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Before the

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Committee on the Judiciary

Reducing Prescription Drug Prices: How Competition Can Make Medications Affordable for Patients

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Chair Durbin, Ranking Member Graham, and members of the United States Senate Committee on the Judiciary, my name is Rachel Sachs and I am a Professor of Law at Washington University in St. Louis, where my research focuses on innovation into new healthcare technologies, primarily pharmaceuticals, and access to those same technologies. I also serve as a Faculty Scholar with Washington University's Institute for Public Health and a Faculty Fellow with Washington University's Cordell Institute for Policy in Medicine and Law. I am currently the Howard J. and Katherine W. Aibel Visiting Professor of Law at Harvard Law School. Thank you for the opportunity to testify before you today about the role of competition in making prescription drugs more affordable for patients and how this Committee might take steps toward solving these problems. All views I offer today are my own.[1]

In this testimony, I will explain how existing law both keeps branded drug prices high but has also enabled the development of lower-cost generic and biosimilar competition for branded prescription drugs and biological products. This competition can be used to promote access to affordable prescription drugs, benefiting not only patients but also our public payers. However, I will also explain the ways in which existing legislative and regulatory efforts have not always succeeded in promoting competition and will offer a path forward for this Committee to examine reforms that not only encourage the approval of lower-cost products but also ensure access to such products through insurance coverage, physician prescription, and pharmacy substitution. I will also situate the recently passed Inflation Reduction Act in this discussion, as it is part of this tradition of envisioning market competition from generics and biosimilars as the primary tool to drive down prescription drug prices over time.

I. How the Law Keeps Prescription Drug Prices High

Prescription drug prices in the United States are high, and too many patients have difficulty affording essential medications. Today, more than one quarter of adults report difficulty affording their prescriptions, and about 30% report not taking their medicines as prescribed — not filling a prescription, cutting pills in half, or skipping doses — because of the cost.[2] One recent study found that 30% of Medicare beneficiaries who did not have low-income subsidy support failed to fill a new prescription for cancer medication.[3] Spending for public payers is also rising. Between 2009 and 2022, the federal government's Medicare Part B spending increased from $15.4 billion to $46.9 billion, increasing an average of 8.9% per year.[4] Gross spending in Medicare Part D increased from $121.4 billion in 2014 to $240.5 billion in 2022, also growing at an average of 8.9% per year.[5] Increases in the prices of drugs, not simply increases in utilization, played key

[1] From April 2023 to April 2024, I served as a Senior Advisor at the Department of Health and Human Services Office of the General Counsel, Centers for Medicare and Medicaid Services Division.
[2] Grace Sparks et al., *Public Opinion on Prescription Drugs and Their Prices*, Kaiser Family Found. (Oct. 4, 2024), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.
[3] Stacie B. Dusetzina et al., *Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions*, 41 Health Aff. 487, 487 (2022).
[4] MedPAC, A Data Book: Health Care Spending and the Medicare Program 141 (July 2024), https://www.medpac.gov/wp-content/uploads/2024/07/July2024_MedPAC_DataBook_SEC.pdf.
[5] *Id.* at 162.

roles in these spending increases.[6] Median launch prices of new drugs have increased from $2,115 per year in 2008 to $180,007 per year in 2021.[7]

Existing legal structures enable pharmaceutical manufacturers to set and maintain high prices for prescription drugs in the United States over time in two main ways. First, through both patent law and Food & Drug Administration (FDA) regulations, manufacturers may obtain exclusive rights to make, use, and sell their branded products. Second, public payers are often required by law to provide reimbursement for those branded products, which limits the development of market competition and ties the hands of public payers in the negotiating process.

First, pharmaceutical companies typically obtain several patents granted by the United States Patent & Trademark Office (PTO) in the process of bringing their branded small-molecule drugs and biological products to market.[8] Those patents entitle the manufacturers of the relevant branded drugs to exclude others (particularly would-be generic or biosimilar competitors) from making, using, and selling the patented invention while the patents are in force. Pharmaceuticals typically have effective patent lives for their products that are approximately 12 years from approval,[9] or 14-15 years for first-in-class drugs.[10]

Prescription drugs are also typically entitled upon their approval to an exclusivity period overseen by FDA. Depending on the type of drug involved, pharmaceutical companies may receive either five years (for small-molecule drugs where there is no Paragraph IV filing), seven years (for products for rare diseases), or twelve years (for biological products) of exclusivity for their products.[11] In the case of the small-molecule and biological product exclusivity periods, during these times manufacturers seeking to bring generic or biosimilar products to market cannot rely on the clinical trial data developed by the branded drug manufacturer. As a result, these FDA-administered exclusivity periods in many ways function similarly to patents, enabling branded drug manufacturers to exclude small-molecule generic or biosimilar competition.[12]

Second, public payers have to date been structurally constrained or prohibited by statute from negotiating fair prices for these branded pharmaceutical products.[13] Focusing on Medicare, by statute Medicare Part B must cover all prescription drugs which are "reasonable and necessary

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[6] *See, e.g.*, *id.* at 142 ("Growth in the average price that Medicare Part B paid per drug was the largest factor contributing to increased spending" in Part B); *id.* at 162 ("Overall [in Part D], growth in price per prescription accounted for most (4.5 percentage points) of the 5.2 percent average annual growth in spending per beneficiary").

[7] Benjamin N. Rome, Alexander C. Egilman, & Aaron S. Kesselheim, *Trends in Prescription Drug Launch Prices, 2008-2021*, 327 J. AM. MED. ASS'N 2145, 2145 (2022). A significant portion of this trend is due to a compositional change, including the approval of more biological products (as compared to small-molecule drugs). *Id*.

[8] Caroline Horrow et al., *Patent Portfolios Protecting 10 Top-Selling Prescription Drugs*, 184 J. AM. MED. ASS'N INTERNAL MED. 810, 813 (2024) ("At FDA approval, drugs were protected by a median (IQR) of 16 (8-22) active patents.").

[9] C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 336 (2012).

[10] Bo Wang et al., *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 J. AM. MED. ASS'N INTERNAL MED. 635, 636 (2015).

[11] 21 U.S.C. § 355(j)(5)(F)(ii) (2012) (Hatch-Waxman Act, conferring five years of data exclusivity for small-molecule drugs); 21 U.S.C. § 360cc(a) (2012) (Orphan Drug Act, conferring seven years of market exclusivity for Orphan Drugs); 42 U.S.C. § 262(k)(7)(A) (2012) (Biologics Price Competition and Innovation Act, conferring twelve years of data exclusivity for biologics). To be sure, these different exclusivity periods differ slightly in terms of the type of exclusivity and its implementation, but in practice they often perform similarly.

[12] *See* Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals-Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 431 (2012).

[13] Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2308–09 (2018).

for the diagnosis or treatment of illness or injury,"[14] without regard to cost, and Part B has no structural ability to create price competition even among drugs within the same class. As a result, economic experts have referred to Medicare Part B as a "price taker,"[15] arguing that under its coverage and payment system, "a drug manufacturer with a new product with limited competition effectively sets its own Medicare payment rate."[16] At the same time, experts have noted the lack of brand-brand price competition in a class of cancer drugs with at least seven different entrants.[17] Even where there is the potential for competition — such as where multiple drugs exist in a particular class — the regulatory structure creates market power for drug manufacturers in Part B, to which Part B cannot currently provide a counterweight.

Medicare Part D plans must cover at least two FDA-approved drugs per therapeutic class,[18] and under the current statutory and regulatory structure, Part D plans must cover essentially all FDA-approved drugs in six protected classes — anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.[19] In classes where plans have a choice as to which products to cover (and assuming that multiple such products exist), plans may be able to create the conditions for brand-brand competition by offering to cover or to preference only drugs whose manufacturers offer pricing discounts. But where plans must cover essentially all drugs per class or where there are only two (or fewer) drugs per class, such price concessions are difficult to extract, and studies show that the protected class policy is associated with lower price discounts (and therefore higher prices) for products in those classes.[20]

To be sure, these laws and regulations serve important public purposes. The drug approval process is typically lengthy,[21] risky,[22] and costly, with some estimates exceeding a billion dollars for each new drug approval.[23] When juxtaposed against the relatively inexpensive process of

[14] 42 U.S.C. § 1395y(a)(1)(A) (2012).
[15] *See, e.g.*, Medicare PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM at 84 (June 2022) ("Under the Part B ASP-based payment system, the program is a price taker"); Craig L. Garthwaite, *Testimony Before the Senate Committee on Health, Education, Labor, and Pensions* at 23 (March 22, 2023), https://www.help.senate.gov/imo/media/doc/Senate_Testimony_HELP_Garthwaite.pdf.
[16] MEDICARE PAYMENT ADVISORY COMMISSION, *supra* note 15, at 84.
[17] Kyle Blankenship, *With 7 PD-(L)1s on the Market, Price Competition Hasn't Been a Factor. Will Regeneron Be the First to Ask for Less?*, ENDPOINTS NEWS (April 23, 2021), https://endpts.com/with-7-pd-1s-on-the-market-price-competition-hasnt-been-a-factor-will-regeneron-be-the-first-to-ask-for-less/.
[18] 42 C.F.R. § 423.120(b)(2)(i) (2012).
[19] 42 U.S.C. § 1395w-104(b)(3)(G)(iv) (2012).
[20] Pragya Kakani et al., *Medicare Part D Protected-Class Policy Is Associated With Lower Drug Rebates*, 43 HEALTH AFF. 1420, 1426 (2024).
[21] CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY at 14 (2021), https://www.cbo.gov/publication/57126 (noting that "on average" it takes approximately 10.5 years to bring a new drug to market, though noting that estimates differ and timing may be lower in certain fields).
[22] *Id.* at 13–14 (noting that only about 12% of products entering clinical trials are approved by the FDA).
[23] *Id.* at 14–16 (estimating the average R&D cost per new drug between $1 and $2 billion and discussing the evidentiary differences between existing studies providing such estimates).

bringing a small-molecule generic to market,[24] it is understandable that scholars,[25] policymakers,[26] and industry[27] agree that exclusive rights (through the patent and FDA exclusivity system) are important to encourage pharmaceutical innovation. Medicare's coverage requirements, including the Part D protected class rules, also serve important purposes, with Congress and the Centers for Medicare and Medicaid Services (CMS) aiming to prevent discrimination against beneficiaries with these conditions and ensure continuity of care.[28] But the combination of exclusive rights and guaranteed insurance reimbursement has allowed manufacturers to set and maintain ever-higher prescription drug prices over time.

Importantly, the Inflation Reduction Act (IRA) of 2022 begins to establish a counterweight to these types of incentives. As described below in Part II.C, the IRA is very much part of the existing approach of relying on market competition from generics and biosimilars to drive down prescription drug prices over time. But when that competition does not materialize, the IRA recognizes that these above-described market conditions and regulations may disadvantage both patients and taxpayers and creates the opportunity for Medicare to negotiate the prices it pays for prescription drugs, an authority other federal agencies already possess.

II. Promoting Access to Affordable Medicines Through Competition

Members of this Committee and other key legislative and regulatory stakeholders may seek to establish and support robust market competition in order to lower prescription drug prices and promote access to affordable drugs for patients. In many ways, the promotion of such competition has been the primary tool used by Congress and the executive branch to bring down prescription drug prices for the last 40 years, since the passage of the Hatch-Waxman Act[29] in 1984. More recently, both the Biologics Price Competition and Innovation Act (BPCIA), passed in 2009 as part of the Affordable Care Act,[30] and the IRA[31] have become part of this tradition of relying on the role of competition to lower drug prices for patients. Taken as a whole, these laws seek to encourage the approval and market entry of new small-molecule generic or biosimilar versions of branded pharmaceutical products.

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[24] *See, e.g.*, Henry Grabowski, Genia Long, & Richard Mortimer, *Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 Seton Hall L. Rev. 511, 522 (2011) ("the cost of completing bioequivalence studies for generic drugs is estimated to be only $1 to $2 million"); Aylin Sertkaya, Andreas Lord, & Clara Berger, Cost of Generic Drug Development and Approval at 8 (2021), https://aspe.hhs.gov/sites/default/files/documents/20e14b66420440b9e726c61d281cc5a5/cost-of-generic-drugs-erg.pdf (estimating total cash outlays at $2.6 million and providing an average expected capitalized cost of $6.5 million).

[25] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1617 (2003); *see also, e.g.*, Rebecca S. Eisenberg, *The Problem of New Uses*, 2 Yale J. Health Pol'y L. & Ethics 717, 720–21 (2005).

[26] Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy ch. 3, at 14 (2003).

[27] *See, e.g.*, Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 Berkeley Tech. L.J. 1255, 1286 (2009); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 2, 12 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), http://www.nber.org/papers/w7552.

[28] *See* Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., Medicare Prescription Drug Benefit Manual ch. 6, § 30.2.5 (2016), https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

[29] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[30] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, Title VII ("Biologics Price Competition and Innovation Act of 2009"), 124 Stat. 119, 804 (2010).

[31] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (2022).

A. The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984 is more frequently referred to as the Hatch-Waxman Act in honor of the two legislative leaders primarily responsible for its passage: Senator Orrin Hatch, then the Chair of the Senate Committee on Labor and Human Resources, and Representative Henry Waxman, then the Chair of the United States House Committee on Energy & Commerce, Subcommittee on Health and the Environment.[32] But the law's full name more clearly reveals one of its core goals: to promote "drug price competition." To that end, the Hatch-Waxman Act is often described as a "compromise" between the interests of the generic manufacturers and the branded drug manufacturers.[33] The statute established a simplified pathway enabling generic versions of small-molecule drugs to enter the market by relying on the clinical trial data generated by the manufacturer of the branded reference drug.[34] At the same time, it also provided branded drug manufacturers with a period of patent term restoration for some of the patent term lost as the manufacturer traversed the FDA approval process,[35] extending patent protection on the branded drug and delaying generic entry.

The generic approval pathway created by the Hatch-Waxman Act has largely been successful in several ways. First, when generic drugs enter the market, they quickly take over more than 80% of the branded drug's market share.[36] Second, the market entry of multiple generic products can drive down the price for a particular drug compound by over 90%.[37] Third, and partially as a result, generic drugs have achieved widespread acceptance: today, 91% of all prescriptions dispensed in the United States are for generic drugs.[38]

Importantly, The Hatch-Waxman Act is not the only legal intervention responsible for these high rates of generic prescription and substitution. The Hatch-Waxman Act creates the conditions for market entry of small-molecule generics, but not necessarily for their dispensation at the pharmacy counter. As a result, these high rates of generic drug uptake in the market stem significantly from state generic substitution laws. All states have laws that either permit or require pharmacists to substitute an FDA-approved generic for a prescribed branded drug.[39]

To be sure, there continues to be ongoing policy focus on the ability of small-molecule generics to be approved by FDA and to enter the market, and specifically on whether branded drug

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[32] *See, e.g., Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before the S. Comm. on Lab. & Hum. Res.*, 98th Cong. 36 (1984); *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Com.*, 98th Cong. 1 (1983).

[33] *See, e.g.*, Rachel E. Sachs, *The Accidental Innovation Policymakers*, 72 DUKE L.J. 1431, 1466–67 (2023) (describing the legislative history of the Act and the ways in which key actors described it as a compromise between these stakeholders).

[34] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, Title I ("Abbreviated New Drug Applications"), 98 Stat. 1585, 1585 (codified at 21 U.S.C. § 355(j)).

[35] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, Title II ("Patent Extension"), 98 Stat. 1585, 1598 (codified at 35 U.S.C. § 156).

[36] Benjamin N. Rome, et al., *Factors Associated With Generic Drug Uptake in the United States, 2012 to 2017*, 24 VALUE IN HEALTH 804, 806 (2021).

[37] Food & Drug Admin., *Generic Competition and Drug Prices* (Oct. 5, 2023), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (demonstrating that, with a larger number of generic entrants, prices decline by over 90% relative to the brand price).

[38] FOOD & DRUG ADMIN., OFFICE OF GENERIC DRUGS 2022 ANNUAL REPORT, at 1 (Jan. 2023), https://www.fda.gov/media/165435/download?attachment.

[39] Chana A. Sacks et al., *Assessment of Variation In State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 181 J. AM. MED. ASS'N INTERN. MED. 16, 18 (2021) (noting that 19 states mandate generic substitution and 31 states and Washington, D.C. permit but do not require substitution).

manufacturers are engaging in different types of business strategies in an attempt to delay generic competition. For example, focusing as it relates to the jurisdiction of this committee over intellectual property law, experts have identified branded pharmaceutical companies' use of continuation patents,[40] double patenting,[41] terminal disclaimers,[42] or the time limitations on the PTO staff who review patent applications[43] as potential areas of interest. Additional issues, such as the listing of patents in the Orange Book[44] or "pay for delay" agreements,[45] may also play key roles in delaying generic drug approval and market entry. But in general, the Hatch-Waxman Act has been highly effective at accomplishing its core goals.

B. The Biologics Price Competition and Innovation Act

The BPCIA as enacted in the Affordable Care Act in 2010 partially replicated Hatch-Waxman's "compromise" model for more complex biological products, creating a pathway to market for biosimilar versions of biological products in exchange for an extended period of data exclusivity for branded biologic manufacturers. The type of traditional small-molecule drugs encompassed under the Hatch Waxman Act's framework — products like aspirin or a statin, for example — are produced through standard chemical synthesis technologies. But many new prescription drugs that treat cancer or autoimmune conditions like arthritis are more complex biological products "produced by living cells,"[46] now encompassed within the BPCIA's framework. As Professors Nicholson Price & Arti Rai have written, "[i]n terms of size and rough complexity, if an aspirin were a bicycle, a small biologic would be a Toyota Prius, and a large biologic would be an F-16 fighter jet."[47]

To date, the BPCIA has been less successful at creating biologic-biosimilar competition than the Hatch-Waxman Act has been at creating brand-generic competition. Since the BPCIA's passage in 2010, as of this writing just 61 biosimilars for 17 distinct biological products have been approved,[48] and many of these have not yet been marketed. Even those biosimilars that have been

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[40] *See, e.g.*, S. Sean Tu et al., *Changes in the Number of Continuation Patents on Drugs Approved by the FDA*, 330 J. AM. MED. ASS'N 469, 470 (2023); Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 65 (2004).

[41] Mark A. Lemley & Lisa Larrimore Ouellette, *Fixing Double Patenting* (July 5, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4888563.

[42] S. Sean Tu, Rachel Goode, & William B. Feldman, *Biologic Patent Thickets and Terminal Disclaimers*, 331 J. AM. MED. ASS'N 355, 356–57 (2024).

[43] Michael D. Frakes & Melissa F. Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, 15 AM. ECON. J.: ECON. POL'Y 151, 171 (2023) (arguing that "as examiners are allocated more time to review secondary drug-patent applications, they are notably less likely to issue invalid patents" and noting that reforms providing examiners with more time may produce benefits including "earlier generic entry").

[44] Federal Trade Comm'n, *Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book* (Sept. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Jacob S. Sherkow, *Administrating Patent Litigation*, 90 WASH. L. REV. 205, 215–16 (2015).

[45] Robin C. Feldman, *The Price Tag of "Pay-for-Delay"*, 23 COLUM. SCI. & TECH. L. REV. 1 (2022).

[46] W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1026 (2016).

[47] *Id.*

[48] Food & Drug Admin., *Biosimilar Product Information* (updated Oct. 18, 2024), https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.

approved have struggled to gain market share and have driven prices down by a smaller amount (typically between 15% and 35%) than the market entrance of small-molecule generics.[49]

The relative weakness of biosimilar approval and market entry to date in the United States is traceable to a range of factors, both scientific and legal. From a legal perspective, to provide just one example, manufacturers of both potential generic and biosimilar competitors to existing branded products would benefit from being aware of the patents that cover their reference branded products. That information could be used to determine both when the primary patents covering a product's active ingredient would expire and when secondary patents covering additional uses or formulations would expire,[50] potentially enabling manufacturers of generic and biosimilar products to devise a strategy for entering the market. However, at present only small-molecule generic manufacturers (and not biosimilar manufacturers) can easily identify the patents covering the relevant branded reference product. Small-molecule drug manufacturers are required to submit all patents that reasonably cover their products to FDA,[51] and the patent information is then made public in the Orange Book.[52] Branded biologic manufacturers are not required to make such a disclosure, and there is no comprehensive public database of such biological product patents.[53] More generally, the statutory distinction between biosimilars that possess an "interchangeable" distinction and those that do not, when combined with comparatively weak state biosimilar substitution laws, has limited the uptake of even the biosimilars that have been approved. At the same time, the creation of a biosimilar pathway remains a significant step forward for the use of competition to lower prescription drug prices for patients.

C. The Inflation Reduction Act

The IRA and its creation of a Medicare drug price negotiation program are part of this tradition of envisioning market competition from generics and biosimilars as the primary tool to drive down prescription drug prices over time. That is, the IRA fundamentally still elevates the role of competition within the market (through small-molecule generic or biosimilar products) as being the primary or first strategy to lower prescription drug prices, and only if that competition does not emerge does the IRA then envision a role for Medicare to negotiate the prices of the drugs it purchases in its capacity as a market participant. In other words, the law recognizes that its previous compromises (both the Hatch-Waxman Act and BPCIA) have in some cases not fully succeeded in enabling market entry of generic and biosimilar versions of branded drugs. In those circumstances, the IRA establishes a role for the government to come to the table and negotiate to lower the prices of the drugs it purchases as an insurer, as a participant in the market for prescription drugs.

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[49] Kimberly Feng et al., *Patient Out-of-Pocket Costs for Biologic Drugs After Biosimilar Competition*, 5 J. AM. MED. ASS'N HEALTH FORUM e235429 (2024).

[50] *See, e.g.*, Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLoS ONE e49470 (2012), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470 (describing the distinction between primary and secondary patents).

[51] 21 U.S.C. § 355(b)(1)(A)(viii).

[52] 21 U.S.C. § 355(j)(7); Food & Drug Admin., *The Listing of Patent Information in the Orange Book* at 1 (2021), https://www.fda.gov/media/155200/download.

[53] Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1728 (2016) ("The Orange Book is so useful that biologics manufacturers have fought, thus far successfully, to exclude patent listings of covered biologics from the FDA's comparable Purple Book").

Perhaps most importantly, the IRA only permits a drug to qualify for negotiation after it has been FDA-approved or licensed for many years and where no generic or biosimilar competitor for the drug has been approved and marketed.[54] More specifically, the statute envisions that any prices resulting from negotiations between manufacturers and Medicare would not take effect for at least 9 years from the date of approval for small-molecule drugs, and 13 years from the date of licensure for biological products.[55] These figures represent statutory lower bounds. One of the drugs selected for the first cycle of the negotiation program, for example, was first approved in 1998 and yet lacks biosimilar competition 26 years later.[56] Once a drug has been approved for the relevant period of time, a drug that has a generic or biosimilar competitor that is approved and marketed is not eligible for selection for the negotiation program.[57] Where a drug is selected for the negotiation program, the law envisions that a drug would begin the process of being deselected from the program after such a generic or biosimilar competitor is approved and marketed.[58]

The IRA's solicitude for the role of competition in driving down prescription drug prices goes even farther in the case of biosimilars. The statute contains a "special rule" that delays the selection and negotiation of a biologic drug if there is a "high likelihood" (as so defined)[59] that a biosimilar will be "licensed and marketed" in the next two years for that biologic drug. That is, a biologic drug may avoid selection for the negotiation program even where biosimilar competition is highly likely but has not yet occurred. To be sure, the IRA also specifies that the biosimilar delay rule cannot be invoked where a biologic has been approved for more than 16 years without biosimilar competition,[60] placing an outer limit on the use of such "likely" competition to delay a product's selection into the negotiation program.

Although the preceding analysis has focused on various legal reforms which are targeted at supporting the market entry of small-molecule generic and biosimilar versions of existing branded products, it is important to make clear that the approval and market entry of such products is necessary for but not sufficient to enable robust generic competition. The example of biosimilar competition as described above most vividly illustrates these dynamics. Even where biosimilars have been approved, they must be *covered* by insurance companies in order to have the ability to lower prescription drug prices. Physicians must further decide when to *prescribe* a particular drug or its competitors to their patients. Finally, pharmacists must *substitute* the relevant small-molecule generic or biosimilar for its branded reference drug. Although FDA is approving increasing numbers of biosimilars, they often struggle to gain insurance coverage, to be prescribed by physicians, or be substituted at the pharmacy counter.

Consider the example of Humira. In 2023, 20 years after Humira was first approved, nine Humira biosimilars entered the market.[61] Yet a little over a year after the first Humira biosimilar

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[54] 42 U.S.C. § 1320f-1(e)(1).
[55] *Id.*
[56] Food & Drug Admin., *Prescribing Label: Enbrel* (Sept. 12, 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103795s5600lbl.pdf; Joshua P. Cohen, *Blockbuster Biologic Enbrel Will Continue As a Monopoly for Another 8 Years*, FORBES (May 22, 2021), https://www.forbes.com/sites/joshuacohen/2021/05/22/blockbuster-biologic-enbrel-will-continue-as-a-monopoly-for-another-8-years/.
[57] 42 U.S.C. § 1320f-1(e)(1).
[58] 42 U.S.C. § 1320f-1(c)(1).
[59] 42 U.S.C. § 1320f-1(f)(1)(A).
[60] *Id.*
[61] Fraiser Kansteiner, *As Humira Biosim Sales Languish, Boehringer Ingelheim Plots Layoffs in Pivot to Hybrid Marketing Model*, FIERCE PHARMA (April 5, 2024), https://www.fiercepharma.com/pharma/humira-biosimilar-revenues-languish-boehringer-ingelheim-plots-layoffs-pivot-hybrid-sales.

entered the market, biosimilars had captured just 4% of the market,[62] compared with the more than 80% which would be expected for a small-molecule drug. Insurers often failed to cover the Humira biosimilars or did not preference them. For example, a study focusing on Medicare Part D plans as of January 2024 found that just over half of all Part D plans covered any of Humira's biosimilars. In other words, nearly half of plans covered only Humira.[63] Physicians often prescribed Humira rather than its biosimilars.[64] And pharmacists were limited in their ability to substitute biosimilar versions at the pharmacy counter when the brand was prescribed. In the context of small-molecule generics, by contrast, additional policy efforts over the 40 years since the passage of the Hatch-Waxman Act have largely addressed these issues of insurance coverage, physician prescribing, and pharmacy substitution. To be sure, more work is needed on these fronts. But the focus of the Hatch-Waxman Act and BPCIA are fundamentally on market entry.

III. PROTECTING THE ROLE OF INNOVATION

Critics of drug pricing reform often argue that such reform will jeopardize pharmaceutical innovation in the future. For example, the trade group PhRMA memorably argued that a 2019 drug price negotiation bill would bring "nuclear winter" for innovation.[65] Because the intended result of such reform would be to pay less for existing pharmaceuticals, the argument is that prescription drug manufacturers would be less willing to maintain existing levels of research and development funding going forward, with a potential outcome being that fewer drugs are brought to market. In keeping with these arguments, the Congressional Budget Office (CBO) estimated at the time the IRA was being debated that the law would result in 2 fewer drugs brought to market in the decade after its passage, 5 over the decade after that, and 8 over the decade after that, or approximately 1% of the 1,300 drugs CBO otherwise would have expected to be approved over the next 30 years.[66] For too long, the continued apocalyptic rhetoric from industry and other stakeholders has been successful in blocking even common-sense, bipartisan drug pricing reforms, and industry and others have reacted with arguments similar in tone regardless of the size of the pricing reform, the timing in the life cycle of a product when it would take effect, and which products it would most likely impact.

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[62] Samsung Bioepis, Biosimilar Market Dynamics: 5th Edition, Q2 2024, at 20 (April 2024), https://www.samsungbioepis.com/upload/attach/SB+Biosimilar+Market+Report+Q2+2024.pdf.

[63] Matthew J. Klebanoff et al., *Formulary Coverage of Brand-Name Adalimumab and Biosimilars Across Medicare Part D Plans*, 332 J. AM. MED. ASS'N 74, 74 (2024) (finding that 53.4% of plans covered biosimilars).

[64] Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167 (2016); U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND REFORM, DRUG PRICING INVESTIGATION: ABBVIE – HUMIRA AND IMBRUVICA, at 40-42 (May 2021), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf.

[65] Jonathan Gardner, *House Passes Drug Pricing Bill That Pharma Warned Would Bring "Nuclear Winter,"* BIOPHARMA DIVE (Dec. 12, 2019), https://www.biopharmadive.com/news/house-approves-hr3-drug-pricing-bill-pharma/568966/.

[66] Cong. Budget Office, *Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation, as Posted by the Senate Committee on Finance on July 6, 2022* (July 8, 2022), https://www.cbo.gov/system/files/2022-07/senSubtitle1_Finance.pdf. CBO's final post-enactment budgetary estimate, issued after the passage of the law and after the reconciliation procedure limited some of the law's impacts, reduced these numbers, estimating that the law would result in 1 fewer drug brought to market in the decade after its passage, 5 over the decade after that, and 7 over the decade after that. Cong. Budget Office, *Summary: Estimated Budgetary Effects of Public Law 117-169* (Sept 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

One critical and often overlooked aspect of this discussion relates to not just the amount, but the value of innovation. That is, a discussion of the impact on innovation of a bill or proposed regulatory change must consider the clinical value of the relevant innovation for patients and not merely the amount of it. What matters most is innovation that delivers new clinical value for patients — for example, a drug with a novel mechanism of action or one that meets an unmet medical need.[67] Critics who point only to analyses of the number of new drugs that might or might not come to market after a law's passage but who ignore whether those new drugs would provide real clinical value to patients miss this key element.[68]

One example of this dynamic stems from the creation of Medicare Part D.[69] Economists analyzing the Part D program did find that it provided a large new financial subsidy for pharmaceutical companies and encouraged them to invest more in research on products with higher market share among senior citizens.[70] In other words, Congress' decision to provide seniors with a prescription drug plan served as a demand-side policy lever that increased rewards for pharmaceutical firms developing drugs which would be expected to have high market share under the new program.[71] Economists also found, however, that most of the increased investment in the decade after Part D's creation was concentrated in disease classes with multiple existing treatments.[72] Drug pricing reforms that would impact what Medicare pays for prescription drugs that it covers, for example, might have a greater impact on the development of me-too drugs or drugs with a number of existing therapeutic alternatives, not necessarily on first-in-class products.

More generally, the baseline of this discussion matters here. Whenever Congress or the executive branch proposes an action that might lower drug prices and improve access for beneficiaries, critics claim that it will destroy innovation.[73] But Congress has often passed laws that *expand* markets for industry, including through the creation of Medicare Part D or the Affordable Care Act. When those laws were being debated and passed, the primary discussion in Congress was framed around providing seniors or Americans with access to insurance that would allow them to pay for and access prescription drugs or health care more generally.[74] In other words, Congress did not appear to be motivated by providing large new innovation subsidies to the pharmaceutical industry through substantially expanding their potential markets in the United States. And yet, the significant expansion of markets for prescription drugs (and increased revenues for pharmaceutical manufacturers) was one effect of the passage of those laws. There is no reason to think that our current level or type of investment in innovation — driven by current patterns of insurance coverage and pricing across programs — was even chosen intentionally, let

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[67] Rachel E. Sachs, Loren Adler, & Richard Frank, *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, 1 HEALTH AFFAIRS SCHOLAR 1, 1 (July 2023); Rachel E. Sachs & Austin B. Frakt, *Innovation-Innovation Tradeoffs in Drug Pricing*, 165 ANNALS OF INTERNAL MEDICINE 871, 871 (2016).

[68] Sachs & Frakt, *supra* note 67, at 871.

[69] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (creating the Medicare Part D program).

[70] Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 327 (2013).

[71] *See generally, e.g.*, Mark A. Lemley, Lisa Larrimore Ouellette, & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 NYU L. REV. 75 (2020); Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J. L. & TECH. 153 (2016).

[72] David Dranove, Craig Garthwaite, & Manuel Hermosilla, *Pharmaceutical Profits and the Social Value of Innovation* 2–3, 6–7 (Nat'l Bureau of Econ. Research, Working Paper No. 20212, 2014).

[73] Michael A. Carrier & Genevieve Tung, *The Industry That Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019), https://www.statnews.com/2019/09/26/innovation-boy-criedwolf-pharma-industry.

[74] *See generally* Sachs, *supra* note 33.

alone represents an optimal innovation strategy. Congressional appreciation of the context for these innovation-based arguments is necessary to prevent these criticisms from becoming a one-way ratchet, in which prices and spending can only rise over time and cannot be reduced in any circumstances. This is especially concerning if the savings from those reductions would have been intended to be reinvested in additional benefits for Americans or seniors more specifically, as is true of the IRA.

The IRA provides a key illustration of these dynamics. The pharmaceutical industry and other critics of the law have continued to argue that the IRA's drug price negotiation program in particular will have harmful effects on innovation. But these critics have not considered the ways in which the IRA itself centers innovation. As I have previously argued with colleagues Dr. Richard Frank and Loren Adler, the IRA preserves "innovation *as a whole*, innovation in *certain classes of products*, and innovation specifically delivering *high value for patients*."[75]

To identify a few specific examples (though there are others), Congress directed Medicare to consider as part of the IRA's negotiation process a range of factors which specifically relate to innovation and clinical value for patients. In the negotiation process, Medicare must consider a drug's clinical value — whether it "represents a therapeutic advance as compared to existing therapeutic alternatives," the drug's "comparative effectiveness" relative to its therapeutic alternatives, and whether the drug "address[es] unmet medical needs."[76] In implementing Congress' directive, Medicare has chosen to use these factors to determine and adjust their starting point for determining initial offers to manufacturers.[77] The manufacturer of a drug selected for the negotiation program that delivers additional clinical value for patients relative to existing treatments, for example, may be able to negotiate a higher price for that drug with Medicare, relative to a drug selected for the negotiation program that does not deliver such additional clinical value. Congress also instructed Medicare to consider the "research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs.[78] In implementing this statutory directive, Medicare has stated that "if a Primary Manufacturer has not recouped its R&D costs, [Medicare] may consider adjusting the preliminary price upward,"[79] reflecting the agency's solicitude for innovation incentives. Taken as a whole, the IRA's negotiation process has been constructed in a way that "should maintain strong financial incentives for manufacturers to develop new drugs that represent clinical improvements and to invest in the development of evidence to demonstrate those improvements."[80]

Early empirical analyses of R&D investments after the passage of the IRA support this conclusion. Given the recency of the law, several analyses have begun to look at markers of early innovation activity, including mergers and acquisitions (M&A) and venture capital funding. One analysis of M&A found "little evidence suggesting a disruption in activities and investments that will yield new pharmaceutical products in the years to come," including "for the number of M&A deals being pursued, the total dollars being spent on M&A, and importantly, the types of products

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[75] Sachs, Adler, & Frank, *supra* note 67.
[76] 42 U.S.C. § 1320f-3(e)(2).
[77] Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at Section 60.3 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.
[78] *Id*. at § 1320f-3(e)(1).
[79] Ctrs. for Medicare & Medicaid Servs., *supra* note 77, at 259.
[80] Sachs, Adler, & Frank, *supra* note 67.

involved in M&A actions including early stage (small molecule drugs) and products that serve older adults."[81] Two analyses of venture capital investments — one by CBO and one by independent academic researchers — similarly found "no evidence of a systematic decrease in the percentage of venture capital flowing to pharmaceutical companies after August 2022 — or in the period immediately preceding the law's enactment."[82] To be sure, there may be reasons why potential negative impacts of the IRA would not be observable in data like these. But it is also possible that "the IRA will not have the adverse consequences some of the discourse around it suggests or that the law's effects will not manifest as changes in investment levels, but rather changes in investment allocation across drug development projects."[83] Analyses using historical data similarly suggest that the IRA "will not likely result in large-scale defunding of research and development."[84] It will be critical to assess the impact of the IRA on a range of innovation outcomes – for example, experts have also highlighted the potential for the law to affect the ways in which manufacturers of oncology products seek to sequence clinical trials for new indications for those products.[85] But at least at this time, the apocalyptic projections of many industry pundits do not appear to be on the horizon.

Many critics argue that innovation will be harmed no matter what the potential drug pricing reform is. Former Health and Human Services Secretary Alex Azar, himself a former pharmaceutical company executive, has referred to this as a "tired talking point."[86] It's just not the case, he said, that "if one penny disappears from pharma profit margins, American innovation will grind to a halt."[87] Going forward, both this Committee and others must critically evaluate these types of claims in context.

IV. Areas for Legislative Focus

Congress in general — and this Committee in particular — ought to consider legislative interventions with the goal of improving prescription drug competition. To date, much of the work of this Committee has focused on the approval of both new drugs and their potential generic and biosimilar competitors, to the extent that PTO and patent law more generally play key institutional and doctrinal roles. Additional work remains to be done on this front, particularly as it relates to biosimilar approval, but necessary legislative and regulatory intervention goes beyond the context

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[81] Richard G. Frank & Ro W. Huang, *Early Claims and M&A Behavior Following Enactment of the Drug Provisions in the IRA*, Brookings (Aug. 23, 2023), https://www.brookings.edu/articles/early-claims-and-ma-behavior-following-enactment-of-the-drug-provisions-in-the-ira/.

[82] Cong. Budget Office, *Letter Re: Additional Information About Drug Price Negotiation and CBO's Simulation Model of Drug Development*, at 4-5 (Dec. 21, 2023), https://www.cbo.gov/system/files/2023-12/59792-Letter.pdf; Matthew Vogel, Rena M. Conti, & Amitabh Chandra, *Biopharma Venture Capital And The Inflation Reduction Act*, Health Affairs Forefront (March 5, 2024), https://www.healthaffairs.org/content/forefront/biopharma-venture-capital-and-inflation-reduction-act.

[83] Vogel, Conti, & Chandra, *supra*.

[84] Matthew Vogel, Pragya Kakani, Amitabh Chandra, & Rena M. Conti, *Medicare Price Negotiation and Pharmaceutical Innovation Following the Inflation Reduction Act*, 42 Nature Biotech. 406, 406 (2024).

[85] Stacie B. Dusetzina & Frank S. David, *Cancer Drug Access and Innovation Under the Inflation Reduction Act—A Balancing Act*, J. Am Med. Ass'n Oncology (Oct. 24, 2024).

[86] Carolyn Y. Johnson, *Trump's Big Campaign Promise on Drug Prices Wouldn't Have Worked, Health and Human Services Secretary Says*, Wash. Post. (May 14, 2018), https://www.washingtonpost.com/news/wonk/wp/2018/05/14/trumps-big-campaign-promise-on-drug-prices-wouldnt-have-worked-health-and-human-services-secretary-says/.

[87] Alison Kodjak, *Trump Administration's 3 Biggest Ideas For Lowering Drug Prices*, Nat'l Pub. Radio (May 14, 2018), https://www.npr.org/sections/health-shots/2018/05/14/611075950/trump-administrations-3-biggest-ideas-for-lowering-drug-prices.

of approval. For example, as articulated above, biosimilars must not only be approved, but also covered by insurance companies, prescribed by physicians, and substituted by pharmacists for their branded reference drug. Legislative and regulatory intervention at each of these stages — particularly at the often-overlooked stages of coverage and prescription — are likely to be essential to more thoroughly establish robust competition in the prescription drug marketplace. Many of the below-described policy categories have elements that fall within the jurisdiction of this Committee, but some may require additional support from other Committees.

A. Approval

The Hatch-Waxman Act and the BPCIA provide the foundation for approval of generic and biosimilar versions of branded prescription drugs. However, more work can be done — particularly in the context of biosimilar products — to respond to efforts by branded drug manufacturers to extend their monopoly periods and discourage generic or biosimilar entry. Much of this work would be squarely within the substantive jurisdiction of this committee. Bills including the Interagency Patent Coordination and Improvement Act of 2023,[88] Preserve Access to Affordable Generics and Biosimilars Act,[89] Stop STALLING Act,[90] and Affordable Prescriptions for Patients Act of 2023[91] are all intended to help promote such market entry.

Recent actions by the Federal Trade Commission challenging over 400 patents allegedly improperly or inaccurately listed in the Orange Book would also fall into this category,[92] as "[b]y listing patents [in the Orange Book], brand drug manufacturers may benefit from a 30-month stay of FDA approval of generic drug applications, regardless of whether a court ultimately finds the patent at issue is valid or infringed by the competing product."[93] The Committee might seek to support the Commission's activities in this area.

B. Coverage

Even where a generic or biosimilar competitor has been approved, insurance companies must decide both *whether* and, if so, *how* to provide coverage for that competitor. As noted above, in the context of many biosimilar products, insurers have been slow to cover lower-priced versions of branded biological products. Many of these decisions by insurers regarding which products to cover on their formularies will be mediated through insurers' relationships with pharmacy benefit managers (PBMs). PBMs negotiate with pharmaceutical companies on insurers' behalf and play a role in deciding which drugs will be covered by insurers, and in theory PBMs work to obtain

[88] S. 79, 118th Cong., https://www.congress.gov/bill/118th-congress/senate-bill/79.
[89] S. 142, 118th Cong., https://www.congress.gov/bill/118th-congress/senate-bill/142.
[90] S. 148, 118th Cong., https://www.congress.gov/bill/118th-congress/senate-bill/148.
[91] S. 150, 118th Cong., https://www.congress.gov/bill/118th-congress/senate-bill/150.
[92] Federal Trade Comm'n, *FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs* (April 30, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.
[93] Federal Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, at 1 (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

pricing discounts for those insurers.[94] A PBM might, for example, negotiate a preferred formulary placement for a particular drug in exchange for the manufacturer offering a discount on that drug.[95]

In practice, PBMs have been increasingly criticized for "steer[ing] patients toward pricier drugs, charg[ing] steep markups on what would otherwise be inexpensive medicines and extract[ing] billions of dollars in hidden fees."[96] A recent Federal Trade Commission report documented the ways in which PBMs sometimes "negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives."[97] Both the Federal Trade Commission and several state attorneys general have now sued the nation's largest PBMs over their conduct in the market for insulin, alleging that the PBMs' business practices preferenced high list price products over lower list price products, and that doing so harmed both competition and patients.[98] This Committee should consider to what extent elements of PBM reform might be implemented through its jurisdiction, including through support for the Commission's lawsuit against the PBMs.

C. PRESCRIPTION

At present, in the case of biosimilar versions of branded biological products, approval and coverage are not enough. For non-interchangeable biosimilars, physicians must also decide when to prescribe a particular drug or its competitors to their patients. This Committee might work collaboratively with other Committees to encourage the prescribing of lower-cost products where they exist, either through legislation that would influence physicians themselves or that would influence insurers' relationships with physicians. For example, many experts have previously argued for reform of the existing payment system for prescription drugs within Medicare Part B, arguing that the existing system "can create incentives for some providers to choose higher-priced products over lower-priced products."[99] Some physician-centered reforms to the Part B average sales price-based payment structure might move toward a flat fee reimbursement structure,[100]

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[94] Robin Feldman, *The Devil in the Tiers*, 8 J.L. & BIOSCIENCES 1, 10 (2021).
[95] *Id.* at 12.
[96] Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, N.Y. TIMES (June 21, 2024), https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html.
[97] FEDERAL TRADE COMM'N, PHARMACY BENEFIT MANAGERS: THE POWERFUL MIDDLEMEN INFLATING DRUG COSTS AND SQUEEZING MAIN STREET PHARMACIES – INTERIM STAFF REPORT at 4 (July 2024).
[98] Fed. Trade Comm'n, *FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices* (Sept. 20, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices; Benjamin Ryan, *California Joins Other States in Suing Companies Over Insulin Prices*, N.Y. TIMES (Jan. 18, 2023), https://www.nytimes.com/2023/01/18/health/insulin-drug-prices-california.html; Casey Smith, *Indiana AG Todd Rokita Files Lawsuit Against Drug Companies, PBMs Over Inflated Insulin Prices*, INDIANA CAPITAL CHRON. (March 20, 2024), https://indianacapitalchronicle.com/2024/03/20/indiana-ag-todd-rokita-files-lawsuit-against-drug-companies-pbms-over-inflated-insulin-prices/; Emily Olsen, *Texas Sues Major PBMs, Pharma Companies Over High Insulin Prices*, HEALTHCARE DIVE (Oct. 4, 2024), https://www.healthcaredive.com/news/texas-pharmacy-benefit-manager-pharma-company-lawsuit-insulin-prices/728937/.
[99] *See, e.g.*, MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM at 32 (June 2023).
[100] *See, e.g.*, MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM at 62 (June 2015) (presenting "two policy options that convert part or all of the 6 percent add-on to a flat fee add-on").

while others would pursue reforms at the level of the institution or insurer, such as Medicare's Accountable Care Organization program.[101]

D. SUBSTITUTION

Finally, increasing pharmacists' ability to substitute a small-molecule generic or biosimilar product for its branded reference drug is critical to ensuring patient access to these products. While state generic substitution laws are robust, current state laws regarding biosimilar substitution typically only permit pharmacists to substitute a biosimilar for its branded reference biologic where the biosimilar has been deemed "interchangeable" by FDA.[102] To date, most of the approved biosimilars lack the interchangeable designation, limiting their ability to gain market share.[103]

FDA has more recently, however, published research finding "no difference in the safety profiles" of patients who "switched" between a biologic and an approved biosimilar product,[104] including but not limited to those without the "interchangeable" designation.[105] Following from the conclusions of this research,[106] in June 2024 FDA issued draft guidance proposing that manufacturers may attempt to demonstrate interchangeability without requiring a fully separate switching study.[107] FDA has even asked Congress to "eliminate the statutory distinction between the approval standard for biosimilar and interchangeable biosimilar products and deem that approved biosimilars are interchangeable,"[108] though Congress has not yet done so. In light of this research and FDA's scientific findings, this Committee might support efforts to alter state biosimilar prescribing statutes to permit biosimilar substitution even where FDA has not specifically determined that a biosimilar is "interchangeable" and might support efforts by other Committees regarding the existence of the "interchangeable" designation, as FDA has argued.

V. CONCLUSION

This Committee has the ability to help promote access to affordable prescription drugs through the creation of robust competition by generic and biosimilar products, benefiting not only patients but also our public payers. In considering potential avenues for reform, this Committee should consider reforms that not only help promote the FDA approval of competitive generics and

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[101] *See, e.g.*, Melissa Morley, Biruk Bekele, & Gabriel Sullivan, *Comparing Part B and D Treatment Patterns of ACO and Non-ACO Providers*, AVALERE (Oct. 22, 2020), https://avalere.com/insights/comparing-part-b-and-d-treatment-patterns-of-aco-and-non-aco-providers.

[102] Sacks et al., *supra* note 39, at 17, 18.

[103] Kevin Noonan, *FDA Approves Three Interchangeable Biosimilar Drugs in 2024*, PATENT DOCS (March 11, 2024), https://www.jdsupra.com/legalnews/fda-approves-three-interchangeable-3811961/ (noting that at the time, FDA had approved 48 biosimilars, just 10 of which were interchangeable).

[104] Thomas M. Herndon et al., *Safety Outcomes When Switching Between Biosimilars and Reference Biologics: A Systematic Review and Meta-Analysis*, 18 PLoS ONE 1, 1 (2023).

[105] *Id.* at 3.

[106] *Id.* at 11 ("The findings reported here support reducing the regulatory burden of switching studies as the default approach for addressing the switching standard for the interchangeable designation.").

[107] Food & Drug Admin., *Considerations in Demonstrating Interchangeability With a Reference Product: Update*, at 7 (June 2024), https://www.fda.gov/media/179456/download. The effect of this position on agency approvals of interchangeable biosimilars remains to be seen.

[108] Food & Drug Admin., *FY25 Legislative Proposals*, at 2 (2024), https://www.fda.gov/media/176924/download. As FDA notes, this standard would be "more consistent with… the approach adopted by other major regulatory jurisdictions such as the European Union." *Id.*

biosimilars, but that also ensure access to these lower-cost products through insurance coverage, physician prescription, and pharmacy substitution. Chair Durbin, Ranking Member Graham, and Members of the Committee, I am appreciative of your focus on this important issue and I thank you for the opportunity to testify before you today. I look forward to answering your questions.