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U.S. Senate Committee on Health, Education, Labor and Pensions

On

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

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Chairman Cassidy, Ranking Member Sanders, and distinguished members of the Committee:

My name is Brian Miller, and I practice hospital medicine at the Johns Hopkins Hospital. As an academic health policy analyst, I serve as an Associate Professor of Medicine and Business (Courtesy) at the Johns Hopkins University School of Medicine and as a Visiting Fellow at the Hoover Institution. My research focuses on how we can build a more competitive and vibrant health sector to make healthcare more efficient, flexible, and personalized for patients. This perspective is based upon my prior regulatory experience at four federal regulatory agencies. Through my current role as a faculty member, I regularly engage with regulators, policymakers, and businesses in search of solutions to help create a better healthcare system for all. Today I am here in my personal capacity, and the views expressed are my own and do not necessarily reflect those of the Johns Hopkins University or the Johns Hopkins Health System, the Hoover Institution, the North Carolina State Health Plan, or the Medicare Payment Advisory Commission.

Prescription drug affordability remains a persistent challenge to consumers: according to the Kaiser Family Foundation, 4 out of 10 Americans report that they did not take medications as prescribed due to costs.[1] This is a market-wide concern that crosses payer markets from the Medicare program to the 164 million Americans with employer-sponsored health insurance. American consumers have valid concerns about the cost of drugs and fundamentally what consumers want and health plans need is – to quote North Carolina State Treasurer Brad Briner – "lower unit costs without nonsense." The North Carolina State Health Plan on whose board I serve will spend an estimated $869 million on prescription drugs annually out of $4.7 billion in annual spending in 2026.

Policy has multiple tools available besides payment to address drug affordability, many of which are consensus policies that are within the jurisdiction of the Committee.

Regulation shapes competition. In pharmaceutical product markets, competition occurs along both price and non-price factors (e.g. safety, monitoring, efficacy), both of which matter to patients and purchasers. FDA-driven product competition supports both. Branded competition frequently focuses on non-price features while generics and biosimilars competition drive price competition. Changing FDA product regulation while preserving efficacy and safety standards offers a tool to improve price competition that dynamically balances affordability and innovation.

In my testimony today, I will focus on three practical areas where overhauling U.S. Food and Drug Administration (FDA) regulatory policy can drive product competition and prescription drug affordability for consumers:

1. **Biosimilars:** *recent work and a future Abbreviated Biologics Licensing Application pathway (ABLA)*
2. **Generics:** *improving regulatory process, market dynamics, and increasing channels of access*
3. **Modernizing drug review & development:** *reviewer job redesign and evidence generation*

[1] Kearney, A., Montaro, A., Montalvo III, J., Valdes, I., Kirzinger, A., & Hamel, L. (2026, March 13). Public Views on Prescription Drug Costs: Regulation, Affordability and TrumpRx. KFF. https://www.kff.org/public-opinion/public-views-on-prescription-drug-costs-regulation-affordability-and-trumprx/

1. Improving Biologics Price Competition

Overall drug spending reached $806 billion in 2024[2] with biologic drugs comprising 49.6% of expenditures.[3] The lack of biologic drug competition is problematic despite the passage of the 2010 Biologics Price Competition and Innovation Act (BPCIA): 81% of biologic products or 216 products in 2022 had only 1 manufacturer whereas 18 had 4 or more manufacturers.[4] Biosimilar product development is stagnant with only 12 biosimilars in development for the 118 biologics losing patent protection in the subsequent decade.[5] More concerning, the FDA has approved 81 biosimilar drugs with only 21 achieving reference-product (not class) interchangeability.

Challenges remain numerous. Scientific market entry requirements raised clinical trial costs,[6] with McKinsey reporting biosimilar development costing up to $300 million and taking 9 years. Patient and physician confusion remain a challenge. Back in the 1980s during the early rapid growth of the generic small molecule marketplace after the passage of the 1984 Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act), innovator firms spread concerns about the quality of generics[7] resulting in clinicians hesitancy. With biosimilars, some physicians and professional societies have similarly questioned studies showing equivalent performance.

The framing of "copycat" biologic products as inferior persists despite evidence demonstrating reference product drift[8] and (ironically) potential biosimilar product superiority.[9] Critically, no approved biosimilar has been found to be less effective than the reference product. No population-level difference in the safety profile of FDA-approved biosimilars has been observed, with a systematic review and meta-analysis finding no definitive harm from switching from the innovator to the biosimilar product.[10]

The biosimilar market is repeating the early history of generic markets due to the small number of interchangeable products and high market entry barriers. To make matters worse, biosimilar interchangeability has focused on sole-product interchangeability between the reference product and biosimilar product, and lacks class-level interchangeability like the small molecule generic market.

Improving biosimilar market entry and hence biologic drug price competition is a national bipartisan policy imperative, with efforts underway. The proposed Expedited Access to Biosimilars Act[11] would streamline premarket requirements by requiring FDA to justify requiring immunogenicity, pharmacodynamics or comparative clinical efficacy studies while the bipartisan Biosimilar Red Tape Elimination Act[12] would eliminate the requirement for interchangeability studies. Streamlining manufacturing oversight remains an untapped policy area.

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[2] Tichy, E. M., Rim, M. H., Cuellar, S., Tadrous, M., Schumock, G. T., Johnson, T. J., Newell, M. K., & Hoffman, J. M. (2025). National trends in prescription drug expenditures and projections for 2025. American Journal of Health-System Pharmacy: AJHP, zxaf092. https://doi.org/10.1093/ajhp/zxaf092

[3] Biologics Market Size, Share & Growth Analysis Report, 2030. (2023, May). Grand View Research. https://www.grandviewresearch.com/industry-analysis/biologics-market

[4] Parasrampuria, S., & Murphy, S. (2023). Competition in Prescription Drug Markets, 2017-2022. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. https://aspe.hhs.gov/sites/default/files/documents/1aa9c46b849246ea53f2d69825a32ac8/competition-prescription-drug-markets.pdf

[5] IQVIA Institute for Human Data Science. (2024, February 3). Assessing the Biosimilar Void in the U.S.: Achieving Sustainable Levels of Biosimilar Competition. https://www.iqvia.com/Insights/The-IQVIA-Institute/Reports-and-Publications/Reports/Assessing-the-Biosimilar-Void-in-the-US

[6] Eastern Research Group, Inc. (2025). U.S. Biosimilar Market Entry Challenges and Facilitating Factors. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. https://aspe.hhs.gov/sites/default/files/documents/2d5c0a194c180b52d1c760d3bb09f70a/Biosimilars%20Final%20Report_250825_v508.pdf

[7] Lewin, T. (1987, July 28). Drug Makers Fighting Back Against Advance of Generics. The New York Times. https://www.nytimes.com/1987/07/28/business/drug-makers-fighting-back-against-advance-of-generics.html

[8] Kim, S., Song, J., Park, S., Ham, S., Paek, K., Kang, M., Chae, Y., Seo, H., Kim, H.-C., & Flores, M. (2017). Drifts in ADCC-related quality attributes of Herceptin®: Impact on development of a trastuzumab biosimilar. MAbs, 9(4), 704–714. https://doi.org/10.1080/19420862.2017.1305530

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[10] Herndon, T. M., Ausín, C., Brahme, N. N., Schrieber, S. J., Luo, M., Andrada, F., Kim, C. H., Sun, W., Zhou, L., Grosser, S., Yim, S., & Ricci, S. M. (2023). Safety outcomes when switching between biosimilars and reference biologics: A systematic review and meta-analysis. PLOS ONE, 18(10), e0292231–e0292231. https://doi.org/10.1371/journal.pone.0292231

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With 15 years of regulatory and market experience with biosimilars and over 40 years of experience with small molecule generics, policymakers together can take a critical step to drive biologics drug price competition by creating a simplified FDA pathway to market for biosimilars by updating the standards for the existing biosimilar 351(k) BLA pathway to market, functionally creating an Abbreviated Biologics License Application (ABLA) pathway akin to the Abbreviated New Drug Application (ANDA) pathway created by Hatch-Waxman.

With biosimilar market competition a consensus issue, now is the time to finally unleash their potential with a streamlined FDA pathway to market. An ABLA pathway, a concept supported by a former FDA CDER director[13] and noted in the President's proposed FY2027 budget[14] would function akin to the ANDA pathway for generics. FDA would need to set up a review program independent of the new drugs program, similar to how FDA has the Office of New Drugs and Office of Generic Drugs. The agency would also need a mechanism to determine candidate eligibility and adjudicate any residual uncertainty about biosimilarity along with the evidentiary requirements to resolve such uncertainty.

Policymakers would need to statutorily emphasize the minimum evidence necessary for biosimilarity such as pharmacokinetic studies while preserving the agency's regulatory flexibility, recognizing that some products may necessitate more evidence such as immunogenicity and pharmacodynamics studies while other products may require streamlined evidence such as characterization of structural features and manufacturing practices (i.e. not conducting new pharmacokinetic studies). Fundamentally, an ABLA pathway would function as a risk-adaptive framework, with a newly streamlined evidentiary standard to marketing approval coupled with the flexibility for FDA to provide the level of oversight needed tailored to the product under review. An ABLA pathway should also incorporate relevant aspects similar to the 505(b)(2) pathway so that sponsors do not undertake new scientifically and clinically unnecessary, duplicative studies which delay market entry and consumer benefits of price competition. Finally, both the FDA and physician groups would need to undertake a public education campaign about the important role of biologic drugs and the function of biosimilars so as not to repeat the early history of the generics marketplace.

In this way, the evolution of the biosimilar 351(k) BLA pathway into an ABLA pathway would drive price competition in biologics markets by attracting entrants, providing regulatory certainty, and safely streamlining entry barriers. An ABLA pathway would also ensure that older biologics drugs become affordable through price competition, which otherwise remains an unattained policy goal. Patients and health plans desperately need price competition, with 2024 biologics spending for the North Carolina State Health Plan representing $269 million or 30% of total net pharmacy spend, a number which grew 9% in 2025.

2. Improving Generics Competition

Historically, American generic markets are stronger than their European counterparts. European prices for branded products are traditionally lower due to the deployment of assertive health technology assessment,[15] while in contrast American prices can be lower in other markets such as generic drugs[16] due to robust price competition from market entry[17] coupled with broad uptake powered by state-level generic substitution laws – with variation in efficacy.[18,19,20]

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[13] Miller, B. J., & Woodcock, J. (2026). The Future of Biologics: Lessons from Hatch–Waxman. Therapeutic Innovation & Regulatory Science. https://doi.org/10.1007/s43441-026-00961-9

[14] FDA. (2025). Expedited programs for regenerative medicine therapies for serious conditions. In U.S. Food and Drug Administration (FDA) (p. 20). https://www.fda.gov/media/191778/download?attachment

[15] Raimond, V. C., Feldman, W. B., Rome, B. N., & Kesselheim, A. s. (2021). Why France Spends Less than the United States on Drugs: a Comparative Study of Drug Pricing and Pricing Regulation. The Milbank Quarterly, 99(1), 240–272. https://doi.org/10.1111/1468-0009.12507

[16] Wouters, O. J., Kanavos, P. G., & McKee, M. (2017). Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. The Milbank Quarterly, 95(3), 554–601. https://doi.org/10.1111/1468-0009.12279

[17] Conrad, R., & Lutter, R. (2019). Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. In FDA. https://www.fda.gov/media/133509/download?attachment

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[19] Rome, B. N., Sarpatwari, A., & Kesselheim, A. S. (2022). State Laws and Generic Substitution in the Year After New Generic Competition. Value in Health. https://doi.org/10.1016/j.jval.2022.03.012

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Despite these benefits over European product regulation, improving FDA regulation offers an untapped opportunity to drive price competition and thus improve access for consumers. Policymakers have multiple levers, including improving regulatory process, modulating market dynamics, increasing channels of access, and addressing longstanding challenges in combination product regulation.

Policymakers have undertaken prior work to improve FDA regulatory process, including the bipartisan CREATES Act, which blocked branded manufacturers from refusing to sell drugs for use as a reference product by and to generic product developers. Recent efforts have focused on addressing abuse of the FDA citizen petition process, with the 2018 case involving Shire ViroPharma bringing this challenge into focus.[21] In *FTC v. Shire ViroPharma Inc.*, the FTC alleged that ViroPharma submitted 43 citizen petition filings with the FDA as ViroPharma knew that the FDA refrained from approving generic applications until it resolved pending citizen petition filings. The FTC alleged that ViroPharma sought to delay generic entry and thus prevent competition. While the case was dismissed due to questions regarding FTC authority over past versus ongoing/impending anticompetitive conduct, the case highlighted an important example of anti-competitive abuse of FDA regulatory mechanisms to delay generic entry.

The proposed bipartisan Ensuring Timely Access to Generics Act aims to address this and other abuse of the citizen petition process.[22] Policymakers have multiple related policy alternatives and could require or the FDA could initiate on its a notice of proposed rulemaking to update the citizen petition process, including activities that warrant consideration of referral to FTC for consideration of bringing anti-competitive conduct cases. Policymakers could also require that FDA share data with and that the FTC Bureau of Competition's Healthcare Anticompetitive Practices group and jointly file an annual public report on analysis of likely abuses of the FDA citizen process. This would mirror prior efforts such as those required by the 2003 Medicare Prescription Drug, Improvement and Modernization Act, which required manufacturers to file patent settlement agreements with competition authorities[23] who monitor and issue regular reports.[24,25,26] Furthermore, policymakers could require the FDA and FTC Office of Policy Planning to hold a joint public workshop on anti-competitive abuses of FDA regulatory mechanisms that prevent or delay generic entry, which could include highlighting other abuses of the generic entry process such as "parking," a practice targeted by the proposed 2023 Expanding Access to Low-Cost Generics Act.[27]

Policymakers could also work to improve market dynamics and increase competition. Data suggests emerging challenges in generics markets, with ANDA filings down over 50% from peak of 1,306 in FY2016[28] to 600 in FY2025.[29] Robust price competition in generics markets is both a boon for consumers[30,31] and a challenge for

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[21] Shire ViroPharma. (2017, February 7). Federal Trade Commission. https://www.ftc.gov/legal-library/browse/cases-proceedings/121-0062-shire-viropharma

[22] Shaheen, J. (2025, October 16). Text - S.3014 - 119th Congress (2025-2026): Ensuring Timely Access to Generics Act of 2025. Congress.gov. https://www.congress.gov/bill/119th-congress/senate-bill/3014/text

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[24] Federal Trade Commission. (2010). Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

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[27] Smith, T. (2023). S.1114 - 118th Congress (2023-2024): Expanding Access to Low-Cost Generics Act of 2023. Congress.gov. https://www.congress.gov/bill/118th-congress/senate-bill/1114

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[30] Dave, C. V., Hartzema, A., & Kesselheim, A. S. (2017). Prices of Generic Drugs Associated with Numbers of Manufacturers. New England Journal of Medicine, 377(26), 2597–2598. https://doi.org/10.1056/nejmc1711899

[31] Conrad, R., & Lutter, R. (2019). Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. In FDA. https://www.fda.gov/media/133509/download?attachment

product developers. Generics exhibit varying cost to develop.[32] Depending on the product, development costs can range from $250,000 to $25 million.

To improve incentives for market entry and competition in generic markets, policymakers could expand the priority review voucher (PRV) program. PRVs are used to incentivize development in a variety of markets including the Tropical Diseases,[33] Rare Pediatric Diseases,[34] and Material Threat Medical Countermeasures.[35] A PRV is worth around $100M on the secondary market, and can be resold to other manufacturers, a feature that distinguishes it from the Commissioner's National Priority Review Voucher. The ability to resell a PRV to another manufacturer, increases the net present value of a generic development program that may otherwise be unprofitable. FDA staff remain supported: the agency receives a higher user fee to support the speedier effort of a priority review.[36]

Policymakers could introduce a PRV for limited generic competition markets[37] to drive entry and price competition. Eligible markets could include those of critical importance to the health care system (e.g. World Health Organization Essential Medicine) or to national security or alternatively a market that does not have a generic alternative or has a HHI >2,500[38] indicating high concentration. As part of an expanded PRV program, policymakers could require manufacturers to have a plan to produce, market and sell the product for a minimum of 3 years.

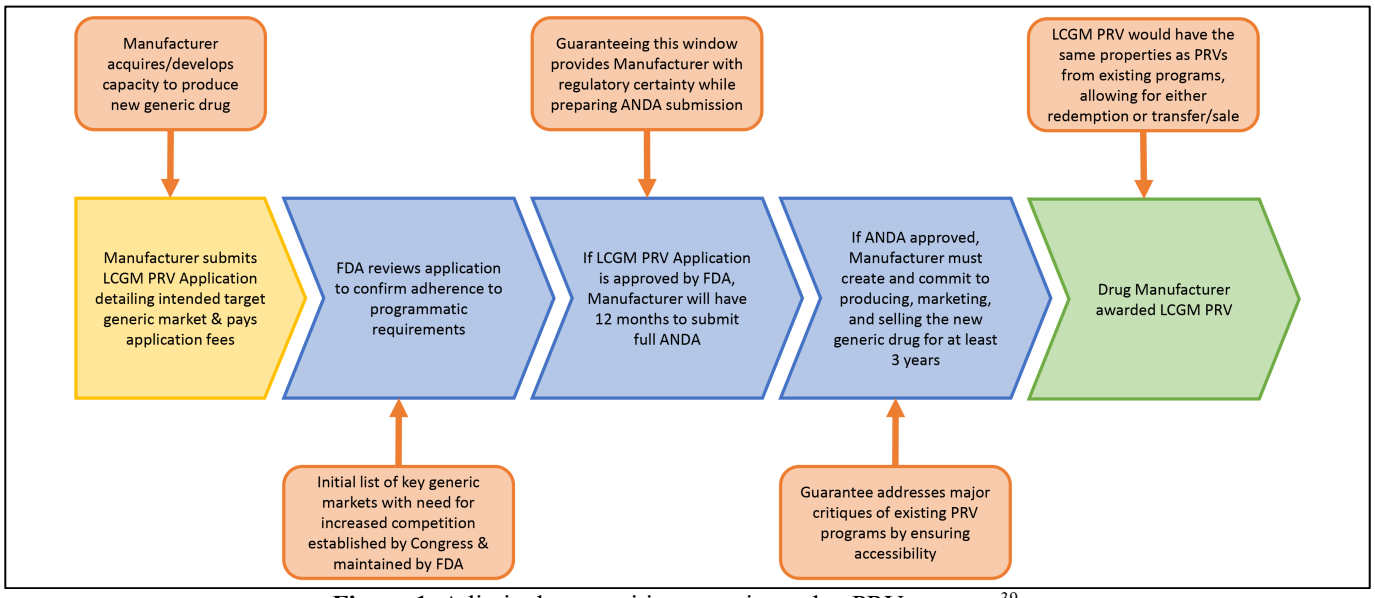

Figure 1: A limited-competition generic market PRV program[39]

Increasing channels of access offers another opportunity to lower prices and expand access through competition. Different countries have different approaches to managing channels of access to pharmaceutical products, often with a range of risk from direct consumer access to distribution mediated by a learned intermediary (either a prescriber or

[32] Eastern Research Group, Inc. (2021, December 31). Cost of Generic Drug Development and Approval. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. https://aspe.hhs.gov/sites/default/files/documents/20e14b66420440b9e726c61d281cc5a5/cost-of-generic-drugs-erg.pdf
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[36] Food and Drug Administration. (2025, September 18). Fee Rate for Using a Priority Review Voucher in Fiscal Year 2026. Federal Register. https://www.federalregister.gov/documents/2025/09/18/2025-18075/fee-rate-for-using-a-priority-review-voucher-in-fiscal-year-2026
[37] Cho, T., Dumas, P., & Miller, B. J. (2023). A Priority Review Voucher Program To Fuel Generic Drug Development. Forefront Group. https://doi.org/10.1377/forefront.20230705.334685
[38] "Herfindahl-Hirschman Index." Department of Justice Antitrust Division. January 17, 2024. https://www.justice.gov/atr/herfindahl-hirschman-index
[39] Ibid.

a pharmacist). In the U.S., there are three channels mediated directly through FDA product regulation: over the counter (OTC), OTC with an Additional Condition for Nonprescription Use (ACNU, new in 2024),[40] and prescription. Other countries have approached distribution and risk mitigation differently, with the U.K channels consisting of general sales list (GSL) sold in retail outlets without the supervision of a pharmacist, p-medicines sold in pharmacies without a prescription (under the supervision of a pharmacist), and prescription-only medications. Australia, with a widespread rural population has managed distribution directly through the scheduling of medicines and chemicals[41] with pharmacy medicines (schedule 2), pharmacist-only medicines (schedule 3), prescription only (schedule 4), and controlled medicines (schedule 8).

Increasing channels offers a new, nonpartisan opportunity to improve price competition and expand access. Thinking creatively about expanding channels to drive price competition and expand access is critical. Americans will find it harder to access or purchase access to services associated with prescription drugs, as the U.S. faces a physician shortage projected to reach 86,000 by 2036[42] with the Health Resources and Services Administration projecting a shortage of just over 70,000 primary care physicians (PCP) by 2038.[43] Many patients will be unable to access a physician to obtain a prescription and others will face rising services prices along with rising prescription drug prices. A PCP shortage results in inadequate access to treatment for chronic disease and significant downstream impacts, with untreated diabetes resulting in secondary limb amputations in 4.8 out of 1,000 patients and concomitant individual loss of functional status, independence, and population-level economic productivity.[44] In contrast, 38% of Americans with hypertension are unaware that they have it,[45] and of those who were treated at least one-third were uncontrolled, more likely to occur in the elderly, women and non-Hispanic black adults.[46]

Increasing consumer-facing channels to modulate access to prescription drugs both to drive cross-channel competition improving affordability and expand affordable access for treating chronic disease through growing the role of the community pharmacist offers an untapped policy opportunity. Policymakers already have undertaken work in this arena, with the 2024 OTC ACNU final rule,[47] a policy finalized in the Biden Administration that originated in the first Trump Administration[48] creating a new long-term channel for both branded and generic products. Consumers currently use OTC drugs for a variety of conditions such as fever reduction, pain management, and allergy control amongst others based upon the bottle's drug facts label (DFL). As the DFL is limited, the ACNU rule provides a space to gather additional information from consumers to allow them, independent of a clinician, to determine appropriate use within predefined limits, through either an in-pharmacy kiosk, online questionnaire or other venue for the consumer to interact and answer additional questions. This is already a reality in clinical trials, with AstraZeneca recently testing this as a venue for expanding access to statins.[49] In order to grow the OTC ACNU market and improve affordability, policymakers could direct FDA to issue detailed guidance on how ACNU will be

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[40] Jouaneh, T. M. M., Gowda, V., & Miller, B. J. (2024). Expanding Pharmaceutical Access Via Over the Counter Drugs. Therapeutic Innovation & Regulatory Science. https://doi.org/10.1007/s43441-024-00709-3

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[42] Association of American Medical Colleges. (2024). The Complexities of Physician Supply and Demand: Projections The Complexities of Physician Supply and Demand: Projections From 2021 to 2036. https://www.aamc.org/media/75236/download?attachment

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[44] Harding, J. L., Andes, L. J., Rolka, D. B., Imperatore, G., Gregg, E. W., Li, Y., & Albright, A. (2020). National and State-Level Trends in Nontraumatic Lower-Extremity Amputation Among U.S. Medicare Beneficiaries With Diabetes, 2000–2017. Diabetes Care, 43(10), 2453–2459. https://doi.org/10.2337/dc20-0586

[45] Sakhuja, S., Colvin, C. L., Akinyelure, O. P., Jaeger, B. C., Foti, K., Oparil, S., Hardy, S. T., & Muntner, P. (2021). Reasons for Uncontrolled Blood Pressure Among US Adults: Data From the US National Health and Nutrition Examination Survey. Hypertension, 78(5), 1567–1576. https://doi.org/10.1161/hypertensionaha.121.17590

[46] Muntner, P., Miles, M. A., Jaeger, B. C., Hannon III, L., Hardy, S. T., Ostchega, Y., Wozniak, G., & Schwartz, J. E. (2022). Blood Pressure Control Among US Adults, 2009 to 2012 Through 2017 to 2020. Hypertension, 79(9), 1971–1980. https://doi.org/10.1161/hypertensionaha.122.19222

[47] Food and Drug Administration. (2024, December 26). Nonprescription Drug Product With an Additional Condition for Nonprescription Use. Federal Register. https://www.federalregister.gov/documents/2024/12/26/2024-30261/nonprescription-drug-product-with-an-additional-condition-for-nonprescription-use

[48] U.S. Food and Drug Administration. (2018, July 17). Statement from FDA Commissioner Scott Gottlieb, M.D. on new efforts to empower consumers by advancing access to nonprescription drugs. Prnewswire.com; Cision PR Newswire. https://www.prnewswire.com/news-releases/statement-from-fda-commissioner-scott-gottlieb-md-on-new-efforts-to-empower-consumers-by-advancing-access-to-nonprescription-drugs-300682122.html

[49] AstraZeneca. (2024, October 30). Technology-Assisted Cholesterol Trial in Consumers (TACTiC) (TACTiC). Clinicaltrials.gov. https://clinicaltrials.gov/study/NCT04964544

applied and evaluated in behavioral studies, providing a clearer path to market entry. Policymakers could also direct the FDA to refine the Rx-To-OTC process by improving the process for providing advice to sponsors on evidentiary needs, clearly define which studies are pivotal when multiple studies are under consideration, and create a rapid response, bidirectional channel for timely scientific exchange between sponsors and FDA staff. Finally, in order to execute on these and other policy changes to drive innovation in the nonprescription product continuum, FDA should move to revise its Manuals of Policies and Procedures for novel OTC, OTC ACNU, and Rx-To-OTC products.

A next step for policymakers is to increase channels and broaden the pool of learned intermediaries who help consumers access prescriptions through the creation of a behind the counter (BTC) channel for prescription drugs – branded and generic. This would increase price competition and expand access as almost 90% of Americans live within 5 miles of a community pharmacy[50] with 139,000 practicing in a retail, patient-facing setting,[51] access at risk due to closures.[52]

A BTC channel would grow the role of the community pharmacist, deploying federal policy to expand options in local community pharmacy practice. Pharmacists could dispense short courses of new medications, intensify existing treatment, or extend existing therapy. This is critical to combatting "therapeutic inertia" wherein clinicians do not appropriately intensify treatment. A problem in the clinical mindset for over two decades,[53,54,55] with large shares of patients with chronic diseases such as diabetes, hypertension and chronic kidney disease not undergoing titration or intensification. For impoverished patients or those with limited access to primary care, access to affordable pharmacist-driven initiation and titration of chronic disease meds is a population-level policy win.

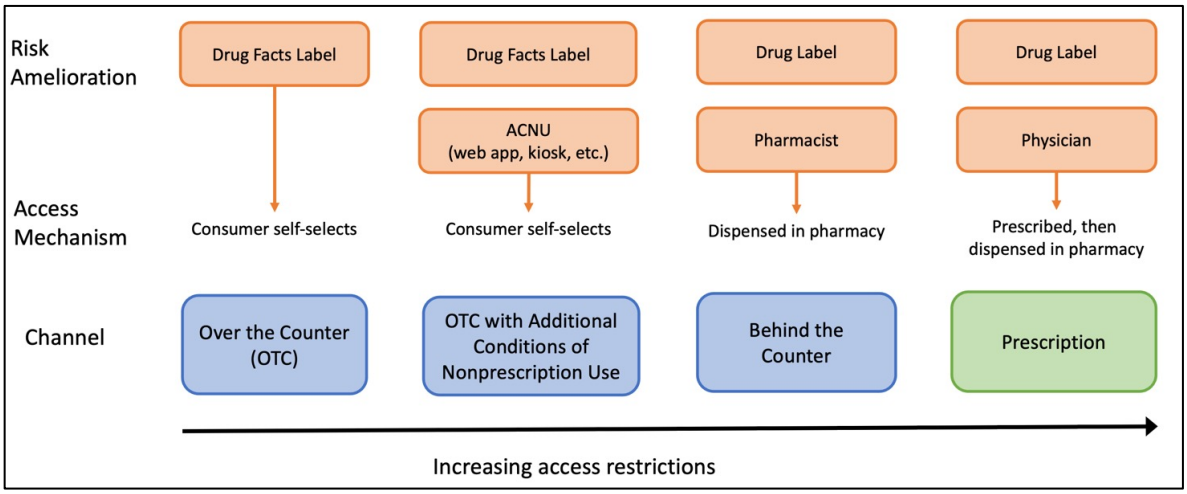

Figure 2: Nonprescription products and the continuum of risk

Improving the Rx-To-OTC pathway, growing the OTC ACNU market, and the creation of BTC channels would all expand the role of the community pharmacy, grow community pharmacy practice, and drive product and price competition across channels, generating access and improving affordability simultaneously.

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Finally, policymakers could tackle longstanding challenges in FDA oversight of combination products that raise barriers to entry and inhibit price competition. Combination products present a unique challenge with weak price competition due to jurisdictional questions, unclear evidentiary barriers, human factors barriers, and other hurdles. With the FDA currently forced to address drug-device combination products via classification as primarily a drug or device,[56] product developers engage in jurisdictional gamesmanship while FDA also at times misclassifies products' real-world functions. Challenges in product classification increase regulatory uncertainty, raise barriers to raising capital for development, increase market entry costs and thus reduce product competition. With fewer market participants, combination products suffer from higher prices.

Regulatory challenges are real across product areas. For example, orthopedic surgical products frequently have a structural use with a pharmacologic or biologic component. In this setting, Cerament (BoneSupport) is an antibiotic-eluding bone cement regulated primarily as a device. In contrast, MACI (Vericel) is a collagen matrix that comes pre-cultured with cells, is regulated primarily as a drug[57] and is arguably clinically used as a device. Other therapeutic areas face similar challenges, with Juvederm (Hyaluronic acid with lidocaine), a filler from Allergan, regulated as a device.[58] Despite this, in 2018 the FDA considered re-classifying these products as a drug,[59] which would have significantly shifted the pre- and post-market regulatory framework for existing and new products.

Product developers need predictable, reasonable pathways to market and efficient processes in order to promote product development and ultimately drive competition. In order to address regulatory uncertainty, policymakers could create a fit-for-purpose pathway to market for combination products with clear administrative process (e.g. akin to how BLAs can be reviewed by CDER or CBER). Doing so would reduce regulatory gamesmanship, improve transparency, and clarify market entry barriers promoting product development and ultimately price competition benefitting consumers.

3. Modernizing Drug Review and Evidence Generation

Policymakers have two primary levers to reduce entry cost and lower prices for new branded drugs while preserving the FDA standards of safety and efficacy. First, FDA can modernize drug review through reviewer job redesign.[60] The current state treats drug review as both an artisanal and a manual process. FDA drug reviewers often have to complete a litany of mundane administrative (e.g. typing out drug history) and routinized analytical tasks (i.e. the same safety analysis for different products in a therapeutic area). The lack of process automation both deprives reviewers of the cognitive space to ask important questions (e.g. new methods of data acquisition, novel trial design) and fails to elevate them to the highest level of skill. As agency review staff frequently lack time to think creatively about product development, industry is unwilling to assume additional regulatory risk in thinking creatively about evidence generation. FDA's drug review centers are heavily focused on administration and not the core task of product review. For example, CDER has ~6,000 employees[61] of which 340 are primary reviewers supported by 176 physician team leaders or supervisors.[62] Of the 12 offices reporting to the CDER Center Director only two are directly responsible for drug review.[63] A minority of center staff focus on the core function of the agency which is reviewing products and facilitating innovation.

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Policymakers could direct the FDA to refocus its center staff on its core task: product regulation. In doing so, oversight or statutory change could ensure that the FDA works to modernize operations, unburdening reviewers and elevating them to their maximal level of practice. A variety of levers would make this possible. First, repurposing administrative and managerial physician staff back to front-line reviewer roles would decrease the average workload of reviewers. This would ensure maximal return on investment for taxpayers funding the salaries of technical experts (with the average physician at the FDA grossing $221,710 in salary in 2023)[64] and simultaneously free up FDA reviewer bandwidth to facilitate easier access for small companies looking for guidance on how to creatively design and execute trials. Policymakers could also insist on the appropriate and routine deployment of automation through algorithms/AI in medical product review – standardized initial analysis in order to support efficiency and subsequent customized review. This would transition FDA drug review from an artisanal craft into a factory with customized controls, decreasing the reviewer lottery effect, helping reviewers work at the top of their intellectual license, and lowering the cost of market entry for innovative branded drugs improving affordability.

The second major policy lever to lower market entry costs is the modernization of evidence generation. Long discussed, modernizing evidence generation requires directly admitting a wide range of challenges. Clinical trials are not diverse[65,66] and do not fully represent the populations that medical products are subsequently used in in clinical practice. Clinical trials are inconvenient - patients must travel to study sites for assessment, interview, and exam by clinical staff throughout the duration of a clinical study. Outcomes do not necessarily correlate with the needs of real-world clinical practice, patients, or the concerns of payers. All of these raise costs.

Fortunately, solutions are real and multi-faceted. First, FDA can encourage and product developers can use patient-reported outcomes or remote functional assessments (performed at home by the patient themselves, assisted by family, or remotely with automated or live guidance) in the appropriate context to provide cost effective alternatives to traditional biomarkers and intensive assessments. Examples include improvements in breathlessness[67] or the six-minute walk test distance traveled [68] for chronic obstructive pulmonary disease while impairments in strength and coordination can be measured through simple functional tests[69] for movement disorders like Parkinson's disease or the case of accepting as a secondary outcome a decrease in the nagging itching sensation in eczema patients.[70] As a regulator of market entry, the FDA has long focused on evidence generation with prior guidance on real-world evidence[71] and patient-reported outcomes[72] from 2009 in addition to draft guidance for decentralized clinical trials.[73] This focus on customization specific to the patient in a truly patient-centered manner is in sharp contrast to lab tests and intermediate biomarkers – valid scientific/clinical options – that are less convenient for patients and favor larger companies due to the large population required to have adequate power to detect a statistically meaningful outcome (let alone a clinically outcome).[74] Modernizing assessment would both reduce the cost of development for small companies and lower barriers to trial participation for impoverished, rural, and minority beneficiaries.

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Policymakers and FDA can also encourage flexibility in trial design. Creativity in trial design can take many forms including enrichment,[75] adaptive designs,[76] master protocols,[77] and the transition of clinical trials into community settings[78] as part of routine clinical practice. These interventions can expand access, increase the diversity of trials, and lower costs. The FDA's 2017 review of valbenazine indicated for a tardive dyskinesia represents one such example of this exact principle,[79] with delayed, remote assessment of some clinical features by remote video raters to reduce costs coupled with extension of the existing trial after initial demonstration of efficacy in order to increase the power to assess differences in dosing ranges. Other steps such as deploying less frequently used historical trial designs could allow product developers to "do more with less." Examples include repurposing a study population after a washout period or conducting crossover trials. FDA and product developers can also consider entirely new modalities of evidence generation such as AI biosimulation models[80,81,82] and digital twin[83] models that could replace animal studies and generate preliminary human safety data, accelerating preclinical research and driving some components of Phase 1 studies. Currently, novel evidence generation strategies are less attractive for companies as a management top-heavy FDA with overburdened review staff incentivizes companies to tread well-traveled, low risk paths, which ultimately result in higher market entry costs and more limited patient populations studied. By directing FDA to write guidance for, integrate into review, and evangelize modern evidence generation, policymakers can lower entry costs, preserve or improve FDA safety and efficacy standards, and improve consumer affordability and uptake: a product prescribed and not filled at the pharmacy counter lacks real world effectiveness.

4. Conclusion

In pharmaceutical product markets, competition occurs along both price and non-price factors, both of which matter to patient-consumers and purchasers. Policymakers can overhaul U.S. Food and Drug Administration (FDA) regulatory policy to drive product competition and drug affordability for consumers.

Price competition in biologics drug markets can be improved by streamlining the evidentiary requirements and providing FDA flexibility in the existing 351(k) entry pathway for biosimilars, thus finally unleashing the promise of biosimilars through an ABLA pathway. Generic markets would benefit from increased entry through the creation of a limited competition generics market PRV program, improving FDA regulatory process by addressing anti-competitive abusive practices, increasing access channels by improving the Rx-To-OTC process and OTC ACNU regulations in addition to creating a pharmacist-mediated BTC drug channel, and improving combination product regulatory pathways. Finally, policymakers can spur or even require FDA to update drug review and push for modernized evidence generation, lowering entry costs for branded drugs and simultaneously expanding diversity in clinical trials.

All of these changes would preserve if not strengthen FDA standards of efficacy and safety. These nonpartisan changes are also within the jurisdiction of the committee, and deploy the dynamic tool of competition to improve drug affordability. With prescription drug affordability a persistent challenge for consumers, now is a good time to try something different.

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