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Specialty Drugs and the Health Care Cost Crisis

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Specialty drugs, often dispensed by specialty pharmacies, are among the most expensive drugs on the market. They are significant contributors to the American health care cost problem, but in many ways they escape public and regulatory scrutiny. Surprisingly, medications are designated as specialty drugs by pharmacy benefit managers (PBMs), entities that are part of the insurance industry, rather than by the Food and Drug Administration or medical authorities.

Specialty drugs have thus far received little attention in the legal literature. Yet, they raise important legal and regulatory questions. For example, there are no federal government rules (and only a handful of state laws) concerning what "specialty drug" means. As a result, PBMs could be motivated to designate drugs as specialty medications because they own many of the large specialty pharmacies and stand to profit by directing consumers to them. PBMs' ownership of specialty pharmacies raises troubling questions about conflicts of interest and patient choice. In addition, the lack of regulatory pricing constraints in the United States disproportionately affects specialty drug consumers because of these items' very high prices. The activites of specialty drug manufacturers, PBMs, and pharmacies raise antitrust concerns as well. This Article is the first to analyze specialty drugs from a legal and policy perspective and to formulate recommendations for regulatory interventions that are necessary to safeguard the welfare of specialty drug consumers.

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INTRODUCTION

Andy is a Parkinson's disease patient who visits his neurologist every few months. During one such visit, the neurologist recommended that Andy try a new drug, Gocovri.[1] The drug is a pill to be taken once a day at bedtime.[2] Gocovri could not be purchased at a regular pharmacy. Rather, it could be obtained only through a specialty pharmacy. Moreover, Andy had no choice of retailers. He had to use a particular specialty pharmacy that supplied the drug only through mail order. After a cumbersome registration process that included multiple phone calls, he paid $1300 for the initial prescription of thirty pills despite having good insurance coverage.[3] Andy is the husband if this Article's first author.

Andy had been introduced to specialty drugs and specialty pharmacies. They are growing forces in American health care, and yet they receive little attention in the legal literature. This Article aims to begin filling this gap and shines a spotlight on the specialty drug phenomenon.

Surprisingly, there are no government rules or regulations concerning how medications receive the designation of "specialty drug." The term is generally understood to refer to high-cost drugs that require special handling or administration.[4] However, it is entirely up to pharmacy benefits managers (PBMs) to determine which drugs they will classify as specialty drugs.[5] PBMs administer health plans' drug benefit programs.[6] Traditionally, they serve as intermediaries that process and pay prescription drug claims and negotiate with manufacturers for lower drug prices.[7] Contemporary PBMs, however, are much more powerful than that. They also conduct drug utilization reviews, develop drug plan formularies, set patient cost-sharing amounts, establish clinical policies such as preauthorization requirements, determine which pharmacies are members of the insurer's network, decide reimbursement amounts for network

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[1] Gocovri, https://www.gocovri.com/ (last visited Apr. 23, 2019).

[2] Gocovri, https://www.gocovri.com/dosing#taking-gocovri (last visited Apr. 23, 2019).

[3] The drug was prescribed early in the year, so he had not yet met his deductible.

[4] *See supra* Part I.A.

[5] *See infra* note 80 and accompanying text.

[6] *See* Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 NORTHWESTERN J. L & SOC. POL'Y, 1, 7-9 (2013); Jessica Wapner, *Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers*, NEWSWEEK, March 17, 2017, http://www.newsweek.com/big-pharma-villain-pbm-569980.

[7] *See supra* note 6.

pharmacies and operate mail order and specialty pharmacies of their own.[8] In some cases, there appears to be no rhyme or reason to specialty drug classifications. Drugs that are classified as specialty medications by one PBM may not be designated specialty drugs by other PBMs.[9]

In addition, specialty drugs are generally the most expensive drugs on the market.[10] Thus, they are significant contributors to the American health care costs problem. American drug pricing suffers from an extreme lack of transparency. No federal laws or regulations constrain manufacturers' pricing decisions, and manufacturers are not obligated to provide any justification for their prices.[11] It is difficult to determine why certain specialty drugs cost as much as they do and whether anything can be done to control their prices.

PBMs often require patients to fill their specialty drug prescriptions through their own specialty pharmacies and further limit participants to delivery by mail-order.[12] These constraints deprive consumers of the ability to choose how they will obtain products that are critical to their well-being. They also engender troubling conflicts of interest.[13] PBMs, which are meant to serve the interests of health plans and patients,[14] instead might be motivated by prospects of profiting themselves by directing business to their pharmacies and may in fact designate drugs as specialty medications in order to augment their revenues.[15]

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[8] 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; Applied Policy, *Concerns Regarding the Pharmacy Benefit Management Industry*, Nov. 2015, p. 3, http://www.ncpa.co/pdf/advocacy/concerns-pbm-issue-brief.pdf. PBMs earn revenues in part through rebates. Rebates are discounts that manufacturers provide to PBMs in return for agreeing to cover a drug product within the health plan or for placing a drug in a preferred tier (such as preferred brand tier with low patient copays). PBMs pocket a portion of the rebates rather than fully passing them on to consumers. In addition, PBMs often charge health plan sponsors and manufacturers administrative fees. A third source of revenue may be "pharmacy spread" whereby PBMs reimburse a pharmacy a particular dollar amount for a filled prescription but charge the plan sponsor a higher price for the drug and then keep the difference. *See* Elizabeth Seeley & Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, THE COMMONWEALTH FUND, March 26, 2019, at 3-5. https://www.commonwealthfund.org/sites/default/files/2019-03/Seeley_pharmacy_benefit_managers_ib_v2.pdf. *See also*, Applied Policy, at 2 and Hoffman-Eubanks, both cited above.

[9] *See infra* note 82-83 and accompanying text.

[10] *See infra* Part I.C.

[11] *See infra* Part II.B.

[12] *See infra* Part II.C.

[13] *Id.*

[14] *See supra* notes 6-8 and accompanying text.

[15] *See infra* Part II.C.

These constraints may also implicate the antitrust laws. If PBMs force consumers to use their own affiliated or wholly-owned specialty pharmacies when this arrangement was not agreed to contractually, their conduct could run afoul of anti-tying rules under the antitrust laws.[16] Additional antitrust violations may occur if manufacturers bundle a specialty drug that no other manufacturer produces with other drugs that consumers could obtain from competitors but for the bundling requirement.[17] Similarly, specialty pharmacies might tie specialty drugs to educational and monitoring services that consumers cannot decline to purchase.[18]

The remainder of the article will proceed as follows. Part I provides background information regarding specialty drugs and specialty pharmacies. Part II highlights regulatory gaps relating to specialty drug designation, medication pricing, conflicts of interest, patient choice and antitrust violations. Part III develops recommendations to address specialty drug concerns. It also discusses the Employee Retirement Income Security Act (ERISA), a federal statute that limits the applicability of state laws that regulate insurance. The section offers a variety of strategies to overcome the ERISA preemption problem. Part IV concludes the analysis.

I. DEFINING SPECIALTY DRUGS AND SPECIALTY PHARMACIES

Specialty drugs and pharmacies are unfamiliar to many Americans.[19] This Part explains what the two terms mean. It also discusses the cost of specialty drugs.

A. Specialty Drugs

It is important to understand that specialty drugs receive their designation from PBMs rather than from the Food and Drug Administration or medical authorities.[20] Medications that are labeled as specialty drugs are traditionally drugs that treat complex, chronic, or rare conditions.[21] Surprisingly, however, there is no standard definition

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[16] *See infra* Part II.D.
[17] *See infra* Part II.D.
[18] *Id.*
[19] Roni Shye, *Specialty Pharmacy and Specialty Medications: What You Should Know*, GOODRX Jan. 7, 2014, https://www.goodrx.com/blog/specialty-pharmacy-and-specialty-medications-what-you-should-know/.
[20] *See infra* Part II.A.
[21] Rabah Kamal et al., *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, PETERSON-KAISER HEALTH SYSTEM TRACKER, https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start (last visited July 19, 2019).

of the term "specialty drug."[22] The principal determinant is often the high cost of the drug.[23] Medicare, for example, defines a specialty-tier drug as any drug costing at least $670 per month, while other sources use a $600 per treatment threshold.[24] CVS Health defines specialty drugs as follows:

> First, they are expensive — the average monthly cost to payers and patients for a specialty medication is $3,000, ten times the cost for non-specialty medications. Second, they can be difficult to administer. They are often given by injection or infusion to treat complex, chronic conditions such as rheumatoid arthritis, multiple sclerosis and psoriasis. Third, the drugs may require special handling, including temperature control. And finally, patients taking these medications may need ongoing clinical assessment to manage challenging side effects.[25]

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[22] Alan M. Lotvin et al., *Specialty Medications: Traditional And Novel Tools Can Address Rising Spending On These Costly Drugs*, 33 HEALTH AFFS. 1736, 1737 (2014).

[23] *Id.* (relating that "one recent survey indicated that cost is the dominant factor, with 85 percent of respondents at health plans rating cost as very or extremely important in their decision to assign the specialty designation to a medication").

[24] CENTERS FOR MEDICARE AND MEDICAID SERVICES, ANNOUNCEMENT OF CALENDAR YEAR (CY) 2019 MEDICARE ADVANTAGE CAPITATION RATES AND MEDICARE ADVANTAGE AND PART D PAYMENT POLICIES AND FINAL CALL LETTER, (Apr. 2, 2018), p. 233, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf; Juliette Cubanski et al., *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019*, HENRY J. KAISER FAMILY FOUNDATION (Feb. 1, 2019), https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/; Bradford R. Hirsch et al., *The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs*, 33 HEALTH AFFS. 1714, 1714 (2014).

[25] Lotvin, *supra* note 22. *See also*, Jennifer Hagerman et al., *Specialty Pharmacy: A Unique and Growing Industry*, APHA, July 1, 2013, https://www.pharmacist.com/specialty-pharmacy-unique-and-growing-industry; National Pharmaceutical Services, *Specialty Medications*, https://www.pti-nps.com/nps/index.php/specialty-medications/ (accessed Apr. 24, 2019):

> NPS defines a specialty medication as a biologic or traditional drug, which requires additional management for a complex, chronic, or life-threatening condition that typically has two or more of the following attributes:
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> - Treats a condition, which requires intensive clinical monitoring of the patient.
> - Requires special patient training or patient compliance assistance.
> - Requires special handling, such as storage or preparation.
> - Requires special administration by the patient or the healthcare professional.

Historically, medications classified as specialty drugs were administered by injection or infusion, but now the category includes drugs that are simply taken orally.[26] Certain categories of U.S. Food and Drug Administration (FDA) approved drugs, such as biologics[27] and orphan drugs[28] are routinely classified as specialty drugs. While most specialty drugs are brand-name medications, there are some generic specialty drugs on the market as well, though they too have high price tags.[29] These drugs at times serve very small patient populations, which can fall below 10,000 patients or even be limited to five-hundred patients nationwide.[30]

- Has a limited distribution network.
- Has a high total cost.

[26] Hagerman et al., *supra* note 25.

[27] U.S. Food & Drug Administration, *What Are "Biologics" Questions and Answers*, https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (accessed Aug. 5, 2019) ("Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins…. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies.").

[28] Orphan drugs are drugs for rare diseases, defined as those affecting fewer than 200,000 people. *See* Food & Drug Administration, *Designating an Orphan Product: Drugs and Biological Products*, https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products (accessed Aug. 5, 2019) ("The Orphan Drug Act … provides for granting special status to a drug or biological product … to treat a rare disease or condition upon request of a sponsor"); U.S. Dept. of Health and Human Services, *FAQs About Rare Diseases*, https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases (updated Nov. 30, 2017) ("In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people.").

[29] Joshua Cohen, *Specialty Generics: Barriers To Uptake*, FORBES, Nov. 12, 2018, https://www.forbes.com/sites/joshuacohen/2018/11/12/specialty-generics-barriers-to-uptake/#6093a36c576f; Jalpa A. Doshi et al., *Addressing Out-Of-Pocket Specialty Drug Costs In Medicare Part D: The Good, The Bad, The Ugly, And The Ignored*, HEALTH AFFAIRS BLOG, July 25, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180724.734269/full/ ("Prior projections of the short- to mid-term savings from [specialty] biosimilars arrived at a reduction in drug price of 10–50 percent, as opposed to the typical 80–85 percent reduction in generic versions of traditional brand-name drugs"); Mark Thomas, *Generic Specialty Medications: The Paradigm Shift*, SPECIALTY PHARMACY TIMES, Oct. 8, 2018, https://www.specialtypharmacytimes.com/news/generic-specialty-medications-the-paradigm-shift.

[30] Dean Erhardt, *Specialty Pharmaceuticals and the Emergence of Sub-Specialty Pharmacy*, PHARMACEUTICAL COMMERCE, Feb. 18, 2009, https://pharmaceuticalcommerce.com/opinion/specialty-pharmaceuticals-and-the-emergence-of-sub-specialty-pharmacy/; Sandra Levy, *Specialty Pharmacies Toe the Line between Access, Cost, and Outcomes*, DRUG STORE NEWS, Oct. 3, 2018,

Specialty drugs are becoming an increasingly dominant presence in the healthcare market and account for a startling portion of healthcare spending.[31] According to one source, in 2017, 5.8 billion prescriptions were dispensed, but of these, only 1.9% (110 million) were for specialty medications, and yet they accounted for over forty percent of total U.S. drug costs.[32] In 1990, there were only ten specialty drugs on the market, but the number grew to nearly three-hundred by 2012.[33] The Food and Drug Administration approved forty-six new drugs in 2017, and PBMs considered eighteen of these, that is forty percent, to be specialty drugs.[34] In 2018, PBMs designated as many as thirty-nine of the new drugs that the FDA approved as specialty medications.[35]

B. Specialty Pharmacies

It follows that specialty pharmacies, which dispense specialty drugs,[36] are a booming business. While they generated $20 billion in sales in 2005, the sales figure burgeoned to $78 billion by 2014, according to one estimate.[37]

In 2017 there were approximately 730 accredited specialty pharmacies.[38] However, the top four specialty pharmacies accounted

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https://www.drugstorenews.com/pharmacy/specialty-pharmacies-toe-the-line-between-access-cost-and-outcomes/.

[31] *See infra* Part I. C. (addressing the cost of specialty drugs).

[32] Tara Menkhaus et al., *Pursuing Specialty Pharmacy Accreditation*, SPECIALTY PHARMACY TIMES, Jan. 25, 2019, https://www.specialtypharmacytimes.com/news/pursuing-specialty-pharmacy-accreditation. *See also*, David Dross, *Attention Turns to Specialty Pharmacy*, 33 BENEFITS Q. 12, 12 (2nd quarter 2017) (stating that specialty drugs account for 1-2% of prescriptions and are required by 1-2% of patients but generate 35% or more of costs).

[33] National Pharmaceutical Services, *supra* note 25. *See also*, Scott Kober, *The Evolution of Specialty Pharmacy*, 5 BIOTECHNOL. HEALTHCARE 50, 50 (Jul/Aug. 2008), (stating that in the mid-1990s there were fewer than 30 specialty drugs, by 2008 there were over 200, and the number was expected to rise to more than 400 by 2018).

[34] Levy*, supra* note 30.

[35] Aimee Tharaldson, *2019 Specialty Pipeline Highlights*, SPECIALTY PHARMACY TIMES, Jan. 23, 2019, https://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2019/January-2019/2019-Specialty-Pipeline-Highlights.

[36] Shye, *supra* note 19.

[37] Katie Thomas & Andrew Pollack, *Specialty Pharmacies Proliferate, along with Questions*, N.Y. TIMES, July 15, 2015, https://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html;

[38] Adam J. Fein, *The State of Specialty Pharmacy in 2018*, FIRST REP. MANAGED CARE 28, Apr. 2018, http://drugchannelsinstitute.com/files/State-of-Specialty-Pharmacy-2018-Fein-Asembia.pdf. Specialty pharmacies can be accredited by four

for two-thirds of prescription revenues.[39] The four are CVS Health, Express Scripts specialty pharmacies, AllianceRx Walgreens Prime, and BriovaRx.[40] All four industry giants are owned or co-owned by PBMs.[41] For example, AllianceRx Walgreens Prime combined Walgreen's specialty pharmacy and mail order pharmacy operations with its PBM, Prime Therapeutics.[42] Other specialty pharmacies are either independent or owned by retail chains, health insurers, pharmaceutical wholesalers, physician groups, or hospital systems.[43]

Specialty pharmacies assert that they contribute to improving health outcomes and lowering medical costs.[44] They teach patients how to inject their drugs, comply with medical protocols, and address side effects.[45] According to the American Pharmacist Association, specialty pharmacies' services include the following:

- 24-hour access to pharmacists
- Adherence management
- Benefits investigation
- Communication and follow-up with the physician
- Dispensing of specialty pharmaceuticals and shipping coordination
- Enrollment in patient assistance programs
- Financial assistance
- Patient education and medication adverse effect counseling
- Patient monitoring for safety and efficacy

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accrediting bodies: URAC (which is preferred by two-thirds of insurers), the Accreditation Commission for Health Care, the Center for Pharmacy Practice Accreditation, and the Joint Commission. Menkhaus et al., *supra* note 32.

[39] Fein, *supra* note 38, at 29.

[40] Adam J. Fein, *The Top 15 Specialty Pharmacies of 2017: PBMs and Payers Still Dominate*, DRUG CHANNELS, Mar. 13, 2018, https://www.drugchannels.net/2018/03/the-top-15-specialty-pharmacies-of-2017.html.

[41] Joseph C. Bourne & Ellen M. Ahrens, *Healthcare's Invisible Giants: Pharmacy Benefit Managers*, THE FEDERAL LAWYER, May 2013, at 50 (stating that "most PBMs own both mail order and specialty pharmacies"); Fein, *supra* note 38, at 29.

[42] *Walgreens and Prime Therapeutics Complete Formation of AllianceRx Walgreens Prime, a Combined Central Specialty Pharmacy and Mail Services Company*, Apr. 3, 2017, https://www.primetherapeutics.com/en/news/pressreleases/2017/alliancerx-walgreens-prime-release.html.

[43] Fein, *supra* note 38, at 29.

[44] Bijal Nitin Patel & Patricia R. Audet, *A Review of Approaches for the Management of Specialty Pharmaceuticals in the United States*, 32 PHARMACOECONOMICS 1105, 1108-09 (2014); Thomas & Pollack, *supra* note 37.

[45] Nick Calla, *What Is a Specialty Pharmacy?*, SPECIALTY PHARMACY TIMES, Dec. 18, 2013, https://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2013/nov_dec-2013/what-is-a-specialty-pharmacy; Levy, *supra* note 30; Patel & Audet, *supra* note 44, at 1109.

- Payer and/or manufacturer reporting
- Proactive patient outreach for prescription refill and renewal
- Prior authorization assistance[46]

Many of these services can be Risk Evaluation and Mitigation Strategies (REMS) that the FDA requires for drugs that raise special safety concerns.[47] While the FDA imposes the requirements on manufacturers,[48] specialty pharmacies can manage and perform the necessary steps of REMS programs for pharmaceutical companies.[49] PBMs' own utilization reviews may also demonstrate the need for such services in order to improve patient compliance with drug protocols.[50]

Some patients, however, complain about "onerous refill policies that require hours on the phone, shipments that are delayed or error-ridden, and difficulty reaching a pharmacist or other representatives."[51] At times phone calls that are purportedly meant to counsel patients, in reality are designed to pressure them to order refills.[52] In addition, the cost of hiring personnel to provide training and other services to patients is presumably included in the cost of specialty pharmacy drugs even for patients who are simply swallowing a pill and need no special assistance.[53]

C. The Cost of Specialty Drugs

In 2004, nineteen percent of Americans' drug spending was attributable to specialty drugs, but the figure rose to thirty-three percent in 2015 and forty-one percent in 2018, and it is expected to reach fifty

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[46] Hagerman et al., *supra* note 25.
[47] U.S. Food & Drug Administration, *Risk Evaluation and Mitigation Strategies | REMS*, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last updated Aug. 8, 2019).
[48] *Id.*
[49] PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, PBM SPECIALTY PHARMACIES IMPROVE PATIENT OUTCOMES AND REDUCE COSTS 5 (2017), https://www.pcmanet.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs_whitepaper_final.pdf.
[50] Academy of Managed Care Pharmacy, *Drug Utilization Review*, July 18, 2019, https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/drug-utilization-review ("Drug utilization review (DUR) is defined as an authorized, structured, ongoing review of prescribing, dispensing and use of medication.").
[51] Thomas & Pollack, *supra* note 37.
[52] Gary F., Giampetruzzi & Jonathan Stevens, *A Special Type of Government Scrutiny: Pharmaceutical Manufacturer Relationships with Specialty Pharmacies: Part I*, 15 PHARM. L. & INDUSTRY REP. 13, Mar. 31, 2017, *available at* https://www.paulhastings.com/publications-items/details/?id=ce3fec69-2334-6428-811c-ff00004cbded.
[53] *See supra* notes 1-3 and accompanying text.

percent by 2020 to 2025.[54] Americans spent $150 billion on specialty drugs in 2015.[55] Furthermore, prices for commonly used brand-name specialty drugs rose by fifty-seven percent between 2014 and 2018.[56]

Medicare Part D is a public insurance program that provides seniors with prescription drug coverage.[57] Its average annual spending on specialty drugs per beneficiary increased from $11,330 in 2010 to $33,460 in 2015.[58] Medicare Part D's net spending for specialty drugs almost quadrupled, rising from $8.7 billion in 2010 to $32.8 billion in 2015.[59] By comparison, Medicare Part D's *total* cost increase was far less dramatic during this time period, rising from $62 billion in 2010 to $90 billion in 2015.[60] For Medicaid, a public health insurance program for low income Americans,[61] the spending figure in 2015 was $9.9 billion, roughly double its payments for specialty drugs in 2010.[62]

In response to the high cost of specialty drugs, some insurers have created "specialty tiers" in which participants' coinsurance

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[54] Chadi Nabhan, *How Pharmacy Benefit Managers Add to Financial Toxicity The Copay Accumulator Program*, 4 JAMA ONCOLOGY 1665, 1665 (2018) (specialty drugs are "now on pace to account for half of prescription drug spending by 2020"); IQVIA, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* (Apr. 19, 2018), https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022 ("The balance of medicine spending has shifted strongly to specialty medicines from traditional treatments"); Tharaldson, *supra* note 35 (spending on specialty drugs "is estimated to reach close to 50% in the next two years"); Thomas & Pollack, *supra* note 37 (indicating that spending on specialty drugs is "heading toward 50 percent in the next 10 years").

[55] National Pharmaceutical Services, *supra* note 25. *See also* Fein, *supra* note 38, at 28 ("Total prescription dispensing revenues from specialty drugs at retail, mail, long-term care, and specialty pharmacies reached $138 billion in 2017."). *But see* Menkhaus et al., *supra* note 32 ("In 2017, specialty medications accounted for 46.5% ($210 billion) of the total $453 billion drug spend in the United States.").

[56] Kamal et al., *supra* note 21 (noting that "prices for generic drugs dropped by 35%" during the 2014-2018 period).

[57] Patricia Barry, *Part 1: How Medicare Part D Works*, AARP, https://www.aarp.org/health/medicare-insurance/info-11-2009/how_medicare-part_d_drug_coverage_works.html (updated Oct. 2016).

[58] Anna Anderson-Cook, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis*, p. 4, (March 2019) (Congressional Budget Office working paper 2019-02), *available at* https://www.cbo.gov/system/files/2019-03/55011-Specialty_Drugs_WP.pdf.

[59] *Id.* at 3.

[60] Juliette Cubanski & Tricia Neuman, *The Facts on Medicare Spending and Financing*, HENRY J. KAISER FAMILY FOUNDATION 2, June 22, 2018, http://files.kff.org/attachment/Issue-Brief-Facts-on-Medicaid-Spending-and-Financing.

[61] Robin Rudowitz et al., *10 Things to Know about Medicaid: Setting the Facts Straight*, HENRY J. KAISER FAMILY FOUNDATION, March 6, 2019, https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/.

[62] Anderson-Cook, *supra* note 58, at 4.

payments[63] can reach as high as twenty-five to thirty-three percent of the drug's price.[64] By contrast, under one Medicare plan, patients pay only one to three dollars for preferred generic drugs, seven to eleven dollars for non-preferred generic drugs, and thirty-eight to forty-two dollars for preferred brand name drugs.[65] Thus, specialty drugs can generate prohibitive out-of-pocket costs for enrollees.[66] According to the Henry J. Kaiser Family Foundation, in 2019, median annual out-of-pocket costs for the specialty-tier drugs it examined under Medicare Part D ranged from $2,622 (for the hepatitis C drug Zepatier) to $16,551 (for the leukemia drug Idhifa).[67] In 2013, only 2.3% of prescriptions were for specialty drugs, but 29.9% of patients' out-of-pocket costs were attributable to these drugs.[68]

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[63] Coinsurance is the "percentage of costs of a covered health care service you pay (20%, for example) after you've paid your deductible." HealthCare.gov, *Coinsurance*, https://www.healthcare.gov/glossary/co-insurance/ (accessed May 22, 2019).

[64] G. Caleb Alexander et al., *Reducing Branded Prescription Drug Prices: A Review of Policy Options*, 37 PHARMACOTHERAPY 1469, 1470 (2017); Joseph J. Hylak-Reinholtz, & Jay R. Naftzger, *Is It Time to Shed a "Tier" for Four-Tier Prescription Drug Formularies? Specialty Drug Tiers May Violate HIPAA's Anti-Discrimination Provisions and Statutory Goals*, 32 N. ILL. U. L. REV. 33, 34-35 (2011); Patel & Audet, *supra* note 44, at 1107-08; Blue Cross Blue Shield Blue Care Network of Michigan, *How Do Drug Tiers Work*, https://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html (last updated Aug. 9, 2018) (explaining that under most plans, enrollees pay "25% to 33% of the retail cost for drugs" in the specialty tier").

For further information about specialty tiers, *see* Cubanski et al., *supra* note 24 at 161-62:

> - Ninety-eight percent of covered workers at large firms have coverage for specialty drugs…. Among these workers, 52% are in a plan with at least one cost-sharing tier just for specialty drugs….
>
> - Among covered workers in a plan with a separate tier for specialty drugs, 34% have a copayment for specialty drugs and 59% have coinsurance…. The average copayment is $99 and the average coinsurance rate is 26%.... Eighty-one percent of those with coinsurance have a maximum dollar limit on the amount of coinsurance they must pay.

[65] Blue Cross Blue Shield Blue Care Network of Michigan, *supra* note 64.

[66] Cubanski et al., *supra* note 24.

[67] *Id.* (basing conclusions on 28 drugs that were studied).

[68] Rebekah L. Hanson, *Specialty Pharmacy and the Medication Access Dilemma*, 72 AM. J. HEALTH-SYST. PHARM. 695, 695 (2015).

By way of background, note that retail prices (also called list prices) are not equivalent to what most patients pay for drugs.[69] Individuals with insurance coverage pay a share of the price, which is either a fixed dollar amount (a co-pay)[70] or a percentage of the drug's cost (co-insurance).[71] The patient's payment is her out-of-pocket cost.[72] Moreover, PBMs negotiate with drug manufacturers for large discounts so that insurers pay far less than the retail prices for the drugs they cover.[73]

Out-of-pocket costs for specialty drugs that are *not* covered by insurance can be astronomical for patients. The Kaiser study focused on fourteen drugs that are excluded from some or all Medicare Part D plans[74] and found that in 2019, patients' median annual expenditures for them would fall between $26,209 (for Zepatier) to $145,769 (for the targeted therapy cancer drug Gleevec).[75] A 2019 article in *Health Affairs* listed the annual retail prices of thirteen specialty drugs, which ranged from $35,000 to $750,000 for the first year followed by

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[69] David Lazarus, *She Paid $3.47 for a Prescription Drug. The Retail Price Was 10,000% Higher*, L.A. TIMES, Aug. 18, 2018, https://www.latimes.com/business/lazarus/la-fi-lazarus-fantasyland-drug-pricing-20180828-story.html.

[70] Blue Cross Blue Shield Blue Care Network of Michigan, *How Do Deductibles, Coinsurance and Copays Work?*, https://www.bcbsm.com/index/health-insurance-help/faqs/topics/how-health-insurance-works/deductibles-coinsurance-copays.html (accessed July 19, 2019).

[71] *Id.*; Harris Meyer, *Why Prescription Drug List Prices Matter*, MODERN HEALTHCARE, Mar. 2, 2019, https://www.modernhealthcare.com/technology/why-prescription-drug-list-prices-matter.

[72] HealthCare.gov, *Out-of-Pocket Costs*, https://www.healthcare.gov/glossary/out-of-pocket-costs/ (accessed July 19, 2019).

[73] Lazarus, *supra* note 69; Jessica Wapner, *How Prescription Drugs Get Their Prices, Explained*, NEWSWEEK, Mar. 17, 2017, https://www.newsweek.com/2017/04/14/prescription-drug-pricing-569444.html.

[74] Cubanski et al., *supra* note 24, at 2 (explaining that "[n]ot all specialty tier drugs are covered by all Medicare Part D plans, unless they are in one of the six protected classes"). Medicare Part D must cover "all or substantially all" drugs in the following six categories: "immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics." These drugs are used to treat HIV, cancer, epilepsy, and other serious conditions. Henry J. Kaiser Family Foundation, *An Overview of the Medicare Part D Prescription Drug Benefit*, Oct. 2018 Fact Sheet, p. 4, http://files.kff.org/attachment/Fact-Sheet-An-Overview-of-the-Medicare-Part-D-Prescription-Drug-Benefit; Tom Wilbur, *Changes to the Six Protected Class Policy Are the Wrong Prescription for Medicare and HIV Patients*, THE CATALYST, Mar. 15, 2019, https://catalyst.phrma.org/changes-to-the-six-protected-class-policy-the-wrong-prescription-for-medicare-and-hiv-patients.

[75] *Id.*; Chemocare, *Gleevec ™*, http://chemocare.com/chemotherapy/drug-info/gleevec.aspx (accessed Apr. 24, 2019).

$375,000 for subsequent years.[76] The cost of ten of the thirteen medications exceeded $100,000 annually.[77]

Some manufacturers offer coupon or discount programs to help patients pay their out-of-pocket costs.[78] These programs, however, may be limited in scope and be discontinued once the patient is committed to the drug.[79]

II. PATIENT CONCERNS AND LEGAL QUESTIONS

Specialty drugs and pharmacies raise a number of legal and ethical concerns. They are rooted in several startling regulatory gaps. This part analyzes the following questions:

1) How do medications receive the designation of specialty drug?
2) How do manufacturers determine drug prices?
3) What choice limitations do PBMs impose on specialty drug consumers and do these constraints generate conflicts of interest?
4) Are actions by PBMs, manufacturers, and specialty pharmacies indicative of anticompetitive behavior under the antitrust laws?

A. Specialty Drug Designation

There appear to be no rules or regulations that determine which medications can and cannot be designated as specialty drugs. The determination is made by PBMs, which also decide whether the drug must be purchased from a specialty pharmacy.[80]

Different private and public insurance plans have different drugs in their specialty tiers.[81] For example, the 2019 specialty drug

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[76] Ezekiel J. Emanuel, *When Is the Price of a Drug Unjust? The Average Lifetime Earnings Standard*, 38 HEALTH AFFS. 604, 605 (2019).
[77] *Id.*
[78] Lotvin, *supra* note 22, at 1741.
[79] *Id.*; Debra Shute, *Understand Pharma Discount Coupons*, 95 MED. ECON., Oct. 3, 2018, https://www.medicaleconomics.com/article/understand-pharma-discount-coupons.
[80] Darrel Rowland, *Specialty Drugs: The New Arena for Pharmacy Benefit Manager Profits?*, COLUMBUS DISPATCH, Apr. 24, 2019, *available at* https://www.dispatch.com/news/20190423/specialty-drugs-new-arena-for-pharmacy-benefit-manager-profits; Applied Policy, *supra* note 8, at 9 (noting that concerns have "been raised with how PBMs categorize particular drugs as 'specialty' drugs").
[81] *See* Medicare.gov, *What Drug Plans Cover*, https://www.medicare.gov/drug-coverage-part-d/what-drug-plans-cover (accessed July 19, 2019) ("Plans can vary the list of prescription drugs they cover (called a formulary) and how they place drugs into different "tiers" on their formularies.").

list for Aetna's Premier Plan includes 467 medications.[82] By contrast, BlueCross BlueShield of North Carolina lists 604 specialty medications in 2019.[83] A comparison of an Express Scripts Medicare 2019 Formulary Value Plan ("Express Scripts Formulary")[84] and a Basic Blue® Rx Value (PDP) 2019 Formulary ("Basic Blue Formulary")[85] further highlights the differences that can exist among drug formularies, which are insurance plans' lists of the drugs that they cover.[86] Eighty-three medications listed as Tier 5 (specialty drugs) on the Basic Blue Formulary were listed as lower tier (non-specialty drugs) on the Express Scripts Formulary. In addition, there were over one-hundred specialty drugs offered on one of the two plans that were not offered at all on the other formulary.

PBMs may be financially motivated to classify medications as specialty drugs. Recall that PBMs own the industry's largest specialty pharmacies.[87] Once a medication is designated as a specialty drug, the PBM can instruct patients to purchase it from its own specialty pharmacy and thus profit considerably from sales.[88]

Some specialty drugs require complex handling or administration,[89] but some do not.[90] For example, the 2019 Basic Blue® Value formulary listed Asacol HD, a drug that treats ulcerative colitis,

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[82] Aetna, *Specialty Drug Coverage*, http://www.aetna.com/individuals-families-health-insurance/document-library/pharmacy/2019-specialty-drug-list-premier.pdf (accessed July 5, 2019).

[83] BlueCross BlueShield of North Carolina, https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/formulary/specialty-network/specialty-drug-list.pdf (accessed May 24, 2019).

[84] Express Scripts, *Express Scripts Medicare (PDP) 2019 Formulary (List of Covered Drugs)*, https://www.express-scriptsmedicare.com/pdf/medicare/medicare-part-d-2019-formulary-value.pdf (last updated May 24, 2019).

[85] Basic Blue® Rx (PDP), *Basic Blue® Rx Value (PDP) 2019 Formulary*, https://www.basicbluerx.com/sites/default/files/2019_BBRx_formulary_Value-508.pdf (last updated June 1, 2019).

[86] Medicare.gov, *supra* note 81.

[87] *See supra* notes 39-42 and accompanying text.

[88] *See supra* notes 41-42 and accompanying text; Darrel Rowland, *Questions Raised on How Pharmacy Benefit Managers Profit from Specialty Drugs*, COLUMBUS DISPATCH, Apr. 24, 2019, *available at* https://www.dispatch.com/news/20190424/questions-raised-on-how-pharmacy-benefit-managers-profit-from-specialty-drugs. *See infra* Part II.C for further discussion of patient choice limitations and associated conflicts of interest and Part II.D for antitrust concerns.

[89] *See supra* note 25 and accompanying text.

[90] Maryann Dowd, *Valued Services from Specialty Pharmacy: A Manufacturers Perspective*, SPECIALTY PHARMACY TIMES, Oct. 21, 2014, https://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2014/october-2014/valued-services-from-specialty-pharmacy-a-manufacturers-perspective/p-2 (stating that "each product that falls into the specialty pharmacy category demands its own set of unique services.").

as a specialty drug.[91] This medication is merely a pill that patients swallow.[92] The same is true for the Parkinson's disease drug Gocovri, discussed in the Introduction[93] and a drug called Ingrezza for adults with tardive dyskinesia.[94] Other medications come with simple instructions that ordinary retail pharmacies can provide to patients along with easy-to-follow literature. For example, a drug called Perforomist, used by patients with chronic obstructive pulmonary disease (COPD), is a specialty drug on the 2019 Basic Blue® Value formulary.[95] This drug is inhaled orally twice a day, using a standard jet nebulizer.[96] Unlike Basic Blue, the Express Scripts Medicare (PDP) 2019 Formulary lists Asacol HD and Perforomist as tier three drugs.[97] This means that rather than specialty drugs, they are preferred brand-name drugs with "lower copayments than non-preferred drugs."[98] For patients, having a drug designated as a specialty medication can be quite punishing because of very high specialty tier coinsurance payments and pharmacy choice restrictions.[99] One wonders if there is any justification for designating certain drugs as specialty medications other than the PBMs' own profit motives.[100]

Several states have adopted statutory definitions of "specialty drugs." Some statutory provisions focus on the medication's price. Connecticut, for example, defines specialty drugs as those that exceed Medicare's specialty tier cost threshold.[101] In other states, the

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[91] Basic Blue® Rx (PDP), *supra* note 85, at 46 (listing the item as a tier-5 drug, which indicates specialty status).

[92] U.S. National Library of Medicine, Label: ASACOL HD- Mesalamine Tablet, Delayed Release, DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2f68f68c-58d2-4575-b573-f2e62f95d7e3&audience=consumer (last accessed June 30, 2019).

[93] *See supra* notes 1-3 and accompanying text.

[94] Aetna, *supra* note 82 (listing Ingrezza as a specialty drug); U.S. National Library of Medicine, *Label: Ingrezza- Valbenazine Capsule*, DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4c970164-cafb-421f-9eb5-c226ef0a3417&audience=consumer (accessed July 5, 2019).

[95] Basic Blue® Rx (PDP), *supra* note 85, at 57 (listing the item as a tier-5 drug, which indicates specialty status).

[96] U.S. National Library of Medicine, *Label: Perforomist - Formoterol Fumarate Dihydrate Solution*, DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fb2fe258-fe2e-47f6-8adf-ca75bf6f90af&audience=consumer (last accessed June 30, 2019).

[97] Express Scripts, *supra* note 84, at 60, 76.

[98] *Id.* at vii.

[99] *See supra* notes 63-64 and accompanying text.

[100] *See supra* note 88 and accompanying text.

[101] CONN. GEN. STAT. ANN. § 38a-479ooo(12) (2020). *See also*, CAL. HEALTH & SAFETY § 1367.243(c) (2018).

designation requires special handling or administration of the drugs.[102] Thus, Michigan's statute provides:

> (i) "Specialty prescription drug" means a prescription drug used to treat a rare, complex, or chronic medical condition that meets any of the following requirements:
>
> (*i*) Requires special administration including, but not limited to, inhalation or infusion.
>
> (*ii*) Requires special delivery or special storage.
>
> (*iii*) Requires special oversight, intensive monitoring, or care coordination with a person licensed under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838.[103]

The statutes that define "specialty drugs" address various prescription drug reporting requirements, coverage guidelines, and, in some cases, copayment or coinsurance limitations, as discussed below.[104]

It is important to understand that state legislation regarding health insurance generally has limited reach because a large portion of insurance policies are not subject to statutory compliance.[105] The "deemer clause" in the Employee Retirement Income Security Act of 1974 (ERISA) establishes that state laws regulating insurance are preempted with respect to self-funded health insurance plans.[106] Employers with self-funded plans collect premiums and pay all medical claims themselves, though they may use a third party to do administrative work for the plan.[107] According to the Henry J. Kaiser Family Foundation, in 2018, sixty-one percent of workers were enrolled in fully or partially self-funded health plans, which are particularly popular among large companies.[108] The ERISA exemption significantly diminishes the efficacy of state laws such as those defining "specialty drugs" for insurance purposes.

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[102] *See* CAL. WELF. & INST. CODE ANN. §14105.45(13) (2017); D.C. CODE ANN. § 48-855.01(10) (2017); DEL. CODE ANN. tit 18 § 3364(7) (2014); MD. INS. CODE ANN. §15-847(5) (2014); N.D. CENT. CODE ANN. § 19-02.1-16.2 (2017).

[103] MICH. COMP. LAWS ANN. § 124.73(i) (2019).

[104] *See supra* notes 101-103 and *infra* 127-130 and accompanying text.

[105] *See* Sharona Hoffman, *Step Therapy: Legal, Ethical, and Policy Implications of a Cost-Cutting Measure*, 73 FOOD & DRUG L. J. 38, 55-56 (2018).

[106] *Id.*; 29 U.S.C. § 1144(b)(B) (2010). *See infra* Part III.B.1 for further details regarding ERISA.

[107] Healthcare.gov, *Self-Insured Plan*, https://www.healthcare.gov/glossary/self-insured-plan/ (last visited June 17, 2019).

[108] HENRY J. KAISER FAMILY FOUND., EMPLOYER HEALTH BENEFITS 2018 ANNUAL SURVEY 12 (Oct. 2018), http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.

B. Specialty Drug Prices

American manufacturers are free to price their drugs as they see fit without constraint.[109] Two experts describe the United States pricing system as follows:

> Under the current US system, drug manufacturers estimate what the market will bear for a novel therapy. Then, if there is concern about negative publicity about drug prices, a fraction of the cost may be subtracted, at least while attention persists. Absent competition or negotiation, this fraction is determined by the company's internal moral compass and the degree of awareness in the biomedical ecosystem, which is often driven by public perception of the specific disease.[110]

Drug prices are generally inflated in the United States,[111] but the problem is acute for specialty drugs.

Drug companies often justify their prices by citing their research and development costs.[112] However, many experts accuse the drug industry of grossly exaggerating its expenditures.[113] For example, one study concluded that the cost of developing a cancer drug is $648 million rather than the $2.7 billion that manufacturers claim.[114]

Even after drugs become established in the marketplace, manufacturers often increase their prices.[115] These increases generally

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[109] Franklin Liu, *The Daraprim and the Pharmaceutical Pricing Paradox A Broken System?*, 2015 B.C. INTELL. PROP. & TECH. F. 1, 14 (2015) (asserting that "pharmaceutical companies can exploit the life-saving nature of their products and capitalize on a vulnerable segment of the population by demanding unconscionably high prices for their products").

[110] Robert M. Califf & Andrew Slavitt, *Lowering Cost and Increasing Access to Drugs without Jeopardizing Innovation*, 321 JAMA 1571, 1571 (2019).

[111] Robert Langreth, *Drug Prices*, BLOOMBERG, Feb. 5, 2019, https://www.bloomberg.com/quicktake/drug-prices.

[112] Brittany Humphries & Feng Xie, *Canada's Amendment to Patented Drug Price Regulation: A Prescription for Global Drug Cost Control?*, 32 JAMA 1565, 1566 (2019).

[113] *Id.*; Ezekiel L. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up: Just How Expensive Do Prescription Drugs Need to be to Fund Innovative Research?*, THE ATLANTIC, March 23, 2019, *available at* https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/.

[114] Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 JAMA INTERN. MED. 1569, 1569 (2017).

[115] *Id.*; Stacie B. Dusertzina & Peter B. Bach, *Prescription Drugs – List Price, Net Price, and the Rebate Caught in the Middle*, 321 JAMA 1563, 1563 (2019) ("In recent

are not justified by any showing that the drug is more effective or beneficial than expected.[116] In some cases, price increases are egregious. An infamous example is Martin Shkreli's decision to raise the price of Daraprim by 5000 percent, from $13.50 to $750 per pill in 2015.[117]

Drug prices in the United States are notoriously higher than in other countries. As just one illustration, the antiretroviral drug dolutegravir costs twenty-seven dollars per year in the country of Georgia and $20,130 per year in the United States.[118] Other nations have proactively tackled the challenge of affordable drug pricing. In 1987, for example, Canada established a Patented Medicine Prices Review Board to control patented drug prices.[119] The Board conducts scientific reviews, which include comparisons of prices in seven other countries in order to establish a maximum list price for each drug.[120]

By contrast, in the United States, Medicare is not permitted to negotiate drug prices directly with pharmaceutical manufacturers, let alone to take regulatory steps to control them.[121] A few states have undertaken limited cost-containment initiatives, but the federal government has failed thus far to launch successful efforts.[122]

One stalled federal proposal specifically targeted specialty drugs. In June of 2017, Representatives David McKinley (R-WV) and G.K. Butterfield (D-NC) introduced the Patients' Access to Treatment Act in the 115th Congress.[123] The bill would disallow large percentage

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years, pharmaceutical manufacturers have consistently increased the list prices of their products.").

[116] Califf & Slavitt, *supra* note 110, at 1571.

[117] Michael A. Carrier et al., *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECH. L.J. 1379, 1379 (2016). Daraprim is used to treat Toxoplasmosis, a serious infection caused by a parasite. *Daraprim*, https://www.daraprimdirect.com/ (accessed May 27, 2019).

[118] Joel Sim & Andrew Hill, *Is Pricing of Dolutegravir Equitable? A Comparative Analysis of Price and Country Income Level in 52 Countries*, 4 J. VIRUS ERADICATION 230, 231 (2018).

[119] Humphries & Xie, *supra* note 112, at 1565.

[120] *Id.* The seven countries are Italy, France, Germany, Sweden, Switzerland, United Kingdom, and the United States. Given high pharmaceutical costs in Canada, some have questioned the Board's efficacy in recent years, and the government is considering regulatory changes. *Id.*

[121] Dusertzina & Bach, *supra* note 115, at 1563.

[122] Jane C. Horvath & Gerard F. Anderson, *The States as Important Laboratories for Federal Prescription Drug Cost-Containment Efforts*, 321 JAMA 1561, 1561 (2019) (reporting on several state efforts, including Maryland's enacting "legislation that would prevent 'unconscionable' price increases for off-patent drugs that have fewer than 3 competitors").

[123] H.R. 2999, 115th Cong., 1st Sess. (2017); American Society of Hematology, *2018 ASH Advocacy Efforts to Ensure Patient Access to Care*, Dec. 10, 2018, https://www.hematology.org/Advocacy/Policy-News/2018/9253.aspx.

coinsurance charges for specialty tier drugs.[124] It would permit only fixed co-pays that are consistent with those that apply to the lowest cost nonpreferred brand name drug tier.[125] The bill did not become law, but advocates hope that legislators will reintroduce it in the 116th Congress.[126]

A number of states have been more successful in tackling cost-sharing for specialty tier drugs. California places a limit of $250 or $500 of cost sharing for a thirty-day supply, depending on the type of drug.[127] Delaware, the District of Columbia, Louisiana, and Maryland limit patients' out-of-pocket costs to $150 for a thirty-day supply.[128] New York disallows cost sharing that exceeds the amount applicable to non-preferred brand name drugs, thereby effectively eliminating specialty tiers.[129] Recall, however, that state regulations restricting health insurance practices do not govern self-funded plans, which now cover the majority of individuals with employer-provided benefits.[130]

By definition, specialty drugs are among the most expensive drugs on the market.[131] The dearth of price control mechanisms in the United States disproportionately affects the sickest patients who often need these drugs and must pay exorbitant amounts for them.[132] In fact, there is nothing to prevent a manufacturer from deliberately assigning a very high price to a drug in order to have the specialty drug label bestowed upon it. This classification, in turn, confirms that it should have an astronomical price tag because that is the nature of specialty medications.

C. Conflict of Interest and Patient Choice

Consumers often have little choice as to who will fill their specialty drug prescriptions.[133] PBMs frequently require patients to purchase specialty drugs from the specialty pharmacies that they own.[134] Many experts assert that this requirement creates a conflict of

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[124] See *supra* notes 63-64 and accompanying text.
[125] Congress.Gov, *H.R.2999 - Patients' Access to Treatments Act of 2017*, https://www.congress.gov/bill/115th-congress/house-bill/2999 (accessed May 27, 2019); American Society of Hematology, *supra* note 123.
[126] American Society of Hematology, *supra* note 123.
[127] CAL. HEALTH & SAFETY CODE § 1342.73(a) (2019).
[128] DEL. CODE ANN. tit. 18 § 3364(b) (2014); D.C. CODE ANN. §48-855.02 (2017); LA. STAT. ANN. § 22:1060.5(A) (2015); MD. INS. CODE ANN. § 15-847(c)(1) (2014).
[129] N.Y. INS. LAW § 3221(a)(16) (2019); N.Y. PUB. HEALTH LAW §4406-c(7) (2019).
[130] *See supra*, notes 105-108 and accompanying text.
[131] *See supra* note 24 and accompanying text.
[132] *See supra* note 24 and accompanying text.
[133] Fein, *supra* note 38, at 29; Thomas & Pollack, *supra* note 37.
[134] Bourne & Ahrens, *supra* note 41, at 50 ("Critics have suggested that PBMs improperly prevent other pharmacies from dispensing specialty drugs and force

interest.[135] While PBMs purportedly exist in order to save health plans money,[136] their zeal for cost-savings may be tempered by the prospect of large profits for their specialty pharmacies.[137] The National Community Pharmacists Association powerfully describes the concerns about PBM activities in this area:

> When PBMs own mail order or specialty pharmacies, PBMs utilize such road blocks to steer patients to their proprietary pharmacies. Specifically, in the specialty pharmacy space, PBMs arbitrarily define high-cost drugs as "specialty drugs" and encourage or require that beneficiaries fill these prescriptions at PBM-owned or affiliated specialty pharmacies. Forcing patients, particularly those on specialty drugs for complex conditions, to get their prescriptions from a pharmacy with which it has no personal relationship severely limits patients' choice and may impact the quality of care and adherence.[138]

In addition, many specialty pharmacies supply drugs only through mail order.[139] This delivery mechanism can deprive patients of control over the timing of their refills and provoke anxiety. Patients may worry that their drugs will be stolen or exposed to extreme weather if they arrive when no one is home.[140] Indeed, some patients may feel compelled to plan vacations or business trips around their anticipated drug delivery dates.

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patients to use the PBMs' own specialty pharmacy services."); Rowland, *supra* note 80.

[135] Cathy Candisky, *Ohio Medicaid Officials to Crack Down on PBM Specialty Drug Practice*, COLUMBUS DISPATCH, Apr. 30, 2019, https://gatehousenews.com/sideeffects/ohio-medicaid-officials-crack-pbm-specialty-drug-practice/site/dispatch.com/; Thomas & Pollack, *supra* note 37.

[136] *See supra* note 7 and accompanying text.

[137] Applied Policy, *supra* note 8, at 8; Thomas & Pollack, *supra* note 37.

[138] *See* Letter, *Comments to the Federal Trade Commission's (FTC) 21st Century Hearings, Constitution Center September 21st Hearings Session (Docket ID: FTC-2018-0076),* From National Community Pharmacists Association Vice President of Pharmacy Policy and Regulatory Affairs, Ronna B. Hauser, Nov. 15, 2018, p. 3, *available at* https://www.ftc.gov/system/files/documents/public_comments/2018/11/ftc-2018-0076-d-0018-162492.pdf (last accessed Jul. 20, 2019).

[139] Applied Policy, *supra* note 8, at 9; Shye, *supra* note 36; Thomas & Pollack, *supra* note 37.

[140] Olga Khazan, *Invisible Middlemen Are Slowing Down American Health Care*, THE ATLANTIC, Apr. 9, 2019, *available at* https://www.theatlantic.com/health/archive/2019/04/pbms-health-care-drug-delays-prices/586711/.

Patients vary as to how they prefer to fill their prescriptions. In one study, fifty-four percent of respondents preferred to pick up their prescriptions at a retail pharmacy, while more than forty percent favored home delivery.[141] In another study, there was approximately an equal split between preferences.[142] A particularly important finding is that choice matters. Enabling patients to choose how they fill their prescriptions can improve adherence to medication protocols.[143]

Patients who do not pick up their drugs in person lose the opportunity to have face-to-face conversations with pharmacists regarding their instructions and concerns, and such conversations can enhance patient compliance with drug protocols.[144] Specialty drug mail-order consumers can receive personal attention from specialty pharmacy staff,[145] but these discussions occur through separate phone calls rather than at the point of delivery.

Some legislators and regulators have already recognized the importance of patient choice. At the federal level, the Centers for Medicare and Medicaid Services (CMS) prohibits Medicare plans from requiring enrollees to use mail-order pharmacies.[146]

Many states have taken action as well. For example, Mississippi provides that insurance plans may not prohibit enrollees from selecting a participating pharmacist of their choice, and thus, presumably, PBMs cannot require covered individuals to purchase specialty drugs only from their own specialty pharmacies.[147] Furthermore, under Mississippi law, PBMs may not require enrollees to obtain medications exclusively through mail-order or impose higher costs or restrictions (such as quantity limitations) on patients who do not opt for mail-order delivery.[148] Alabama, Delaware, Hawaii, Idaho, Iowa, Louisiana, Maryland, New Jersey, North Carolina, North Dakota, Pennsylvania, South Dakota, Tennessee, and West Virginia,

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[141] Janice M. Moore et al., *The Adherence Impact of a Program Offering Specialty Pharmacy Services to Patients Using Retail Pharmacies*, 56 J. AM. PHARMACIST ASS'N 47, 52 (2016).

[142] Joshua N. Liberman et al., *Revealed Preference for Community and Mail Service Pharmacy*, 51 J. AM. PHARM. ASS'N 50, 55 (2011) ("Among those who initiated therapy under the new benefit design [that enhanced patient choice], nearly equal proportions elected mail service and community pharmacy channels, while among those who previously used community pharmacy, nearly 79% elected community pharmacy if they had not recently used mail service pharmacy.").

[143] *Id.* at 51; Moore et al., *supra* note 141, at 52-53.

[144] Applied Policy, *supra* note 8, at 8.

[145] *See supra* notes 44-46 and accompanying text.

[146] CENTERS FOR MEDICARE AND MEDICAID SERVICES, YOUR GUIDE TO MEDICARE PRESCRIPTION DRUG COVERAGE 24 (revised June 2018), *available at* https://www.medicare.gov/pubs/pdf/11109-Your-Guide-to-Medicare-Prescrip-Drug-Cov.pdf.

[147] MISS. CODE ANN. § 83-9-6(3)(a) (2013).

[148] *Id.* at § 83-9-6(3)(f)-(g).

have likewise adopted pharmacy choice statutes, though not all are as comprehensive as Mississippi's.[149]

All of these legal interventions, however, are limited in scope. The federal rule covers only Medicare Part D enrollees.[150] As previously discussed, state legislation regarding health insurance applies only to plans that are not self-funded employer-sponsored plans.[151] Therefore, despite the states' best intentions, many of their residents will not benefit from their patient choice mandates.

D. Antitrust: Tying Arrangements

The activities of manufacturers, specialty pharmacies, and PBMs raise antitrust concerns because these entities may bundle goods or services in ways that foreclose competition.[152] Unlawful bundling is called "tying," which is defined as "an agreement under which the seller agrees to sell a product to a buyer, but only on the condition that the buyer also purchases a different product from the seller,"[153] or "at least agrees that [it] will not purchase that product from any other supplier."[154]

Tying arrangements constitute a combination that forecloses trade or commerce in violation of Sections 1 or 2 of the Sherman Act.[155] The Act prohibits "[e]very contract, combination … or conspiracy in restraint of trade."[156] Based on contemporary Supreme Court cases, scholars have articulated a four-part test for an unlawful tying arrangement: (1) separate products must be tied and sold together, (2) the seller holds "appreciable" economic power over the tying product, (3) the seller coerces the buyer by "afford[ing] consumers no choice

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[149] ALA. CODE § 27-45-3 (1975); DEL. CODE ANN. tit. 18 § 7303 (1995); HAW. REV. STAT. § 431R-3(b) (2013); IDAHO CODE § 41-1844(1) (1991); IOWA CODE § 514C.5 (1990); LA. REV. STAT. ANN. § 22:1964(15)(a)(i) (2014); MD CODE ANN., INS. § 15-806 (1997); N.J. REV. STAT. § 17:48-6j (2000); N.C. GEN. STAT. § 58-51-37(c) (2017); N.D. CENT. CODE § 26.1-36-12.2(1) (1989); PA. STAT. ANN. tit. 40 § 764*l* (2013); S.D. CODIFIED LAWS ANN. § 58-18-37 (1990); TENN. CODE ANN. §56-7-2359 (a) and (e) (2016); W. VA. CODE, § 33-24-7h (2003).

[150] *See supra* note 146 and accompanying text.

[151] *See supra*, notes 105-108 and accompanying text.

[152] *See* United States of America v. CVS Health Corp., Civ. Case No. 1:18-cv-02340-RJL, Brief of Amicus Curiae by AIDS Healthcare Fourndation (D.D.C. Feb. 5, 2019) ("a post-merger CVS, with the inclusion of Aetna's 22 million lives, will have the leverage and incentive to use increasingly aggressive tactics to narrow its networks to exclude small and specialty pharmacies").

[153] Uri Benoliel, *The Behavioral Law and Economics of Franchise Tying Contracts*, 41 RUTGERS U. L.J. 527, 527 (2010). *See also* Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 12-14 (1984).

[154] Northern Pacific Railway Co. v. U.S., 356 U.S. 1, 5 (1958).

[155] 15 U.S.C.A. §§ 1-2 (2010).

[156] *Id.* at § 1.

but to purchase the tied product from it," and (4) the arrangement impacts a "substantial volume" of commerce in the tied market.[157]

Bundled ties involve connected purchases that occur when a business sells multiple separate products together, often relying on its monopoly power in one market to influence another.[158] Alleged bundling ties often hinge on whether the products are separate (which would violate the antitrust laws) or single products (which would not).[159]

The key for bundled tying is whether the business is preventing goods "from competing directly for consumer choice on their merits, i.e., being selected as a result of 'buyers' independent judgment.'"[160] Further, "[w]ith a tie, a buyer's 'freedom to select the best bargain in the second market [could be] impaired by his need to purchase the tying product, and perhaps by an inability to evaluate the true cost of either product.'"[161] Finally, "[d]irect competition on the merits of the tied product is foreclosed when the tying product either is sold only in a bundle with the tied product or, though offered separately, is sold at a bundled price, so that the buyer pays the same price whether he takes the tied product or not."[162]

Several forms of tying may exist in the specialty drug space. First, in some cases, manufacturers who are the sole producers of high cost drugs (often deemed specialty drugs) bundle those drugs with medications that their competitors likewise make. Thus, PBMs that want to contract with a manufacturer for a drug that they cannot obtain elsewhere, must also purchase the bundled drugs from that same manufacturer. For example, in 2018, Sugartown Pediatrics sued Merck & Co., for an alleged anticompetitive bundling scheme.[163] Merck is the

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[157] U.S. v. Microsoft Corp., 253 F.3d 34, 87 (2001). *See* Mark DeFeo, *Unlocking the IPhone: How Antitrust Law Can Save Consumers from the Inadequacies of Copyright Law*, 49 B.C. L. REV. 1037, 1059, nn. 166-69 (2008), *relying on* Eastman Kodak Co. v. Image Technical Servs., Inc. 504 U.S. 451 (1992), Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2 (1984), Fortner Enters. Inc. v. U.S. Steel Corp., 394 U.S. 495 (1969), U.S. Steel Corp. v. Fortner Enters., Inc., 429 U.S. 610 (1977); N. Pac. Ry. V. U.S., 356 U.S. 1 (1958), Int'l Salt Co. v. U.S., 332 U.S. 392 (1947).

[158] *See Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act: Chapter 5*, U.S. DEPT. OF JUSTICE, June 25, 2015, *available at* https://www.justice.gov/atr/competition-and-monopoly-single-firm-conduct-under-section-2-sherman-act-chapter-5 (last accessed Jul. 20, 2019); Travis Clark, *Google v. Commissioner: A Comparison of European Union and United States Antitrust Law*, 47 SETON HALL L. Rev. 1021, 1026 (2016).

[159] *Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act: Chapter 5*, *supra* note 158.

[160] U.S. v. Microsoft Corp., 253 F.3d 34, 87 (2001), quoting Jefferson Parish Hospital District No. 2 v. Hyde, 466 U.S. 2, 13 (U.S. 1984) (abrogated on other grounds).

[161] *Id*.

[162] *Id*.

[163] Sugartown Pediatrics LLC v. Merck & Co., Inc., No. 18-1734 (E. D. PA, filed Apr. 25, 2018).

only United States manufacturer of several pediatric vaccines, such as the measles, mumps, rubella vaccine.[164] Sugartown alleged that when GlaxoSmithKline was about to introduce a rotavirus vaccine that would compete with Merck's, "Merck added a condition to its contracts that required customers to buy all or nearly all of their pediatric rotavirus vaccines from Merck or face substantial price penalties on all other Merck vaccines."[165]

Second, specialty pharmacies provide educational, monitoring, and other services along with the drugs they sell.[166] Patients receive these services from specialty pharmacies whether they want them or not, even if they are simply swallowing pills and do not need extensive oversight.[167] Our research revealed no clear data about specialty pharmacy services' costs or charges. Thus, these costs are subject to the same lack of transparency that characterizes so much in the specialty drug arena. However, it stands to reason that there are expenses associated with these services, such as hiring staff, and that these costs are incorporated into the price of specialty drugs. Because specialty pharmacies do not allow patients and payers to choose whether to obtain particular services, they may be engaging in unlawful bundling.[168]

Third, PBMs may bundle their PBM services with services from their wholly-owned specialty pharmacies.[169] When employers contract with PBMs for their services, they may agree to a requirement that beneficiatiaries use the the PBM's specialty pharmacy.[170] In such a case, the court is likely to find no antitrust violation.[171] However, if PBMs compel use of their specialty pharmacies without addressing the requirement in their services contract, they could be engaging in anticompetitive conduct. Nevertheless, a further hurdle to a successful

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[164] *Id.* at ¶ 3.
[165] *Id.* at ¶ 4.
[166] *See supra* note 46 and accompanying text.
[167] See supra notes __ and accompanying text (p. 14).
[168] Federal Trade Commission, *Tying the Sale of Two Products*, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/single-firm-conduct/tying-sale-two-products (accessed Oct. 5, 2019) ("The FTC challenged a drug maker that required patients to purchase its blood-monitoring services along with its medicine to treat schizophrenia.").
[169] See supra Part II.C. This has been raised as a concern related to the proposed CVS-Aetna merger. *See* Letter, *Competitive and Consumer Concerns Raised by the CVS-Aetna Merger*, From Diana L. Moss, President, American Antitrust Institute, Mar. 26, 2018, at 7 (on file with authors) ("For example, CVS-Caremwark could … offer pharmacy networks that do not provide important options (e.g., independent specialty pharmacies) or force rival insurers into CVS-Caremark mail order pharmacy services").
[170] Prime Aid Pharmacy Corp. v. Humana Inc., Case No. 16-2104, 2017 WL 3420933 (D.N.J. Aug. 9, 2017) at *2.
[171] *Id.*

antitrust claim is the fact that dissatisfied employers can change PBMs once their contracts expire, and employees can often change insurance plans every year during open season.[172] Therefore, consumers are not "locked in" to the bundling arrangement in the long-run.

III. RECOMMENDATIONS

Concerns about specialty drug designation, drug prices, lack of patient choice, conflict of interest, anticompetitive behavior, and services that lack medical necessity are all significant for patients and their health care providers. These matters are ripe for regulatory and legal interventions. The challenging questions are who should undertake regulatory initiatives and how should they be achieved. While the federal government sets standards for Medicare and Medicaid coverage, it is unclear whether the federal government or the states are in a better position to establish specialty drug rules for private health plans. This Part offers recommendations for specialty drug guidelines and analyzes pathways for such regulation in light of ERISA's exemption of self-funded health insurance plans.[173]

A. Substantive Protections

Below we provide general principles that should guide lawmakers in fashioning specialty drug rules. We leave the details to the discretion of state or federal policy-makers, and outline only the core of recommended remedial provisions.

1. Specialty Drug Designation

PBMs should not be entirely at liberty to determine which medications are and are not specialty drugs.[174] Labeling a medication as a specialty drug can have serious adverse consequences for patients. Insurers' specialty tiers often have very high coinsurance,[175] and patients may face restrictions as to how and from whom they can obtain the medications.[176] By contrast, PBMs have much to gain from such designations since they can instruct patients to purchase specialty drugs from their own specialty pharmacies.[177]

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[172] *Id.* at 3.
[173] *See supra* notes 105-108.
[174] *See supra* note 80 and accompanying text.
[175] *See supra* notes 63-64 and accompanying text.
[176] *See supra* notes 133-140 and accompanying text.
[177] *See supra* note 137.

Statutory guidelines should establish boundaries for the specialty drug designation.[178] Following the precedent set by several states, such drugs should be characterized by special requirements for their handling or administration rather than by their price.[179] The services of specialty pharmacists may be beneficial when the patient needs complex training or unusual delivery methods, but not when ordinary retail pharmacies can easily fill the prescription and educate patients about its use.

2. Specialty Drug Costs

Addressing the overwhelming problem of drug costs in the United States is well beyond the scope of this Article. The robust literature that already exists can fill many library shelves.[180] Legislators are encouraged to continue to work diligently to harness American medical costs.

A more modest effort that some states have successfully undertaken is to limit patients' out-of-pocket costs for high-priced drugs (both specialty and non-specialty). All private and public health plans should cap co-payments for specialty-tier drugs at a particular dollar amount. Plans should be prohibited from charging coinsurance based on a percentage of a drug's price.[181]

Another possible approach is a mandate that allows patients to obtain just a few pills or doses for an initial trial period, such as a week or two.[182] A patient who cannot tolerate the drug or finds it to be ineffective would thus save the (possibly exorbitant) cost of a full

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[178] The Food and Drug Administration (FDA) does not have a role in the specialty drug designation of new drugs, and it cannot consider cost when approving new drugs. However, it can impose Risk Evaluation and Mitigation Strategies (REMS) that limit uses and distribution of the specialty drug, and it can facilitate competition by speeding follow-on biologics to market to help bring down costs. *See* Aaron S. Kesselheim, *Exisiting FDA Pathways Have Potential to Ensure Early Access To, And Appropriate Use of, Specialty Drugs*, HEALTH AFFAIRS, Oct. 2014, *available at* https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0529.

[179] *See supra* notes 101-103.

[180] *See e.g.* ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES (2019); ED SCHOONVELD, THE PRICE OF GLOBAL HEALTH: DRUG PRICING STRATEGIES TO BALANCE PATIENT ACCESS AND THE FUNDING OF INNOVATION (2017); *Opinion Spotlight: Prescription Drug Pricing*, 321 JAMA (Apr. 23/30, 2019).

[181] *See supra* notes 123-129 and accompanying text.

[182] MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 414 (March 2018), *available at* http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf ("They can also reduce waste by, for example, initially dispensing a 7- or 14-day supply and observing the patient for side effects, treatment effectiveness, and adherence before providing a 30-day supply.").

thirty-day supply. In a 2019 senate hearing, Ohio's Senator Portman stated, "The bottom line is that a lot of drugs are being thrown away because of the packaging and we should only be paying for the products patients actually use."[183]

Some insurers already offer split-fill or partial fill programs for specialty drugs. For example, BlueCross BlueShield of New Mexico allows patients with new prescriptions for one of eight listed drugs to obtain an initial sixteen-day supply to determine if they can tolerate the medication.[184] ClearScript limits participants to a fifteen-day supply of certain high cost specialty medications for the first six fills.[185] The cost-savings generated by general adoption of this approach would likely be significant.

3. Conflict of Interest and Patient Choice

PBMs should not be permitted to dictate that patients must purchase their drugs from their own specialty pharmacies and obtain them only through mail order.[186] Such rules raise concerns about conflict of interest and are likely designed to enrich PBMs.[187] They also deprive patients of choice and autonomy and are vexing to individuals who prefer face-to-face contact with pharmacists and more control over the timing and delivery of their medications.[188]

Nationally consistent rules should promote patient choice. All patients should be able to choose between mail order and retail pharmacies unless it is impossible for them to obtain a particular drug from a local pharmacy. If PBMs wish to offer patients incentives for opting for mail order delivery, those incentives should be modest and capped at a particular amount. Moreover, patients who have access to more than one pharmacy that can supply the drug should be able to utilize whichever pharmacy they prefer.

4. Antitrust Enforcement

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[183] Sabrina Eaton, *Senators Question Pharmaceutical Executives*, PLAIN DEALER, Feb. 27, 2019.

[184] BLUECROSS BLUESHIELD OF NEW MEXICO, 2019 PROVIDER REFERENCE MANUAL 14-9, Mar. 2019, https://www.bcbsnm.com/pdf/provider_ref_manual/prov_man_toc.pdf#page=113. The eight medications are Bosulif®, Lysodren®, Nexavar®, Sutent®, Tarceva®, Targretin®, Zolinza®, and Zytiga®.

[185] ClearScript, *Partial Fill Program*, Jan. 2017, https://www.preferredone.com/shared/ClearScript%20Partial%20Fill%20Program.pdf.

[186] *See supra* Part II.C.

[187] *See supra* notes 135-137.

[188] *See supra* notes 141-145.

Antitrust enforcement should be used in a creative and aggressive manner to seek to prevent the worst excesses in the specialty drug marketplace. As an example of a contemporary tying case, CVS Health was recently sued for allegedly tying its services to the services of its wholly acquired 340B[189] drug pricing program administrator Wellpartner.[190] CVS Health required its covered hospitals to use Wellpartner for its 340B program.[191] One of the plaintiffs, Sentry Data Systems, has settled its case against CVS.[192]

In a less successful challenge, Prime Aid sued Humana Inc., alleging that Humana forced its insurance beneficiaries to use its wholly-owned pharmacy, Humana Pharmacy Solutions, Inc.[193] Prime Aid's lawsuit was dismissed in the summer of 2017.[194] The court noted that Humana agreed to provide both services—health insurance and specialty pharmacy services—simultaneously in its insurance contracts.[195] Therefore, the entity that contracted with Humana for insurance services was on notice and agreed to Humana's specialty pharmacy restriction.[196]

Further, the court found that beneficiaries were not "locked-in" to Humana, as they had the option of purchasing different insurance plans every year during reenrollment.[197] Although patients may have hesitated to change health plans because of concerns about continuity of care, this concern did not constitute a lock-in, according to the district court.[198]

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[189] American Hospital Association, *Fact Sheet: The 340B Drug Pricing Program*, https://www.aha.org/factsheet/2018-03-29-fact-sheet-340b-drug-pricing-program (accessed July 22, 2019) ("Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients.").

[190] Meg McEvoy, *CVS Facing Twin Lawsuits Over Conduct in Drug Market*, BLOOMBERG LAW, May 29, 2018, https://bnanews.bna.com/health-law-and-business/cvs-facing-twin-lawsuits-over-conduct-in-drug-market.

[191] *Id*.

[192] Sentry Data Systems reaches settlement agreement with CVS and Wellpartner, Sentry Data Systems, Sept. 20, 2019, https://www.sentryds.com/sentry-data-systems-reaches-settlement-agreement-with-cvs-and-wellpartner/.

[193] Prime Aid Pharmacy Corp. v. Humana Inc., Case No. 16-2104, 2017 WL 3420933 (D.N.J. Aug. 9, 2017).

[194] *Id*. at 3.

[195] Prime Aid Pharmacy Corp. v. Humana Inc., Case No. 16-2104, 2017 WL 3420933 (D.N.J. Aug. 9, 2017) at 2.

[196] *Id.*; *Specialty Pharmacy's Antitrust Claim Against Humana Fails*, INSURANCE ANTITRUST NEWSLETTER, Baker Donelson, Aug. 31, 2017, *available at* https://www.bakerdonelson.com/new-jersey-specialty-pharmacys-antitrust-claim-against-humana-fails (last accessed Jul. 20, 2019).

[197] Prime Aid Pharmacy Corp. v. Humana Inc., supra note 193, at 3.

[198] *Id.*

An example of a successful challenge to a manufacturer's tying practice is the 1992 Federal Trade Commission (FTC) case against Sandoz Pharmaceuticals.[199] The FTC alleged that Sandoz illegally bundled its schizophrenia drug, Clozaril, with blood-monitoring services that patients could obtain from other providers.[200] The case was resolved through a consent order prohibiting Sandoz from engaging is such tying.

It is often difficult for plaintiffs to prevail in antitrust cases. However, some of the hallmarks of the specialty drug and pharmacy marketplace raise concerns about anti-competitive behavior that could be ripe for antitrust challenges.

B. Overcoming the ERISA Problem

It is natural for the states to regulate insurance and take the lead in combatting unfair and prohibitively costly specialty drug policies.[201] The primary obstacle to comprehensive protection at the state level is the ERISA preemption problem, noted several times in this Article.[202] This section explains relevant provisions of the ERISA statute. It also analyzes how Congress could empower states to regulate specialty drugs effectively and how it could develop relevant legislation on its own. All alternatives involve advantages and disadvantages, and there is no easy answer as to how reform is most likely to be achieved. For purposes of this Article we do not take a position as to which path is most promising but urge only that Congress tackle the specialty drug problem in the near future.

1. ERISA Background

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[199] Federal Trade Commission, supra note 168; Patricia M. Danzon, *Competition and Antitrust Issues in the Pharmaceutical Industry*, p. 34, https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf (July 2014).

[200] Mark A. Hurwitz, *Bundling Patented Drugs and Medical Services: An Antitrust Analysis*, 91 COLUM. L. REV. 1188, 1188 (1991).

[201] Ezekiel J. Emanuel et al., *State Options To Control Health Care Costs And Improve Quality*, HEALTH AFFFS. BLOG, Apr. 28, 2016, https://www.healthaffairs.org/do/10.1377/hblog20160428.054672/full/ ("The current political environment makes it unlikely that reforms to control system-wide health care costs will be achieved at the federal level in the near future. States, however, are well-positioned to take the lead on implementing cost control and quality improvement reforms."); National Conference of State Legislatures, *Health Insurance Regulations*, http://www.ncsl.org/research/health/health-insurance/health-insurance-regulations.aspx (last visited June 15, 2019) ("In general terms, all 50 states regulate health insurance.").

[202] *See supra* notes 105-108.

A further explanation of ERISA will provide useful context. ERISA is a federal law that governs employer-provided retirement and health plans.[203] Employer-provided health plans cover approximately 152 million Americans and thus are a critical component of the insurance landscape.[204]

ERISA includes a preemption provision establishing that the statute "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee [health] benefit plan."[205] However, the statute includes a significant preemption exception. ERISA's savings clause provides that ERISA does not preempt state laws that regulate insurance.[206] Thus, for example, a 1985 Supreme Court decision upheld a Massachusetts statute mandating that group insurance policies provide particular minimum benefits and found that it was not preempted by ERISA.[207]

The Supreme Court, however, has ruled that ERISA's "deemer clause" rolls back the savings clause exception, providing that state laws regulating insurance *are* preempted with respect to self-funded health insurance plans.[208] According to the Supreme Court, self-funded plans by which employers pay workers' medical claims out of pocket do not sufficiently resemble the "business of insurance," and states cannot deem them to be insurance plans for regulatory purposes.[209] Because over sixty percent of individuals with employer-provided health benefits (approximately one-third of the country's non-elderly population) are now in self-insured plans, this exception to the exception significantly impedes state regulatory efforts.[210]

2. Revising or Eliminating the Deemer Clause and the Option of Waivers

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[203] United States Department of Labor, *Health Plans & Benefits: ERISA*, https://www.dol.gov/general/topic/health-plans/erisa (last visited June 15, 2019).

[204] The Henry J. Kaiser Family Foundation, *2018 Employer Health Benefits Survey - Section Three: Employee Coverage, Eligibility, and Participation*, Oct. 3, 2018, https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-3-employee-coverage-eligibility-and-participation/.

[205] *Id*.

[206] 29 U.S.C. § 1144(b)(2)(A) (2010) ("Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance…").

[207] Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 724 (1985).

[208] 29 U.S.C. § 1144(b)(B) (2010); Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. at 747.

[209] Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. PA. L. REV. ___, 46 (forthcoming 2020).

[210] Erin C. Fuse Brown & Ameet Sarpatwari; *Removing ERISA's Impediment to State Health Reform*, 378 N. ENGL. J. MED. 5, 6 (2018); Fuse Brown & McCuskey, *supra* note 209, at 47.

To broaden the reach of state regulatory initiatives, Congress could revisit ERISA and either eliminate the deemer clause altogether or modify its language to state explicitly that it does not apply to self-funded plans.[211] It is likely that Congress never intended to exempt the majority of employer-provided health plans from state regulation. As Professors Fuse Brown and McCuskey note in a recent article, when Congress passed ERISA in 1974, only seven percent of individuals with employer-provided health coverage were enrolled in self-funded plans.[212] Forty-five years ago the deemer clause affected only a very small percent of American patients. The same is not true today.

However, repealing or amending the deemer clause may be an aspirational and unrealistic solution. Self-insured employers are likely to lobby vigorously against such a change, arguing that state law mandates could significantly raise their costs.[213] Moreover, large employers with facilities in multiple states will object to the burden of tracking and complying with inconsistent state law requirements. Nevertheless, amending ERISA would enable states to maintain their autonomy, tailor solutions to their own populations, and experiment creatively with different specialty drug policies.

An alternative to revising or eliminating the deemer clause would be to amend ERISA in order to establish a waiver process by which different sections of the statute could be waived, allowing for reasonable regulation of specialty drugs.[214] Professors Fuse Brown and McCuskey propose the creation of such a waiver process—one that "would lift the gate for certain state efforts"[215]

As they argue, an ERISA waiver could be flexible, and could "delegate to an agency the power to suspend certain core statutory rules" within ERISA.[216] This would likely involve a procedure whereby states could file an application for a waiver with the Department of Labor.[217] Additionally, as they note, it would "shift some of the authority over state health reform options from courts to agencies, relying on agencies' substantive expertise rather than courts' preemption precedents."[218] For our purposes, it would give enterprising states the much-needed ability to regulate the specialty drug market.

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[211] Fuse Brown & Sarpatwari, *supra* note 210, at 7; Fuse Brown & McCuskey, *supra* note 209, at 69-70.
[212] Fuse Brown & McCuskey, *supra* note 209, at 46.
[213] *Id.* at 72.
[214] *Id.* at 72. For work analyzing the use of waivers in health policy, *see* Elizabeth Y. McCuskey, *Agency Imprimatur and Health Reform Preemption*, 78 OHIO ST. L.J. 1099 (2017).
[215] Fuse Brown and McCuskey, *supra* note 163, at 72.
[216] *Id*. at 75.
[217] *Id*. at 75-76.
[218] *Id.* at 76.

3. Federal Statute Addressing Specialty Drugs

Finally, Congress could address specialty drug concerns directly through a federal statute. Unlike state law, a federal law governing specialty drugs would not be preempted by ERISA.[219]

The time may be ripe for such legislation. In 2018, Congress enacted two laws relating to PBMs: the Know the Lowest Price Act of 2018[220] and the Patient Right to Know Drug Prices Act.[221] These statutes prohibit prescription drug plans from instituting "gag clauses" that would not allow pharmacies to inform patients that they could pay less for certain prescriptions if they did not use their insurance and simply paid retail drug prices.[222]

Congress has also considering other proposals that would constrain PBMs. As noted above, a bill introduced in the 115th Congress, the Patients' Access to Treatment Act,[223] sought to limit patients' cost-sharing for specialty tier drugs, though it was not ultimately successful.[224] In 2019, Senators Lamar Alexander and Patty Murray proposed an ambitious, bipartisan bill called the "Lower Health Care Costs Act of 2019,"[225] which is under discussion at the time of this writing. In part, the proposal tackles the problem of "surprise billing."[226] To that end, the proposal would require all health care providers working in in-network facilities to accept in-network rates even if they are out-of-network clinicians.[227] A second part of the draft legislation bans PBMs' practice of spread pricing, by which PBMs

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[219] Fuse Brown & Sarpatwari, *supra* note 210, at 7.
[220] Pub. L. No. 115–262, 132 Stat. 3670 (to be codified at 42 U.S.C. § 1395w– 104).
[221] Pub. L. No. 115–263, 132 Stat. 3672 (2018) (to be codified at 21 U.S.C. § 355 note and 42 U.S.C. § 300gg–19b).
[222] The Know the Lowest Price Act of 2018 applies to prescription drug plan under Medicare or Medicare Advantage and the Patient Right to Know Drug Prices Act applies to all other health insurance plans and pharmacy benefits managers.
[223] H.R. 2999, 115th Cong., 1st Sess. (2017);
[224] See *supra* notes 123-126 and accompanying text.
[225] U.S. Senate Committee on Health, Education, Labor, and Pensions, *Senate Health Committee Leaders Release Bipartisan Discussion Draft Legislation to Reduce Health Care Costs*, May 23, 2019, https://www.help.senate.gov/chair/newsroom/press/senate-health-committee-leaders-release-bipartisan-discussion-draft-legislation-to-reduce-health-care-costs.
[226] *Id.*; Joshua Cohen, *Surprise Billing: Another Healthcare Market Failure*, FORBES, June 10, 2019, https://www.forbes.com/sites/joshuacohen/2019/06/10/surprise-billing-another-healthcare-market-failure/#12f8533a399e (explaining that surprise billing "happens when a patient receives care from a doctor or hospital outside of her insurer's network, [and thereafter] … the doctor or hospital bills the patient for the amount insurance didn't cover").
[227] Sara Heath, *Breaking Down the Senate Draft Bill on Patient Healthcare Costs*, PATIENT ENGAGEMENT HIT (May 28, 2019), https://patientengagementhit.com/news/breaking-down-the-senate-draft-bill-on-patient-healthcare-costs.

reimburse a pharmacy a particular dollar amount for a filled prescription but charge the insurer a higher price for the drug and then keep the difference.[228] The bill includes numerous other proposals, though none focuses on specialty drugs.[229]

Congress could further develop legislation relating to specialty drugs. The bill could include mandates concerning specialty drug designation, specialty tier charges, conflict of interest, and patient choice. Admittedly, however, passing any legislation that is likely to face opposition from insurers requires great political will. In the current political climate, achieving bipartisan agreement might be particularly challenging.

IV. CONCLUSION

Specialty drugs are a significant component of the American health care cost crisis, but they often fly under the radar of policy makers and scholars. Controlling drug spending is a top priority for American consumers according to public opinion polls.[230] It is wrong to assume that specialty drugs merit special deference and a hands-off approach. Quite to the contrary, they are often designated as specialty drugs at the whim of PBMs and are no more complex than many other drugs. The operations of PBMs, manufacturers, and pharmacies in the specialty drug space raise significant questions about drug classification, drug pricing, conflict of interest, patient choice, and antitrust violations. State and federal authorities must fashion remedies that protect specialty drug consumers against abuses such as unreasonable cost-sharing and PBM profiteering through their own specialty pharmacies. Such protections would constitute a meaningful step towards making American health care more affordable and accessible for severely ill patients.

[228] *Id. See also*, *supra* note 8.
[229] U.S. Senate Committee on Health, Education, Labor, and Pensions, *supra* note 225.
[230] Horvath & Anderson, *supra* note 122, at 1561.