

Testimony of Stacie B. Dusetzina, PhD

Associate Professor of Health Policy and Ingram Associate Professor of Cancer Research
Vanderbilt University School of Medicine, Nashville, Tennessee

HEARING TITLE: The Complex Web of Prescription Drug Prices
Part II: Untangling the Web and Paths Forward

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Chairman Collins, Ranking Member Casey, and distinguished members of the Committee,

Thank you for the opportunity to testify today on the topic of prescription drug access and affordability.

My name is Stacie Dusetzina and I am an Associate Professor of Health Policy at Vanderbilt University School of Medicine. I have spent my professional career focused on prescription drugs and the policies that facilitate or impede their use. I was also a member of the National Academy of Medicine's committee on ensuring patient access to affordable drug therapies. The findings and recommendations of this consensus study report were published last year under the title "*Making Medicines Affordable: A National Imperative.*"

My research includes findings related to the prescription drug supply chain, including the role of drug rebates for increasing patient and taxpayer spending in the Medicare Part D program,^{1,2} how having higher out-of-pocket costs is associated with lower use of needed medications,^{3,4} and how prescription drug list prices and price increases over time have made many drugs unaffordable for Americans.⁵⁻⁸ My work has touched on access to prescription drugs for patients who are Medicare beneficiaries, enrolled in commercial health insurance plans, or uninsured.

In the United States, many patients are facing the reality that prescription drugs are unaffordable for them. Patients are choosing to go without treatment, even if that puts their lives at risk. For example, our work has shown that the Medicare Part D benefit requires patients to pay a percentage of the drug's price for virtually all anticancer drugs. This means that most Medicare beneficiaries needing these drugs will spend thousands of dollars out of pocket to fill their first prescription and, in some cases, over one thousand dollars per month after they reach the catastrophic coverage of the benefit. This has also been shown to occur for patients with other complex diseases.

Commercially-insured patients are also exposed to high out-of-pocket spending in some cases; particularly when they are paying deductibles (paying full price for drugs until you hit a pre-specified level of spending like \$2,500) and coinsurance (paying a percentage of the drug's price instead of a flat fee). Deductibles and coinsurance have become more common in recent years in commercial health plans and they are used in the Medicare Part D benefit, as well. Under both arrangements, patient out-of-pocket spending is calculated using the drug's "list price", which can be much higher than the price paid by the health insurance plan or the pharmacy benefits manager. For example, a patient filling an 84-day course of hepatitis C treatment on Part D

would have their out-of-pocket costs calculated based on the list price of nearly \$93,000 instead of the net price paid by their insurer and PBM of roughly \$35,000.² This could make a big difference in how much a patient is expected to spend, but both of these prices are likely to result in an out-of-pocket spending that is completely unaffordable for most people.

Insurance should be designed in a way that protects people from catastrophic levels of health care spending when they are sick. Today's Part D program does not function in that way. Instead, patients needing expensive drugs or using many drugs are exposed to unlimited out-of-pocket spending. To add to the confusion, patients cannot easily predict how much they will pay during any given visit to the pharmacy and their prices may differ at one pharmacy versus another in their same neighborhood, even under the same health plan.

Congress and the American public have heard and will continue to hear from other stakeholders involved in the prescription drug supply chain. They all point to each other as the reason for such problems. In fact, they all contribute and they all need to be engaged in solutions. The complexity of the prescription drug supply chain makes single or narrowly focused policy proposals risky. This is indeed a complex area and solutions will be complex, too.

When considering solutions, I would recommend focusing on three key goals:

- 1) Ensuring that patients have access to high value drugs at reasonable out-of-pocket cost.
- 2) Removing incentives for high list prices and price increases.
- 3) Encourage innovation by paying for value.

I thank the Committee for the opportunity to be here today and look forward to working with you on solutions to these complex problems.

Prescription Drug Spending in the United States

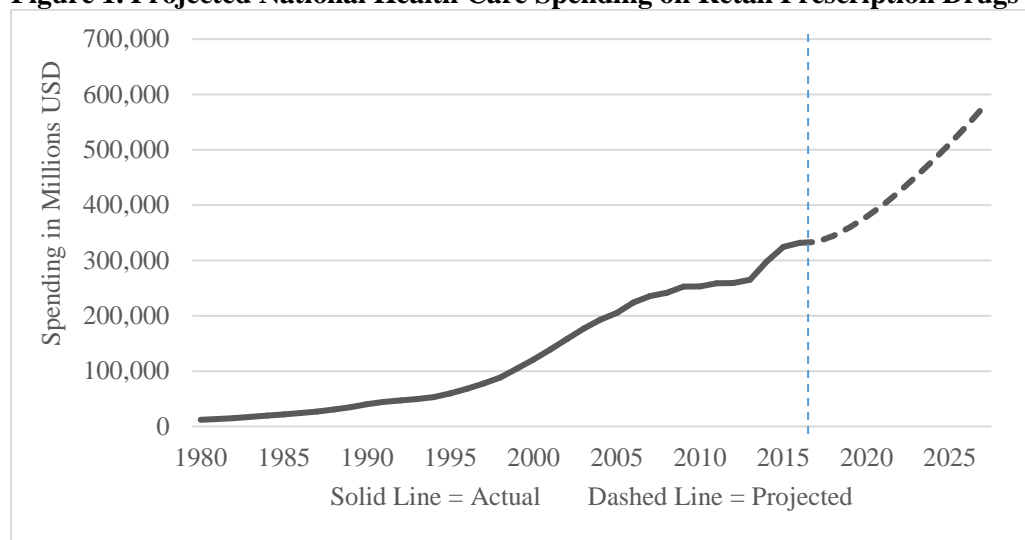
In 2017, national health expenditures for retail prescription drugs (those filled in retail pharmacies) reached nearly \$334 billion and recent projections suggest that spending could reach nearly \$600 billion by 2027.⁹ The United States now spends more on prescription drugs than other high-income countries, largely explained by higher prices paid by insurers and consumers.¹⁰⁻¹³ Brand named drug prices for widely used prescriptions increased by 8.4% in 2017, four times the rate of inflation.¹⁴ The number of high priced specialty drugs has also increased over time, with spending on these drugs likely now exceeding 50% of retail prescription drug spending on commercial health plans.¹⁵ The introduction of new and exciting technologies like curative therapies for Hepatitis C, and gene and cell therapies used to treat rare diseases such as inherited blindness and cancers for which other treatments have failed promise major advances for patients but boast substantial prices. We may in fact develop cures for diseases that only the wealthiest among us can access.

Spending on health care, including prescription drugs, is a cost that we all bear. We bear costs directly in higher premiums and less generous insurance coverage when we need to seek care. We bear costs in stagnant wages as employers aim to shield employees from rising costs. We bear costs as our taxes pay for Medicare and Medicaid.

In 2016, on average, Medicare households spent 14% of their income on health care (or \$5,355 annually); nearly the same amount spent on food.¹⁶ For those with complex health care needs, they will spend much more.

In 2015, approximately one million Medicare beneficiaries who lack out-of-pocket subsidies reached catastrophic spending levels in Part D.¹⁷ Under the current system, as drug list prices continue to climb, we should expect to see continued growth in both patient and taxpayer spending on the Part D benefit.¹ For patients filling anticancer drugs on Part D, our work has shown that they can reach catastrophic spending with one fill (or roughly one month of drug supply).⁵ Others have shown that for patients using high priced “specialty” drugs, most will spend more in the catastrophic part of the Part D benefit than in the other phases of the benefit combined.¹⁸ This means that closing the “doughnut hole” has done little to reduce patient out-of-pocket spending on high priced drugs.

Figure 1. Projected National Health Care Spending on Retail Prescription Drugs Through 2027



Source: National Health Expenditures Historical and Projections. Accessed on 2/27/2019 from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>

Why are drug prices so high?

Drug prices are high in many cases because, aside from public pressure, companies lack motivation to make drugs more affordable. This is particularly true for branded drugs that have limited or no competition¹³ and for products where payer and pharmacy benefit manager (PBM) negotiation is not functioning due to mandatory formulary inclusion of products. Even with substantial public pressure, prices are not reduced in many cases.

Take for example the now infamous drug, Daraprim, used to treat an infection called toxoplasmosis. Turing Pharmaceuticals CEO, Martin Shkreli obtained this product and increased the price from \$13.50/tablet to \$750/tablet. Despite extensive criticism by the public, media, and Congress, the price remains unchanged today and a 90-tablet prescription has a price of almost \$70,000.^{19,20} In another example, a cancer drug maker was criticized last year by physicians regarding a new pricing strategy that created a single price across a variety of drug doses when evidence suggested that patients could use a lower dose and still obtain benefit.^{21,22} The company

faced some significant media and public criticism and responded at that time that they would not increase prices as planned for the 140mg product.²³ While they kept the original 140mg version of the drug on the market, they also moved forward with the planned price increase under the new one-pill-one-price scheme where the 140mg pill has a price that is three times that of the original version. In the Medicare Part D plan finder the 140mg version of their product in a capsule costs \$4,315/month while the 140mg tablet costs \$12,682/month.

Companies largely set prices using a “what the market will bear” approach, often justifying very high prices by concerns related to the size of the population that could be treated, the costs of research and development, and the length of time available to recoup these investments. Notably, these factors are typically used to justify high prices but are rarely used to lower prices. Even in instances where products are introduced to the market at very high prices, year-to-year list price increases for these products are often well above inflation.^{7,24,25}

Prescription Drug Coverage in the United States

Out-of-pocket spending for prescription drugs is a key concern for Americans. According to a February 2019 public opinion poll, 79% of respondents believe the costs of prescription drugs is unreasonable and a majority endorse a broad range of proposals to keep costs down.²⁶

What patients pay is related to how they are insured. In 2017, over half of the population had commercial insurance (employer sponsored or individually-purchased), 21% had Medicaid insurance, 14% had Medicare insurance, and 9% were uninsured.²⁷ My remarks will focus on out-of-pocket spending for commercially-insured and Medicare insured individuals. However, it is important to note that patients without insurance would likely find that virtually all branded prescription drugs are unaffordable to them. In addition, these patients pay based on the drug’s list price and they are typically not allowed to obtain prescription drug copayment coupons to help to lower their out-of-pocket spending. They face extensive barriers to receiving medications, highlighting the importance of insurance in this context.

Side Effects of High Drug Prices: Financial Toxicity

One of the principle concerns around excessive patient out-of-pocket spending is “financial toxicity”.²⁸ This concept has been defined as a key issue for patients undergoing treatment for cancer but can be extended to other areas. For those patients who have substantial out-of-pocket spending, they may exhaust savings and retirement accounts, face housing insecurity, borrow money, or file for bankruptcy due to medical bills.²⁸ It is also well documented that higher cost sharing or unexpected changes in costs for prescription drugs can reduce patient uptake and adherence to treatments, particularly for high priced drugs.^{3,4,29-32}

Patients in employer-sponsored plans are now paying more of their out-of-pocket costs for retail prescription in the form of deductibles and coinsurance, as opposed to copays. For example, out-of-pocket spending on deductibles for commercially-insured patients grew from 28.8 percent of total cost-sharing payments in 2006 to 51.7 percent in 2016.³³ Despite having out-of-pocket maximums, many people in commercial health plans would still struggle to afford their prescriptions and these limits are high – currently \$7,900/individual or \$15,800/family. Some of my prior work has documented that, even for patients taking life saving cancer drugs, having modestly higher out-of-pocket costs was related to patients discontinuing treatment or taking less medication than prescribed. For example, patients with monthly out-of-pocket costs above

approximately \$50 had a 70% higher risk of discontinuing their cancer treatment compared with those with lower out-of-pocket costs.³

For Medicare beneficiaries, receiving Part D, those who do not receive low-income subsidies can face substantial out-of-pocket costs for prescriptions, particularly if they use expensive specialty drugs or multiple higher-cost brand-name drugs.^{5,17,18,34} Unlike most commercial insurance plans, Medicare Part D does not include a hard, annual cap on out-of-pocket costs for prescription drugs. This is true for people in traditional “fee-for-service” Medicare plans and those in Medicare Advantage plans. Today many beneficiaries have higher out-of-pocket spending in the catastrophic phase of Part D than in the other benefit phases combined.^{17,18}

For patients with commercial insurance or Medicare Part D who are paying deductibles or coinsurance, they pay these costs on the drug’s list price. For patients who are uninsured, they also face the full drug list price when filling prescriptions. Our prior work has shown that health plans, PBMs, and manufacturers all benefit in Medicare Part D when list prices increase as patients and taxpayers take on more spending in these cases.¹ List price is important for patients and increases in list prices make drugs less affordable for many patients.

National Academy of Medicine Report Recommendations

In 2018, the National Academy of Medicine released a report documenting key findings and recommendations related to making medications more affordable.³⁵ Notably, as recommendations were made in the context of a complex and opaque system, implementation of these recommendations will likely be complex. In some cases, there may be opportunities to consider demonstration or pilot projects to study the likely impact of these actions before full implementation is pursued. Further, actions directed at one area will have spillover effects in other areas, making it important to partner efforts to lower costs to patients with other initiatives to manage drug spending more broadly.

These recommendations include the following³⁵:

- a. Accelerate the market entry and use of safe and effective generics as well as biosimilars, and foster competition to ensure the continued affordability and availability of these products.
- b. Consolidate and apply governmental purchasing power, strengthen formulary design, and improve drug valuation methods.
- c. Assure greater transparency of financial flows and profit margins in the biopharmaceutical supply chain.
- d. Promote the adoption of industry codes of conduct, and discourage direct-to-consumer advertising of prescription drugs as well as direct financial incentives for patients.
- e. Modify insurance benefits designs to mitigate prescription drug cost burdens for patients.
- f. Eliminate misapplication of funds and inefficiencies in federal discount programs that are intended to aid vulnerable populations.
- g. Ensure that financial incentives for the prevention and treatment of rare diseases are not extended to widely sold drugs.
- h. Increase available information and implement reimbursement incentives to more closely align prescribing practices of clinicians with treatment value.

I believe that the Committee should prioritize actions related to the following recommendations: expediting generic entry, strengthening formulary design and improving drug valuation methods, increasing transparency, and modifying insurance benefit designs for lowering out-of-pocket spending (recommendations a, b, c, and e). These changes could produce meaningful savings for taxpayers and patients. I discuss each of these areas below.

Accelerate Generic Entry / Increase Competition

Scholars have noted the importance of generic competition for driving down drug spending by payers and patients.^{13,36,37} Branded drug manufacturers typically get an average of 12-14 years of competition free exclusivity^{38,39}. After this point, generic drug products can enter the market, offering lower priced options for patients and payers. Historically, generic entry and uptake has dramatically reduced spending for commonly used products such as statins and antihypertensive drugs. While the U.S. Food and Drug Administration has increased the number of generic drug approvals substantially over recent years,⁴⁰ competition is often dampened through anticompetitive tactics used by branded drug manufacturers such as “pay for delay”, “product hopping”, and blocking access to product samples needed for competitors to complete bioequivalence testing for FDA approval.⁴¹ Opportunities to address many of these anticompetitive tactics that serve as barriers to generic drug entry have been highlighted within recent Congressional hearings.^{42,43}

Even after products are approved, uptake of generic or biosimilar products may be hampered by health plans and PBMs electing to provide “preferred” status to branded drugs over the generic entrant. Plans would likely elect to encourage branded drugs over generics in cases where net prices for branded drugs (after rebates or discounts) are similar or lower than generic drug prices.¹⁸ This is theoretically more likely to occur with “specialty” generic drugs and biosimilars as these products often have fewer generic manufacturer entrants than in the traditional generic drug market.^{25,44} Indeed, evidence of such behavior is beginning to emerge.^{18,45,46}

Notably, by covering branded drugs on preferred status over generics, this may serve to further discourage generic competition, impeding generic drug price decreases. Patients who elect to take a generic drug in these instances may find themselves paying more for it than the branded drug, an obvious concern for encouraging generic drug use. Furthermore, for Medicare Part D beneficiaries who have high levels of drug spending, those who use generic drugs could pay more out-of-pocket for these products relative to using brands due to the coverage gap discount program. This program currently requires drug manufacturers to pay 70% of the branded drug price for products filled in the coverage gap (doughnut hole). These funds are then counted as beneficiary out-of-pocket spending and they help patients to reach the catastrophic phase of coverage faster. For example, in 2019 branded drug users who enter the coverage gap would reach catastrophic coverage after spending \$982 out-of-pocket versus \$3,730 for generic drug users (who get no manufacturer contributions).

The Committee should consider opportunities to increase competition in the specialty generic drug and biosimilar market, including modifying the Part D benefit to remove incentives for plans to use branded drugs when generics are available.

Increase Negotiating Success

The National Academy of Medicine report noted several opportunities to improve negotiations for prescription drugs, including by consolidating purchasing power, testing methods for determining product value, and allowing more flexibility in formulary design.

Regarding consolidating negotiating under Medicare Part D, there is disagreement among experts regarding the relative value of allowing the Secretary of Health and Human Services to negotiate on behalf of the Medicare Part D program. Currently, several PBMs operate on behalf of Medicare beneficiaries today and each represent millions of covered lives in the Medicare Part D program and through their commercial clients. Further consolidation of purchasing power may not drive much deeper discounts unless stricter formulary management efforts were also available.

Efforts to improve negotiations are complex, primarily because we lack leverage for negotiating in precisely those areas where treatment options are limited, or disease are complex. Notably, due to protections built into the Part D program when it was initially developed, plans are required to cover at least two products within every drug class and all the products in the “protected classes.” Protected class drugs have historically achieved very low rebates and discounts relative to drugs outside of these classes, particularly for drugs for complex diseases such as cancer, rheumatoid arthritis, and multiple sclerosis. Mandatory coverage of these products effectively reduces plan / PBM ability to negotiate, which results in higher prices to taxpayers and to patients needing such drugs.

Proposals to modify the benefit design and relax rules related to “protected class” status have been made in an attempt to reduce spending by the Part D plan sponsors and beneficiaries. However, changes to protected classes should be approached cautiously due to the importance of these drugs for patients. The Congress should carefully evaluate whether drugs within the protected classes should be subject to more scrutiny, either when prices are initially set or when prices increase.

Reference pricing, value-based pricing, or arbitration have been proposed as ways to ensure that drugs that have limited competition are priced appropriately when introduced on the market.⁴⁷ These tools could also be used to determine formulary placement of products, including which drugs should be offered at low cost or, possibly, no cost to patients.

Increasing Transparency in Financial Flows

We lack critical information regarding who benefits most under current payment arrangements. There is an intentional lack of transparency within the drug pricing and reimbursement system that should be addressed.³⁵ There are some concerns that disclosure of rebates or other price concessions may increase Medicare spending if the Part D program currently extracts larger rebates than other payers. This could theoretically occur as payers that received the largest discounts could see those discounts shrink as payers with the smallest discounts demanded lower prices. Further, there are risks that disclosure could lead to tacit collusion among companies offering similar products. The Congressional Budget Office reviewed the potential impact of disclosure in 2003 and 2007 but, to my knowledge, has not evaluated this topic since. In 2007, they determined that disclosure of Medicare rebate data would have a smaller upward impact on

prices than originally assumed.⁴⁸ It may be useful to revisit these estimates to understand the likely impact of transparency today as plans now have substantial experience with the Part D.

Transparency efforts have been proposed in some states or for some select products (e.g., insulin) and have been met with fierce resistance from the industry. However, limited disclosure of information to relevant parties may protect confidentiality of negotiations while creating a deeper understanding of areas in need of reform. Given the goals of each supply chain member to maximize their own profits, it may be beneficial to require transparency on the many transactions occurring in the system to better target policies for reducing spending overall. For example, understanding the net payments made by the health plan and PBM and the net price received from drug manufacturer would provide needed insight into how well our current negotiations are working to lower spending overall (versus shifting profits from drug manufacturers to other supply chain members).

Modifying Insurance Benefits to Lower Out-of-Pocket Spending for Patients

Patients need financial relief from high drug prices. Several policy options aimed at providing out-of-pocket savings for patients and potential challenges related to their implementation are noted below. Notably, these efforts to limit patient out-of-pocket spending must be coupled with efforts to limit drug spending more broadly to ensure that changes made here do not exacerbate drug spending overall.

Use copayments rather than coinsurance

Use of copayments (flat fees) for preferred drugs - rather than coinsurance and deductibles - may improve patient access and adherence to high-value treatments by providing more predictability for out-of-pocket expenses for patients. Because such a design may make patients less price sensitive (relative to paying a percentage of the drug's list price) plans could differentiate between preferred and non-preferred products through use of copayment tiers (with lower copayments for preferred products) to steer patients to more cost-effective treatments when competitors exist within a drug class. This recommendation would also require a statutory change to the standard benefit design in Part D, which currently requires coinsurance during the coverage gap, regardless of a plan's cost-sharing design in the initial coverage phase.

Align cost sharing to reflect value

For drugs that provide high value for preventing disease or managing disease progression, payers could use "value based" benefit design to increase access to certain high-value prescription drugs⁴⁹. Drugs used to prevent chronic disease progression or complications could be exempt from deductibles or subject to preferred (or zero) cost sharing. Evidence from value-based health plan design has focused primarily on chronic disease medications with generic competitors,⁵⁰ but this approach could also be used to offer specialty drugs with very high clinical benefit at lower out-of-pocket costs to patients.

Limit out-of-pocket spending in Part D

Medicare Part D does not currently have an annual out-of-pocket spending maximum for outpatient prescription drugs. Policymakers should consider placing a limit on out-of-pocket prescription drug spending in Part D by removing the 5 percent coinsurance payment from the

catastrophic phase of benefit. For patients using expensive drugs, the 5 percent coinsurance can represent a significant financial burden.

If an out-of-pocket spending limit is placed on Part D, the benefit should also be revised to ensure that incentives that plans and manufacturers currently have for increasing list prices are removed. One proposal advanced by the Medicare Payment Advisory Committee (MedPAC) and through the administration's Drug Pricing Blueprint recommends reducing Medicare's catastrophic phase reinsurance from 80% to 20% by incrementally increasing the proportion paid by the Part D plan sponsor and eliminating patient out-of-pocket contributions.⁵¹

Passing Through Rebates at the Point of Sale

Rebates paid to PBMs by drug manufacturers have been intensely criticized as driving up costs to individual patients who do not benefit directly from rebates at the point-of-sale. The administration recently proposed to effectively eliminate rebates from Medicare Part D, except in cases where they were fully passed through to the patient at the point of sale. Rebates can be large for some products where competition is robust. Insulin and Hepatitis C are two examples of products with large rebates, with an estimated 60% difference between list prices and net prices.² Rebates for non-competitive drugs or those in protected classes, on the other hand, are known to be limited. For example, estimated rebates for anticancer drugs are less than 12%.² Even if manufacturers converted their rebates to upfront discounts, only those taking drugs in competitive classes would realize savings; patients taking some of the most expensive medications would not. Furthermore, drug manufacturers are not likely to lower their list prices by as much as needed to maintain current spending. In the recent hearing on the topic, they noted that they might not lower list prices at all if commercial plans did not also ban rebates.

Untangling the Web and Paths Forward

Moving forward, it will be important to consider how to maintain or increase innovation in the pharmaceutical market and to align payment with treatment value. Ultimately, any action taken will involve tradeoffs. I believe there are opportunities to lower costs to patients and improve their access to drugs, and hope that these efforts will be combined with rational policies that target drug prices, increase competition, and improve transparency.

Thank you for the opportunity to testify regarding this important topic.

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