FDA Working to Lift Barriers to Generic Drug Competition

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Too many patients are being priced out of the medicines they need. While 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.

Over the last decade alone, competition from safe and effective generic drugs has saved the health care system about $1.67 trillion. When generics are dispensed at the pharmacy, the immediate savings to each of us are clear. We could see even greater cost savings if we helped more safe and effective generic drugs get to market sooner, after patent and statutory exclusivity periods have lapsed, by addressing some of the scientific and regulatory obstacles to generic competition across the full range of FDA-approved drugs. These barriers may delay and, in some cases, ultimately deny patient access to more affordable drugs.

That's why we're working on a Drug Competition Action Plan. As part of this effort, today, we're announcing in the Federal Register our intent to hold a public meeting on July 18, 2017, to solicit input on places where FDA's rules – including the standards and procedures related to generic drug approvals – are being used in ways that may create obstacles to generic access, instead of ensuring the vigorous competition Congress intended.

Innovation in pharmaceutical development is essential because it creates new and sometimes life-saving therapies. But access to lower-cost alternatives, once patent and exclusivity periods lapse, also is critical to the nation's health.

We know that sometimes our regulatory rules might be "gamed" in ways that may delay generic drug approvals beyond the time frame the law intended, in order to reduce competition. We are actively looking at ways our rules are being used and, in some cases, misused.

One example of such gaming is the increasing unavailability of certain branded products for comparative testing. To perform the studies required to develop a generic alternative to a branded drug, a generic sponsor generally needs 1,500 to 3,000 doses of the originator drug. I understand that generic sponsors are willing to buy these products at fair market value; but, in some cases, branded companies may be using regulatory strategies or commercial techniques to deliberately try to block a generic company from getting access to testing samples.

This might occur, for example, when branded companies might use restrictions they place in their commercial contracts or their agreements with distributors to make it hard for intermediaries in the drug supply chain to sell the drugs to generic drug developers.

We also see problems accessing testing samples when branded products are subject to limited distribution – whether the company has voluntarily adopted limitations on distribution, or the limitations have been imposed as part of a Risk Evaluation and Mitigation Strategy, or REMS, a program that FDA implements to help ensure the safe use of certain drugs. I have been made aware that, in some of those cases, branded sponsors may use these limited distribution arrangements, whether or not they are REMS-related, as a basis for blocking generic firms from accessing the testing samples they need.

Besides limiting access to testing samples, some branded companies may be using the statutory default requirement to have a single shared REMS across both the branded and generic versions of a drug as a way to block generic entry. They might prolong negotiations with the generic firms over the implementation of these single shared systems, which could delay the entry of safe and effective generic drugs onto the market.

I want to take steps to address these concerns, to make sure that we are facilitating appropriate competition in circumstances where Congress intended. The forthcoming public meeting is intended to solicit public comment to inform us of circumstances where generic competition may be thwarted by these and other techniques.

As we solicit additional information, we also are going to be looking at policy and programmatic changes to address these issues. Some of these steps may be actions we can take by using our own authorities more forcefully. Other steps might involve our need to collaborate with sister agencies.

We're also going to be looking hard at how best to coordinate with the Federal Trade Commission in identifying and publicizing practices that the FTC finds to be anti-competitive. FDA is not the FTC. It is the FTC's responsibility to prevent anticompetitive business practices. But Congress set out certain laws that are meant to strike a careful balance between pharmaceutical innovation and access to lower cost generic products, and FDA has an important responsibility to enforce those laws in a manner that adheres to the balance struck by Congress.

We'll be unveiling additional aspects of our larger Action Plan and providing updates, as these initial elements are implemented. I'm confident that these actions and the dedicated work of the outstanding staff in our generic drug program will help to address the issues patients are facing today when they're priced out of buying the drugs they need. At the meeting on July 18 we want to hear from the public about ways our current rules may not be having their intended effects, and where current policies are falling short in ensuring the careful balance between new innovation and patient access.

Our goal is to broaden access to safe and effective generic drugs that can improve access to medicines and help consumers lower their health care costs. As in all of the things we do, we will steadfastly maintain FDA's gold standard for rigorous, science-based regulation.

Over the past five years our generic drug program staff has evolved and grown remarkably, while implementing the first generic drug user fee program. The staff has demonstrated that they can rise to new challenges and they have my full support. Their hard work will serve as a strong foundation for the program as it moves forward. I want the policy framework they operate under to be as efficient, fair, and robust as the review program that they're operating.

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