Testimony Submitted to the Senate Committee on Health, Education, Labor, and Pensions:

"Making Medicines More Affordable: How Competition Can Lower Drug Prices"

April 16, 2026

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I. INTRODUCTION

Chairman Cassidy, Ranking Member Sanders, and distinguished Members of the Committee: thank you for the opportunity to testify today regarding the critical role that generic drugs and biosimilars play in reducing prescription drug costs for American patients. I am Ryan Long, a Senior Research Fellow at the Paragon Health Institute and a Nonresident Senior Scholar at the USC Schaeffer Institute. I also previously served as Senior Policy Advisor to House Speaker Kevin McCarthy during the last user fee reauthorization cycle and as FDA Counsel and Chief Health Counsel for the House Energy and Commerce Committee when Congress considered the Food and Drug Amendments Act and the Food and Drug Safety and Innovation Act. My comments are my own and not necessarily the positions of the organizations with whom I am affiliated.

Due to the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA), generic drugs and biosimilars have collectively saved the U.S. health care system over $3 trillion in the last decade alone. [1] The opportunity for additional savings is significant.

My testimony today covers six areas: (1) the history and promise of biosimilars; (2) the design of the Hatch-Waxman framework for generic drugs; (3) progress and remaining barriers in generic drug approvals; (4) the opportunity to improve generic utilization among Medicare's most vulnerable beneficiaries; (5) the role of FDA's over-the-counter (OTC) switch policy in reducing costs; and (6) how the 340B program's incentive structure actively undermines the use of generics and biosimilars, increasing costs for all Americans.

I have a biosimilar infusion every two months. It is to prevent a flare that can make normal daily living difficult and has resulted in emergency room visits and hospitalization. I am thankful for the development of that biosimilar, but I am keenly aware that biosimilars and the promises they hold for patients do not exist unless the innovative biologic or drug is first developed. I lost a family member to a rare form of cancer four years ago and lost another family member a month after that from complications of a rare disease. My hope is that others who have loved ones struggling with disease will have treatment options that my family members did not. That can only happen if we preserve and foster an environment that rewards the initial breakthrough while permitting lower-cost generics and biosimilars to eventually flourish within that ecosystem.

[1] Association for Accessible Medicines, "2024 Generic & Biosimilar Medicines Savings Report," IQVIA Institute (2024). Cumulative savings figure covers 2014-2023.

II. BIOSIMILARS: A BIPARTISAN ACHIEVEMENT WITH UNREALIZED POTENTIAL

A. The Origins of the Biologics Price Competition and Innovation Act

Biologics—complex medicines derived from living cells—represent some of the most effective therapies in modern medicine. Until 2010, there was no approved pathway for lower-cost versions of these drugs. The BPCIA changed that. Enacted as part of the Affordable Care Act (ACA) and signed into law on March 23, 2010, the BPCIA was a bipartisan policy that passed the Energy and Commerce Committee with a 46-10 vote and this Committee by a bipartisan vote of 16-7. It established the first FDA pathway for "biosimilars"—products that are highly similar to, and have no clinically meaningful differences from, an already-approved biologic—and for "interchangeable" biosimilars that may be automatically substituted at the pharmacy.[2]

Like the Hatch-Waxman Act before it for small-molecule generics, the BPCIA sought to balance innovation and access. Biologic manufacturers receive 12 years of data exclusivity to recoup their substantial research investments. After that window, biosimilar manufacturers can seek approval by demonstrating high similarity in structure, function, safety, and efficacy without repeating all clinical trials from scratch. The intended result was to create a flourishing marketplace of lower-cost alternative biologics while allowing continued innovation to treat and cure disease.

B. How Many Biosimilars Have Been Approved?

The biosimilar pipeline has expanded substantially. Since the first approval (Zarxio) in 2015, the FDA has approved 90 biosimilars.[3] In 2025 alone, the FDA approved 18 biosimilars for multiple reference products, including new product classes.[4] Of all approved biosimilars, 25 carry an interchangeability designation, allowing pharmacists in states with substitution laws to dispense them automatically without a new prescription.[5]

The market impact of biosimilars is also substantial. Savings from biosimilar use increased more than 30 percent to $12.4 billion in 2023 alone.[6] Notable biosimilar market shares include 86 percent for trastuzumab biosimilars that treat HER2-positive breast and metastatic gastric cancers, 89 percent for bevacizumab biosimilars that treat colorectal, lung, kidney, and other cancers, and 87 percent for filgrastim biosimilars that treat chemotherapy-induced neutropenia.[7] As a patient who takes a biosimilar regularly, I am a strong proponent of ensuring access to these therapies.

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[2] Biologics Price Competition and Innovation Act of 2009, Pub. L. 111-148, Title VII, Subtitle A (2010).
[3] GaBI Online, "Biosimilars Approved in the US" (updated January 2026), available at https://gabionline.net/biosimilars/general/biosimilars-approved-in-the-us. Zarxio (filgrastim-sndz) was approved March 6, 2015.
[4] Ibid.
[5] Ibid.
[6] Association for Accessible Medicines, "2024 U.S. Generic & Biosimilar Medicines Savings Report," IQVIA Institute (2024), available at https://accessiblemeds.org/resources/reports/2024-savings-report/.
[7] Samsung Bioepis Report Showcases Adalimumab Biosimilar Growth in Market Share," Center for Biosimilars (October 11, 2024), available at https://www.centerforbiosimilars.com/view/samsung-bioepis-report-showcases-adalimumab-biosimilar-biosimilar-growth-in-market-share.

However, the drugs listed above are primarily administered in physician offices or hospital outpatient departments under Medicare Part B. In the pharmacy benefit (Part D), uptake has been far slower, exposing problems that warrant policymakers' attention.

C. What Happens to Biologic Prices After Biosimilar Entry?

Biosimilar entry was meant to create meaningful downward pressure on both biosimilar and originator biologic prices—though the effect has varied. Under Medicare Part B, biosimilar competition reduced program spending and beneficiary out-of-pocket costs on affected drugs by approximately 62 percent in 2023 compared to projected spending without biosimilar competition, and beneficiaries using these biologics saved nearly $2,000 a year on average in potential out-of-pocket costs.[8] Biosimilar uptake in Part B ranged from 26 percent to 80 percent, depending on the product.[9]

Research published in JAMA found that biosimilar entry was associated with originator biologic price reductions of 7.4 percent at one year, 31.7 percent at three years, and 43.1 percent at five years after first biosimilar entry—with the largest reductions for pegfilgrastim and infliximab.[10]

D. FDA's Move to Streamline Interchangeability: An Important Step Forward

FDA has recently moved to streamline the biosimilar approval and interchangeability designation process by eliminating the requirement for clinical studies, including switching studies and clinical efficacy studies (CES), as well as scaling back pharmacokinetic (PK) testing.

Under the traditional BPCIA framework, a biosimilar manufacturer seeking the "interchangeable" designation—which can allow for automatic pharmacy substitution—had to conduct studies requiring patients to switch back and forth between the reference biologic and the biosimilar to ensure there were not immunogenicity concerns.

In June 2024, the FDA issued draft guidance proposing that these switching studies are generally no longer necessary, noting that analytical and clinical data can instead demonstrate interchangeability.[11] In November 2025, the FDA announced it would also remove the requirement for comparative clinical efficacy studies for biosimilar approval entirely, relying instead on advanced analytical technologies.[12] FDA Commissioner Makary stated this would "shave off 3-4 years from the approval process."[13] In March 2026, the FDA further announced that it would no longer require certain PK testing, which would " save biosimilar developers up to 50% of their PK study costs, or approximately $20 million."[14]

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[8] ASPE, "Medicare Part B Enrollee Use and Spending on Biosimilars, 2018-2023" (2024), available at https://aspe.hhs.gov/reports/biosimilars-medicare-part-b.
[9] Ibid.
[10] Kevin Volpp et al., "Biologic Drug Prices in Medicare Part B After Entry of Biosimilars to the Market," JAMA Network Open (November 2025).
[11] FDA, "Considerations in Demonstrating Interchangeability With a Reference Product: Update" (Draft Guidance, June 20, 2024).
[12] "The FDA Proposes Ditching Comparative Efficacy Studies for Biosimilars," Managed Healthcare Executive (December 19, 2025).
[13] FDA Commissioner Marty Makary, M.D., remarks at GRxBiosims2025 Conference (October 29, 2025), as reported by Center for Biosimilars.
[14] https://www.fda.gov/news-events/press-announcements/fda-takes-further-steps-streamline-biosimilar-development-and-make-medicines-more-affordable.

These are welcome reforms that Congress should consider codifying.[15] But regulatory streamlining addresses only part of the challenge. Even fully approved biosimilars face a marketplace distorted by formulary design, the so-called rebate trap, and the 340B drug discount program, factors that collectively suppress biosimilar utilization.

E. The Rebate Trap: How Formulary Design Undermines Biosimilar Adoption in Part D

While biosimilar uptake in Medicare Part B has been substantial for many products, uptake in Medicare Part D remains disappointingly low. Research published in Health Affairs found substantial disparity between Medicare Part D and employer-sponsored plans in biosimilar coverage and found that Part D plan design elements actively encourage the adoption of more expensive biologic drugs.[16]

The root cause is what is commonly called the "rebate trap." To gain placement on a pharmacy benefit manager's (PBM) formulary — the list of covered drugs — manufacturers must offer rebates. PBMs and health plans prefer products with high list prices and generous rebate percentages, because rebates generate revenue for the PBM, improve the plan's net cost, and create a competitive advantage for PBMs marketing their formulary management services. A biosimilar with a genuinely low list price simply cannot offer a large enough rebate to compete for preferred formulary status with a high-price reference biologic that offers 50-60 percent rebates. Generic drugs do not face the same obstacles because of generic formulary tiers.

The 2021 Viatris launch of Semglee, a biosimilar of insulin, provides a vivid illustration. Semglee was the first FDA-approved interchangeable biosimilar in history. Yet when Viatris initially launched a non-interchangeable version of Semglee in 2020 with a wholesale acquisition cost (WAC) of $99 — a steep discount from Lantus' $284 list price — PBMs refused to grant preferred formulary status. When Semglee received its historic interchangeability designation in July 2021, Viatris was forced to triple the WAC to $279 to generate the rebate capacity needed to secure formulary access.[17]

To reach as many patients as possible, Viatris launched two versions of the same product: branded Semglee priced at a WAC of $404 per package (just below Lantus' $425) to compete for formulary placement through rebates, and an unbranded Insulin Glargine at $147.98 — 65 percent below Lantus' list price — for uninsured patients and those outside rebate-driven channels.[18] The branded Semglee received formulary placement by only one of the big three PBMs, and the non-branded Glargine was not placed on any of the three PBMs' formularies.[19]

This is the rebate trap in its purest form: a biosimilar manufacturer must artificially inflate its list price to offer a large enough rebate to entice PBMs to grant formulary access. Patients whose cost-sharing is pegged to list price pay more, not less, than they would under a direct-

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[15] Chris Medrano, "Platinum-Standard Science: FDA's New Streamlined Framework for Biosimilars and Interchangeability" Paragon Health Institute, December 2025, https://paragoninstitute.org/public-health/platinum-standard-science-fdas-new-streamlined-framework-for-biosimilars-and-interchangeability/.
[16] Luca Bertuzzi et al., "Benefit Design and Biosimilar Coverage in Medicare Part D: Evidence and Implications From Recent Reforms," Health Affairs (May 2024).
[17] Fierce Pharma, "Viatris launches two versions of its interchangeable biosimilar Semglee" (November 18, 2021).
[18] Ibid.
[19] Adam Fein, Ph.D., "Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions," Drug Channels Institute (January 2022), available at https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html.

discount model. Rebate reform—moving from a system of opaque rebates to one of transparent discounts passed directly to patients at the point of sale—would fundamentally alter this dynamic and accelerate biosimilar adoption.

The Humira biosimilar market illustrates this dynamic. By early 2024, multiple adalimumab biosimilars had received full FDA approval, and several had obtained the interchangeable designation. Yet biosimilar uptake remained stuck at just 2–3 percent of adalimumab prescriptions. PBMs kept Humira on their formularies as the preferred product. The interchangeable designation was effectively nullified by formulary design. FDA approval status proved irrelevant so long as PBMs chose to preference the branded originator.

In April 2024, CVS Health flipped its formulary to exclude Humira and preference a "private-label" biosimilar distributed through Cordavis, its wholly owned subsidiary. Within months, CVS had converted 97 percent of its commercial Humira patients to a biosimilar. Express Scripts (through its Quallent subsidiary) and OptumRx (through Nuvaila) quickly followed with their own private-label products. The result was dramatic market-share gains for biosimilars. This raises serious questions about whether vertical integration by PBMs into biosimilar distribution is producing genuine competition and patient savings or simply replacing one form of market distortion with another.

Congress and the Federal Trade Commission (FTC) have recently taken meaningful steps toward addressing the rebate trap. The Consolidated Appropriations Act of 2026, signed into law in February, mandates that PBM compensation in Medicare Part D be delinked from drug list prices and rebates, requiring instead flat-dollar, fair-market-value administrative fees. The law also requires 100 percent pass-through of all manufacturer rebates to plan sponsors in both Medicare and the commercial market, eliminating the ability of PBMs to retain rebate revenue as profit. These are structural reforms that remove, at least in the Medicare context, the financial incentive for PBMs to favor high-list-price biologics over lower-cost biosimilars.

Additionally, in February, the FTC announced a settlement with Express Scripts—one of the three largest PBMs. Under the settlement, Express Scripts is prohibited from favoring high-list-price drugs over lower-cost equivalents on its formularies, must delink its compensation from drug list prices across both Medicare and commercial plans, and must base patient out-of-pocket costs on net prices rather than inflated list prices. Taken together, these actions represent significant pressure on the model that has created the rebate trap.

III. GENERIC DRUGS AND THE HATCH-WAXMAN FRAMEWORK

A. The Power of Generic Competition: What the Data Show

U.S. patients pay less for generics than most patients around the world—Generic prices in the U.S. are 33 percent lower than the OECD median.[20] In 2024, generics accounted for approximately 90 percent of all prescriptions filled in the U.S.—the highest utilization rate in the world—and accounted for just 12 percent of total prescription drug spending.[21] In

[20] Ibid
[21] DrugPatentWatch, "Generic Drug Markets: U.S. vs. Europe" (August 28, 2025), available at https://www.drugpatentwatch.com/blog/comparing-generic-drug-markets-europe-united-states-prices-volumes-spending/.

2023, savings from the use of FDA-approved generic and biosimilar medicines totaled $445 billion for patients and the U.S. health care system.[22]

FDA data analyzing drugs with initial generic entry between 2015 and 2017 found the following:

- With a single generic producer, the generic price is approximately 39 percent lower than the brand price before generic competition.[23]
- With two competitors, generic prices are approximately 54 percent lower than the pre-entry brand price.
- With four competitors, generic prices are approximately 79 percent lower than the pre-entry brand price.
- With six or more competitors, price reductions exceed 95 percent compared to the pre-entry brand price.

In practical terms, the first generic entrant often produces a modest but real cost reduction; the second generic produces a substantial price drop—reaching roughly half the brand price; and the third generic marks the "true tipping point" where competition intensifies sharply, driving prices down by around 80 percent or more. The 2023 cohort of generic drug approvals yielded $18.6 billion in total savings, with first-generics contributing $2.4 billion (13 percent) and subsequent approvals contributing the remaining $16.2 billion.[24]

B. The Genius of Hatch-Waxman: Balancing Innovation and Access

The Drug Price Competition and Patent Term Restoration Act of 1984, colloquially known as Hatch-Waxman, represents one of the most important pieces of pharmaceutical legislation in American history. It created the Abbreviated New Drug Application (ANDA) pathway, which allows generic manufacturers to demonstrate bioequivalence to an already-approved reference drug without repeating costly clinical trials, because the FDA can rely on the data from the reference product to determine that the generic is safe and effective.

A critical component of Hatch-Waxman is the so-called "Bolar exemption," codified at 35 U.S.C. § 271(e)(1). Before the Act, the law as interpreted by the U.S. Court of Appeals for the Federal Circuit in Roche Products, Inc. v. Bolar Pharmaceutical Co. (1984) held that a generic manufacturer could be sued for patent infringement simply for conducting the bioequivalence testing needed to file an FDA application—even before a single product was sold. This ruling effectively extended a brand-name company's market exclusivity well beyond the nominal patent term, because generic competitors could not even begin the years-long development and testing process until the last patent expired. The Bolar exemption, named for that case, directly overturned this effect. It provides that it is not an act of infringement to make, use, offer to sell, or sell a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."

[22] Ibid
[23] Conrad R, Lutter R. "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices." U.S. Food and Drug Administration, December 2019.
[24] FDA, "Report Estimating Cost Savings from New Generic Drug Approvals in 2023" (2025).

The Bolar amendment allows generic companies to begin developing and testing their products during the life of a brand-name patent, so that a finished generic can reach pharmacy shelves essentially the moment the patent expires rather than years later.

Hatch-Waxman also structured an incentive for generic companies to challenge weak or invalid patents through the "Paragraph IV" certification process, awarding the first challenger a 180-day exclusivity period before other generics may enter. This important incentive has brought generic competition to market years earlier than it would have otherwise arrived, saving billions.

The genius of Hatch-Waxman was its framework to allow lower-cost generics to come to market while ensuring that patients still benefit from future innovation. It embodies the policy truth that we cannot have affordable generic drugs unless we first have the innovative branded drugs they copy. The law recognized that generics are only possible because innovation happened first and future generics are predicated on continued innovation.

C. The GDUFA Era: Transforming Generic Drug Approval Timelines

By 2012, the FDA's generic drug approval program was stalling. In March 2012, the median review time for an Abbreviated New Drug Application (ANDA) was approximately 31 months, and the FDA had a backlog of more than 2,500 pending applications. ANDAs were approved in a single review cycle less than 1 percent of the time.[25]

The Generic Drug User Fee Act (GDUFA), enacted in July 2012 as part of the FDA Safety and Innovation Act, was critical in easing the backlog and getting generics to patients more quickly. By allowing FDA to collect user fees from generic manufacturers in exchange for measurable review performance commitments, GDUFA funded additional scientific staff and modernized the review process. Under GDUFA, the FDA set goals to act on 90 percent of standard ANDAs within 10 months of submission and on priority applications within 8 months.[26]

The results have been dramatic. FDA is now meeting—and in many cases exceeding—its GDUFA performance goals. In FY 2024, FDA acted on 97 percent of standard original ANDAs within the 10-month goal and on 100 percent of priority original ANDAs within the 8-month goal, a transformation from the 31-month average of the pre-GDUFA era.[27] The FDA now processes over 1,100 generic applications annually, and the 2023 cohort of 773 fully approved ANDAs represents a performance that would not have been possible before the GDUFA era.[28] Critically, FDA met the GDUFA backlog goal in June 2016, fifteen months ahead of the September 2017 deadline, having taken action on 90 percent of the more than 2,800 ANDAs that were pending as of October 1, 2012.[29]

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[25] Congressional Research Service, "The Generic Drug User Fee Amendments (GDUFA): Background and Reauthorization" (R46778).
[26] FDA, "FDA-TRACK: Generic Drug User Fee Amendments (GDUFA) Performance Reports," available at https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance.
[27] FDA, "Generic Drugs Program Fiscal Year 2025 Activities Report" (updated FY 2024 cohort performance data), available at https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-fiscal-year-2025-activities-report.
[28] Ibid.
[29] FDA, "FY 2017 Performance Report to Congress for the Generic Drug User Fee Amendments" (2017).

D. Drug Competition Action Plan

In 2017, the FDA launched the Drug Competition Action Plan (DCAP), focused specifically on breaking down barriers to generic entry for "complex" drug products. Complex generics are products for which it is inherently more difficult to replicate the innovator product, including drug-device combinations (like inhalers and auto-injectors), extended-release injectables, and complex molecule chemical drugs. In this respect, complex molecule drugs share some of the same replication challenges as biologics, where the difficulty of fully characterizing the molecule means that establishing true sameness is scientifically difficult.

The FDA published guidance documents spelling out exactly how a manufacturer could demonstrate bioequivalence for each type of complex product. Among other products, this led to the approval of the first generic EpiPen in August 2018.

The DCAP led to critical progress on complex inhaled products used to treat asthma and COPD. Even though the active ingredients in products like Advair Diskus had been off-patent since 2010, the complexity of drug-device inhaler combinations made it nearly impossible for generic manufacturers to prove bioequivalence. Under DCAP, the FDA published specific guidance that resulted in the FDA approval of the first generic of Advair Diskus in January of 2019. The Advair example demonstrates precisely why DCAP's model of publishing clear scientific guidance for complex generics works: it creates a roadmap for manufacturers to navigate the regulatory pathway, enabling multiple entrants and patients to benefit from the price competition that followed. Under GDUFA III, FDA committed to issuing product-specific guidance for at least 50 percent of complex drug products within two years of the New Drug Application (NDA) approval and 75 percent within three years.[30] While GDUFA IV is currently being negotiated, continued focus on complex generic guidance is imperative to ensure future generic availability.

IV. GENERIC UTILIZATION: THE LIS OPPORTUNITY

A. Our Utilization Rate Leads the World

The U.S. has achieved a remarkable generic utilization rate exceeding 90 percent of all prescriptions filled.[31] Europe, by contrast, has a generic utilization rate averaging approximately 70 percent, though rates vary substantially by country.[32] Our competitive generic market and regulatory framework also lead to substantially more savings from generic utilization. In the U.S., the 90 percent generic utilization rate translates to 13 percent of total prescription drug spending, while in Europe, their 70 percent generic utilization rate accounts for 19 percent of prescription drug spending. Our high utilization rate and the associated savings are a testament to the Hatch-Waxman framework, tiered formulary design, and mandatory substitution laws in most states that together create powerful incentives to use generics whenever they are available and appropriate.

[30] GDUFA III Commitment Letter, available at https://www.fda.gov/media/153631/download.
[31] DrugPatentWatch, "A Tale of Two Markets," supra note 22.
[32] Ibid.

B. The LIS Gap: When Low Cost-Sharing Reduces Generic Use

However, evidence suggests that patients who could most benefit from generic drug prices may not be getting them. Medicare Part D beneficiaries receiving the Low-Income Subsidy (LIS) are the most economically vulnerable seniors, but they use generic drugs at a lower rate than non-LIS beneficiaries.

Research published in the American Journal of Managed Care found that dual-eligible beneficiaries and those receiving the LIS were 24 percent and 28 percent, respectively, less likely to receive a generic compared with non-subsidized beneficiaries, after controlling for patient, plan, and area characteristics.[33]

LIS beneficiaries pay very low copays for both generic and brand-name drugs. These subsidies mask the significant out-of-pocket difference between a $5 generic and a $200 brand drug, inadvertently removing an LIS beneficiary's incentive to request or accept generic drugs over brand drugs when they are available.

Research comparing generic dispensing rate (GDR) trends from 2006 through 2012 confirmed that LIS enrollees have consistently lagged non-LIS enrollees in generic substitution rates throughout Part D's history—not because they receive worse care, but because their cost-sharing structure removes the incentive.[34]

C. A Policy Fix: Restructuring LIS Cost-Sharing to Incentivize Generic Use

The solution is not to harm LIS beneficiaries but to modify the LIS cost-sharing schedule so that there is a meaningful financial incentive to choose generics over brands when a therapeutically equivalent generic is available. Structured properly, low-income seniors will see their out-of-pocket costs reduced while the program will realize savings from higher generic utilization rates.

Congress should consider: (1) lowering the LIS copay for generics to $0 or a nominal amount; and (2) modestly increasing the LIS copay for brand-name drugs when a generic equivalent is available, while ensuring that the copay remains well within reach of LIS-eligible beneficiaries' means. This change would result in lower out-of-pocket costs for beneficiaries consistent with how the rest of the Part D benefit works.

Research suggests that implementing a generic-tier $0 copay is one of the most effective tools to increase generic substitution rates among Part D beneficiaries.[35] Based on the data, if LIS beneficiaries could be brought to the same generic dispensing rates as non-LIS beneficiaries through appropriate incentive restructuring, the savings to the Medicare program and taxpayers would be meaningful. With approximately 13.5 million LIS enrollees and average annual drug costs substantially higher than those of non-LIS beneficiaries, even a modest shift toward generic utilization could yield substantial annual savings while also reducing patient copays. In 2011, the Medicare Payment Advisory Commission (MedPAC)

[33] Christine Buttorff et al., "Variation in Generic Dispensing Rates in Medicare Part D," American Journal of Managed Care (November 2020).
[34] CMS, "Does Enrollment in Generic-Tier Zero-Copay Plans Improve Generic Use?" (2013) (documenting LIS-non-LIS GDR gap from 2006-2012); Buttorff et al., supra note 37.
[35] Ibid

estimated this type of policy could save $17 billion over ten years.[36] Given that the estimate is 15 years old, the savings are likely to be dramatically higher now.

V. OVER-THE-COUNTER SWITCHES: EXPANDING ACCESS AND REDUCING COSTS

Another underappreciated tool for reducing drug costs and improving patient access is the transition of safe and effective medicines from prescription to over-the-counter (OTC) status. A 2022 study by the Consumer Healthcare Products Association (CHPA) estimated that OTC medicines save the U.S. health care system $167.1 billion annually, with $110.3 billion coming from avoided unnecessary doctor visits.[37] The direct costs avoided include physician visit copays as well as insurer reimbursements and lost patient time.

Consider common conditions like allergic rhinitis or heartburn. In many cases, patients already know what they have and what they need. Requiring them to visit a physician first — paying a copay and waiting for an appointment — to obtain a prescription for a well-understood, low-risk medicine creates cost and friction without improving safety. When these drugs switch to OTC, patients get faster access, payers save on unnecessary visits, and competition typically drives prices down.

In December 2024, the FDA finalized a rule for "Additional Conditions for Nonprescription Use" (ACNU), creating a pathway for drugs requiring extra steps — such as apps, questionnaires, or pharmacist consultations — to gain OTC status without full physician supervision, overcoming traditional labeling limitations.[38] In December 2025, the FDA issued a Request for Information (RFI) on increasing nonprescription drug access, seeking input on scientific, regulatory, and practical barriers. This RFI will be used to organize a public meeting on the topic in 2026.[39]

Congress reinforced the value of OTC access in 2020 when the CARES Act restored the ability to purchase OTC drugs with Health Savings Account (HSA) funds, reversing a provision from the ACA that had required a physician's prescription for OTC drugs to qualify for HSA tax benefits.[40] This restored incentive encourages the roughly 35 million Americans with HSAs to choose lower-cost OTC alternatives rather than seeking unnecessary prescriptions.

The recently enacted OMUFA II legislation took meaningful steps to accelerate the Rx-to-OTC switch process. Specifically, OMUFA II requires the FDA to create a formal process for industry to request meetings with the agency to develop Rx to OTC switching plans, and tasks the FDA with publishing guidance on the standards for approval of Rx-to-OTC applications by May 2027. President Trump's first executive order on drug pricing, issued in April 2025, directed the FDA Commissioner to improve the Rx-to-OTC switching process as

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[36] Medicare Payment Advisory Commission (MedPAC), Letter to Congressional Committee Chairmen and Ranking Members, "Moving forward from the sustainable growth rate (SGR) system" (October 14, 2011), available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/10142011_MedPAC_SGR_letter.pdf.

[37] Consumer Healthcare Products Association (CHPA), "Value Created by OTC Medicines Generates Billions in Savings to the U.S. Healthcare System" (December 1, 2022), available at https://www.chpa.org/news/2022/12/value-created-otc-medicines-generates-billions-savings-us-healthcare-system.

[38] FDA, "Additional Conditions for Nonprescription Use" final rule (December 2024).

[39] FDA, Increasing Access to Nonprescription Drugs; Request for Information (December 2, 2025)

[40] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. 116-136 (2020), Section 3702 (restoring OTC drug eligibility for HSA/FSA spending).

a tool for lowering drug costs. Successful switches reduce costs for patients and payers by eliminating unnecessary physician visits and creating OTC market competition.

Each successful OTC transition represents real savings for patients, employers, and government programs. The recent actions of Congress and the FDA to prioritize the OTC switch process should be applauded, and the FDA's public meeting will provide another forum on how the OTC process can be modernized to allow more patients to take advantage of lower-cost OTC products.

VI. THE 340B PROGRAM: HOW MISALIGNED INCENTIVES UNDERMINE BIOSIMILAR USE

A. The 340B Program: Background and Growth

Any discussion of competitive drug pricing must consider the 340B Drug Pricing Program and how its current structure undermines biosimilar uptake and competition.

Created in 1992, the 340B program requires drug manufacturers to offer discounted prices to eligible "covered entities"—hospitals and clinics that serve a disproportionate share of low-income patients. Covered entities purchase drugs at discounts of 20-50 percent off the average wholesale price, then bill payers (Medicare, Medicaid, commercial insurers) at standard or non-discounted rates. The "spread" between the 340B purchase price and the standard rate becomes unrestricted revenue for the entity.[41]

The program has grown dramatically—from $4 billion in annual discounted purchases in 2007-2009 to $66.3 billion in 2023, making it the second-largest prescription drug program in the U.S.[42] The number of covered entity sites has grown from approximately 1,000 in 1992 to over 66,000 today.

B. Perverse Incentives: Why 340B Drives Higher Drug Utilization and Suppresses Generics and Biosimilars

The 340B program's "buy low, sell high" mechanism creates powerful incentives that produce a host of negative policy outcomes. First, covered entities make more revenue per drug from 340B when the drug has a higher list price, because the spread (reimbursement minus 340B acquisition cost) is larger. This directly incentivizes using higher-cost drugs over lower-cost alternatives.

Second, revenues increase as higher volumes of drugs are administered. This directly incentivizes administering more drugs and more frequently.

Third, because generics and biosimilars generate relatively less revenue under the 340B spread mechanism, covered entities have a financial incentive to use more expensive branded products rather than lower-cost equivalents. In 2023, branded drugs accounted for 89.6 percent of 340B sales, whereas they accounted for only 77.8 percent of non-340B

[41] USC Schaeffer Center, "The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments" (October 14, 2021).
[42] Ibid.

sales.[43] This 11.8 percentage point gap represents the distorting effect of 340B incentives on prescribing behavior.

A study published in Health Affairs in 2023 analyzed biosimilar uptake at hospitals just above and just below the 340B eligibility threshold for filgrastim and infliximab. It found that 340B program eligibility was associated with a 22.9 percentage-point reduction in biosimilar adoption, equivalent to a 66 percent relative reduction in biosimilar use.[44] The same study found that 340B eligibility was associated with 13.3 more biologic administrations annually per hospital and $17,919 more in biologic revenue per hospital.[45]

C. 340B Increases Medicare Costs and Private Premiums

These distorted incentives have direct consequences for the Medicare program and private insurance premiums.

Research published in the New England Journal of Medicine found that 340B eligibility was associated with a 90 percent increase in Part B drug spending for oncology drugs and a 177 percent increase for ophthalmology drugs at newly eligible hospitals.[46] Commercial payers similarly face higher drug spending at 340B-eligible hospitals. An IQVIA model estimates $5.2 billion in extra employer costs from lost rebates attributable to 340B.[47]

Higher Medicare spending from 340B's incentives ultimately hurts Medicare beneficiaries via higher Part B and Part D premiums and cost sharing. Higher commercial spending similarly raises premiums, affecting employers and families. The beneficiaries of the 340B program are generating revenue for covered entities, with the bulk of assistance flowing to comparatively wealthier entities, at the direct expense of every other premium payer in the system.

D. 340B Drives Health Care Consolidation, Reducing Competition and Raising Prices

Another harmful consequence of 340B's spread mechanism is the powerful incentive it creates for health care consolidation. To maximize 340B revenues, entities need: (1) as many 340B-eligible patients as possible; (2) a high proportion of commercially insured patients to maximize revenue from the spread; and (3) the ability to administer drugs at high volumes.

These incentives drive hospital systems to acquire independent physician practices—particularly oncology, rheumatology, and infusion practices that administer expensive injectable biologics—and to open "child sites" in wealthier communities to access high-commercial-payer-mix patient populations. The number of 340B hospital child sites has grown from 1,339 in 2010 to over 36,000 today.[48]

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[43] Shanyue Zeng, William Sarraille, and Rory Martin, "What is Driving 340B Growth: Utilization or Price?" Health Affairs Scholar, Vol. 3, No. 6, qxaf104 (May 21, 2025), available at https://doi.org/10.1093/haschl/qxaf104.
[44] Amelia M. Bond, Emma B. Dean, and Sunita Desai, "The Role of Financial Incentives in Biosimilar Uptake in Medicare: Evidence From the 340B Program," Health Affairs 42, no. 5 (May 2023).
[45] Id.
[46] Sunita Desai and J. Michael McWilliams, "Consequences of the 340B Drug Pricing Program," New England Journal of Medicine 378, no. 6 (February 8, 2018): 539–548, https://doi.org/10.1056/NEJMsa1706475.
[47] IQVIA Institute, "The 340B Drug Discount Program Grew to $124 Billion in 2023," IQVIA White Paper (May 2024), available at https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2023-2027.
[48] Ryan Long, Karen Mulligan, et al., "Cui Bono? Misaligned Incentives in the 340B Program," USC Schaeffer Center White Paper Series (September 2025), available at https://schaeffer.usc.edu/wp-content/uploads/2025/09/2025-09-Misaligned-Incentives-340B-web.pdf.

This consolidation reduces competition in local health care markets. As independent physicians are absorbed into large hospital systems, facility fees are added to previously lower-cost office visits, and negotiating leverage with commercial payers increases. Studies consistently find that hospital-employed physicians generate higher health care costs per patient than independent physicians providing the same services. The 340B program is thus a subsidy machine for the very health care consolidation that drives up costs throughout the system.

E. 340B Revenues Flow Disproportionately to Wealthier Institutions

Perhaps most troublingly, the entities that benefit most from 340B are not the poorer rural or urban safety-net hospitals for which the program was intended, but rather large, financially robust health systems that have learned to maximize 340B revenues through aggressive acquisition of physicians and child sites in commercially insured markets.

Data from Minnesota's 340B Covered Entity Report found that commercial insurance accounted for 53 percent of covered entities' net 340B revenues, Medicare accounted for 31 percent, Medicaid for 14 percent, and cash-pay patients (including the uninsured) for less than 1 percent.[49] This is the opposite of what the program's safety-net rationale would predict.

USC Schaeffer Center's Cui Bono analysis, which I coauthored, found that "the degree to which 340B covered entities can generate revenues from the current 340B program... is largely tied to payer mix, particularly the proportion of commercially insured patients. However, entities with higher shares of commercial patients are less likely to need subsidies to remain financially viable."[50]

F. Reforming 340B: Moving to Direct Assistance

The evidence compels a fundamental structural reform of 340B. The current program, premised on drug pricing and reimbursement differentials, cannot be fixed by tinkering at the margins. As we stated in the Cui Bono report, "any reforms to 340B that leave the spread in place will not address the market distortions it causes."[51]

A better model would provide direct financial assistance to qualifying covered entities based on demonstrable financial need — measured by factors such as payer mix, uncompensated care burden, and indigent patient share — rather than their ability to game drug utilization and prescription patterns. Such a model would:

- Eliminate the financial incentive to use higher-priced drugs over generics and biosimilars, as covered entities would no longer profit from the spread, thereby reducing Medicare and commercial insurance spending and associated premiums;
- Eliminate the incentive to consolidate physician practices and expand into wealthier communities to maximize commercial payer revenue;

[49] Minnesota 340B Covered Entity Report (2024), cited in Long et al., supra note 50.
[50] Long et al., supra note 50.
[51] Id.

- Target assistance to the hospitals and clinics that need it most—rural safety-net hospitals and urban indigent-care providers—rather than large medical centers maximizing revenue;
- Dramatically increase biosimilar and generic utilization at formerly 340B-covered entities, as those institutions would no longer have any reason to prefer expensive branded biologics.

VII. CONCLUSION AND RECOMMENDATIONS

Generic drugs and biosimilars represent the most powerful, market-based advances to reduce prescription drug costs while preserving the incentives for innovation that produce tomorrow's breakthroughs. This Committee through Hatch-Waxman and BPCIA has already built a remarkable framework. The task now is to ensure that framework functions as intended—without being undermined by misaligned incentive structures in programs such as 340B, formulary designs driven by rebate economics rather than patient benefit, or regulatory barriers.

I respectfully offer the following recommendations:

1. Support FDA's elimination of switching study and comparative efficacy study requirements for biosimilars. Further streamline the approval process and interchangeable designation, in line with scientific evidence.
2. Remove the structural barriers that force biosimilar manufacturers to inflate list prices to gain formulary access.
3. Restructure LIS cost-sharing to create meaningful incentives for generic substitution—lowering generic copays to zero and modestly raising brand-name copays when generics are available—saving the Medicare program and taxpayers potentially billions of dollars annually.
4. Support FDA's OTC switch programs and the Additional Conditions for Nonprescription Use pathway, reducing unnecessary physician visits and lowering costs for patients.
5. Reform the 340B program to eliminate the spread-based revenue mechanism that incentivizes higher-priced drug utilization, health care consolidation, and suppressed biosimilar adoption—replacing it with direct financial assistance targeted to entities that serve low-income patients.

Competition, transparency, and properly aligned incentives are the most reliable and durable mechanisms for reducing drug prices while preserving the innovation ecosystem that has made American medicine the envy of the world and that provides hope to patients and families struggling with the physical and emotional pain of disease.

I thank the Committee for its attention to these issues and look forward to your questions.