# *Preserving Progress:* Why America's Intellectual Property System is Vital to Innovation and Competition

**Introduction**

The U.S. biopharmaceutical industry is responsible for the development of the vast majority of new medicines each year, delivering innovative treatments for patients with conditions like cancer, heart disease, rare genetic disorders, and other costly and debilitating diseases. This is made possible by America's system of intellectual property (IP) protections. Our carefully crafted IP framework and market-based system also enables robust competition from both innovative medicines within the same therapeutic area as well as lower-cost generics and biosimilars.[1] As a result, U.S. patients have access to more medicines and are able to access those medicines faster than patients in any other country, including those in Europe where governments set prices.[2] The U.S. market's ability to harness competition has helped keep spending on medicines a small and stable share of total health care costs. Notably this share of spending is in line with our global counterparts.[3]

Our IP framework should be celebrated for its distinct ability to balance the important goals of fostering innovation and promoting competition to control overall health care costs. Unfortunately, however, critics often rely on a misguided understanding of the biopharmaceutical innovation model and the dynamics of the marketplace to call for reforms that purport to drive competition in the near-term but could put this longstanding and carefully balanced system at risk over the long term. Efforts to improve generic and biosimilar competition should instead focus on other aspects of the marketplace, such as reducing market distortions caused by middlemen and addressing the root causes of generic drug shortages. Addressing these aspects of our system, without disrupting our carefully balanced IP framework, will help ensure the system can help sustain the development of new medicines in the years ahead.

**America's IP Framework: Balancing Incentives for Competition and Innovation**

Patents and other forms of IP protection play an essential role in America's IP framework and in encouraging the development of new treatments and cures that improve patients' lives. Over the last four decades, Congress has established this carefully balanced framework, through the Hatch-Waxman Act (1984) (Hatch-Waxman) and the Biologics Price Competition and Innovation Act (2010) (BPCIA), to promote competition by generics and biosimilars, while at the same time providing critical incentives for continued innovation.

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[1] A generic is copy of a brand small molecule drug that is permitted to enter the market under the existing IP framework after a set period of time. Small molecules typically come in pill or tablet form and can be copied exactly. A biosimilar is exactly what its name implies: a medicine that is highly similar and has no clinically meaningful differences to a brand biologic medicine. Biologic medicines are made from living organisms and highly complex. For these reasons they cannot be exactly reproduced (hence the term biosimilars). Like generics, biosimilars are permitted to enter the market under the existing IP framework after a set period of time.

[2] PhRMA, Global Access to New Medicines Report, April 2023.

[3] Altarum Institute. "Projections of the Non-Retail Prescription Drug Share of National Health Expenditures." September 2020. Available at: https://altarum.org/publications/projections-non-retail-prescription-drug-share-national-health-expenditures; IQVIA. Drug Expenditure Dynamics 1995–2020: Understanding medicine spending in context, October 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-expenditure-dynamics.

Hatch-Waxman and the BPCIA encourage the introduction of generics and biosimilars by creating abbreviated regulatory pathways for manufacturers of these products. These pathways allow for substantially shortened development time and cost compared to a traditional marketing application for a new drug by allowing generics and biosimilars to rely on valuable clinical data of the original branded product when obtaining approval from the Food and Drug Administration (FDA). Hatch-Waxman and the BPCIA also set forth patent litigation frameworks with clear processes and predictable timetables through which a generic or biosimilar manufacturer can challenge certain innovator patents in federal court without risking liability for patent infringement damages.

On the other hand, Hatch-Waxman and the BPCIA also foster investment in new medicines by setting periods of time before generic and biosimilar applicants can apply for or gain FDA approval. These periods provide certainty that should a medicine successfully reach the market, its manufacturer will be able to earn revenues on its substantial R&D investment for a period of time before facing generic and biosimilar competition. Though U.S. patent term is 20 years from application at the U.S. Patent and Trademark Office, the amount of time drug manufacturers can rely on patents to protect medicines is often significantly shorter due to the time needed to conduct clinical trials and seek FDA approval before companies can sell their medicines. Other forms of regulatory exclusivity separate from patents also provide critical IP protections by providing for a period of time, generally running on a timeline concurrent with any patents, during which FDA is prohibited from accepting or approving generic or biosimilar drug applications.

The certainty provided by IP protections is necessary for the development of new medicines due to the high costs and the low probabilities of success involved. Unlike products sold by other industries, on average it takes $2.6 billion and 10 to 15 years to develop a single medicine, with no guarantee of success. In fact, just 12% of drug candidates entering clinical trials are ultimately successful in obtaining FDA approval.[4] Patents and other forms of IP protection are designed to ensure that research-intensive biopharmaceutical companies have the necessary incentives to conduct their costly and lengthy R&D activities, particularly given the immense uncertainty inherent in the biopharmaceutical development process.

Importantly, America's IP framework is what fuels cost savings and competition by requiring innovators to publicly disclose information about their inventions in patents. This disclosure aids market entry of generic and biosimilar products after the brand product's patents and other IP protections expire. This swift entry fuels competition and drives down costs, benefiting patients and the healthcare system over the long term. It also encourages innovators to develop competing brand products different from others already on the market, which drives not only improvements in any given class but also brand-to-brand competition that further drives savings to the system and patients.

By many measures, America's IP framework has been a resounding success, promoting incentives for continued innovation and patient access to needed medicines while leveraging our market-based system to drive competition to achieve cost containment. Prior to passage of Hatch-Waxman, just 19% of prescriptions in the U.S. were filled with generics and only 35% of top-selling pharmaceuticals had generic competitors after their

[4] Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics, Volume 47,2016, Pages 20-33, ISSN 0167-6296.

patents expired.[5] Today 90% of prescriptions filled in the U.S. are filled with generics or biosimilars,[6] offsetting spending on newer brand drugs and keeping spending on medicines a small and stable share of overall healthcare spending. Since Congress enacted the BPCIA in 2010, a robust biosimilars market has emerged in the U.S, with 38 biosimilars launched and competing on the market against 16 brand biologics.[7] The introduction of biosimilar competition into the biologics market has also led to dramatically lower prices not only for biosimilars, but also for brand biologics.[8] Overall, generic and biosimilar competition has resulted in $2.9 trillion in savings over the past ten years.[9]

Our robust IP framework is what has enabled America's decades-long leadership in the discovery and development of new medicines. Since 2000, biopharmaceutical companies have brought more than 750 new medicines to U.S. patients.[10] Last year, novel treatments and vaccines approved by the FDA for U.S. patients reached a five-year record high of 71.[11] This progress is only possible because of the significant R&D investments made by biopharmaceutical companies each year – totaling over $100 billion in 2022 by PhRMA member companies alone. Since 2000, PhRMA's member companies have invested more than $1.2 trillion in the search for new treatments and cures for patients battling serious life-threatening illnesses.[12]

It's also worthwhile to note innovation doesn't stop once a new medicine becomes available to patients. IP protections are critical in encouraging biopharmaceutical manufacturers to continue to conduct R&D to improve upon medicines after initial approval. Post approval R&D increases treatment options for patients by demonstrating, for example, that an existing medicine can treat a different disease or stage of disease, or a new dosage form is safe and effective or can be used in children. This research also leads to improved forms of medicines which can improve patient adherence and improve health outcomes.

IP incentives fuel not only innovation, but also competition among brands. As described above, brand medicines face robust competition from other generic drugs and biosimilars competing in the same therapeutic area, as well as other brand medicines. Big health insurance companies and middlemen in the system known as pharmacy benefit managers (PBMs) have historically leveraged these options to negotiate steep discounts and rebates on medicines to drive down net prices they pay for brand medicines. For example, less than a year after market entry of the first highly effective curative treatments for hepatitis C virus, multiple other competing brand products entered the market, some offering improved cure rates for patients. The resulting competition was so

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[5] Congressional Budget Office, How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry, July 1998; Michael A. O'Shea and Christopher M. Mikson, "The Hatch-Waxman Act: Still Critical, Still in Flux," The National Law Journal, January 23, 2006.
[6] Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.
[7] https://www.amerisourcebergen.com/-/media/assets/cencora-biosimilars-usmarketlandscape-11mar24.pdf.
[8] Xcenda Issue Brief. Biosimilars are lowering costs in the Medicare Part B and across the healthcare system overall. Available at; https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_biosimilar_trends_issue_one_july2022.pdf.
[9] Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.
[10] US Food and Drug Administration. Summary of NDA Approvals & Receipts, 1938 to the Present; US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2012 – 2014.
[11] FDA, Center for Drug Evaluation and Research, New Drug Therapy Approvals 2023; FDA, Center for Biologics Evaluation and Research, 2024 Biological License Application Approvals.
[12] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.

fierce that the average net cost for this class today is nearly 80% lower than the first product's launch price.[13] Taking a broader look at these dynamics, a recent Health Affairs study found that new brand medicines launched between 2013 and 2017 led to an immediate decrease in the average net price of competitors already on the market, generating more than $10 billion in savings across just 12 therapeutic classes.[14]

The competitive dynamics in the market for prescription medicines have worked successfully to balance innovation, patient access to new medicines and cost containment for decades. As a result of this system, U.S. patients also have broader and faster access to new medicines than patients in other countries, while keeping overall spending on medicines under control. Of all new medicines launched since 2012, 85% are available in the U.S., compared to less than 40%, on average, in Europe where governments set prices. In Europe, patients wait an average of two years longer for new cancer treatments compared to patients in the U.S.[15] And when generics enter the U.S. market, they make up a far greater portion of prescriptions than in other countries. They also tend to be cheaper here than they are abroad, with one recent study finding that generic drugs cost, on average, 33% less in the U.S. than in other countries.[16] Despite common misconceptions, the U.S. market's ability to harness competition has constrained spending on medicines to just 14% of total U.S. health care spending over the past decade – and is projected to remain a stable share of spending through the next decade – despite many new treatments quickly reaching patients with unmet needs. Notably, this is on par with the percentage of overall health care spending on medicines in other countries.[17]

**Common Claims Misrepresent America's IP Framework**

Despite many indicators that our carefully crafted system supports both innovation and competition, continued calls for short-sighted reforms threaten to throw America's balanced IP framework off-kilter. These reforms are often rooted in a fundamental misunderstanding of America's IP framework and the biopharmaceutical innovation model.

*Claims of "product hopping" and "evergreening"*

As noted previously, the process of developing a new medicine is long, costly and uncertain, and that path rarely ends with FDA approval. Whether reducing side effects, improving product quality, finding new diseases a medicine can treat, or developing a new way to make it easier for patients to take their medicines, patent protections incentivize innovators to continue working to improve their medicines for patients after FDA approval, which creates new competition in the marketplace.

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[13] S Silseth, H Shaw, Analysis of prescription drugs for the treatment of hepatitis C in the United States, June 2021. https://www.milliman.com/en/insight/analysis-of-prescription-drugs-for-the-treatment-of-hepatitis-c-in-the-united-states.
[14] S Dickson, N Gabriel, I Hernandez, Changes In Net Prices And Spending For Pharmaceuticals After The Introduction Of New Therapeutic Competition, 2011–19, Health Affairs, 2023. https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00250.
[15] PhRMA, Global Access to New Medicines Report, April 2023.
[16] https://www.rand.org/pubs/research_reports/RRA788-3.html.
[17] Altarum Institute. "Projections of the Non-Retail Prescription Drug Share of National Health Expenditures." September 2020. Available at: https://altarum.org/publications/projections-non-retail-prescription-drug-share-national-health-expenditures; QVIA. Drug Expenditure Dynamics 1995–2020: Understanding medicine spending in context, October 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-expenditure-dynamics.

Allegations of so-called "product hopping" and "evergreening" inaccurately characterize the way America's IP system actually works and exaggerate the extent to which IP protections block competition. Patent law requires that all patented inventions be new, useful and non-obvious; this means a biopharmaceutical company cannot simply add patents to existing products or obtain patents for trivial changes to a medicine.

Moreover, earning a patent is an early step in developing a new medicine for patients. A patent is only protected from the date its application was filed, and it can be several years before a patent is granted. Once an initial patent is granted, innovators still typically spend years in clinical trials proving the safety and effectiveness of their drug before they can bring it to market. Because of the time spent running clinical trials, on average there is generic competition against a patented drug after it has been on the market for around 13 years, which is substantially less than the 20 years afforded to other products by the patent system generally.[18]

Most modern innovations, especially technologically advanced ones like medicines, encompass multiple inventions that may each be covered by an individual patent. Indeed, coverage of products by multiple patents is common across many industries as a patent can only cover a single invention. To put this into context, one of the best-selling golf balls has 60 patents alone, but those patents obviously do not prevent competitors from also making non-identical golf balls. Likewise, patents do not prevent competition from non-identical medicines that treat the same conditions. In fact, as noted previously, brand patented medicines often have many competitors that compete on both price and clinical effects.

Additionally, post-approval advances require supplemental applications (or even new applications) to the FDA, many requiring costly and labor-intensive Phase III clinical trials, which can take four years or more to complete and are held to the same rigorous FDA standards as the initial approval.[19] Patent protections are therefore sought to protect the investments that result in additional, critical benefits to patients. Despite misguided claims that post-approval innovation blocks competition, in reality, new patents protect only the *new* innovations – any earlier patents expire at the end of their term, and do not prevent FDA approval of generic or biosimilar copies of earlier products or uses. Moreover, new brand options will succeed only if they add value for patients because payers also have tools to drive generic and biosimilar use. If not, generic or biosimilar copies of the earlier forms are likely to be used. Moreover, generics are routinely substituted at the pharmacy counter for the prescribed brand drug.[20]

Similarly, patents on certain uses do not block generics or biosimilars from coming to market for any FDA approved uses (indications) not subject to IP protection. The FDA often permits both generic and biosimilar manufacturers to carve out indications protected by patents or other exclusivities from their labeling – a practice referred to as "skinny labeling"[21] – which allows generic drugs and biosimilars to enter the market before a brand drug's patents for other indications expire.

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[18] Grabowski HG, Long G, Mortimer R, Bilginsoy M. Continuing trends in U.S. brand-name and generic drug competition. J Med. Econ. 2021; 24:1, 908–917.
[19] FDA, The Drug Development Process, Step 3: Clinical Research.
[20] *See Bristol-Myers Squibb Co. v. Shalala*, 892 F. Supp. 295, 296 (D.D.C. 1995) (stating that a therapeutic equivalence rating "allows pharmacists to substitute the generic version of [a product] for the original product.).
[21] *See, e.g.*, 21 C.F.R. § 314.94(a)(8)(iv); Biosimilars and Interchangeable Biosimilars Guidance, *supra* note 17, at 3-4.

*Patent settlement agreements*

Generic companies can seek to market their products prior to patent expiration if they dispute the validity of any patents covering a brand medicine. Such disputes are litigated in federal court. Due to the costly and uncertain nature of patent litigation, competitors often enter into settlement agreements to resolve litigation and allow for generic or biosimilar entry. These settlement agreements do not extend the patent term of an innovator's drug. Even patent settlement agreements with so-called reverse payments, which some misleadingly called "pay-for-delay agreements," generally permit generics and biosimilars to enter the market *before* the branded version's patents expire, generating significant savings for consumers.

Furthermore, the Federal Trade Commission (FTC) has robust authority to review and evaluate individual patent settlement agreements for their potential anticompetitive effects. And the FTC is not shirking its watchdog role in this area: the FTC has aggressively investigated and litigated settlements that it believed violated the antitrust laws and continues to do so in the wake of a pivotal Supreme Court decision that provided a framework to challenge settlements on a case-by-case basis.[22] Since that decision, a 2019 FTC review of data on the frequency of pharmaceutical patent settlements indicated a decline in the number of settlements it considered to raise potential issues due to "changes in the prevailing legal standard."[23] As explained above, patent settlement agreements help both brand and generic/biosimilar manufacturers to avoid the costs and uncertainty of litigation. Therefore, proposals that make it harder for companies to enter into these agreements may harm generic and biosimilar manufacturers by reducing their incentive to challenge patents, as they would have fewer options to resolve a patent challenge in litigation.[24] These proposals may in turn discourage settlements that would have otherwise brought a generic or biosimilar to market sooner.

*Authorized generics*

An authorized generic is a generic version of a brand drug manufactured by the innovator or a third-party licensee under the innovator's original marketing application. Authorized generics have been shown to increase competition and save consumers money – without reducing incentives for generic competition or development of new products, contrary to claims that innovators use authorized generics for anticompetitive purposes. In fact, an analysis by the FTC found that "there is little evidence of authorized generic competition affecting the number of patent challenges."[25]

*Citizen petitions*

The citizen petition process, through which any individual can petition the FDA, is an important avenue for raising safety and public policy issues to the FDA through a transparent public process and is the required pathway for

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[22] *Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013).
[23] FTC, Bureau of Competition, Then, now, and down the road: Trends in pharmaceutical patent settlements after FTC v. Actavis, May 2019. https://www.ftc.gov/enforcement/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent-settlements-after-ftc-v-actavis.
[24] *Asahi Glass Co.*, 289 F. Supp. 2d at 994; *see also In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d at 256 (to maximize incentives for generic entry in Hatch-Waxman, the generic company should be permitted not only to choose when to initiate a patent challenge, but also when to terminate patent litigation).
[25] FTC, "Authorized Generics: Short-Term Effects and Long- Term Impact," August 2011. http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

raising certain concerns with the FDA regarding abbreviated applications for generics or biosimilars.[26] The public nature of the citizen petition process affords all interested stakeholders an opportunity to provide input on issues raised in a petition, which contributes to both an informed FDA and an informed and engaged public.

Critics claim that innovative brand manufacturers misuse the citizen petition process to delay the entry of generics and biosimilars into the market. However, the FDA is authorized to summarily deny any citizen petition if it "determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues."[27] To date, the FDA has never invoked its authority to summarily deny a petition based on intent to delay. In fact, recent data suggests that concerns that citizen petitions are delaying approval of generics or biosimilars are overstated; FDA's most recent annual report to Congress on citizen petitions for abbreviated applications states that during fiscal year (FY) 2019, the agency received only 11 such petitions, but during this same period, FDA approved 935 generic applications and 11 biosimilar applications.[28]

**Market Distortions and Drug Shortages Impede Generic and Biosimilar Competition**

Critics commonly misrepresent and inaccurately characterize the biopharmaceutical innovation model and the dynamics of the marketplace to suggest America's IP framework impedes generic and biosimilar competition. However, evidence shows perverse incentives exist in the biopharmaceutical marketplace that distort the market and impede access to generics and biosimilars.

*PBMs impede generic and biosimilar uptake*

PBMs exercise an enormous amount of influence in the prescription drug market, from negotiating rebates with manufacturers, setting up pharmacy networks, administering the pharmacy benefit on behalf of health plan sponsors, crafting utilization management protocols, setting up formularies, and operating mail order, specialty, and/or retail pharmacies. PBMs use their clout to demand rebates and fees tied to the list price of a medicine,[29] which experts say create perverse incentives that can lead PBMs to prefer medicines with higher prices.[30]

Evidence suggests that the largest PBMs routinely deny access to lower-cost products, including generics and biosimilars that would save patients money. Indeed, despite the availability of lower cost generic versions of many brand medicines, PBMs do not uniformly include these medicines on preferred formulary tiers. For example, in Medicare Part D, 57% of generic medicines were placed on non-generic tiers in 2022 (which are generally coverage tiers associated with higher patient cost-sharing and/or greater access restrictions), up from 36% in 2016.[31] Not only are these lower-cost products often placed at a disadvantage on formularies, but coverage of newly launched generic products has been slow moving. In 2021, just 21% of generic medicines

[26] *See* FDCA § 505(q)(1)(A); FDA, Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (Nov. 2014).
[27] Section 505(q)(1)(E) of the Food, Drug, and Cosmetic Act.
[28] https://www.fda.gov/media/143518/download.
[29] https://mailchi.mp/nephronresearch.com/pbmcompensation.
[30] https://phrma.org/Blog/ICYMI-in-WSJ-Same-Drug-Two-Prices-Why-the-Higher-Price-Prevails.
[31] Avalere (2022). 57% of Generic Drugs Are Not on 2022 Part D Generic Tiers. Avalere. https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers.

newly launched in 2020 were covered on Part D formularies and only 66% were covered on commercial formularies.[32] Similarly, starting in 2018, the three largest PBMs began excluding biosimilars from their formularies for patients with commercial insurance.[33] The prevalence of this practice has skyrocketed since then: as of 2022, 14 biosimilars were excluded from the formulary of at least one of the three largest PBMs.[34]

For example, newly available Humira (adalimumab) biosimilars have struggled to gain market share as PBMs have continued to prefer the brand, even though the brand was more costly to plans and patients. According to a recent report from IQVIA, biosimilar versions of Humira account for just 1% of the market.[35] Just 1 in 3 patients who were prescribed biosimilar versions were able to fill the prescription due to PBM and health plan access restrictions. Notably, if all adalimumab prescriptions were filled with biosimilars, patient costs would be reduced by 68% and employer costs would be reduced 58%. But PBM profits on the market for Humira and its biosimilars would be reduced by 84%.

*The 340B program impedes uptake of biosimilars*

Growth of the 340B Drug Pricing Program may also be interfering with the uptake of biosimilars and reducing patient access. The program was designed to help improve access to medicines for vulnerable, low-income patients through price reductions on outpatient medicines acquired by specific qualifying hospitals and federally funded clinics. However, the program has strayed far from its intended purpose with more and more hospitals keeping for themselves the significant "spread" between the total payments they receive from insurers and patients on 340B medicines and the low price at which they acquire those medicines. Research shows that market distortions driven by hospitals' pursuit of 340B profits on the "spread" are encouraging the prescribing of medicines with higher list prices and discouraging uptake of biosimilars in 340B hospital settings.[36]

As biosimilars generally enter the market with lower list prices compared to their corresponding brand biologic, they may offer smaller margins to hospitals than higher list price alternatives. In fact, a Milliman analysis found that 340B hospitals have lower utilization of biosimilars than non-340B hospitals among their commercially insured patients, potentially leading to higher patient out-of-pocket costs.[37] The study found that among commercially insured patients who paid cost sharing, those who received biosimilar products at 340B hospitals

[32] Medicines, A. f. A. (2021). New Generics Are Less Available in Medicare Than Commercial Plans. Association for Accessible Medicines. https://accessiblemeds.org/sites/default/files/2021-07/AAM-New-Generics-Are-Less-Available-in-Medicare-2021.pdf.
[33] https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[34] https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[35] https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf?utm_source=costcurve.beehiiv.com&utm_medium=newsletter&utm_campaign=iqvia-makes-clear-where-the-blame-should-fall-for-the-broken-humira-biosims-market.
[36] https://mycoa.communityoncology.org/education-publications/studies/examining-hospital-price-transparency-drug-profits-and-the-340b-program-2022; T Hagan, "Biosimilars Advance in the Oncology Space," AJMC, April 2021; T Hagan, "COA's Okon Takes Aim at Biosimilar Misconceptions," AJMC, April 2021; R Gal, Moto Advisors, "Examining Hospital Price Transparency, Drug Profits, & the 340B Program," September 2021. https://communityoncology.org/wp-content/uploads/2021/09/Moto-COA-340B_Hospital_Markups_Report.pdf; P Kolchinsky. "When drug prices are a Trojan Horse for other costs, we all lose," July 14, 2021. Rapport. https://rapport.bio/all-stories/when-drug-prices-are-a-trojan-horse.
[37] https://www.milliman.com/en/insight/2020-outpatient-drug-spend-at-340b-hospitals.

in 2020 had 16% lower out of-pocket costs compared to patients who received the brand biologic at such hospitals that year. In other words, if 340B hospitals had biosimilar utilization rates that were in line with non-340B hospitals, patient out-of-pocket costs at 340B hospitals would generally have been lower.

*Drug shortages can impede access to generics*

Another challenge to a competitive biopharmaceutical marketplace is the growing incidence of generic drug shortages. While brand medicines are not immune from shortages, shortages tend to occur significantly more frequently among generic drugs.[38] Drug shortages can occur for many reasons, with manufacturing quality issues being a primary driver; other causes include production or supply chain delays and discontinuations of products or components.[39] Low profit margins for generic drugs have also driven consolidation among manufacturers to just a few players, resulting in a highly concentrated generic drug market that can exacerbate these issues.[40]

**Policy Reforms Should Seek to Address Market Distortions and Drug Shortages**

The evidence is clear that America's IP framework and patent system support a competitive market where more than 90% of prescriptions for medicines are filled with generics and biosimilars. This framework is critical to driving patient access and affordability, as well as health system sustainability, and maintaining strong incentives for continued investment in innovation. Heavy-handed reforms to our current IP framework will do little to bolster competition and may only reduce incentives for innovation. Efforts to drive greater competition and savings in the health system should look beyond patents and seek to address the underlying causes of misaligned incentives in our health care system such as the distortive effects of PBMs and generic drug shortages.

For example, addressing the underlying misaligned incentives that can lead PBMs to favor medicines with high list prices and large rebates over lower cost generics and biosimilars is critical to enabling a competitive biopharmaceutical marketplace. Additionally, policymakers could pursue a number of approaches, including policies to spur increased infrastructure investments by generic manufacturers, tax and other investment incentives for new manufacturing facilities and the expansion and enhancement of existing facilities to prevent generic drug shortages.

Addressing these market distortions can help support a more competitive marketplace for generics and biosimilars while preserving America's IP framework which has proven a remarkable success in incentivizing the development of new medicines in the United States over the years.

[38] IQVIA. Drug Shortages in the U.S. 2023. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/instutereports/drug-shortages-in-the-us-2023/drug-shortages-in-the-us-2023.pdf.
[39] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Fact-Sheets/S-U/Understanding-Prescription-Drug-Shortages_Apr-2024.pdf.
[40] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Fact-Sheets/S-U/Understanding-Prescription-Drug-Shortages_Apr-2024.pdf.

May 14, 2024

Oregon Prescription Drug Affordability Board (PDAB)
Re: April 17, 2024, board meeting
*Submitted via email*

Chair Bailey, Vice-Chair Burns and members of the board,

I am writing to express concern over remarks made by PDAB's Executive Director Ralph Magrish during the April 17, 2024, board meeting. During an update on upper payment limits, Mr. Magrish addressed a recent report by PhRMA, categorizing it as "inflammatory" and "fear mongering." Through the course of the update, the tenor of his comments came across as inflammatory and unprofessional, particularly his comment calling Pharmacy Benefit Managers "drug dealers."

We are not under the illusion that Mr. Magrish is neutral in the policy issues before PDAB, nor do we question the ability of PDAB staff to respond to comments provided by interested parties. We do, however, expect department and program directors to adhere to a level of professionalism as they facilitate important policy debates for Oregonians. So blatantly inserting personal bias into discussions—particularly when comments are directed at those who have not been afforded an opportunity to engage directly with the PDAB—does nothing but fuel harmful rhetoric and divisive approaches to critical conversations.

OBI's statement here is not about any particular policy proposal or item on the table for debate. It is about good government and process. Our foremost interest is in ensuring that Oregonians can rely on boards such as yours to foster healthy, productive and respectful debate.

Thank you for your consideration.

Best,

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PIPC Partnership to Improve Patient Care

May 14, 2024

Ms. Shelley Bailey, MBA
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350 Winter Street NE
Salem, OR 97309-0405

Mr. Ralph Magrish,
Executive Director
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Chair Bailey and Mr. Magrish:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Oregon Prescription Drug Affordability Board's ongoing affordability review activities. Our comments follow letters sent to the Board urging it to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment, as well as encouraging the Board to include patients and people with disabilities throughout its decision-making process.[1] I am writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations related to its use of discriminatory value assessments and to request robust engagement of patients and people with disabilities.

The State of Oregon has a long history related to the use of QALYs in developing its prioritized list of services under Medicaid. Over the last few years, PIPC was engaged in advocacy with the Health Evidence Review Commission (HERC) to shift away from the use of quality-adjusted life years (QALYs) and similar measures that discriminate. Recently, the legislature passed Senate Bill 1508 barring the use of generalized quality of life measures by statute.[2] We have been very concerned that the legislative provisions governing the use of QALYs and similar measures in legislation creating the Prescription Drug Affordability Board may be interpreted narrowly. Entities supporting the use of QALYs as the gold standard for value assessment, such as the Program on Regulation, Therapeutics and Law (PORTAL) and the Institute for Clinical and Economic Review (ICER), may be playing a role in the Board's decisions.

On May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving

[1] https://caringambassadors.org/pnw-advocates-confab/
[2] https://www.droregon.org/releases/landmark-legislative-healthcare-wins-for-people-with-disabilities

federal financial assistance.[3] In response to the proposed rule last year, PIPC joined 100 organizations and individuals on a letter supporting agency rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.[4]

The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating, "The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment." As you may be aware, section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. PIPC was pleased the final rules governing Section 504 would be interpreted as broader than section 1182.

The agency referenced both § 84.56 and § 84.57 as relevant to entities receiving federal financial assistance, which includes state Medicaid programs. For example, the agency stated, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others." Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. As PIPC and others noted in its comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.[5] Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

[3] https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov
[4] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf
[5] Ne'eman Et. Al, "Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic," October 2022, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504.

In summary, the new rules clarify that recipients of federal financial assistance, including Medicaid programs, may not rely on measures like QALYs.

Alternatively, PIPC recommends:

- The Board should engage directly with patients and people with disabilities to learn about their real-world experiences, consistent with recommendations from experts in the patient and disability communities.[6,7,8,9]
- The Board should collaborate directly with the patient and disability communities to solicit information. To date, we have seen very little participation from patients in the Board's meetings and listening sessions. We are also concerned that the Board did not develop its survey for patients in collaboration with patients. We have learned from other states how survey data may be misleading or fail to solicit the kind of information that is most useful to Board decisions.[10,11]
- The Board should respond to new federal regulations by making its process and decisions transparent related to its use of value assessments. We hope that the evidentiary basis for its decisions will be made public in a manner that is accessible and clear.

Thank you for your consideration of our comments.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

[6] https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf
[7] https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf
[8] https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf
[9] https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/
[10] https://drive.google.com/file/d/1oYGIPVVLrXL7ZXeu-eZ2vLZEunPhzN3u/view
[11] https://drive.google.com/file/d/1hF5-4Lxf5IHNNHMunRVm-fBaDt6QF-M3/view

From: Michelle Cole
Tuesday, May 14, 2024
To: PDAB * DCBS <pdab@dcbs.oregon.gov>
Topic: Drug costs

I'm married to a soon-to-be 76 year old man with health problems. It's amazing to learn about the possible medications that would bring him relief and then we learn about the costs. Why create and market these drugs if nobody can afford them? I also, as part of my work, often hear from people (usually senior citizens) who are forced to choose between medication and rent or food. That's just not right.

Michelle Cole, Tualatin
Voices for Affordable Health