# New FDA Efforts to Address Gaming Tactics to Delay Generic Drug Competition

Enhancing generic competition is an effective way to promote access to needed medicines.

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Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition

By Scott Gottlieb, MD

No patients should be priced out of medicines they need to support their health. As stressed by the President and Secretary Azar last week, one of the Administration's highest priorities is advancing policies that increase competition as a way to help make drugs more affordable and improve access.

There isn't one single action that's going to solve this issue. We will achieve these public health goals through the coordinated effort of different federal agencies working in partnership with industry and other stakeholders. At the FDA, we're taking steps across a broad range of areas to improve new and generic drug competition as a way to improve access and affordability. Among these efforts, we're especially focused on addressing tactics we sometimes hear of branded companies pursuing as a way to forestall expected generic entry.

One such abuse that I've spoken about often is a practice by brand companies to create obstacles for generic developers in purchasing samples of their brand drugs. In general, generic drug developers need the samples of the brand drug to develop their generic product and/or to conduct testing to show that their product is bioequivalent to the brand drug for FDA approval. A generic drug developer generally needs 1,500 to 5,000 units of the brand drug to perform what are often relatively straightforward studies for FDA approval. Without these samples, generic drug makers may not be able to develop generic alternatives. Yet, the FDA has heard that some brand companies will adopt tactics to make it hard for the generic companies to purchase these brand drugs at a fair value and in the open marketplace. The FDA is taking new steps to address this issue.

Today, we're making public a list of companies that have potentially been blocking access to the

samples of their branded products. We hope that this increased transparency will help reduce unnecessary hurdles to generic drug development and approval. We often hear of these tactics when it comes to generic drug developer access to samples when the brand products are subject to limited distribution programs. In some cases, these limitations on distribution may be asserted in connection with a Risk Evaluation and Mitigation Strategy (REMS), a program that the FDA implements for certain drugs to help ensure that the benefits of these drugs outweigh their risks. We have heard that some drug makers have either refused to sell samples of products with REMS with Elements to Assure Safe Use (ETASU) impacting distribution to potential generic competitors, or have imposed conditions on the sale of such samples that generic companies find hard or impossible to comply with.

In other cases, we understand that brand companies have placed restrictions in their commercial contracts or agreements with prescription drug distributors, wholesalers or specialty pharmacies that limit the ability of these intermediaries in the drug supply chain to sell samples to generic drug developers for testing. But I want to be very clear: a path to securing samples of brand drugs for the purpose of generic drug development should always be available. Even in the case of limited distribution programs such as those required by certain REMS, there should be a path forward for generic drug development.

Despite this, the FDA has received more than 150 inquiries from generic drug developers seeking assistance in obtaining samples from brand companies.

Upon receipt of such inquiries, we're taking several steps to determine the factors at play and appropriate next steps. First, the FDA will determine whether these products have in place a REMS program with ETASU that may impact distribution, which has been cited as a reason to refuse to provide samples. In many cases, we find that there's no such REMS program in place. In these cases, the FDA informs the generic drug developer that there are no FDA-required restrictions on the distribution of the drug that would impede obtaining samples. We're also notifying the Federal Trade Commission (FTC) — the agency responsible for addressing anticompetitive business practices — about these inquiries. We also encourage the generic drug developers to raise these cases with the FTC if they believe that anticompetitive conduct has taken place. Many of the products that we have received inquiries about are not subject to REMS with ETASU. This suggests that brand companies may be inappropriately using limited distribution to impede generic drug competition.

But even in cases where the FDA confirms there is an existing REMS program with ETASU for the brand drug that impacts distribution, generic drug developers should be able to secure samples of the product. To facilitate the transfer of samples in these cases, the FDA has a voluntary process through which generic companies can submit their bioequivalence testing protocols to the agency, and we will evaluate these protocols to ensure that their plan for testing the product contains safety protections comparable to the brand product's REMS program. Assuming that the generic drug developers' plans include appropriate protections, then the generic drug developers can request that the FDA send a letter to the brand company stating that the REMS program does not mean the brand drug maker can't sell their product to generic drug developers for comparative

testing. These notifications are called Safety Determination Letters. To date, we've issued 21 of these letters in response to requests from generic drug companies.

Today we've posted to our website a list of the inquiries we've received from generic drug developers who report having trouble accessing testing samples they need. We'll continue to update this list periodically. The information we're disclosing now includes, among other things, the brand drug company, the drug product and the number of inquiries we've received. We're also specifying those products that have been the subject of a Safety Determination Letter from the FDA clarifying that there are no REMS-related reasons why samples of their product can't be provided to generic drug developers. We're taking these steps today because we believe greater transparency will help reduce unnecessary hurdles to generic drug development and approval.

We'll continue to look at more ways we can expand upon today's action and call public attention to situations where the careful balance that Congress sought between product innovation and access may be being disrupted. We'll also continue working with the FTC where there may be anticompetitive business practices at play. And we'll continue to strengthen our internal processes for handling inquiries related to problems generic drug developers report having in obtaining samples of brand products.

We're committed to advancing policies to help bring more competition to the prescription drug market. We know that enhancing generic competition is an effective way to promote access to needed medicines.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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