How the Next FDA Commissioner Can Address Drug Prices by Promoting Drug Competition

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EXECUTIVE SUMMARY

Pharmaceutical competition is critical to the U.S. health care system. It yields cost savings, as both generic drugs and competing brand drugs lead to lower prices. In the current political climate, marked by outrage over high drug prices, the benefits of competition are particularly important. This is where the Food and Drug Administration (FDA) comes in. While the FDA does not directly control drug prices, what the agency does (or fails to do) can affect drug prices for the simple reason that it can affect the number of suppliers.

Recognizing the importance of pharmaceutical innovation, the FDA offers economic incentives and expedited review for certain products to encourage the development and speed the approval of new drugs and biologics. The widespread public frustration over drug prices is an indication that competition must begin receiving attention at the FDA comparable to what has been focused on innovation.

As the Prescription Drug User Fee Act (PDUFA) and the Generic Drug User Fee Amendments (GDUFA) are reauthorized and a new commissioner takes over the helm of the FDA, both Congress and the agency should work to address drug pricing by prioritizing drug competition. First, it is important to recognize that, like innovation, drug competition is multifaceted. Generic drugs compete with their brand counterparts and with each other. Brand drugs compete with other brands in the same drug class. And biosimilars compete with their reference products. With these distinctions in mind, this paper recommends five ways the FDA can foster competition:

1. **Encourage "First Generic" Applications.** The FDA should reduce the review time for first generics – that is, generics for products that do not yet have a generic equivalent. The agency is on the right track with its commitment letter for GDUFA II, which outlines a goal for processing priority original ANDAs within 8–10 months.
2. **Prevent Misuse of Risk Evaluation and Mitigation Strategies (REMS) Programs.** Brand manufacturers use these programs to deny access to drug samples for generic manufacturers, who need samples to develop generics. Congress must give the FDA authority to prevent the misuse of REMS programs. The FDA has been supportive of a solution to the problem.
3. **Reduce Barriers to Generic Entry.** The FDA should ensure that generic user fees do not discourage firms from seeking approval for generic drugs and reduce the review period for standard ANDAs.
4. **Dedicate More Resources to Brand-to-Brand Competition.** Improve operational processes inside the FDA and, if necessary, provide more resources for the agency to expedite approvals for competing brand products.
5. **Streamline Application Process for Biosimilars.** The FDA should carefully review biosimilar guidance and regulations and look for ways to facilitate the application process and reduce review times. The agency should also provide additional clarity and predictability to stakeholders on biosimilar interchangeability. Key to successfully nurturing this emerging market is cooperative engagement and clear communications with biosimilar applicants and other stakeholders.

INTRODUCTION

Over the last two years, frustration has mounted in the United States over drug prices. The outrage reached such heights that Donald Trump, in his first address to Congress, enjoined members to "work to bring down the artificially high price of drugs and bring them down immediately."[1] Later in this speech, President Trump lamented undue regulatory constraints affecting pharmaceuticals: "Our slow and burdensome approval process at the Food and Drug Administration [FDA] keeps too many advances . . . from reaching those in need."[2] To some, drug prices, which are set in the market, and drug approvals, which are controlled by government regulators, are distinct. It is true that the FDA – responsible for ensuring the safety and efficacy of drugs and other products – does not directly control prices. But what the FDA does (or fails to do) can affect drug prices for the simple reason that it can affect the number of suppliers. In the U.S. market, competition in the pharmaceutical sector is key to moderating drug prices, and the FDA plays an important role in fostering (or discouraging) this competition.

Despite President Trump's complaint about the FDA being sluggish in approving innovative products, the agency has long prioritized drug innovation and has been vocal about this emphasis. After a blockbuster 2015, during which the agency approved 45 new drugs, approvals slowed to 22 in 2016. Nevertheless, 86 percent of the products approved in 2016 were approved in the United States before any other country, and more than one-third were "first in class" – that is, drugs with a new and unique mechanism for treating a medical condition.[3] Thus far in 2017, 8 novel drugs have been approved.[4]

The FDA's impact on competition, and therefore its impact on prices in the marketplace, is less understood. With high drug prices capturing sustained national attention, new leadership at the FDA, and the upcoming reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Generic Drug User Fee Amendments (GDUFA), now is an appropriate time to highlight this issue.

In this paper, after briefly reviewing the FDA's core functions as they relate to prescription drugs, I identify five policy priorities for the new FDA commissioner that would facilitate competition in the U.S. drug market. A statutory and regulatory agenda for the FDA that acknowledges the agency's effect on competition is an important step for lowering drug prices and increasing consumer welfare.

FDA'S CORE MISSION AND COMMITMENT TO INNOVATION

The FDA is tasked with protecting public health through regulations and activities related to the safety and efficacy of prescription drugs and a host of other products, including food, cosmetics, and medical devices, among others. Recognizing the importance of pharmaceutical innovation, the FDA also employs incentives to encourage the development and speed the approval of new drugs and biologics.

Ensuring Safety and Efficacy of Prescription Drugs

Prescription drug oversight is housed in the FDA's Center for Drug Evaluation and Research (CDER), whose primary functions include reviewing applications for new pharmaceutical products, overseeing post-market surveillance, and maintaining manufacturing and quality standards.[5] Before a new drug is ready for review, the FDA requires that it undergo rigorous testing, including three successive phases of human testing. After completing this strict regimen, drug companies hopeful of bringing a new product to market can apply for FDA approval using a new drug application (NDA) for small-molecule drugs or a biologics license application (BLA) for biologics. Small-molecule generic drugs, which are not required to repeat all of the testing performed by the innovator drug, receive FDA review under an abbreviated new drug application (ANDA). Manufacturers of biosimilars, which are copies of biologics, use a 351(k) application.

In addition to evaluating the safety and efficacy of the drug under review, the FDA inspects manufacturing facilities and reviews the drug label that will accompany the new product. Following approval, the agency continues to monitor the quality of manufacturing facilities as well as the clinical safety of the drug itself. In addition to agency review of adverse event reporting, FDA oversight of drug safety and efficacy after approval includes post-market risk management plans such as Risk Evaluation and Mitigation Strategies (REMS) that the agency may require of the manufacturer.

FDA oversight, intended to ensure the critically important safety and efficacy of prescription drugs, also results in high regulatory compliance burdens and generates significant costs for drug manufacturers. By raising the cost of entry to the pharmaceutical industry, the safety and efficacy requirements also affect the degree of competition among similar products.

Promoting Innovation

Recognizing that drug development is a lengthy process that entails enormous costs, the FDA, generally at the direction of Congress, has established various ways to promote drug innovation and speed market entry, primarily by expediting certain new drug approvals and offering pre- and post-approval economic incentives for new drugs.

Expedited Approval

The FDA has four ways to expedite the approval of certain new drugs:

1. **Breakthrough** therapy designations for drugs in clinical trials that show greater promise than available products for treating serious conditions;
2. **Fast track** designations for drugs that address an unmet medical need;
3. **Priority review** for NDAs and BLAs that demonstrate significant improvement over available treatments; and
4. **Accelerated approval** for drugs with an intermediate clinical endpoint that indicates the likelihood of substantial clinical benefit.[6]

The median time from application submission to FDA approval for standard NDAs and BLAs is 12 months, and for priority NDAs and BLAs, 8 months.[7]

Economic Incentives

The FDA also makes available to drug manufacturers economic incentives, pre- and post-approval, for certain kinds of new drug development. Pre-approval incentives include grants and user-fee waivers for some applications.[8]

Post-approval incentives – namely, patent term restoration and marketing exclusivity – for non-orphan drugs were established as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the

Hatch-Waxman Act), which was intended to balance incentives for drug innovation and competition. Under Hatch-Waxman, the FDA is authorized to award a qualifying new drug three or five years of marketing exclusivity (depending on the product's merits) and restore to the drug's patent term the time elapsed during FDA review of the product.[9] Biologic drugs are awarded twelve years of exclusivity, as established by the Affordable Care Act of 2010. And under the Orphan Drug Act of 1983, orphan drugs, which treat rare diseases and conditions, receive both pre- and post-approval economic incentives, including research grants, tax credits, and seven years of marketing exclusivity.

Commitment to Innovation

The FDA not only actively supports and promotes drug innovation, but is also vocal about its obligation to do so. CDER recently identified "scientific innovation" as one of its four primary strategies.[10] And the agency touts its role in facilitating new drugs thus:

> Innovation drives progress. When it comes to innovation in the development of new drugs and therapeutic biological products, [CDER] supports the pharmaceutical industry at every step of the process. . . . The availability of new drugs and biological products often means new treatment options for patients and advances in health care for the American public. For this reason, CDER supports innovation and plays a key role in helping to advance new drug development.[11]

In short, the FDA has embraced its role as a facilitator of innovation – a role that legislation over the last several decades has made an increasing share of the agency's responsibilities. Promoting innovation is now inextricably interwoven with the FDA's core mission of ensuring safety and efficacy.

Drug innovation has been indisputably beneficial to patients and the health care system, but innovation is not the only way that the drug industry improves consumer welfare. Competition is another important way. In fact, one of the benefits of competition is that it creates incentives for innovation, as manufacturers pursue new products to avoid losing market share to competitors. Like innovation, competition is directly affected by the FDA. But competition has not been prioritized by the agency or by Congress to the same degree as innovation.

HOW THE FDA CAN FOSTER COMPETITION

While drug prices are not (and should not be) a factor when the FDA determines if a drug should be approved, how the FDA makes such a determination can ultimately contribute to the market dynamics that affect a product's price. Like innovation, drug competition is multifaceted.

- ***Generic drugs compete with their brand counterparts and with each other.*** When a brand drug goes generic, the generic version enters at a lower price. But the biggest price declines occur when multiple generics compete for market share. Health economists have found that when there are more than four generic manufacturers for a given product, prices decline significantly.[12]
- ***Brand drugs compete with other brands in the same drug class.*** While a brand drug would not be interchangeable with another brand, as a generic is, brand drugs would be in competition if they treat the same condition.
- ***Biosimilars compete with their reference products.*** Biosimilars represent the newest form of drug competition. The pathway for these alternatives to biologics to come to market was established in 2010, but the first U.S. biosimilar was not approved until 2015.

The widespread public frustration over drug prices is an indication that competition must begin receiving attention at the FDA comparable to what has been focused on innovation. As PDUFA and GDUFA are reauthorized and a new commissioner takes over the helm of the FDA, both Congress and the agency should work to address drug pricing through the prioritization of the multiple types of drug competition. Below are five specific ways to do this.

Because the FDA's commitment to innovation must remain intact, efforts to prioritize competition may require additional agency resources, either appropriated by Congress or collected through user fees. Given that President Trump has proposed a $40 million cut to the FDA's budget for the remainder of FY 2017,[13] there may be pressure to increase user fees.

Policy Priorities to Promote Drug Competition

Generic-to-Brand Competition

Encourage First Generic Applications

The FDA's regulation of generic drugs under the Hatch-Waxman Act represents the most prominent way in which the agency promotes pharmaceutical competition. The approval of thousands of generic drugs by the FDA in the thirty years since Hatch-Waxman's enactment has led directly to enormous consumer benefit, as generic drugs yield hundreds of billions of dollars in savings annually. But applications for "first generics" – that is, generics for products that do not yet have a generic equivalent – have slowed. In 2016, the FDA approved 73 first generics.[14] Currently, however, there are not even 20 applications pending.[15]

RECOMMENDATION #1:

The FDA should reduce the review time for first generics. The agency is on the right track with its commitment letter for GDUFA II, which outlines a goal for processing priority original ANDAs within 8–10 months.[16] Legislation in the House and Senate in the last several sessions – for example, H.R. 749, the Lower Drug Costs Through Competition Act, introduced in January 2017 – has proposed even shorter review periods and priority review vouchers for drugs without competition.

Prevent Misuse of REMS Programs

As mentioned above, Risk Evaluation and Mitigation Strategies (REMS) programs are post-market risk management plans that the FDA requires for some drugs. The FDA requires REMS programs for nearly 40 percent of new drugs.[17] Many REMS programs restrict product distribution as a safety measure, and brand manufacturers have begun using these required restrictions to deny access to drug samples for generic manufacturers, who need samples to develop generic versions of brand products. Brand manufacturers have also begun extending this practice to drugs that are not under REMS programs.

At a hearing in March 2017 before the House Oversight Committee's Subcommittee on Health Care, Benefits, and Administrative Rules, Gerard Anderson, a professor of public health at Johns Hopkins University, noted the difficulty of addressing this practice:

> There is a lack of federal guidance regarding which medications can be a part of a limited distribution network; the decision is primarily at the discretion of the pharmaceutical company. Aside from the drugs that are part of the REMS program there is no federal guidance

> on which drugs can be placed into limited distribution networks. The problem is that some drug companies are placing drugs into limited distribution networks to maximize profits not to maximize safety.[18]

Also in March 2017, at a Senate Health Committee hearing on user fees, CDER Director Janet Woodcock stated that the agency has alerted the Federal Trade Commission approximately 150 times to brand companies' anticompetitive use of REMS programs.[19]

In 2014, I quantified the lost savings from brand manufacturers' preventing generic market entry in this way. By my estimate, $5.4 billion in annual drug spending could be saved if generic versions of the forty brand drugs in the analysis were allowed to come to market.[20]

RECOMMENDATION #2:

Congress must give the FDA authority to prevent the misuse of REMS programs. The FDA is aware of the problem and has been supportive of a solution. There have been legislative attempts to address the REMS problem – most recently the CREATES Act of 2016 – but thus far nothing has been enacted.

Generic-to-Generic Competition

Reduce Barriers to Generic Entry

According to the FDA, generic drugs are 80–85 percent cheaper than their brand counterparts.[21] The Congressional Budget Office (CBO), citing the National Association of Chain Drug Stores, estimates the average generic price discount to be 75 percent.[22] This is the case because the generic drug industry in the 30 years since its inception has seen robust competition. To preserve the dynamics in the generic drug industry, it is important to keep barriers to entry for generic manufacturers low because the profit margins on generic drugs are low. Adding high fixed costs in a low-margin business can have significant disincentive effects.

In addition, speedy FDA review of ANDAs is essential. The FDA recently cleared a substantial backlog of ANDAs. According to the Office of Generic Drugs (OGD), "Today there is no backlog, and filing is performed in real time. OGD issued filing decisions within 60 days for 99% of ANDAs submitted in FY 2015 that had GDUFA goal dates, and, on average, filing decisions are made and communicated to industry in approximately 40 days."[23] However, the median review time for ANDAs is 36 months – fully three times longer than the median review time for standard NDAs and BLAs and four and a half times longer than the median review time for priority NDAs and BLAs.[24]

RECOMMENDATION #3:

The FDA should ensure that generic user fees do not discourage firms from seeking approval for generic drugs and reduce the review period for standard ANDAs.

Brand-to-Brand Competition

Dedicate More Resources to Brand-to-Brand Competition

Brand-to-brand competition within a given drug class is particularly undervalued in FDA priorities. The FDA's focus on streamlining approvals for certain types of new drugs means that fewer resources are available for agency activities that prioritize competition within a given drug class. While the public health benefit from drugs that receive expedited approval is undeniable, it is important to recognize that other products are leapfrogged in the process and to acknowledge

that this has consequences for competition. For example, in 2016, 73 percent of new drugs approved by the FDA received expedited review – 27 percent received accelerated approval; 32 percent, breakthrough therapy designations; 36 percent, fast track designations; and 68 percent, priority review.[25] These four routes for expedited approval (described in greater detail above) apply to drugs that address unmet needs or represent significant improvements over currently available products. But brand drugs offering benefits comparable to existing products are not eligible for any type of expedited review.

Because the FDA does not prioritize approving competitive products, the first brand drug in a given class may benefit from additional market access with limited or no competition from a potentially competing brand.

RECOMMENDATION #4:

Improve operational processes inside the FDA and, if necessary, provide more resources for the agency to expedite approvals for competing brand products. Manufacturers may be willing to pay more to accelerate the review of applications if those funds are used effectively.

Biosimilar Competition

Streamline Application Process for Biosimilars

Biologics, drugs derived from living cells, are among the most expensive pharmaceuticals and represent a growing share of U.S. drug spending. Biosimilars, essentially lower-priced, competing copies of biologics, are expected to yield cost savings for payors and patients. In the lead-up to Affordable Care Act (ACA), which created the pathway for biosimilars in the United States, CBO projected that biosimilar prices would be 40 percent lower than biologic prices.[26]

Though the ACA was signed into law in March 2010, it took more than four years for a manufacturer to even file an application for biosimilar approval.[27] Currently, there are only five biosimilars approved. (By comparison, there are more than 20 biosimilars on the market in Europe.) The FDA's lengthy delays in releasing draft guidance on various issues related to biosimilars seriously thwarted the development of a U.S. biosimilars industry. In fact, the FDA did not release its guidance document on the important issue of interchangeability of biologics and biosimilars until January 2017.[28] And the agency is still working on other guidances.[29]

Other areas the FDA has weighed in on will have the effect of limiting the marketability of biosimilars. The agency recently finalized a unique naming convention for biosimilars that was widely considered before its adoption to impede biosimilar prescribing and utilization.[30]

In short, the FDA's actions may result in a smaller prospective biosimilars market for a given drug, which naturally would reduce the probability that a biosimilar product would be developed.

RECOMMENDATION #5:

The FDA should carefully review biosimilar guidance and regulations and look for ways to facilitate the application process and reduce review times. The agency should also build on its recent positive start on biosimilar interchangeability guidance by providing additional clarity and predictability to stakeholders. Key to successfully nurturing this emerging market is cooperative engagement and clear communications with biosimilar applicants and other stakeholders.

CONCLUSION

Pharmaceutical competition is critical to the U.S. health care system. It yields cost savings, as both generic drugs and competing brand drugs lead to lower prices. And competition promotes drug innovation, as brand manufacturers seek to capture market share by introducing new and superior products. The FDA's actions affect the market price for drugs and have a meaningful impact on access to medicines and consumer welfare. Congress must consider this impact carefully when reauthorizing PDUFA and GDUFA. The FDA, too, must be cognizant of the consequences of its actions on competition.

NOTES

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