Considerations of the FDA's Impact on Competition in the Drug Industry

By Alex Brill

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MATRIX GLOBAL ADVISORS

1350 Connecticut Ave. NW | Suite 610 | Washington, DC 20036
www.matrixglobaladvisors.com

EXECUTIVE SUMMARY

New costly pharmaceuticals have caught the attention of the media and policymakers because of concerns about the impact of these expensive drugs on health care spending and access to care. Most prominent among these products is Sovaldi, the innovative new $1,000-per-pill cure for hepatitis C, a disease that afflicts approximately 3.2 million Americans. Other examples include Opdivo, a cancer drug expected to enter the U.S. market in the near future that currently costs $143,000 a year in Japan, and Keytruda, another cancer drug that recently won Food and Drug Administration (FDA) approval and will cost $77,500 for an average course of treatment. These drugs, like many new pharmaceuticals, are important innovations, providing critical advances in health care. But some lawmakers, seemingly unconcerned about the costs, risks, and time involved in successful drug innovation and dismissive of sellers' and buyers' right to freely negotiate prices, have pointed fingers at drug manufacturers for their pricing strategies.

Concerns about the budget implications of costly medicines have led to proposals of federal government engagement (or "interference") directly in price negotiations. Government involvement in pricing has been thoroughly studied and determined to be both ineffective from a budget perspective and harmful to innovation. But the impact of other federal policies on drug prices deserves consideration. This paper is intended to explore this topic by examining how the FDA affects, perhaps unintentionally and unknowingly, the prices of prescription drugs, and to encourage the agency to investigate and evaluate the impact it has on both brand vs. generic competition and brand vs. brand competition within the drug industry.

While the FDA's core mission is to protect the public heath by ensuring the safety and efficacy of drugs (among other products), the agency also makes it a priority to facilitate drug innovation. As this paper argues, the FDA can have a critical impact on the degree of market competition. Competition among pharmaceutical products leads to lower prices and, in many circumstances, encourages additional innovation. Conversely, inadequate incentives for innovation may deny the marketplace new and efficacious treatments that patients need. A critical balance between competition and innovation must be struck.

As policy experts examine the causes and consequences of high drug prices, greater attention should be paid to the FDA's impact on competition. Possible steps for lawmakers and the FDA to take to facilitate competition in the pharmaceutical industry include a more vigorous effort in support of biosimilars, faster review times for drug applications, legislation to prohibit misuse of Risk Evaluation and Mitigation Strategies (REMS), and adequate FDA resources to ensure that expedited approvals for certain novel drug applications do not impede the approval of competing brand drug applications.

INTRODUCTION

The Food and Drug Administration (FDA) is tasked with protecting public health through regulations and activities related to the safety and efficacy of prescription drugs, among other products. Recognizing the importance of pharmaceutical innovation, the FDA also employs incentives to encourage the development and speed the approval of new drugs and biologics. Researchers have examined the FDA's impact on various aspects of drug innovation in the United States and explored the effectiveness of programs geared toward expediting drug approvals.[1] Most recently, researchers have assessed the FDA's tools for ensuring timely approval and appropriate utilization of specialty drugs.[2] This paper examines an often-ignored but equally important aspect of the FDA's role as drug regulator: its impact on competition in the pharmaceutical industry. While drug prices are not directly within the purview of the FDA, the agency's actions do affect the market price for drugs and can have a meaningful impact on access to medicines and consumer welfare.

The benefits of competition are multifaceted, including not only cost-containment, but also innovation, as manufacturers pursue new products to avoid losing market share to competitors. Specific FDA programs and offices (the Office of Generic Drugs, most notably) do facilitate competition, but it is not an acknowledged priority of the agency on par with the commitment to aiding pharmaceutical innovation. The approval of thousands of generic drugs by the FDA in the last thirty years has led directly to enormous consumer benefit, as generic drugs yield hundreds of billions of dollars in savings annually. But competition among pharmaceutical products and manufacturers is not limited to generic drugs, and brand-to-brand competition within a given drug class is particularly undervalued in FDA priorities.

This paper examines how the FDA, within its core mission of safety and efficacy and its acknowledged responsibility to promote innovation, affects competition in the pharmaceutical industry. Such a perspective is especially critical now, as policymakers face public concerns over an increase in the number of high-cost specialty drugs. Without an understanding of the FDA's existing impact on competition, it may not be possible to fully understand the market dynamics that give rise to these high-priced products.

With this in mind, the paper is structured as follows. **Section one** offers an overview of the FDA's efforts to ensure the safety and efficacy of prescription drugs, as well as the programs and processes the agency employs to promote pharmaceutical innovation. **Section two** illustrates several ways (among many) that existing FDA structures and regulations unintentionally hinder competition.

I. FDA REGULATION OF DRUGS AND BIOLOGICS: SAFETY, EFFICACY, AND INNOVATION

The FDA is responsible for regulating a host of products, including food, cosmetics, medical devices, veterinary products, and prescription and non-prescription pharmaceuticals, among others. This paper focuses on the agency's role

as the regulator of prescription drugs—both small-molecule and biologic—for human consumption. This section provides an overview of the FDA's functions in ensuring the safety and efficacy of prescription drugs and promoting pharmaceutical innovation.

Ensuring Safety and Efficacy

In pursuit of its mission to ensure that drugs are safe and effective, the FDA requires that drug manufacturing facilities meet standards of quality and safety, that new products undergo rigorous testing, and that patients receive accurate information about the risks and benefits of approved 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.[3]

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. 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).

In addition to evaluating the safety and efficacy of the drug seeking approval, 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 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 have required of the manufacturer as a prerequisite for approval.

These requirements, intended to ensure the critically important safety and efficacy of prescription drugs, also result in high regulatory compliance burdens and generate significant costs for the innovator drug manufacturer. By raising the cost of entry to the pharmaceutical industry, these safety and efficacy requirements also affect the degree of competition within the industry.

Promoting Innovation

Developing a new drug is risky, time-consuming, and expensive. Estimates of the cost of developing a new approved drug vary, but it is unquestionably an endeavor that involves, on average, hundreds of millions of dollars and a decade or more of time. Recognizing that the enormous development costs and lengthy process can delay or deter vital new medicines, the FDA, often 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 most recent method for expediting the approval of new drugs—known as breakthrough therapy designation—was created by the Food and Drug Administration Safety and Innovation Act of 2012, which reauthorized the Prescription Drug User Fee Act through 2017 and expanded upon the previous approval processes from the Food, Drug, and Cosmetic Act. The FDA now has four means of expediting the approval of new drugs that treat serious conditions:

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.[4]

The median time from application submission to FDA approval for standard NDAs and BLAs is 10 months, and for priority NDAs and BLAs, 6 months.[5]

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, and post-approval incentives include patent term restoration and marketing exclusivity.[6] For orphan drugs, which treat rare diseases and conditions, the FDA, as established by the Orphan Drug Act of 1983, offers both pre- and post-approval economic incentives, including research grants, tax credits, and seven years of marketing exclusivity.

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.[7] Biologic drugs are awarded twelve years of exclusivity, as established by the Affordable Care Act of 2010.

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.[8] 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.[9]

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, as demonstrated by new cures to previously incurable diseases, vaccines for previously debilitating or deadly diseases, and effective treatments to mitigate the consequences of many other diseases. In addition, proper medication adherence can prevent costly hospitalizations and affect health care outlays more broadly. According to the Congressional Budget Office (CBO):

> Taking an antibiotic may prevent a more severe infection, and adhering to a drug regimen for a chronic condition such as diabetes or high blood pressure may prevent complications. In either of those circumstances, taking the medication may also avert hospital admissions and thus reduce the use of medical services.[10]

Nevertheless, innovation is not the only way that the drug industry improves consumer welfare. While drug prices are not (and should not be) a factor when the FDA determines if a drug should be approved for marketing in the United States, how the FDA makes such a determination can ultimately contribute to the market dynamics that affect a product's price. Without a statutory and regulatory agenda for the FDA that carefully examines the agency's effect on pharmaceutical competition, some consumer welfare may be unnecessarily lost.

II. THE FDA'S IMPACT ON COMPETITION

Broadly speaking, there are two types of drug competition: generic drugs competing with their brand counterparts and brand drugs competing with other brands in the same drug class. Like innovation, competition is directly affected by the FDA. But competition—particularly brand-to-brand competition—has not been prioritized by the agency or by Congress to the same degree as innovation. This section examines the FDA's impact on competition and offers examples of ways that the agency unintentionally stymies competition in the drug industry. First, the long delay in elaborating the pathway for biosimilars to enter the U.S. market has thwarted competition in that space. Second, with regard to brand-to-brand competition, the FDA's ability to approve new drugs in a timely manner requires adequate funding either through Congressional appropriations or user fees. And finally, despite the broad success of the Office of Generic Drugs, the agency is plagued by a backlog of generic drug applications.

Biosimilar Competition

Biologics, drugs derived from living cells, are among the most expensive pharmaceutical products on the market and account for a growing share of drug spending in the United States. U.S. spending on biologics totaled $92 billion in 2013 (roughly 28 percent of all U.S. drug spending). This represented a nearly 10 percent increase over 2012 biologics spending.[11] Biosimilars, essentially a lower-priced, competing copy of a brand biologic, are expected to yield cost savings for payors and patients. Because a biosimilar is expected to be "highly similar" to its reference product rather than identical (as is the case for small-molecule generics), economists and market analysts generally expect the competition between a biosimilar and its reference product to be distinct from the competitive dynamic among brand and generic small-molecule products. Competition between biologics and biosimilars is expected to look more like the competition generally observed among brand small-molecule products within the same class. Nevertheless, CBO has projected that biosimilar prices will be 40 percent lower than biologic prices.[12] A new analysis by the RAND Corporation estimates that biosimilars would generate $44 billion in savings over ten years.[13]

Though the Affordable Care Act (ACA) established a pathway for biosimilar market entry, there are currently no biosimilars available in the United States. This is because the ACA tasked the FDA with detailing the pathway, but the FDA has made little progress in doing so in more than four years. In July 2014, Sandoz filed a biosimilar application with the FDA to copy Neupogen (filgrastim), a biologic used to counteract the effects of chemotherapy. And in August, Celltrion filed an application for a biosimilar version of Remicade (infliximab). But much about the biosimilar pathway remains obscured, making Sandoz and Celltrion test cases.[14]

While the FDA has released draft guidance on various issues related to biosimilars, the agency's delay in issuing final guidance for biosimilar manufacturers has thwarted the development of a U.S. biosimilars industry—thus preventing the savings that competition would generate. In fact, near the time of the ACA's enactment, CBO estimated that the first biosimilars "could enter the market near the middle of calendar year 2012. In particular, we believe that some applications for [biosimilars] for which regulatory authorities in the European Union have already issued guidance or granted marketing approval would be submitted shortly after enactment of the bill."[15] CBO also projected that budgetary savings from biosimilars would first be realized in FY 2014, a prediction that has proved too optimistic.

Along with the development of regulations, FDA guidance on biosimilar naming, currently under discussion, could limit the marketability of these products. Should the agency require a unique naming convention

for biosimilars that impedes prescribing and utilization of these products, it 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.

Brand vs. Brand Drug Competition

Dedication of Resources to Expedited Approvals

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. The four routes for expedited approval noted above apply to drugs that address unmet needs or represent significant improvements over currently available products. In other words, brand drugs offering benefits comparable to existing products are not eligible for expedited approval. 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.

Availability of Adequate Resources

In 2013, the Prescription Drug User Fee Act user fees totaled $718,669,000 and accounted for approximately 69 percent of the funding for the review of human drug applications, while about 31 percent of funding came from appropriations.[16] The President's FY 2015 budget request to Congress for human drug–related services is nearly $480 million, or $13 million above the enacted level in FY 2014, an increase of just under 3 percent. Some third-party advocacy groups, including Alliance for a Stronger FDA, have called for FDA funding levels higher even than the Administration's current budget request and have noted that appropriated funds to the human drug function have increased just 13 percent over the last five years.[17]

Brand vs. Generic Drug Competition

The FDA's regulation of generic drugs under the Hatch-Waxman Act represents the most prominent way in which the agency promotes pharmaceutical competition. As noted above, Hatch-Waxman was intended to balance innovation and competition in the pharmaceutical industry. On the competition side, the law allowed for an abbreviated approval pathway for generic drugs and rewarded the first successful patent challenger with 180 days of exclusivity for its generic product. Thirty years after enactment, these policies have led to a robust generic drug industry in the United States.

The competition that generics bring to the brand drug industry offers substantial benefits to patients and payors in the form of lower drug prices. According to the FDA, generic drugs are 80–85 percent cheaper than their brand counterparts.[18] CBO, citing the National Association of Chain Drug Stores, estimates the average generic price discount to be 75 percent.[19] Moreover, when multiple generic

manufacturers sell comparable products, the competition among them ensures the greatest amount of price competition. Health economists have found that when there are more than four generic manufacturers for a given product, prices decline significantly.[20] According to the Generic Pharmaceutical Association, the trade association for the generic drug industry, generic drugs saved the U.S. health care system $217 billion in 2012 and $1.2 trillion in the last decade.[21]

Delays in ANDA Approvals

Despite the enormous success of generics in achieving health care savings and the FDA's established programs and policies to promote generic competition, generic drugs are not given the same attention at the agency as innovative products. For example, the median ANDA approval time is 36 months, which means that it takes the FDA on average more than three times longer to approve an ANDA than to approve a standard NDA/BLA, and fully six times longer than it takes to approve a priority NDA/BLA.[22]

These lengthy approval times stem from a backlog of ANDAs at the FDA that has been steadily growing for the last decade. Since the late 1990s, the FDA's Office of Generic Drugs each year has received more ANDAs than the year before, with a 150 percent increase from fiscal year 2001 to fiscal year 2005 alone.[23] The median approval time increased from approximately 16 months in fiscal year 2005 to its current level of 36 months.[24] Despite awareness of this growing problem, it was not until 2012, with the enactment of the Generic Drug User Fee Amendments (GDUFA), that the issue was addressed. Under GDUFA, new generic drug manufacturer fees will help cover the cost of reviewing applications. But even with this new funding, the FDA does not anticipate reducing ANDA review times to 10 months until fiscal year 2017.[25] And there is already some question about the agency's ability to meet its GDUFA goals.[26]

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.[27] 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. A recent study by the author quantified the lost savings from brand manufacturers' preventing generic market entry in this way. By this 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.[28]

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 matter is complicated, however, by the fact that there are obvious reasons that drug innovation deserves some government-imposed barriers to competitors' market entry—namely, to ensure adequate incentives for manufacturers to undertake time-intensive and costly drug development. But, if not appropriately calibrated, such protections can be excessive and thus damaging to national welfare. Congress must balance these tradeoffs carefully when creating drug policy legislation. The FDA, too, must be cognizant of the consequences of its actions on competition.

Today, there is a rigorous health policy debate about the impact of competition on health care spending, but largely absent from this debate is discussion of the FDA's role in promoting or discouraging competition in the drug industry. While the FDA does have a positive impact on pharmaceutical competition in some respects, there are many ways that the agency hinders competition, and the consequences of these impediments need to be better understood and rectified.

ABOUT THE AUTHOR

Alex Brill is the CEO of Matrix Global Advisors, an economic policy consulting firm. He is also a research fellow at the American Enterprise Institute and in 2010 served as an advisor to the Simpson-Bowles Commission. Previously, he was chief economist and policy director to the House Ways and Means Committee. Prior to his time on the Hill, he served on the staff of the President's Council of Economic Advisers.

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NOTES

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