMUNITY PHARMACISTS ASS'N, http://www.ncpanet.org/pdf/leg/one_pager_hr_1188.pdf, (last visited Sept. 10, 2018).

[119] *Id.*

[120] A possible rebuttal to these contracts being considered adhesion contracts is the fact that pharmacists are not forced into contracting with any particular PBM if at all, and the purchasing of a plan can be likened to caveat emptor or "buyer beware." Dean Celia, *Negotiating and Contracting with Pharmacy Benefits Managers*, MANAGED HEALTH CARE CONNECT: PHARMACY NEWS 1, 1 (May 24, 2018), https://www.managedhealthcareconnect.com/article/negotiating-and-contracting-pharmacy-benefits-managers. Still, individuals "with little to no bargaining power may limit ability to negotiate away from a PBM's standard contract." *Id*. One pharmacist explains the dilemma, "I will admit, we freely sign those contracts because without it people will not come to us without having us file their insurance." Dewberry, *supra* note 116.

[121] Firozi, *supra* note 11.

[122] Celia, *supra* note 120. These contracts could be defined as adhesion contracts due to their "take-it or leave-it" nature. *See* Bryan A. Garner, *Black's Law Dictionary* (7th ed. 1999). An adhesion contract is defined as "a standard-form contract prepared by one party, to be signed by the party in a weaker position . . . who has little choice about the terms." *Id.* Moreover, the lack of available information about PBM practices restricts a pharmacist's ability to make judgments about the contract. This could potentially invoke questions about unconscionability. Paul Bennett Marrow, *Contractual Unconscionability: Identifying and Understanding Its Potential Elements*, N.Y. ST. B.J.18, 22 (2000) (describing unconscionability to include "unfair surprise," which is "when the real meaning of its terms are intentionally obscured from one of the parties, thereby precluding the complainant from making a reasoned choice.").

"give us a contract and we take it or leave it."[123] These "take-it-or-leave-it contracts" offer no opportunity to negotiate, and they employ punitive conditions, which allow PBMs to freely audit pharmacies.[124] These audits are then used to extract money based on minor technicalities, which can be crippling to a small pharmacy.[125]

PBMs are not required to share information about their contracting practices.[126] But, the issue with transparency goes beyond contracting. The overall lack of transparency implicates concerns about other business practices. For example, the lack of information leads to concerns about how rebates and discounts are structured.[127] Ultimately, the secretive nature of PBMs allows them to implement business practices that are not always in the best interest of consumers. Due to the lack of transparency, it is not always readily apparent harm has occurred.

V. THE PROHIBITION OF GAG CLAUSES AND OTHER INITIATIVES TO INCREASE TRANSPARENCY AND LOWER DRUG COSTS

Gag clause legislation has gained significant attention in the past few years and was recently a focus at both the state and federal level. States opted to take various approaches to gag clauses and have had varying success in passing such legislation.[128] The federal government similarly decided to take action and was successful in passing legislation prohibiting the use of gag clauses.[129] The motivation to pass these anti-gag clause laws derived from legislative concern that opaque cost-only practices harmed consumers without adding any public benefit.

A. *Legislation at the State Level*

Gag clause legislation at the state level has been around for many years.[130] Most of the traction regarding states opting to take action against

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123 *Local Pharmacist*, *supra* note 117.

124 Dayen, *supra* note 32.

125 *Id.*

126 *See* Michael Carrier, *A Six-Step Solution to the PBM Problem*, HEALTH AFF. (Aug. 30, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180823.383881/full/ ("PBM agreements are audited in secure rooms with few contracts reviewed, restricted notetaking, and only client-specific information . . . .").

127 *See* Jane Horvath, *New NASHP Model Legislation Helps States Bring Transparency to Pharmacy Benefits Managers*, NASHP (Aug. 28, 2018), https://nashp.org/new-nashp-model-legislation-helps-states-bring-transparency-to-pharmacy-benefit-managers/.

128 *See infra* text accompanying notes 131–144.

129 *See infra* text accompanying notes 148–163.

130 The Employer Retirement Security Act of 1974 ("ERISA") "preempts any state law that may or does 'relate to any employee benefit plan' regulated by ERISA." Albert Feuer, *When do State Laws Determine ERISA Plan Benefit Rights?*, 47 J. MARSHALL L. REV. 145, 162 (2014). Since gag clause legislation at the state level may potentially impact ERISA,

gag clauses, however, was gained around 2016 and came to a head in 2018.[131] Between 2016 and 2018, at least twenty-six states enacted laws from a grouping of roughly forty-one states, all of which considered legislation to prohibit gag clauses.[132] This was a noteworthy trend because "[s]tates are sovereign entities; they don't work in tandem."[133] Moreover, not only were the states working in parallel, but gag clause efforts were not contained to the acts of one political party and instead transcended party lines.[134] Ultimately, collective sentiment at the state level overwhelmingly pointed to banning gag clauses.

Lawmakers were clear, they disliked gag clauses because they harmed constituents. Senator Martin Looney, on the issue of gag clauses, stated, "This is information consumers should have . . . but they were denied under somewhat arbitrary and capricious contracts that pharmacists were required to abide by."[135] Accordingly, the goal for lawmakers when passing gag clause legislation was to advocate against the practice as their use was collectively viewed as unfair and deceptive.

There has not been any one specific way to address the issue. In tackling gag clauses, states have addressed the problem in a variety of different ways, whether they choose an outright ban on the practice, increased transparency, a requirement for additional documentation, or a mixture of several different aims.[136] The most basic approach is an outright ban. This is achieved by either explicitly stating gag clauses cannot be utilized in contracting or, alternatively, permitting pharmacists to inform consumers about the availability of a lower cost, regardless of whether a gag clause is contained in the contract.[137] Several states have elected to go

there is question whether ERISA's gag clause preemption clause is triggered. This Comment will not explore the impact ERISA had/has on state legislators as they drafted gag clause legislation.

131 Richard Cauchi, *Prohibiting PBM "Gag Clauses" that Restrict Pharmacists from Disclosing Price Options: Recent State Legislation 2016-2018*, NAT'L CONF. ST. LEGISLATURES (Dec. 1, 2018), http://www.ncsl.org/Portals/1/Documents/Health/Pharmacist_Gag_clauses-2018-14523.pdf.

132 *Id.*; *see also* Jay Phillips, *A 50 State Scan: States Move to Protect Healthcare Consumers by Prohibiting Gag Clauses on Pharmacists*, COUNCIL ST. GOV'TS: JAY PHILLIP'S BLOG (July 3, 2018, 9:59 AM), http://knowledgecenter.csg.org/kc/content/50-state-scan-states-move-protect-healthcare-consumers-prohibiting-gag-clauses-pharmacists.

133 Povich, *supra* note 1 (Richard Cauchi, the health program director for the National Conference of State Legislatures, on the surge of states enacting gag clause legislation as a bipartisan initiative).

134 *See, e.g.*, H.B. 1791, 2018 Leg., Reg. Sess. (N.H. 2018) (enacted) (sponsored by Representative Butler (D), Representative Rosenwald (D), Representative Williams (D), Representative Forthergill (R), Representative Knirk (D)).

135 Pear, *supra* note 14.

136 *See infra* text accompanying notes 137–144.

137 *See, e.g.*, S.B. 3104, 29th Leg., Reg. Sess. (Haw. 2018) (failed); S.B. 576, 2018 Gen.

this route, and while some have been successful, other proposals have failed.[138]

In contrast, other states have approached gag clauses by challenging the practice directly while simultaneously focusing on additional initiatives to curb gag clauses via additional PBM regulations.[139] For example, California has prohibited a formulary from containing more than four tiers.[140] The state has also made it a requirement that if there is a difference in price between a prescription's retail price and the consumer's applicable copay/coinsurance, the consumer will be charged the lesser amount.[141] Comparatively, Nevada law has prohibited PBMs from restricting a pharmacist's ability to provide information regarding payment, drug efficiency, or the availability of a cheaper alternative, and the state further restricts PBMs from penalizing pharmacists who choose to provide the information to consumers.[142] Nevada has also established transparency and recording requirements for prescription drug costs and pricing.[143]

These are only two examples out of many, but they represent different approaches available to states aiming to take on gag clauses. Ultimately, each state must choose the approach that best fits its constituency. Nevertheless, it appears that more states have had success at passing legislation when compared to those who have not.[144] At the heart of it, states are driven by a desire to protect their citizens, and gag clauses do anything but.

B. *Legislation at the Federal Level*

Like state governments, the federal government has been vocal in its opposition to gag clauses. This has been a shared objective between the executive and legislative branches. In the House, Representative Earl "Buddy" Carter introduced the Know the Cost Act on September 13,

Assemb., Reg. Sess. (Md. 2018) (enacted); H.B. 426, 2018 Leg., Reg. Sess. (Miss. 2018) (failed).

138 *See, e.g.*, S.B. 3104, 29th Leg., Reg. Sess. (Haw. 2018) (failed); S.B. 576, 2018 Gen. Assemb., Reg. Sess. (Md. 2018) (enacted); H.B. 426, 2018 Leg., Reg. Sess. (Miss. 2018) (failed).

139 *See infra* text accompanying notes 141–143.

140 S.B. 1021, 29th Leg., Reg. Sess. (Cal. 2018) (enacted).

141 Cauchi, *supra* note 131; *see also* S.B. 1021, 29th Leg., Reg. Sess. (Cal. 2018) (enacted); *Senator Weiner Introduces Dug Co-pay Bill to Permanently Protect Consumers from Price Gouging*, SCOTT WEINER REPRESENTING CAL. SENATE DISTRICT 11, (Feb. 8, 2018), https://sd11.senate.ca.gov/news/20180208-senator-wiener-introduces-drug-co-pay-bill-permanently-protect-consumers-price-gouging.

142 Cauchi, *supra* note 131; *see also* S.B. 539, 29th Gen. Assem., Reg. Sess. (Nev. 2017) (enacted).

143 *Id.*

144 *See, e.g.*, Phillips, *supra* note 132.

2018.[145] Representative Carter spoke about the impact gag clauses have had on his role as a pharmacist.[146] He shared his frustration that practices, such as gag clauses, continually harm consumers and challenged the role of PBMs indicating, "They bring no value whatsoever."[147]

The Senate introduced two bills. First, the Patient Right to Know Drug Prices Act, which Senator Collins introduced on March 14, 2018.[148] Senator Collins described the need to act stating, "Multiple reports have exposed how this egregious practice has harmed consumers, such as one customer who used his insurance to pay $129 for a drug when he could have paid $18 out of pocket."[149] The law is meant to "prohibit an insurer or pharmacy benefit manager from restricting a pharmacy's ability to provide drug price information to a plan enrollee when there is a difference between the cost of the drug under the plan and the cost of the drug when purchased without insurance."[150] This bill focuses on plans offered through exchanges and by private employers.[151]

On the same day, Senator Debbie Stanebow introduced a second bill, the Know the Lowest Price Act.[152] This bill is virtually identical to Senator Collin's bill with the exception that it refers to individuals receiving coverage under Medicare.[153] Senator Stanebow's motivation for introducing the bill was much like Senator Collin's—protecting Americans.[154] And like at the state level, both bills were a bipartisan effort

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145 Know the Lowest Cost Act, H.R. 6733, 115th Cong. (2018).

146 Firozi, *supra* note 11.

147 *Id.* President Trump acknowledged Representative Carter during the signing of the two bills regarding gag clauses that originated in the Senate. Jessie Hellman, *Trump Signs Bills Banning Drug Pricing 'Gag Clauses*,' HILL (Oct. 10, 2018, 2:47 PM), https://thehill.com/policy/healthcare/410813-trump-signs-bills-banning-drug-pricing-gag-clauses.

148 Patient Right to Know Drug Prices Act, S. 2554, 115th Cong. (2018).

149 *Senator Collins, McCaskill, Stabenow Lead Bipartisan Group of Senators in Introducing Legislation to Prohibit "Gag Clauses" That Cause Consumers to Pay Higher Prescription Drugs*, SUSAN COLLINS: U.S. SENATOR ME., (Mar. 15, 2018, 1:10 PM), https://www.collins.senate.gov/newsroom/senators-collins-mccaskill-stabenow-lead-bipartisan-group-senators-introducing-legislation (Senator Collins in a press release regarding gag clause legislation).

150 *Id.*

151 *Id.*

152 Know the Lowest Price Act of 2018, Pub. L. No. 115-262, § 2553, 132 Stat. 3670 (2018).

153 *Id.*

154 *See* Mary Caffrey & Allison Inserro, *Senate Votes 98-2 to Ban Pharmacist Gag Clauses*, AJMC (Sept. 18, 2018), https://www.ajmc.com/newsroom/senate-votes-982-to-ban-pharmacist-gag-clauses ("Patients should have the right to know if they can save money by paying cash out-of-pocket rather than using their insurance and their pharmacists should have the right to tell them.").

and garnered widespread support in Congress.[155]

Not only have legislators voiced their dislike for gag clauses, so has the President. President Trump, and by extension, the Trump Administration, have been vocal about the issue. On May 11, 2018, the Administration released "*American Patients First: The Trump Administration Blueprint to Lower Prices and Reduce Out-of-Pocket Costs*" ("*American Patients First*"), which enumerated the prohibition of gag clauses as a priority.[156] The President further voiced his support through Twitter: "Americans deserve to know the lowest drug price at their pharmacy, but 'gag clauses' prevent your pharmacist from telling you! I support legislation that will remove gag clauses and urge the Senate to act. #AmericanPatientsFirst."[157] Similarly, the President's Secretary of Health and Human Services, Alex Azar, has also expressed a personal commitment to outlawing gag clauses.[158] He praised Senator Collins in her efforts to eliminate gag clauses and indicated he was committed to working with her in further achieving her objective.[159]

On October 10, 2018, President Trump signed the two Senate bills, the Patient Right to Know Act and the Know the Lowest Price Act, into law.[160] During the signing, the President indicated, "It's way out of whack

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[155] *See id*. (describing how the Senate passed the Patient Right to Know Act 98-2 after the Know the Lowest Price Act had been passed the week prior); *A Six-Step Solution to the PBM Problem*, HEALTH AFF.: HEALTH AFF. BLOG (Aug. 30, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180823.383881/full/ (indicating that one bill was introduced by a Republican while the other was introduced by a Democrat).

[156] *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* 1, 25 (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf [*hereinafter American Patients First*] ("Prohibit Part D plan contracts from preventing pharmacists from telling patients when they could pay less out-of-pocket by not using their insurance—also known as pharmacy gag clauses."); *President Donald J. Trump's Blueprint to Lower Drug Prices*, (May 11, 2018) https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/ ("Prohibit Part D contracts that include 'gag rules' that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance.").

[157] Donald J. Trump (@realDonaldTrump), TWITTER (Sept. 17, 2018, 2:10 PM), https://twitter.com/realdonaldtrump/status/1041751173034848260?lang=en.

[158] Alex M. Azar, *Remarks on Value-Based Transformation to the Federation of American Hospitals*, U.S. DEP'T HEALTH & HUM. SERV. (March 5, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-value-based-transformation-to-the-federation-of-american-hospitals.html (sharing how he had personally been affected by the lack of transparency in healthcare pricing during an address to the American Federation of Hospitals).

[159] *Secretary Azar Pledges to Work With Senator Collins on Legislation to Prohibit Gag Clauses That Cause Consumers to Overpay Medications*, SUSAN COLLINS: U.S. SENATOR ME. (June 16, 2018) https://www.collins.senate.gov/newsroom/secretary-azar-pledges-work-senator-collins-legislation-prohibit-gag-clauses-cause.

[160] Clark & Breslauer, *supra* note 18.

[drug pricing]. It's way too high."[161] He then continued, "It's a big win for patients . . . . It's a big win for patients in terms of allowing pharmacists to openly discuss medication prices to save patients money and health care costs."[162] Secretary Azar further indicated there is "more to come" in reference to fixing transparency in pricing and high costs and that the Administration was ready to take on "anybody that [it] need[s] to take on."[163] Nonetheless, while gag clause legislation was a crucial first step, many of the issues revealed by gag clauses are still prevalent. Thus, there is still much more that needs to be done to offer better protection to consumers.

VI. LIFTING THE GAG—NOW WHAT?

While there are many reasons why gag clause legislation came to fruition, the ultimate goal was to protect consumers better. The legislation achieves this objective to a certain extent, but many problems still remain. The gag clause story reveals deeply rooted issues within the PBM system regarding fiduciary duties, conflicts of interest, and transparency—all of which steadfastly remain post-gag clause legislation. With gag clauses a thing of the past, the discussion now turns on the future. According to President Trump, "We're very much eliminating the middlemen. The middlemen became very, very rich, right? Whoever those middlemen were—and a lot of people never even figured it out—they're rich. They won't be so rich anymore."[164] The middlemen are PBMs. It is unclear whether President Trump has true intentions of eliminating PBMs, and it is unlikely this would ever occur.[165] Regardless, the focus should not solely be that PBMs have money but rather why and what it means for consumers.

The existence of gag clauses arguably had, and would continue to have, no bearing on the high cost of drugs.[166] Pricing is based on numerous factors such as the list price and the outcome of negotiations between

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161 *Id.*

162 *Id.*

163 Brittany Shoot, *Trump Signs 2 Drug Pricing Bills, HHS Secretary Promises 'More to Come*,' FORTUNE (Oct. 11, 2018), http://fortune.com/2018/10/11/trump-administration-gag-clause-compare-prescription-prices/.

164 Nathaniel Weixel, *Defending the 'Middlemen' in the Battle on Drug Prices*, HILL (May 15, 2018, 6:00 AM), http://thehill.com/business-a-lobbying/lobbyist-profiles/387669-defending-the-middlemen.

165 Interestingly, there is discussion regarding whether there could be a system without PBMs. *See* Sally Welborn & Pramod John, *Imagine There Are No PBMs. It's Easy if You Try*, STAT (Aug. 23, 2018), https://www.statnews.com/2018/08/23/pbms-rebates-drug-purchasing/.

166 Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform*, 316 JAMA 858, 860 (2016) ("[T]he US health care system allows manufacturers to set their own price for a given product.").

manufacturers and a wholesaler or PBM.[167] With or without a gag clause, prices are "set extraordinarily high."[168] Ultimately, the root issue is not addressed since the "price" otherwise remains the same regardless of the savings realized—not only does consumer cost need to be lowered, so do drug prices.[169] Namely, a $100 prescription remains $100 regardless of how much the consumer pays out-of-pocket (gag clause or otherwise). Likewise, the gag generally did not hinder the sharing of information, it just barred a pharmacist from initiating a conversation about price—a consumer was always free to ask if there were ways to save. Therefore, the issue of cost runs much deeper than just the gag clause itself. Rather, the PBM system has made it possible for situations like gag clauses to occur.

While it is possible the elimination of gag clauses may have significant effects on individuals depending on their specific situation, it is unlikely the legislation will affect a large portion of the population in a meaningful way or protect against other predatory practices. Banning gag clauses without doing more is like putting a bandage on a wound that requires stitches. The effort to curb high drug costs and better protect consumers requires a much larger and longer conversation from the industry and lawmakers. First, lawmakers should look to see how gag clause legislation could be fortified. Second, lawmakers should look beyond gag clauses, consider how else consumers are harmed by PBMs, and seek to reform the structure that allowed gag clauses to be such a commonplace practice. Lawmakers have the ability to amend the PBM system and ultimately protect consumers, but they need to take the initiative.[170]

A. *Strengthening Gag Clause Legislation*

Gag clause legislation is integral to ensuring the practice ceases to exist, although further inspection shows there is room for legislators to take a stronger stance when it comes to protecting consumers. The federal

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[167] Wapner, *supra* note 62.

[168] *Id.*

[169] *See* Robert King, *House Panel Advances Bill to Counter 'Gag Clauses' that Lead to Higher Drug Prices*, WASH. EXAMINER (Sept. 7, 2018, 10:31 AM), https://www.washingtonexaminer.com/policy/healthcare/house-panel-advances-bill-to-counter-gag-clauses-that-lead-to-higher-drug-prices.

[170] The subsequent discussion largely reflects how states could directly legislate to counteract problematic PBM practices. More specifically, however, have been approaches by certain states to regulate PBMs through the state's insurance department. *See, e.g.*, S.B. 1504, 129th Leg., 1 Reg. Sess. (Me. 2019); Sarah Lanford, Montana Explores a New Approach to Regulating Pharmacy Benefit Managers, NASHP (Feb. 26, 2019), https://nashp.org/montana-explores-a-new-approach-to-regulating-pharmacy-benefit-managers/. The use of a state's insurance department's regulatory authority is outside the scope of this Comment.

legislation only prohibits the use of gag clauses and offers no further protection.[171] Just because a consumer is able to immediately save some money at the pharmacy counter by paying out-of-pocket with the elimination of gag clauses, does not mean the consumer will actually save money in the long run; the consumer still needs to be aware of how his or her insurance plan is structured due to other factors that affect out-of-pocket costs.[172]

A pharmacist no longer bound by a gag clause may opt to tell a consumer he or she may save by paying out-of-pocket and forgoing insurance. To most, this sounds like an obvious choice—save the money and pay the cheaper price—however, there is more to consider. For instance, some individuals need to pay a pharmacy deductible before the insurer begins to pay.[173] The more often an individual chooses to pay out-of-pocket, the less likely he or she will pay off the deductible since insurers have no obligation to count these payments towards the deductible.[174] In other words, the deductible may take longer to pay off, and this means more dollars spent before insurance will apply. Unless an individual is diligently tracking his or her savings every time the decision is made not to pay through the insurer, the individual may not actually be saving money. Put differently, saving a few dollars today does not necessarily translate to saving money in the future. The gag clause legislation does not require out-of-pocket costs to be counted towards deductibles, which could result in today's savings being tomorrow's burden. Consumer protections would be much stronger if the law required that lower costs be counted towards deductibles. California's gag clause legislation, for example, contains this

171 *See* Know the Lowest Price Act of 2018, Pub. L. No. 115-262, § 2553, 132 Stat. 3670 (2018); Patient Right to Know Drug Prices Act, Pub. L. No. 115-263, § 2554, 132 Stat. 3672 (2018).

172 *See supra* text accompanying notes 173–174.

173 Amadeo, *supra* note 59 ("The deductible. That's what you pay before the insurance company contributes a dime."). Pharmacy deductibles function the same way as a standard deductible and have grown in popularity amongst insurers. *See generally Emergence and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans*, IQVIA: IMS INST. HEALTHCARE INFORMATICS (Sept. 2015), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/emergence-and-impact-of-pharmacy-deductibles.pdf?la=en&hash=1D397351342823EDEFDECFC4F119CCBFD56E904F (discussing the emergence of pharmacy deductibles).

174 Dickson & Chester, *supra* note 89 ("[M]onies paid outside an insurance plan may not count toward the patient's deductible or out-of-pocket spending limit."); *see also* Elizabeth Davis, *What Counts Toward Your Health Insurance Deductible?*, VERYWELL HEALTH (Jan. 5, 2020), https://www.verywellhealth.com/what-counts-toward-your-health-insurance-deductible-1738559 ("Money you pay out-of-pocket for health care services that aren't a covered benefit of your health insurance won't be credited toward your health insurance deductible.").

requirement.[175]

In addition, the gag clause legislation does not require pharmacists to initiate a conversation regarding lower drug prices.[176] Instead, it is left to each pharmacist's personal discretion whether he or she would like to say something.[177] Since there are no protections to ensure consumers are actually told the lowest price, they may be left in the same situation as they were prior to the legislation being passed, i.e. still having to ask whether there is a lower priced alternative. Moreover, the issue that many consumers are unlikely to think of medication as having a negotiable price still stands, which means they will not prompt the cost conversation themselves because "the act of asking the question ['what is the cash price?'] requires a level of health care literacy which many patients do not possess."[178] Federal or uniform state legislation would be more effective if it required pharmacists to make disclosures about the price to consumers.[179] In California, "pharmacists are not just *allowed* to tell patients when lower prices are available, but are *required* to tell them about those cost savings."[180] As of now, California is an outlier, but if federal and/or state lawmakers were to adopt the California approach, consumers would be better protected.

Even further, the law could prohibit a consumer from paying more than the cash price, if the cash price is the lowest price available. This would ensure the consumer is paying the lowest possible price every single time he or she goes into the pharmacy. No longer would the consumer or pharmacist have to initiate conversation; instead, the savings would be compulsory. Once again, California put a safeguard like this in place to ensure its citizens are able to realize savings whenever possible.[181] This sort of law, however, would be most effective when coupled with a law that

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175 Lisa L. Gill, *Trump Signs Bills Banning 'Gag Clauses,' Helping Consumers Save on Drugs*, CONSUMER REP. (Oct. 10, 2018), https://www.consumerreports.org/drug-prices/trump-signs-bill-banning-gag-clauses-helping-consumers-save-on-drugs/.

176 *See* Know the Lowest Prices Act of 2018 § 2553; Patient Right to Know Drug Prices Act § 2554.

177 *See* Know the Lowest Prices Act of 2018 § 2553; Patient Right to Know Drug Prices Act § 2554.

178 Hayward K. Zwerling, *Drug Costs at Pharmacies Lack Transparency*, COMMONWEALTH (Oct. 19, 2018), https://commonwealthmagazine.org/opinion/drug-costs-at-pharmacies-lack-transparency/.

179 Regulation of a profession in this manner would usually be a matter of state law. *See* U.S. Const. amend. X; *see also* Ronald L. Scott, *Cybermedicine and Virtual Pharmacies*, 103 W. VA. L. REV. 407, 476 (2001) ("[P]harmacists are licensed by the states for the practice of pharmacy within a state's boarders, federal law also regulates aspects of the practice of pharmacy."). As such, regulation such as the one proposed would most likely come from the states rather than the federal government.

180 Gill, *supra* note 175.

181 Cauchi, *supra* note 131.

requires out-of-pocket payments be counted for insurance purposes. Otherwise, such a law could have a negative impact and achieve the exact opposite of what is intended.[182]

B. *The Future of "Those Middlemen": Other Legislative Considerations*

Gag clauses can be viewed as a small-scale representation of much larger issues. Even though gag clauses are gone, many of the problems that legislators and challengers highlighted still remain relevant. Issues regarding fiduciary duties, conflicts of interest, and transparency are as prevalent as ever and continue to be problematic aspects of PBMs. If legislators want to protect consumers, they must move beyond gag clauses and take stronger positions against questionable PBM practices, the very practices that allowed gag clauses to flourish.

In May 2018, the Trump Administration issued *American Patients First*, a blueprint for lowering drug prices and reducing out-of-pocket costs.[183] As part of the initiative to lower out-of-pocket costs, President Trump cited the elimination of gag clauses.[184] The President's plan then went on to list additional opportunities to make improvements regarding transparency and easier access to pricing although he failed to offer a comprehensive plan.[185] In response, the minority staff of the U.S. Senate Committee on Finance issued the report, "*A Tangled Web: An Examination of the Drug Supply and Payment Chain*" ("*A Tangled Web*").[186] The report challenged *American Patients First* indicating the ideas it proposed were "simply not sufficient to reduce costs significantly for Americans[,]" and further, a "majority of the President's plan posed questions rather than solutions."[187] The report is framed as a call to action, describing how complex and broken the system is; yet it does not extend solutions itself.[188] Moving forward, legislators on both sides should consider the following if they intend to better protect consumers.

1. Fiduciary Duties

A recurring issue with PBM transactions is that it is unclear who owes whom what duties or, alternatively, if there are even duties owed to begin with. As it currently stands, PBMs do not owe fiduciary duties to plan

182 *See supra* text accompanying notes 173–175.
183 *American Patients First*, *supra* note 156.
184 *Id.* at 37.
185 *Id.* at 11.
186 *A Tangled Web*, *supra* note 49, at ii.
187 *A Tangled Web*, *supra* note 49, at x.
188 *A Tangled Web*, *supra* note 49, at 45.

participants.[189] While PBMs are tasked with negotiating benefits, they have no duty to ensure those benefits are actually beneficial. *American Patients First* discusses the lack of fiduciary duties.[190] The blueprint appears to contemplate the possibility of PBMs as fiduciaries by briefly mentioning "fiduciary dut[ies] for pharmacy benefit managers," but it does not explain what this would entail.[191] Presumably, the idea is that the PBM would have a fiduciary obligation to the plan, which would mean the PBM has a fiduciary obligation to the consumer.[192] A PBM with a fiduciary obligation to the consumer would have to act in the consumer's best interest. This means the consumer's interests would actually be represented by the PBM and be reflected in the PBM's business practices. In the situation of gag clauses, PBMs had no obligation to act in the interest of plan participants. As such, gag clauses were perfectly permissible.

The solution to this issue does not have to be complex—legislators can impose fiduciary responsibilities on PBMs. Essentially, PBMs would have an obligation to look out for the well-being of plan participants. Such a law would prevent another gag clause situation from occurring because the PBM would have to act with the best interest of the consumer in mind. The PBM, at all times, would be required to meaningfully consider the impact of its actions on the consumer, whether it be during the negotiation of discount, while crafting the formulary, etc. In 2003, Maine first addressed PBMs and fiduciary duties.[193] The state passed the Unfair Prescription Drug Practices Act, which imposed fiduciary duties upon PBMs.[194] The law stated, a PBM "owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law."[195] It continued, "A pharmacy benefits manager shall perform its duties with care, skill, prudence and diligence and in accordance with

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189 Generally, PBMs are not regarded to as fiduciaries. There are also examples of courts finding that PBMs are not fiduciaries. *See, e.g.*, *In re* Express Scripts/Anthem ERISA Litig., 285 F. Supp. 3d 655, 680 (S.D.N.Y. 2018) (holding a PBM was not a fiduciary); *In re* Express Scripts, Inc., No. 1672, 2006 U.S. Dist. LEXIS 65168, at *18 (E.D. Mo. Sep. 13, 2006) (holding a PBM was not a fiduciary under ERISA).

190 *American Patients First*, *supra* note 156, at 33.

191 *Id.*

192 David Balto, *Reigning in the Opaque Practices of PBMs and Payers is Long Overdue*, HILL (July 16, 2018, 7:00 PM), https://thehill.com/opinion/healthcare/397320-reigning-in-the-opaque-practices-of-pbms-and-payers-is-long-overdue.

193 Thomas Sullivan, *Maine Set to Repeal Unfair Prescription Drug Prices Act and End PBM Discrimination*, POL'Y & MED. (May 5, 2018), https://www.policymed.com/2011/06/maine-set-to-repeal-unfair-prescription-drug-prices-act-and-end-pbm-discrimination.html.

194 22 M.R.S. § 2699 (repealed 2011). The National Academy for State and Health Policy ("NASHP") drafted a model act for PBMs. A MODEL ACT RELATING TO PHARMACY BENEFIT MANAGERS (NASHP 2018).

195 22 M.R.S. § 2699(2) (repealed 2011).

the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims."[196]

The Maine law has since been repealed, and those in favor of repeal argued the law "discouraged PBMs from doing business in the state, which was resulting in less competition and higher drug prices."[197] Part of what was notable about the gag clause movement was the overwhelming consensus across state lines that action needed to be taken. The same cannot be said for laws regarding fiduciary duties. If legislation were to be passed at the federal level, situations like Maine's would not occur—if PBMs owe fiduciary duties in every state, no one state would be seen as less desirable.[198]

The Trump Administration has thought about implementing fiduciary obligations, yet it remains silent about where it currently stands.[199] Not only would codifying fiduciary duties deter PBMs from partaking in practices that are harmful to consumers, it would also establish a mechanism to hold PBMs accountable when they fail to put American patients first. Moreover, it would add clarity to the system. One of the system's problematic features is that it is not always clear who is serving whom, whose interests are the priority, and at what cost. Legislation imposing fiduciary duties would help solve these uncertainties and better protect consumers.

2. Conflicts of Interest

Not once does the word "conflict" appear in *American Patients First*, yet the PBM system is inundated with conflicts of interest.[200] One particular source of concern is the rebate and discount system. A rebate is a percentage of the price a PBM receives after a drug is dispensed and the pharmacy is reimbursed.[201] "[T]he typical PBM business model appears to have a very basic conflict of interest" because "the higher the price, the

196 *Id.* § 2699(2)(A).

197 Sullivan, *supra* note 193. DC also attempted to pass a law to hold PBMs as fiduciaries; however, a DC Appeals Court found that Title II of the Act, which contained the language regarding fiduciary duties, was preempted by ERISA. Pharm. Care Mgmt. Ass'n v. D.C., 613 F.3d 179, 190 (D.C. Cir. 2010); AccessRx Act of 2004, 2003 Bill Text DC B. 569. Interestingly, the First Circuit Court of Appeals previously held Maine's PBM law was not preempted by ERISA. Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 301 (1st Cir. 2005). Thus, there is a circuit split regarding whether state law imposing fiduciary duties on PBMs conflicts with ERISA. The Supreme Court declined to review *Rowe*. *Supreme Court Lets Stand Maine Law Regulating Pharmacy Benefit Managers*, INS. J. (June 7, 2008), https://www.insurancejournal.com/news/east/2006/06/07/69265.htm.

198 This would also circumvent ERISA issues.

199 *See American Patients First*, *supra* note 156, at 33.

200 *Id.* Although it is somewhat alluded to in the section discussing fiduciary duties. *Id.*

201 Horvath, *supra* note 38.

higher the rebate."[202] As such, the PBM has an incentive to drive up prices, which directly conflicts with the PBM's function of lowering costs for consumers. Similarly, "the more units dispensed, the more revenue a PBM gains."[203] This further adds to a PBM's profit driven mentality, which ultimately harms consumers because they are the ones that pay. Higher revenue for a PBM correlates to higher drug prices, which is directly proportional to higher prices for consumers.[204]

Conflicts of interest also arise when a PBM owns its own pharmacy operation or, vice versa, when a pharmacy owns its own PBM.[205] This is often the result of vertical integration, which occurs when two different levels of the supply chain consolidate and offer complementary products.[206] In this situation, the PBM directs all of its business to its pharmacy operation instead of exploring whether there is a more cost-efficient option for its plan participants elsewhere.[207] Once again, the PBM and the consumer have misaligned priorities. Consumers want the lowest price, but the PBM has no incentive to negotiate and instead forces the consumer to use the PBM's pharmacy.[208] Consequently, consumers face further harm because these partnerships may restrict their access to certain drugs or hinder access to non-affiliate pharmacies.[209] An example of this would be if Caremark gave preference to CVS and its products instead of aggressively negotiating with other pharmacies in order to secure better deals for consumers.[210]

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202 *Id.*

203 *Id.*

204 *Id.* ("While higher drug prices generate more net revenue for the PBM . . . consumers end up paying more in higher prices.").

205 *Id.*

206 Lisl J. Dunlop & Shoshana S. Speiser, *Vertical Mergers: A Road Map for Success in Healthcare Consolidation*, MANATT (Oct. 23, 2018), https://www.manatt.com/Insights/Newsletters/Health-Update/Vertical-Mergers-A-Road-Map-for-Success-in-Health?utm_campaign=Health%20Update%2010.23.18&utm_medium=email&utm_source=Eloqua.

207 Horvath, *supra* note 38.

208 Vertical integration is controversial. The American Medical Association ("AMA") recently opposed the merger of CVS Health and Aetna. Jennifer Bresnick, *AMA: CVS-Aetna Merger Would Reduce PBM Competition, Raise Prices*, HEALTHPAYER INTELLIGENCE (Aug. 8, 2018), https://healthpayerintelligence.com/news/ama-cvs-aetna-merger-would-reduce-pbm-competition-raise-prices. The AMA argued the merger would result in anticompetitive practices and increased prices. *Id.*

209 Brian S. Feldman, *Big Pharmacies are Dismantling the Industry that Keeps US Drug Costs Even Sort-of Under Control*, QUARTZ (Mar. 17, 2016), https://qz.com/636823/big-pharmacies-are-dismantling-the-industry-that-keeps-us-drug-costs-even-sort-of-under-control/.

210 This example is not to say this is or is not occurring between Caremark and CVS. In fact, a spokesperson for CVS made the statement, "At our PBM, CVS/Caremark, we welcome competition; indeed, our success is predicated on thriving competition in the health care marketplace." *Id.*

It is unlikely lawmakers will be able to eradicate conflicts of interest completely; however, the law could require PBMs to disclose conflicts. Maine's now defunct law that sought to impose fiduciary duties also included a provision for disclosing conflicts of interest.[211] The law stipulated that a PBM "shall notify [a health carrier client] in writing of any activity, policy, or practice of the [PBM] that directly or indirectly presents any conflict of interest . . ."[212] A law like this at the federal level would afford more protection to consumers because a conflict of interest that is fully disclosed is no longer an issue. Disclosure would mean consumers are aware of factors that may be influencing their plan and would subsequently be empowered to "consent" to the conflict or seek an alternative provider who better suits their needs. Gag clauses were problematic because they resulted in consumers paying higher out-of-pocket costs, and arguably more concerning, they were a secret. It is important legislators address the secretive nature of PBMs that give rise to conflicts of interest. Otherwise, consumers will suffer.

3. Transparency

PBMs are mysterious, elusive entities and part of what makes that possible is the lack of transparency laws. In 2017, it was reported, "PBMs [do not] reveal the prices they negotiate with their drug manufacturers even to their insurance company partners," which exemplifies the opacity of practices.[213] Furthermore, there are not many in a position of power to challenge PBMs due to the complexity and lack of transparency. [214] When it comes to consumers, "[f]ew can even understand how the system works—only that [they are] paying through the nose—and those who do [cannot] do anything about it."[215] It is this lack of transparency that "enables PBMs to enjoy multiple hidden revenue streams" and avoid accountability.[216]

The lack of information makes it impossible to decipher what a drug actually costs versus what the PBM has decided it costs.[217] One PBM

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211 22 M.R.S. §2699 (repealed 2011).

212 *Id.* This is also the language that NASHP recommends for future legislation in its sample act. NASHP, *supra* note 194.

213 William McConnell, *Behind the War Between Health Insurers and Pharmacy Benefit Managers*, STREET (May 30, 2017, 7:45 AM), https://www.thestreet.com/story/14152766/1/behind-the-war-between-health-insurers-and-pharmacy-benefit-managers.html.

214 *See* Ryan Cooper, *The Secret Monopoly Behind America's Outrageous Drug Prices*, WEEK (Mar. 29, 2017), https://theweek.com/articles/688826/secret-monopoly-behind-americas-outrageous-drug-prices.

215 *Id.*

216 Dayen, *supra* note 32.

217 *See id.*

contract reserved "full authority to determine whether a drug is brand or generic without being transparent" and stipulated the PBM could "pocket the difference between a brand-drug discount and a generic-drug discount."[218] If pricing information were readily available, it could potentially deter PBMs from setting prices that are not within a reasonable range. Even if a PBM did not change its practices, at the very least, everyone would be able to see what the pricing actually looks like.

Gag clause legislation does nothing to increase accountability or transparency—it only addresses one very specific problem. Separately, various states have passed transparency laws to address this void and better protect consumers. Some states have opted for license and registration requirements while others have gone the route of disclosure requirements. Arkansas took the former approach and signed a bill into law that requires PBMs to be licensed in the state.[219] Alternatively, Louisiana took the latter approach.[220] In Louisiana, PBMs are required to issue "an annual transparency report that discloses aggregate data on rebates received from drug manufacturers and administrative fees obtained from pharmacists."[221] Laws like these allow the government to more meaningfully regulate PBMs and provide savvy consumers with an opportunity to make informed decisions about their pharmacy coverage.

Despite growing concerns that PBMs add no value to the health care system and may be the cause for rising prescription drug costs, it is impossible to gauge whether this is true because of non-transparency.[222] The Office of the Inspector General at Health and Human Services shared this sentiment indicating, "The lack of transparency raises concerns that

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[218] Arielle Kane, *The Problem with PBMs*, PROGRESSIVE POL'Y INST. (Oct. 3, 2018), https://www.progressivepolicy.org/publications/the-problem-with-pbms/ (quoting Bob Herman, *Inside a Drug Pricing Contract*, AXIOS (Mar. 15, 2018), https://www.axios.com/inside-express-scripts-pbm-contract-8be2f09d-cbfa-4275-9855-7bc9c4fcc1a7.html).

[219] S.B. 2, 91st Gen. Assemb., 2d Extraordinary Sess. (Ark. 2018); H.B. 1010, 91st Gen. Assemb., 2d Extraordinary Sess. (Ark. 2018); Joshua Cohen, *Improving Drug Price Transparency: From Removing Pharmacy Gag Clauses to Reforming the Rebate System*, FORBES (Oct. 17, 2018, 7:27 AM), https://www.forbes.com/sites/joshuacohen/2018/10/17/improving-drug-price-transparency-from-removing-pharmacy-gag-clauses-to-reforming-the-rebate-system/#47aec202303b. Other states have similarly adopted licensing and registration requirements. *See, e.g.*, S.B. 117, Gen. Assemb., 16 Reg. Sess. (Ky. 2016); S.B. 1852, Gen. Assemb., Reg. Sess. (Tenn. 2018).

[220] S. 282, Gen. Assemb., 2018 Reg. Sess. (La. 2018). Louisiana also has licensing requirements. S. 283, Gen. Assemb., 2018 Reg. Sess. (La. 2018).

[221] Cohen *supra* note 219; S. 283, Gen. Assemb., 2018 Reg. Sess. (La. 2018); *see also* S. 282, Gen. Assemb., 2018 Reg. Sess. (La. 2018). Another example of a transparency report can be found in Washington legislation. S.B. 5422, 66th Leg., 2019 Reg. Sess. (Wash. 2019).

[222] Horvath, *supra* note 38.

sponsors may not always have enough information to oversee the services and information provided by PBMs."[223] To address this concern, the federal government could adopt legislation that mirrors what the states have done. Other suggestions include fixing drug prices over a contract term, or even more radically, creating a national formulary that focuses on price and transparency.[224] A transparent PBM is not focused on rebates and maximizing profit and is instead accountable to plan participants. Unquestionably, the system needs to change in order to better serve consumers, but proper amendments are impossible unless the system is fully understood.[225] Transparency laws are a necessary step to ensuring American patients are actually put first.

VII. CONCLUSION

The discussion that has emerged regarding gag clauses is an important one. Gag clause legislation is a crucial first step towards addressing problems associated with rising health costs and PBMs, and it is a welcome change to see political parties coming together to advance initiatives at both the state and federal level. Nonetheless, banning gag clauses is not a real solution for the issue is much larger. While efforts to block the practice of gag clauses are commendable and fully appropriate considering the ethical and public policy implications, it is unlikely their removal will make much of a difference for Americans in the long run.[226]

With or without gag clauses, PBMs will continue to retain immense power in the pharmaceutical industry. While the prohibition of gag clauses could potentially save money in the short-term, there is no guarantee those savings will carry into the long-term. With the advent of the pharmacy deductible and other tactics in which PBMs can control an individual's out-of-pocket expenses over an extended period of time, this may be an instance of immediate gratification overshadowing long-term injuries. While the banning of gag clauses is an important first step, there is much more that needs to be done to achieve the ultimate goal of lowering

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[223] Daniel R. Levinson, *Concerns With Rebates in the Medicare Part D Program* ii, DEP'T HEALTH & HUM. SERV. OFF. INSPECTOR GEN. (Mar. 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

[224] Cohen, *supra* note 219; David Dayen, *Want to Bring Down Drug Prices? Go After the Middleman*, AM. PROSPECT (Aug. 11, 2017), http://prospect.org/article/want-bring-down-drug-prices-go-after-middleman.

[225] *A Tangled Web*, *supra* note 49, at 27 ("Without this information [about PBM practices], identifying opportunities to balance the benefits PBMs offer with their potential to drive up drug prices may be impossible.").

[226] In a poll conducted by Politico-Harvard, "81 percent [of Americans] favored eliminating the gag clauses, but only 42 percent believed it would result in lower drug prices." Firozi, *supra* note 11.

healthcare costs and better protecting Americans. Whether it is an expansion of gag clause legislation to fortify its protections or subsequent actions to counter other problematic practices and features of PBMs, more must be done. Thus, the question "how much will it cost?" is still as relevant as ever.