

What Commissioner Gottlieb's FDA Is Doing to Lower Prescription Drug Prices and Steps Congress Can Take to Help

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ABSTRACT

ISSUE: Prescription drug prices have been climbing, creating significant barriers for patients. Since becoming U.S. Food and Drug Administration (FDA) Commissioner, Scott Gottlieb announced an action plan and several policy changes to increase generic drug competition and transparency to address high prescription drug prices.

GOAL: This issue brief aims to explain the FDA's plan of action and assess its implementation to date. It also aims to assess whether FDA actions, if implemented, address the known problems leading to high drug pricing.

METHODS: We analyzed the FDA's announced plans and actions as of March 31, 2018, and compared them to a comprehensive list of potential actions that could improve price competition among drug manufacturers included in our report, *Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions*.

FINDINGS: The FDA's plan includes actions that could indirectly lower prescription drug prices through increased competition. The agency has made progress in implementing its proposed changes, but has not fully executed them. The FDA could use its broad authority over the approval of drug products to take additional actions that improve market competition. Congress also could take action to support the FDA's efforts in increasing competition and addressing anticompetitive behaviors.

CONCLUSION: Implementation of the FDA's vision could create a more competitive drug market leading to more affordable drugs for patients. The FDA should consider additional steps under its current authority to address factors that impact competition and prices, while Congress should do more to support the FDA's work to lower prescription drug prices by working with the FDA and other federal agencies.

KEY TAKEAWAYS

► **High prescription drug prices can prevent patients from getting needed treatment. New FDA Commissioner Scott Gottlieb has proposed a meaningful agenda to encourage competition and transparency — and potentially lower prices — in the prescription drug markets.**

► **The FDA has made progress in certain areas — expediting new drug applications, for instance — but not in others, like addressing anticompetitive behaviors. There are additional opportunities for the agency to act.**

► **The FDA's authority has limits. Congress can take steps to support the FDA and lower drug prices for consumers; some solutions may involve other agencies, like the Federal Trade Commission.**



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BACKGROUND

Many brand-name prescription drugs are protected by patents or market exclusivity; some can take advantage of regulatory loopholes to delay price competition from generic drugs. As a result, brand-name manufacturers can continue to increase their prices without the threat of market competition. A recent study found that prices for brand-name drugs increased by 110 percent between 2012 and 2016, even though use of brand-name drugs decreased by 38 percent over the same time period.¹ High prices can make certain drugs unattainable for consumers. In recent polling, four of five patients cited drug prices as a top priority for the administration and Congress.²

Our 2017 report, *Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions*, identified a lack of competition among generic drugs, resulting in less competition and higher prices, as well as anticompetitive behaviors used to delay price competition.³ This is inconsistent with the intent of the Drug Price Competition and Patent Term Restoration Act of 1984—commonly referred to as the Hatch–Waxman Act, which created the pathway for generic drug approvals.

In the near future, President Trump is expected to make his first major announcement on drug pricing. So far, the administration has signed into law three drug-related provisions in the Bipartisan Budget Act of 2018 and made several proposals in the fiscal year 2019 Presidential Budget Request. However, the most significant administrative actions to date to address drug pricing have come from the FDA, which has announced a series of actions to increase generic price competition.

THE FDA'S ROLE IN PHARMACEUTICAL PRICING

The FDA historically has not played a role in drug pricing policy because, as Commissioner Scott Gottlieb recently stated, it has “no legal authority to investigate or

control the prices set by manufacturers, distributors, and retailers.”⁴ However, Gottlieb also publicly noted, “Too many patients are being priced out of the medicines they need. While the FDA doesn’t have a direct role in drug pricing, we can take steps to help address this problem by facilitating increased competition in the market for prescription drugs through the approval of lower-cost, generic medicines.”⁵ Under Gottlieb’s leadership, and in a relatively short period of time, the FDA set an ambitious agenda to encourage more transparency and generic drug competition and has outlined several other action steps to address gaming by some brand-name manufacturers to maintain monopoly pricing.⁶

This issue brief explains the FDA’s plan of action and its potential to lower prescription drug prices through increased competition by categorizing the types of actions the agency is taking and assessing whether they will address the known problems leading to high drug pricing.

CURRENT, PROPOSED, AND FUTURE ACTIONS TO LOWER PRESCRIPTION DRUG PRICES

The FDA Has Made Progress Implementing Its Action Plans

FDA Commissioner Gottlieb released a proactive agenda to encourage more competition and transparency for generic drugs in June 2017, not long after he was sworn in in May.⁷ On subsequent occasions, he has announced steps to implement his vision, such as the Drug Competition Action Plan that outlines the FDA’s effort to increase generic drug competition and transparency.

As part of the Action Plan, Gottlieb held a public hearing in July 2017 to accept comments from the public on how to increase generic drug competition.⁸ Building on this plan, the FDA published a Strategic Roadmap in January 2018, which included further steps in areas like orphan drug approvals and compounding (Exhibit 1).

Exhibit 1. FDA Actions to Promote Competition and Transparency

ISSUE	ANNOUNCEMENT	DATE ANNOUNCED	ACTION TAKEN AS OF MARCH 31, 2018
Sole Source Markets	FDA will maintain a public list of drugs without competition	June 2017	The list of off-patent, off-exclusivity branded drugs without approved generics was published in June 2017 and updated in December 2017. FDA will continue to update the list periodically. ⁹ This was also a requirement in the FDA Reauthorization Act of 2017 (FDARA). ¹⁰
Abbreviated New Drug Application (ANDA) Process	FDA will institute expedited and priority reviews for abbreviated new drug applications (ANDAs) or generic drug applications where there is a lack of competition	June 2017	FDA began expediting these reviews in June 2017. In November 2017, FDA expanded this policy by creating a new category of applications eligible for priority review. FDA will prioritize applications likely to be ready for approval upon or shortly after the expiration of the 180-day exclusivity period that is awarded to a first-to-file ANDA. ¹¹
	FDA intends to improve the application process for manufacturers to apply for generic drug approval. Will publish guidances for requesting meetings with FDA, including before a manufacturer prepares and submits an ANDA up through the entire process, and for enhanced communication between manufacturers and FDA ¹²	October 2017	Draft guidances not yet final
	FDA will improve submission and review of generic drug applications by publishing draft guidance highlighting best practices for manufacturers in submitting an ANDA and guidance on how FDA staff assess ANDAs ¹³	January 2018	Draft guidance not yet final
	FDA intends to increase overall efficiency of generic drug reviews by increasing productivity, conducting reviews in a timely manner, and keeping costs low to file a generic application ¹⁴	January 2018	No action to date
	FDA will publicize plans to increase access to complex generic drugs by releasing "sameness" requirements for ANDAs and guidance on drug-device combination products ¹⁵	January 2018	No action to date
Risk Evaluation and Mitigation Strategies (REMS)	FDA will eliminate misuse in REMS by publishing draft guidance to streamline the submission and review process for shared system REMS ¹⁶	November 2017	Draft guidance not yet final
Anticompetitive Behaviors	FDA will work with other agencies to identify anti-competitive practices	November 2017	In the 2018 strategic plan, FDA announced plans to establish an interagency working group to explore areas where FDA can more closely collaborate with FTC. ¹⁷ No further action to date.
	FDA will identify and address manufacturers' behaviors that delay generic drug competition ¹⁸	January 2018	No action to date
Citizens Petitions	FDA will evaluate use of Citizens Petitions in blocking generic drug entry ¹⁹	January 2018	No action to date
Biosimilars	FDA stated it will introduce its new Biosimilar Innovation Plan to facilitate approval and adoption of biosimilars ²⁰	January 2018	No action to date
	FDA is educating providers on biosimilars	October 2017	Campaign has been implemented. FDA will conduct additional research with health care professionals to learn more about the types of information providers need to properly communicate with their patients about biosimilars. ²¹
Orphan Drugs	FDA is addressing loopholes within the Orphan Drug Modernization Action Plan. This includes publishing draft guidance that states it will no longer grant orphan drug designation to drugs for pediatric subpopulations of common diseases unless the use of the drug in that subpopulation meets the regulatory criteria for an orphan subset or unless the disease in the pediatric subpopulation is considered a different disease from the disease in the adult population. ²²	June 2017	Draft guidance not yet final
	FDA is making orphan designation requests more efficient	February 2018	FDA started a pilot project of a new electronic fillable form to make submission requests easier to submit and review ²³
	FDA is incorporating patient experience into regulatory discussions on orphan drugs	February 2018	FDA entered into a memorandum of understanding with the National Organization of Rare Diseases ²⁴
Compounding	FDA will restrict compounding of drugs that are essentially copies of FDA-approved drugs	January 2018	Two guidances explaining the agency's policies on the "essentially a copy" provisions of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act are final ²⁵

In his short tenure, Gottlieb has made significant strides by announcing his intent to implement actions that would indirectly address drug prices using FDA authority. Because these actions are in early stages or yet to be implemented, their impact remains uncertain. Gottlieb's actions to encourage competition are expected to have a positive impact on bringing more generic drugs to market and providing lower-priced alternatives to patients. His comments on reducing anticompetitive behaviors, closing loopholes, and continuing to increase competition — including promoting biosimilar development — are promising indications that the FDA is taking the necessary actions to curb gaming by some manufacturers and spur price competition. If fully implemented, the FDA can address high prescription drug prices by creating a more competitive market; however, the agency can do more to lower prices.

The FDA's Broad Authority Allows It to Take Additional Actions that May Indirectly Lower Prescription Drug Prices

By leveraging its existing agency authority, the FDA can do more to encourage competition without congressional action (Exhibit 2). This would also indirectly affect high prescription drug pricing. For example, some of the highest-priced prescription drugs are biologics. Improving the biosimilar pathway by finalizing interchangeability guidance may have great future impact on price competition.

Much of the FDA's authority for oversight of prescription drugs is rooted in approving drug product applications. The Secretary of the U.S. Department of Health and Human Services (HHS) has the authority to approve drug product applications in the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 355(c)).²⁶ The Secretary delegates its authority in the FFDCA to the FDA Commissioner, including reviewing and approving new prescription drug products.²⁷

TRUMP ADMINISTRATION ACTIONS RELATED TO PRESCRIPTION DRUG POLICIES

The President's Budget and Drug Pricing Proposals

The President's 2019 budget includes proposals to lower prescription drug costs. These build on last year's limited efforts by the Centers for Medicare and Medicaid Services (CMS) to lower patient costs, by the U.S. Food and Drug Administration (FDA) to increase price competition, and by proposals put forth by the Obama administration in prior years. Some proposals would require legislative action from Congress to implement while others could be put in place by the administration without new statutory authority.

The President's budget called for increased FDA funding and provided authority for it to eliminate the 180-day exclusivity for first-to-market generic manufacturers if they do not resolve application deficiencies in a timely manner. The majority of the proposals focus on policy changes or demonstrations in Medicaid and Medicare. To learn more on the proposals, read this [Commonwealth Fund blog post](#).

Bipartisan Budget Act of 2018

The Bipartisan Budget Act of 2018 included three provisions to reduce prescription drug prices and costs. Likely the least understood part of that legislation is a technical fix to how the Medicaid program pays for "line extensions," or drugs that have undergone minor changes from their original versions — sometimes referred to as "new formulation drugs." In addition to the technical correction for line-extension drugs, Congress included two other provisions that save Medicare beneficiaries and the federal government money. The legislation builds on important work started in the Affordable Care Act to protect Medicare beneficiaries from high prescription drug costs. To learn more about these provisions, read this [Commonwealth Fund blog post](#).

Exhibit 2. Opportunities for Further FDA Action Under Current Law

ISSUE	AUTHORITY
REMS	The Food and Drug Administration Amendments Act of 2007 authorized FDA to require manufacturers to adhere to a risk-mitigation strategy, known as a Risk Evaluation and Monitoring Strategy (REMS), when there are safety concerns like increased toxicity or other risk factors. Brand-name manufacturers have been misusing REMS to block potential generic competitors from obtaining samples needed to conduct the FDA-required bioequivalence studies. Gottlieb spoke out against the REMS abuses. ²⁸ In approving each REMS, FDA has the authority to require brand-name manufacturers to assure availability of a sample for potential generic manufacturers by making it a condition of approval.
Biosimilars	Currently, there are nine FDA-approved biosimilar products with the first approval in 2015, ²⁹ but only three on the market. ³⁰ The other six are under settlement agreements, patent litigation, or the manufacturer does not have plans to launch. ³¹ Biosimilars have been on the market in Europe since 2006, and they are common in China, India, and South Korea. ³² FDA can finalize guidance for the biosimilar pathway to spur competition in the biologics market, including finalizing the draft guidance on interchangeability that was published in January 2017. ³³ Other actions the FDA can take to facilitate biosimilar competition include: issuing final guidance on labeling, revisiting the guidance on identical international nonproprietary names, and issuing guidance on transitional biological products. Gottlieb acknowledged that biosimilars will increase competition and likely lower drug prices for patients. ³⁴ FDA's 2018 Strategic Policy Roadmap indicates it will soon release a plan dedicated to approving biosimilar drugs. ³⁵
Orphan Drugs	The FDA Reauthorization Act of 2017 amends the FFDCA Section 527 to require an applicant seeking a seven-year period of orphan drug exclusivity for the same disease or condition as a previously approved drug to demonstrate that its product is clinically superior, meaning that "the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care." ³⁶ Thus, when approving orphan drug applications, FDA can require manufacturers to submit comparative effectiveness research, allowing for comparison of multiple drugs based on the effectiveness, harms, and benefits of different treatment options. Comparative effectiveness research may help address arbitrary pricing and spur new innovation. FDA could require this information as a condition of approval for new drug applications when an existing orphan drug therapy is already on the market.
Product Hopping and Evergreening	There may be opportunity for FDA to address the problem of "product hopping" and "evergreening." That is, when a manufacturer modifies an existing drug in a way that has little or no added therapeutic value and then withdraws the original product from the market to block generic competition. Our report identified an opportunity for FDA to conduct a study on the effects of product hopping on company profits, consumer access, physician prescribing behavior, and the broader economic impacts.

The FDA's Authority Is Limited in Some Areas, But Congress Can Take Action

While the FDA has taken promising steps to address the lack of competition and improve its efficiency in approving prescription drugs, its authority has limits. Congress can

support the FDA in addressing high prescription drug prices. This could include reaffirming authority for specific policy actions or establishing new authority to expand current FDA actions (Exhibit 3).

Exhibit 3. Steps Congress Can Take to Support FDA Efforts to Increase Drug Price Competition

ISSUE	POTENTIAL CONGRESSIONAL ACTION
Encourage More Generic Competition 	Congress could provide FDA with new authority to encourage additional generics to enter the market when there is only one manufacturer producing the drug, also known as a sole source situation, including waiving or reducing user fees, granting awards, or other incentives for generic manufacturers.
Biosimilars 	Congress can instruct FDA to finalize guidance for interchangeable biosimilars by a certain time and include legislation to override state anti-substitution laws. Such laws are prohibited for generic drugs and there should be similar policy in place to encourage the use of biosimilars.
Orphan Drugs 	Congress can take steps to modernize the Orphan Drug Act, including closing loopholes that allow manufacturers to get new exclusivity by classifying non-orphan diseases into orphan indications for subpopulations. Congress could require manufacturers to provide up front their plans to FDA if they will be applying for multiple orphan drug designations. Congress could also create incentives for generics to apply for non-orphan use of off-patent drugs that have an orphan designation.
Product Hopping or Evergreening 	Congress can work with FDA to establish a process for designating a “clinically equivalent” standard that would allow generics to be approved as clinically equivalent to the brand-name drug that has undergone minor (i.e., not clinically significant changes), such as shifting from tablet to capsule. This would address some “product hopping” and “evergreening” delay tactics that manufacturers use. Legislation could be narrow in scope so as to not stifle innovation.
Importation 	Congress can provide FDA with authority to allow limited importation of drugs from designated equivalent regulatory countries when only one manufacturer is on the market with an off-patent drug and there are price increases over a certain percentage or when no other generic company will enter the market.

It is important to note that drug pricing problems extend beyond the FDA's jurisdiction. Policy solutions that involve other agencies at the Department of Health and Human Services, the U.S. Patent and Trademark Office, Federal Trade Commission, and the Department of Justice must also be considered.

CONCLUSION

Commissioner Gottlieb has formed a meaningful plan of action that has the potential to create a more competitive prescription drug market and ultimately, more affordable drugs for patients. The agency should continue to move forward in implementing the Drug Competition Action Plan and the FDA's 2018 policy priorities. Congress should work simultaneously to support and complement the FDA's work to lower prescription drug prices and consider what can be done by other federal agencies.

NOTES

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ABOUT THE AUTHORS

Rep. Henry Waxman is one of the most effective legislators of the last 40 years, with health care among his central concerns. During his time in Congress, Waxman used legislative tools to unmask the tobacco industry after years of deception and authored the Affordable Care Act, which has helped 20 million more Americans get health insurance. The Hatch-Waxman Act helped create the generic drug industry, while the Orphan Drug Act incentivized the growth of an industry that has given hope to the millions of Americans afflicted with rare diseases. Evident in all of Waxman's work is his commitment to concrete solutions that transform people's lives for the better. His tenacity has earned him widespread recognition from journalists, fellow elected officials, and President Obama, who described him as "one of the most accomplished legislators of this or any era."

Bill Corr has spent the bulk of his impressive career advocating for better health care access at almost every level of society. Most recently, he served as deputy secretary of the U.S. Department of Health and Human Services from 2009 to 2015. Corr returned to the department after serving as executive director of the Campaign for Tobacco-Free Kids, a privately funded organization established to focus the nation's attention and action on reducing tobacco use among both kids and adults. From March 1998 until 2000, Corr served as chief counsel and policy director for Senate Minority Leader Tom Daschle. Before working this, he served as the chief of staff for the Department of Health and Human Services. In that capacity, he was principal advisor to Secretary Donna E. Shalala on all major policy and management issues and initiatives. He also was deputy assistant secretary for health for the department and counselor to the secretary prior to becoming chief of staff. From 1989 until 1993, Corr served as chief counsel and staff director for the Subcommittee on Antitrust, Monopolies and Business Rights of the Senate Committee on the Judiciary under Chairman Howard M. Metzenbaum. Corr also served as counsel to the Subcommittee on Health and the Environment of the House of Representatives Committee on Energy and Commerce under Chairmen Paul Rogers and Henry A. Waxman.

Kristi Martin most recently was a senior advisor in the Office of Health Reform at the Department of Health and Human Services, where she had primary oversight responsibility for the coordinated and timely implementation of the public health and prevention policy portfolio of the Affordable Care Act. In addition, she provided support and coordination related to cross-cutting departmental initiatives, including the rising cost of drugs and women's health issues. Previously, Martin served as team lead for the State Analysis and Oversight Team in National Healthcare Operations at the U.S. Office of Personnel Management. In this role, she led policy development and state engagement efforts to implement the Multi-State Plan Program. Martin has also worked in the Center for Consumer Information and Insurance Oversight and Government Accountability Office and at American Cancer Society and Easter Seals.

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The mission of the Commonwealth Fund is to promote a high performance health care system. The Fund carries out this mandate by supporting independent research on health care issues and making grants to improve health care practice and policy. Support for this research was provided by the Commonwealth Fund. The views presented here are those of the authors and not necessarily those of the Commonwealth Fund or its directors, officers, or staff.

