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Committee on Energy & Commerce
Health Subcommittee

Lowering Health Care Costs for All Americans: An Examination of the Prescription Drug Supply Chain

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Key Points Regarding the Prescription Drug Supply Chain

- Today, too many Americans cannot afford important medications, and many patients report that they have not taken medication as prescribed due to its costs. Costs are high not only for patients but also for payers, both public and private. Ultimately, these systemic costs are borne by American households.

- Several different actors in the prescription drug supply chain play key roles in setting and maintaining high drug prices. Important features of the market that help keep prices high include horizontal consolidation, vertical integration, and supply chain opacity.

- *Pharmaceutical manufacturers* benefit from a combination of government-provided exclusive rights and legally guaranteed insurance reimbursement for their products, allowing manufacturers to set and maintain high prescription drug prices over time.

- *Pharmacy benefit managers (PBMs), wholesalers, and group purchasing organizations (GPOs)* are both horizontally consolidated and vertically integrated with other supply chain entities, from insurers to medical practices. Reported concerns regarding PBMs include limiting access to lower-cost products, mark-ups on specialty generics, and steering patients to private-label products. Reported concerns regarding wholesalers include limiting practices' choice of wholesalers, steering to higher-priced drugs, and revenue tied to list prices. Reported concerns regarding GPOs include contracting practices preventing uptake of new products.

- The affordability problem is driven significantly by long-lasting high prices for branded products, but also by mark-ups on both brand and generic products, particularly specialty generics. There is no single way to address these issues, and this Committee should develop a package of reforms.

- Reforms should keep in mind three common themes. First, for decades, our system has relied more on competition than on regulation to drive down drug prices. Attention should be paid to policy reforms that can make competition more effective, particularly for biosimilars. Recommendations include eliminating the statutory distinction for "interchangeable" biosimilars, oversight of and enforcement against private-label biosimilars, and adopting reimbursement strategies that encourage price competition.

- Second, where the market is already highly concentrated both horizontally and vertically, solutions beyond those that encourage competition may be needed. The Committee should exercise its oversight functions to bring more transparency to supply chain intermediary business models and learn more about business practices that may be stifling competition, potentially as a prelude to more structural separation proposals.

- Third, given companies' ability to alter their business practices to avoid enacted legislation, it will be important to consider approaches addressing reimbursement directly. This Committee should consider strengthening the Inflation Reduction Act's Medicare Drug Price Negotiation Program, including possibly by incorporating elements of international reference pricing.

Chairman Griffith, Ranking Member DeGette, and other distinguished members of the Health Subcommittee of the House Committee on Energy & Commerce, my name is Rachel Sachs and I am a Professor of Law at Washington University in St. Louis, where my research focuses on innovation and access to new healthcare technologies, primarily pharmaceuticals. I also serve as a secondary faculty member in Washington University's School of Public Health, a Faculty Co-Director of Washington University's Cordell Institute for Policy in Medicine and Law, and a Non-Resident Fellow with the Center on Health Policy at the Brookings Institution. Thank you for the opportunity to testify before you today about the role actors from across the entire prescription drug supply chain can play in addressing the drivers of high drug costs and how this Committee might take steps toward solving these problems. All views I offer today are my own.[1]

My testimony today has two primary areas of focus. First, I will explain how different actors within the prescription drug supply chain currently contribute to the problem of high drug costs and the role that law and policy play in enabling various types of conduct. Key cross-cutting issues include horizontal consolidation, vertical integration, and supply chain opacity. Second, I will identify and describe potential solutions that would act on each entity within the prescription drug ecosystem, offering both broader principles for this Committee to consider and specific policy suggestions. Importantly, due to the complexity of the prescription drug supply chain, the fragmentation of our healthcare system, and the range of legal drivers at issue, multiple approaches will be needed. Every actor in the supply chain plays a role in keeping prices high, and every actor has a role to play in ensuring affordability for both patients and our overall healthcare system. At the same time, there is no single way to accomplish this Committee's goals, and there may be opportunities to collaborate with policymakers not only in other Committees but also in the executive branch, state governments, and elsewhere in making impactful policy interventions.

I. The Problem of Unaffordable Prescription Drug Prices

Today, too many Americans cannot afford important medications. One survey found that 26% of adults have difficulty affording their prescription drugs, including 24% of people with health insurance.[2] Many patients report that they have not taken medication as prescribed due to its costs, with patients declining to fill prescriptions, skipping doses, and taking other actions to ration their medication.[3] These terrible dilemmas can have health consequences for patients, who may be more likely to become sick or even die if they cannot afford to take their medication as prescribed.[4] More than 80% of adults believe that the cost of prescription drugs is "unreasonable," and 73% — including 82% of Democrats and 68% of Republicans — say there should be more regulation surrounding the pricing of prescription drugs.[5]

Costs are high not only for patients but also for payers. Between 2009 and 2023, the federal government's Medicare Part B spending increased from $15.4 billion to $54.0 billion, an average of 9.4% per year.[6] Gross spending in Medicare Part D increased from $121.4 billion in 2014 to $276.0 billion in 2023, an average of 9.6% per year.[7] Increases in the prices of drugs, not simply increases in utilization, played key roles in these spending increases.[8] Median launch prices of new drugs have increased from $2,115 per year in 2008 to $180,007 per year in 2021.[9] Ultimately, these costs are borne by American households as taxpayers.

The United States is an outlier globally for our high drug prices. Brand-name drug list prices in the United States are more than four times higher than prices in other, peer countries.[10] Other countries deploy a range of regulatory strategies to bring down prices, including centralized

negotiation mechanisms, health technology assessment, internal and external reference pricing, market competition from lower-priced products, and other approaches.

II. How Different Actors Contribute to High Drug Prices

Many actors in the prescription drug supply chain play key roles in setting and maintaining high drug prices. In doing so, these actors are responding to existing legal and policy incentives. Important features of the market that help keep prices high and cut across the actors described below include horizontal consolidation, vertical integration, and supply chain opacity.

A. Pharmaceutical Manufacturers

Our existing legal system both provides exclusive rights to pharmaceutical manufacturers and frequently guarantees insurance reimbursement for their products. First, through both patent law and Food & Drug Administration (FDA) regulations, manufacturers may obtain exclusive rights to market their branded products. Pharmaceutical manufacturers typically obtain several patents granted by the Patent & Trademark Office (PTO) in the process of developing their branded products.[11] Approved prescription drugs are also typically entitled to an exclusivity period overseen by FDA.[12] Both patents and FDA-administered exclusivity periods enable branded drug manufacturers to exclude from the market small-molecule generic or biosimilar competition.

Second, public payers are often required by law to provide reimbursement for those products, which limits the development of competition and ties payers' hands even if they are permitted to negotiate the prices of these products.[13] Even just focusing on Medicare, Part B must

provide payment for prescription drugs which are "reasonable and necessary for the diagnosis or treatment of illness or injury"[14] without regard to cost. Economic experts have referred to Part B as a "price taker,"[15] arguing that "a drug manufacturer with a new product with limited competition effectively sets its own Medicare payment rate."[16] Even where there is the potential for competition, such as where multiple drugs exist in a particular class, Part B's regulatory structure creates market power for drug manufacturers. For example, experts have noted the lack of brand-brand price competition in a class of cancer drugs with at least seven different entrants.[17] Medicare Part D plans must cover essentially all FDA-approved drugs in six protected classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.[18] In other classes, plans must cover at least two FDA-approved drugs.[19] Where plans must cover essentially all drugs per class or where there are only two (or fewer) drugs per class, price concessions are difficult for plans to extract in exchange for coverage, and the protected class policy is associated with lower discounts (and higher prices) in those classes.[20]

To be clear, these laws and regulations serve important public purposes. The drug approval process is typically lengthy,[21] risky,[22] and costly.[23] When juxtaposed against the relatively inexpensive process of bringing a small-molecule generic to market,[24] it is understandable that scholars,[25] policymakers,[26] and industry[27] agree that exclusive rights are important to encourage pharmaceutical innovation. Coverage requirements also serve important purposes, with Congress and the Centers for Medicare & Medicaid Services (CMS) aiming to prevent discrimination against beneficiaries and ensure continuity of care.[28] But the combination of exclusive rights and guaranteed payment has allowed manufacturers to set and maintain high prescription drug prices over time. If our public payers must accept the price a branded company with exclusive rights is demanding, it will be difficult to obtain fair prices on these products. Other countries often have

similar patent and exclusivity systems to our own, but unlike the United States, they have used a variety of tools to strengthen their payers in the negotiating process to drive down prices.

Importantly, embedded within these laws is a social bargain: the government will provide pharmaceutical companies with lengthy periods of market exclusivity, to enable them to recoup their research investments and plan for future innovation, after which the public expects generic or biosimilar competitors to enter, driving down prices and improving patient access and affordability. But too often, pharmaceutical companies have violated this social bargain.[29]

The Medicare Drug Price Negotiation Program authorized in the Inflation Reduction Act (IRA) of 2022[30] begins to establish a counterweight to these types of incentives. As described below in Part III.B, the IRA is very much part of the existing approach of relying on market competition from generics and biosimilars to drive down drug prices over time. But when that competition does not materialize, the IRA recognizes that these statutory and regulatory restrictions may disadvantage both patients and taxpayers and creates the opportunity for Medicare to negotiate prices with manufacturers for certain high-cost prescription drugs.

B. Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) play key roles in defining the terms on which insurers will cover certain products. In theory, PBMs negotiate with pharmaceutical companies to obtain discounts for insurers.[31] A PBM might, for example, negotiate a preferred formulary placement for a particular drug in exchange for a discount on that drug.[32] In practice, PBMs have been 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."[33] Recent Federal

Trade Commission (FTC) reports have documented the ways in which PBMs sometimes "negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives"[34] and have "marked up numerous specialty generic drugs dispensed at their affiliated pharmacies by thousands of percent."[35]

Two key features enabling these types of business practices in the PBM industry are horizontal consolidation and vertical integration.[36] In 2024, the three leading PBMs — CVS Caremark, Express Scripts (ESI), and Optum Rx — processed nearly 80% of prescriptions,[37] and the six largest PBMs manage nearly 95% of prescriptions.[38] The market is also vertically integrated, with the three largest PBMs integrated with insurers Aetna, Cigna, and UnitedHealthcare (respectively).[39] This consolidation raises barriers to entry, making it more difficult to introduce new competition.[40] Contracting practices enabling PBMs or actors with whom they are vertically integrated to benefit financially from the rebates they negotiate can decrease PBMs' incentives to compete along a range of dimensions.[41]

PBMs and their vertically integrated insurers have a role to play in enabling patients to access lower-priced biosimilar versions of branded biological products. Recently, however, the three leading PBMs have been doing so through a strategy involving private-label biosimilars in which they have a financial interest. In 2023, nine biosimilars for the blockbuster autoimmune drug Humira entered the market.[42] But a little over a year after the first biosimilar for Humira entered the market, biosimilars had captured just 4% of the market.[43] When PBMs began to list the Humira biosimilars on their formularies, they included their own private-label biosimilars. CVS Caremark's affiliated company Cordavis partnered with Sandoz to produce a private-label Humira biosimilar.[44] As of April 2024,[45] only Humira biosimilars produced in Cordavis' partnership with Sandoz or by Sandoz itself were listed on CVS Caremark formularies.[46] Optum

Rx's affiliated company Nuvaila partnered with Amgen to produce its own private label Humira biosimilar.[47] As of January 2025, Optum Rx formularies covered only Humira biosimilars produced in Nuvaila's partnership with Amgen or by Amgen itself.[48] ESI's affiliated company[49] Quallent Pharmaceuticals partnered with both Boehringer Ingelheim and Alvotech/Teva to produce unbranded[50] Quallent-labeled biosimilars. In addition to covering those products and branded biosimilars from Boehringer Ingelheim and Alvotech/Teva, ESI also covered an unbranded Sandoz biosimilar.[51] All three PBMs have now extended this strategy to Stelara biosimilars,[52] and CVS Health has also begun to cover a private label biosimilar version of Prolia.[53]

In theory, patients benefit from these lower-priced biosimilars, and the PBMs, by driving utilization to their own biosimilars, are "making more money than [they] would have been otherwise."[54] However, this practice may stifle biosimilar competition. First, it may stifle competition in the short term by inhibiting patients' access to biosimilars that are or could be priced lower than the private label products, making it "unlikely other biosimilars will make inroads in terms of uptake."[55] By covering their own private label biosimilars and excluding most or all biosimilars produced by competing manufacturers, the PBMs limit competition in the short term by restricting other biosimilar manufacturers' ability to gain a foothold in the market and drive down prices. Second, in the longer term, the PBMs' behavior threatens the viability of the biosimilar market in general. If manufacturers not already affiliated with one of the big three PBMs know that they are unlikely to secure formulary access for a new biosimilar, limiting their availability to patients, it may decrease incentives to develop the biosimilar in the first place. PBMs that offer favorable formulary inclusion and placement to biosimilars in which they have a financial stake may discourage the development of biosimilars that will compete on price with

branded reference biologics.

Importantly, in the last several days, both Congress (though the appropriations process)[56] and the executive branch (through a proposed FTC settlement)[57] have taken important steps to address key PBM business practices, a topic to which I return in Part III.

C. Wholesalers

Wholesalers' primary function is to purchase drug products from manufacturers and distribute them to medical practices and pharmacies.[58] In theory, wholesalers ought to compete to distribute drugs to both practices and pharmacies, which have incentives to purchase lower-priced drugs. But industry consolidation (both horizontal and vertical) and the wholesaler reimbursement model threaten this potential competition. Importantly, the opacity of the market (both here and for other intermediaries) makes it difficult to determine both whether and to what extent the concerns typically associated with economic incentives and structures of this type are occurring.

As with PBMs, the wholesaler market is highly concentrated, with three wholesalers (McKesson, Cardinal Health, and Cencora – formerly known as AmerisourceBergen) controlling 98% of the market.[59] These wholesalers have also integrated vertically with related entities, including group purchasing organizations as discussed below. In particular, though, these wholesalers have completed multibillion-dollar acquisitions of medical practices, in specialties including oncology, gastroenterology, urology, rheumatology, ophthalmology, and others.[60] These acquisitions could enable the wholesalers to lock in the affiliated medical practices as customers, preventing the medical practices from using a competing wholesaler (either a current competitor or a nascent one), increasing barriers to entry.

This integration also incentivizes wholesalers to steer providers toward drugs for which profit margins are high, increasing costs overall. Further, wholesalers' revenue is tied to list prices, meaning that they have limited incentives to lower total supply chain costs.[61] As a result, efforts to compress list prices to closer to net prices may be supported by other actors within the supply chain, but could be opposed by wholesalers.

C. Group Purchasing Organizations

As their name suggests, group purchasing organizations (GPOs) primarily aim to group their members' purchasing power together, enabling the negotiation of better discounts on drugs than any member could obtain on their own. Unlike wholesalers, GPOs do not distribute the relevant products, but the rates they negotiate can be used in contracts with affiliated wholesalers.[62] GPOs are typically paid fees based on "a percentage of the sales that the members of [GPOs] purchase through the contracts negotiated by" the GPOs.[63] But the opacity of the GPO market limits clear analysis of the contracting arrangements the relevant stakeholders are engaging in.

The traditional GPO market is, like other intermediary markets, highly horizontally consolidated, with large GPOs like Vizient, HealthTrust, and Premier making up a substantial portion of the market.[64] In theory, competition among GPOs should encourage them to use aggressive contracting strategies to "steer[] member hospitals to specific brands for deeper discounts,"[65] including increased adoption of biosimilars. One strategy GPOs use to accomplish this goal is selective or percentage-based contracting, in which a hospital guarantees the purchase of a particular amount or share of a certain product in exchange for a larger discount on that

product. These contracting practices may be effective in the short term, but they "could be anticompetitive in the long run if they prevent entry or uptake of new products."[66]

Notably, the biggest three PBMs have established affiliated entities they refer to as GPOs, though they do not appear to perform the same functions that traditional GPOs do.[67] The FTC's first staff report on PBMs referred to these entities as "rebate aggregators,"[68] concluding that "the PBMs may have spun off these rebate aggregators as separate entities for other purposes, such as to retain revenue from incremental fee structures."[69] Although identifying potential interventions associated with these GPOs may be important, the regulatory approaches targeting these entities may be different from those addressed to traditional GPOs.

III. IDENTIFYING POTENTIAL SOLUTIONS

The affordability problem is multifaceted. It is driven significantly by long-lasting high prices for branded products, but also by mark-ups on both brand and generic products, particularly specialty generics. These problems are complex ones to solve, and every actor within the prescription drug supply chain has a role to play in lowering costs and ensuring affordability. This Part identifies solutions to these problems, particularly focusing on ones potentially within the jurisdiction of this Committee. Because there are multiple problems, there is no single way to address them, and this Committee should develop a package of reforms, including through collaboration with other Committees where relevant. Different reform approaches will reflect different values and center different institutional actors.

Reforms should keep in mind three common themes. First, for decades, our system has relied more on competition than on regulation to drive down drug prices. Attention should be paid

to policy reforms that can make competition more effective, particularly for biosimilars. Second, where the market is already highly concentrated both horizontally and vertically, solutions beyond those that encourage competition may be needed. Some of these solutions may relate to oversight and transparency. For example, the Committee may exercise its oversight functions to bring more transparency to supply chain intermediary business models and develop relevant data. Third and relatedly, companies' ability to alter their internal business practices to avoid proposed or enacted legislation and regulation may be significant. As such, it may not be ideal to tie proposals too closely to particular market structures. It will be important to consider approaches that address reimbursement prices directly, which are agnostic to the structure of the market.

A. Making Generic and Biosimilar Competition Effective

Since the passage of the Hatch-Waxman Act in 1984,[70] Congress has put in place tools to encourage price competition to bring down prescription drug prices over time. 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.[71] The Biologics Price Competition and Innovation Act (BPCIA) as enacted in the Affordable Care Act in 2010 created a pathway to market for biosimilar versions of biological products. The generic and biosimilar approval frameworks established in Hatch-Waxman and the BPCIA are necessary preconditions to establishing lower-priced competition. But they often have not been sufficient to make that competition effective, particularly for biosimilars. This Committee ought to aim to improve prescription drug competition, with particular focus in four core areas:

1. Approval. The Hatch-Waxman Act and the BPCIA provide the foundation for approval of generic and biosimilar versions of branded products. Congress has continued to focus attention in this area, most recently including a provision in the FY2026 appropriations package that may make it easier to bring generic competitors to market.[72] However, more work can be done particularly for biosimilars to decrease the expense and risk of approval and to increase their substitutability. FDA itself has asked Congress to "[e]liminate the [s]tatutory [d]istinction [b]etween the [a]pproval [s]tandard for [b]iosimilar and [i]nterchangeable [b]iosimilar [p]roducts and [d]eem that [a]pproved [b]iosimilars are [i]nterchangeable,"[73] building on the agency's own research finding "no difference in the safety profiles" of patients who "switched" between a biologic and an approved biosimilar product,[74] including but not limited to those without the "interchangeable" designation.[75] Eliminating this statutory distinction, either in standalone legislation or as part of the next user fee cycle, would both reduce barriers to approval and increase the number of biosimilars which could be substituted for the reference biological product (as below), potentially improving price competition.

2. Formulary 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, PBMs and insurers have been slow to cover many lower-priced biosimilars. When they have covered such products, they have often covered private-label products in which they have a financial stake, excluding unaffiliated competitors. Given the potential of these private-label arrangements to harm biosimilar competition, this Committee should consider two separate lines of policymaking. First, oversight, investigations, and potential enforcement. This Committee might draw from the FTC's 1990s investigations of drug manufacturers' proposed acquisitions of PBMs,[76] which potentially would have given the PBMs an incentive to favor the

manufacturer's drugs. In at least two cases (Eli Lilly/PCS Health System and Merck/Medco), FTC reached a settlement aiming to minimize the financial conflicts of interest and enabling the FTC to continue monitoring competition over time. Here, Congressional oversight of PBMs' practices regarding these private label biosimilars, including their relationship to potential concerns regarding exclusionary conduct or unfair competition, will be important to learn more about these companies' practices and to form the basis for potential enforcement referrals. The Committee may be aided in this effort by the PBM reform provisions in its recent FY2026 appropriations package, which include reporting requirements for PBMs within Part D that relate to this question[77] and the resulting information can, under the statute, be made available to MedPAC for its analysis.[78] Second, this Committee (potentially in collaboration with other Committees), should consider whether regulatory approaches ranging from cost-plus reimbursement models to structural separation might be appropriate, given the challenges of monitoring contracting practices within this opaque industry.

3. Prescription. For biosimilars which may be dispensed at the pharmacy and self-administered, reforming the interchangeability designation is likely to meaningfully increase competition, depending on the details of the relevant state substitution law. But for physician-administered products, experts have expressed concern that our reimbursement system currently "encourages use of higher-priced drugs over lower-priced ones."[79] This Committee might consider additional proposals to actively encourage price competition, incentivizing health care entities to stock and physicians to prescribe lower-cost drugs within a particular class. Under one MedPAC proposal, "Medicare should establish a single ASP-based payment rate for groups of drugs and biologics with similar health effects."[80] Part B already groups generic drugs together with their reference small-molecule branded drugs but does not do so for biosimilars and their reference

biologics.[81] Within a consolidated or blended billing code, reimbursement for any product within the group would be based on a weighting of the prices of the products in the group.[82] Over time, "manufacturers would have incentive to lower their prices relative to competitors to make their products more attractive to providers"[83] and physicians would be encouraged to prescribe the lower-priced biosimilars in the consolidated class. Over time, these incentives could lead to much higher biosimilar uptake within many classes of physician-administered drugs. Other, more fundamental reforms to the Part B payment system might change the existing buy-and-bill process to remove these financial incentives from health care facilities and clinicians in the first instance.[84]

4. Substitution. Increasing pharmacists' ability to substitute lower-cost products for their branded reference products is critical to ensuring patient access to these products. While state generic substitution laws are robust, current state biosimilar substitution laws typically only permit pharmacists to substitute a biosimilar for its branded reference biologic where the biosimilar has been deemed "interchangeable" by FDA.[85] Finding ways to effectuate FDA's evidence-based request to eliminate this distinction, rendering all biosimilars interchangeable, would in FDA's judgment "increase uptake of biosimilars."[86]

B. Additional Drug Pricing Reforms

Medicare Drug Price Negotiation. The IRA's Medicare Drug Price Negotiation Program[87] as currently envisioned exists within this tradition of prioritizing market competition from generics and biosimilars as a tool to drive down prescription drug prices over time. Only if a high-cost drug has been FDA-approved for many years and no generic or biosimilar competitor has been approved and marketed does the IRA envision a role for Medicare to negotiate the prices

of the drugs it purchases in its capacity as a market participant.[88] Where a drug is selected for the Negotiation Program, the law creates a process for a drug to be deselected after a generic or biosimilar competitor is approved and marketed.[89] The IRA's solicitude for the role of competition in driving down 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) that a competing biosimilar will be "licensed and marketed" in the next two years.[90]

However, the Negotiation Program remains relatively narrow in scope. The program was weakened in the 2025 reconciliation package, which expanded the program's orphan drug exemption[91] in a way that delayed the selection of blockbuster drugs Keytruda and Opdivo in the near term and likely prevented the selection of other blockbuster drugs, such as Darzalex, even in future years. The Congressional Budget Office (CBO) estimated that this expansion of the orphan drug exemption will cost $8.8 billion over a decade.[92]

This Committee might consider ways to strengthen the Negotiation Program. There are a number of potential options to consider. This Committee might eliminate or alter the 2025 reconciliation package's change to the orphan drug exemption, such as to prevent it from applying in cases where a drug has cost Medicare a certain amount of money. It is not obvious why Keytruda, the best-selling drug in the world, which brought in $31.7 billion in overall sales in 2025 alone,[93] should be delayed for selection. As just a few examples, this Committee might expand the number of drugs eligible for negotiation coupled with moving up the timeline on negotiation, alter the criteria for selecting drugs, or expand access to the program's negotiated prices to the commercial market.

International Reference Pricing. Negotiation is one but not the only way to lower drug prices. Many other countries incorporate international reference pricing as "a method for aggregating information about what other countries pay for drugs to inform pricing choices within one's own country."[94] In the United States, there has been bipartisan interest in this approach. It was incorporated into the Democratic-led Elijah E. Cummings Lower Drug Costs Now Act (otherwise known as H.R. 3)[95] as well as in a Medicare Part B interim final rule issued by the first Trump Administration.[96] The current administration has pursued this strategy more broadly, including in proposed rules within Medicare Part B and D (known as GLOBE and GUARD).[97]

International reference pricing is operationally complex,[98] but differently so than the IRA's Medicare Drug Price Negotiation Program. In passing the IRA, Congress made specific choices about which factors CMS ought to consider in the negotiation process, including whether the "drug represents a therapeutic advance," the "comparative effectiveness" of the drug relative to its therapeutic alternatives, the effects of the drug "on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations," whether the drug "address[es] unmet medical needs," and so on.[99] International reference pricing, depending on how it is used, can have the effect of delegating these important policy decisions about what it is we want to pay for — what it is we value as a society — to other countries, rather than making those judgments ourselves.

International reference pricing could be pursued on its own or as a consideration in the existing Medicare Drug Price Negotiation Program. For example, international reference prices could be used in selecting the drugs to be negotiated (those in which there is a particularly large pricing disparity), in setting the IRA's "ceiling" for offers and counteroffers, as an additional factor for CMS to consider as part of the negotiation process, or in other ways.[100] Each of these choices

would represent a different set of value judgments and create different legal and operational complexities for both this Committee and CMS.

C. Promoting Transparency and Oversight

Particularly within the portions of the prescription drug supply chain which are the most opaque, including but not limited to PBMs, wholesalers, and GPOs, this Committee should use its oversight authorities to promote transparency and to learn more about business practices that may be stifling competition. Consider PBMs. As noted above, the legislative package enacted recently is an important step toward transparency for plan sponsors and also for addressing some of the industry's long-criticized practices. But some observers have argued that the legislation's impact will "likely be muted because the major industry players have anticipated the long-debated changes and adjusted their business models to prepare for them."[101] With one observer describing the back-and-forth as a "Whac-a-Mole game,"[102] continued oversight to identify and quickly disrupt anticompetitive practices is essential.

Given these changing business models, this Committee could choose to focus not on internal industry structures but on the observed problems that result from their behaviors and regulate those practices directly. For example, one longstanding concern regarding PBM business practices has related to the ways they may harm patients through exposure to high out of pocket costs based on the list price of the drug. But insurance companies also have a key role to play in designing plans that don't expose patients to these costs. The IRA caps Medicare beneficiaries' out of pocket costs both in Part D overall and for specific types of products,[103] reducing the pressure on the list price for patients. Even if PBMs continue to preference high list, high rebate products,

by reforming the plans' financial liability, the IRA includes elements of "PBM reform." Similarly with GPOs and wholesalers, this Committee should use its oversight tools to investigate the impacts both horizontal and vertical consolidation may be having on companies' business practices and the contractual arrangements between these entities (including those who may not be represented at this hearing, such as the contracts between hospitals and GPOs). But responses may also include changing reimbursement models rather than regulating companies' business practices.

D. Responding to Consolidation

As noted throughout this testimony, many portions of the prescription drug supply chain are highly concentrated, which limits this Committee's ability to use competition as a tool to lower prices and may raise concerns regarding monopoly pricing, collusion, and anticompetitive practices in general. Fully addressing these issues may require collaboration with other Committees, but it is worth considering a number of policy proposals. One might be to attempt to prevent further consolidation in the market. To the extent that PBMs, GPOs, wholesalers, and other actors continue both horizontal and vertical merger and acquisition activity, this Committee should consider whether it can assist in scrutinizing and preventing additional consolidation.

Other proposals might seek to reverse some of the vertical integration that has already occurred. The bipartisan Patients Before Monopolies (PBM) Act is one example, intending to prohibit joint ownership of PBMs and pharmacies. Given the potential for financial conflicts of interest arising out of such joint ownership to drive up costs and harm competition in both markets, structural separation proposals like these that prohibit joint ownership that does not serve patients for medical or safety reasons may increase competition. A conceptually related bill, the Patients

Over Profits Act, would prevent insurers from purchasing health care facilities.[104] Even if these bills do not fall fully within this Committee's jurisdiction, this Committee may use its oversight authority to develop an evidence base in support of bills like these.

IV. Restoring and Strengthening the American Innovation Ecosystem

Critics of drug pricing reform often argue that such reform will jeopardize future pharmaceutical innovation, particularly if it reduces pharmaceutical company revenues (rather than, for example, reducing margins retained by intermediaries). It is important to consider how this Committee can support not only affordable access to prescription drugs, but also innovation in the next generation of therapies. Insurance reimbursement and its relationship to revenue are certainly important features in innovation decision-making,[105] but they are not the only ones.

A strong National Institutes of Health (NIH) and stable FDA are critical to American biomedical research and innovation. Recent actions taken by the Trump Administration threaten America's scientific research ecosystem in ways that undermine future innovation, as well as national competitiveness. Nearly all newly approved drugs have been supported by NIH funding.[106] But according to one analysis, in 2025 the NIH terminated or froze 5,843 research grants.[107] The agency also funded 24% fewer new grants than its previous average,[108] and the odds of being awarded a new grant fell dramatically, with success rates at the National Cancer Institute falling from one in 10 applicants to one in 25.[109] These funding cuts and the resulting disruption have led at least some American scientists to leave for other countries which promise more stable research support.[110] In its proposed FY2026 budget, the Trump Administration requested cutting

the NIH budget by roughly 40%,[111] and the CBO reported that a hypothetical cut of just 10% would decrease the number of new drugs coming to market by 4.5%.[112]

FDA has undergone particular disruption under this administration. To offer just a small number of examples, over a thousand employees left the Center for Drug Evaluation and Research (CDER) in FY2025, both voluntarily and involuntarily, approximately 18% of staff overall.[113] These departures have not been felt evenly. The FDA group reviewing products for the treatment of blood cancer has lost approximately two-thirds of its medical review staff to voluntary resignations of senior employees.[114] At the same time, "nearly 90% of senior leaders who were at the FDA a year ago are no longer with the agency."[115] In 2025, five separate officials led CDER, with the fourth, longtime agency leader Dr. Rick Pazdur, leaving just three weeks after taking the role,[116] prompting the Biotechnology Innovation Organization to criticize the "constant turmoil" at the agency and express concern that the agency is "at a tipping point."[117] Political leadership at the agency has been criticized on several grounds, including for intervening in individual product review decisions[118] and also for creating a Commissioner's National Priority Voucher program which "grants accelerated review to certain drugs selected by Trump administration officials"[119] for perceived alignment with the Administration's political priorities. At least some companies have reported receiving inconsistent advice from the agency,[120] despite stated commitments to exercise greater flexibility regarding different categories of products.

This Committee can and should both shore up federal funding for important biomedical research and stabilize ongoing turmoil at FDA. Although the recent appropriations package modestly increased NIH funding,[121] there is reason to be concerned about political interference with this funding in light of grant freezes and cancellations, including new reports regarding the lack of members on NIH review panels, which would limit the institutes' ability to issue new

grants.[122] Continued oversight will be essential. In light of the mass firings and departures at FDA, negotiations over user fee commitments during the ongoing user fee cycle will be critical. This Committee should consider a range of possible options, including clarifying the agency's obligation to spend appropriated funds on salaries and potentially raising the floor for the trigger mechanism,[123] amending existing processes to either insulate individual product review decisions from at least some layers of political interference or at a minimum raise the public salience and informational costs of political interference in such decisions, require reporting on deviations from existing procedures, etc.

IV. CONCLUSION

This Committee has the ability to help promote access to affordable prescription drugs through support for robust competition by generic and biosimilar products and oversight and investigation of opaque business practices by consolidated intermediaries in the supply chain. Chairman Griffith, Ranking Member DeGette, and Members of the Subcommittee, 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.

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[1] This testimony draws in part from my scholarly research in this area. Selected representative publications include *A New Framework for Drug Pricing Law and Policy*, __ IND. L.J. __ (forthcoming 2026, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5177133); *Competitive Concerns from Pharmacy Benefit Managers Selling Their Own Drugs*, __ YALE J. HEALTH POL'Y L. & ETHICS __ (forthcoming 2026, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5372944) (with Michael A. Carrier); *Pharmaceutical Wholesalers – Under-the-Radar Middlemen?*, 393 NEW ENG. J. MED. 1358 (2025) (with Hayden Rooke-Ley); *The Role of State Attorneys General in Improving Prescription Drug Affordability* (with Michelle Mello & Trish Riley), 95 S. CAL. L. REV. 595 (2022); *Step Therapy's Balancing Act – Protecting Patients While Addressing High Drug Prices*, 386 NEW ENG. J. MED. 901 (2022) (with Michael Anne Kyle); *Delinking Reimbursement*, 102 MINN. L. REV. 2307 (2018).

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