Association for Accessible Medicines

Your Generics & Biosimilars Industry

Restricted Access Drug Programs Impeding Patient Access to Generic Drugs
Myths and Facts Regarding Maine LD 1280

Brand Manufacturers are Blocking Competition Through Restricted Distribution Channels

In order to receive approval from the U.S. Food and Drug Administration (FDA), generic and biosimilar drug manufacturers are required to demonstrate that their products are therapeutically equivalent or highly similar to their brand counterparts by conducting tests using samples of the brand product. Increasingly, brand manufacturers are blocking generic competition by using restricted distribution arrangements to prevent generic product developers from obtaining samples of the brand product.

Some brand manufacturers are utilizing restricted distribution programs to prevent generic and biosimilar access to drugs that are covered by REMS as well as those that are not. As background, under the Food and Drug Administration Amendments Act (FDAAA) of 2007, FDA can require manufacturers of drugs with known risks to develop a Risk Evaluation and Mitigation Strategies (REMS) program. Manufacturers may also request that a REMS program be applied to their product. REMS programs are intended to ensure safe and proper use of a product so that the benefits of a drug or biologic outweigh its risks to the patient, and sometimes can include "restricted distribution" wholesaler or pharmacy networks designed to implement measures needed for safe use of the product by patients. Despite a federal statutory prohibition on using these REMS programs to delay generic competition, some brand manufacturers have used these closed distribution systems to prevent generic developers from acquiring samples, and some are using similar closed distribution networks for products with no FDA-mandated REMS program.

Preventing or delaying competition has a significant impact on healthcare costs. According to a July 2014 study conducted by Matrix Global Advisors, the ongoing abuse of REMS and restricted distribution programs costs the U.S. health system $5.4 billion annually – $1.8 billion to federal government programs.

Maine LD 1280 Will Eliminate Brand Gamesmanship Around Generic Access to Samples

Maine's LD 1280 targets this anticompetitive behavior to block and delay entry of more affordable generic drugs. It would require brand manufacturers who sell their products in Maine to provide generic manufacturers an opportunity to purchase samples required for FDA approval at a reasonable market rate.

Maine LD 1280 also allows the Attorney General to bring an action in the courts for injunctive relief against a person that violates this act by delaying or denying access to samples of a product through a REMS or other restricted distribution arrangement. The bill also subjects drug manufacturers engaged in anti-competitive behavior to disciplinary action in Maine, including potential loss of their manufacturing license.

This bill if enacted could result in saving billions of dollars for consumers, government, taxpayers and other participants in the healthcare marketplace in Maine and throughout the U.S.

Myths vs Facts

Myth: REMS do not block generic competition – they are rare and restricted distribution systems are even rarer.

Fact: Nearly 40 percent of new FDA approvals are subject to REMS, and the percentage of REMS programs that require distribution requirements has increased dramatically in the last several years. In addition, some brand manufacturers are imposing distribution restrictions on non-REMS products.

Fact: In 2009, fewer than 25% of REMS programs required anything other than medication guides – but now more than 50% of REMS programs require greater restrictions such as restricted distribution. These safety requirements are appropriate and assure patient access to drugs that they otherwise would not be able to use. The problem is abuse of these safety requirements to delay generic competition.

Fact: The July 2014 study conducted by Matrix Global Advisors identified *40* drugs from just eight generic manufacturers where REMS and non-REMS restrictions are being used to block access. This ongoing abuse to block competition to just these 40 drugs costs the U.S. health care system $5.4 billion annually. Additional products approved since 2014 and many future products will also face this barrier to competition without legislations such as LD 1280.

Fact: FDA Office of New Drugs Director Dr. John Jenkins at a 2014 industry conference called the abuse a "growing major problem" for FDA. He went on to say, "I think companies have really gone to the extent of kind of abusing the system, because the system was designed to try to ensure the safe use of the drug and now it's become an evergreening system for avoiding generic competition." He added, "the problem is use of REMS to block generic competition and the innovators have really become very aggressive in using that strategy and hiring the best lawyers to back up that strategy."[1]

[1] Gingery, Derrick. REMS That Block Generics Are 'Major' Problem For FDA, Jenkins Says. *"The Pink Sheet" Daily*. January 8, 2015.

Myth: FDA guidance will facilitate sale of REMS products for testing without passage of LD 1280

Fact: While the guidance is a step in the right direction, there is no enforcement mechanism to ensure that brand companies provide samples to potential biosimilar and generic developers. As Dr. Jenkins noted at the same conference, "Congress gave us some tools to try to address generic entry but they are not as strong as they might have been to avoid what was probably an unexpected or unintended problem." In addition, FDA's guidance does not address non-REMS products with distribution restrictions. Maine's LD 1280 will help to address this issue in a market-oriented approach.

Myth: The proposal may force the sale of medicines carrying serious risks without protecting patient safety or ensuring that generic manufacturers are capable of handling REMS drugs.

Fact: This is not a "forced sale". Inherent in the Hatch-Waxman statute, generic companies have access to product samples to conduct bioequivalence testing. This is about the abuse of safety requirements by certain brand manufacturers to deny patients access to more affordable generic medications.

Fact: Generic manufacturers are committed to patient safety. We support the REMS program when used as intended – to protect patients from severe side effects and adverse events and ensure they have access to these life-saving medicines. Generic and biosimilar companies have decades of experience in the testing and development of products with high safety profiles. Just because certain drugs have REMS requirements does not mean that potential generic and biosimilars manufacturers should not have access to product samples.

Fact: Like the brand company's clinical trials leading to the final approval of the REMS product, studies by generic and biosimilar manufacturers are also subject to FDA regulations regarding subject safety, including Institutional Review Board ("IRB") approval and monitoring requirements, and Good Clinical Practices ("GCP") and Good Laboratory Practices ("GLP") compliance. Unlike commercial marketing of REMS products, the conduct of studies by generic and biosimilar manufacturers is tightly controlled; generic manufacturers can often control or manage the risks associated with the drug to a greater extent in a study than the brand manufacturer can during commercial sales to patients.

Fact: LD 1280 does not remove any existing authority that FDA has to ensure that generic manufacturers have taken necessary precautions to ensure patient safety. Generics and biosimilars of products that have FDA-required safety requirements such as REMS will also be required to have equivalent safety programs as their brand counterparts.

Fact: LD 1280 would not move any authority that currently exists at FDA to the federal courts. It would simply give ensure that generic manufacturers the leverage necessary to get fair, market based access to samples necessary to meet FDA requirements for drug approval.

Myth: The proposal harms patient access to needed therapies by exacerbating drug shortages and directing products to generic companies instead of patients in need.

> Fact: LD 1280 does not require diversion of products away from patients, but only that the brand manufacturer not place restrictions on the sale of samples to generic manufacturers at commercially-reasonable, market-based terms. Generic manufacturers will generally need 1,000 or fewer doses of the brand product for testing. Moreover, ensuring that generic companies have appropriate access to samples for product testing could result in more manufacturers of a product and fewer drug shortages.

Myth: The legislation undermines important drug supply chain security improvements.

> Fact: Nothing in the legislation amends or affects drug supply chain security legislation. LD 1280 merely requires that the market function the same for generic manufacturers who seek to purchase samples as it would for any other legal purchaser.

Myth: The proposal would allow generic manufacturers to infringe the intellectual property rights of brand manufacturers.

> Fact: Nothing in the legislation affects a brand manufacturer's intellectual property rights. Instead, the legislation merely maintains the balance established under the landmark federal Hatch-Waxman Act. Hatch-Waxman creates a specific litigation process for brands to make IP claims against generic manufacturers. LD 1280 would not influence that litigation process at all. Additionally, patent law creates a specific, statutory exemption for any IP claims against the necessary efforts generic manufacturers must go through to get approval for a product. The samples being requested would be solely used for those protected purposes, and therefore would not infringe upon brand IP rights.

Myth: The legislation is broader than necessary to address the supposed problem.

> Fact: LD 1280 is a narrowly tailored proposal to address the well-documented problem of anti-competitive behavior. It does not establish any new requirements on brand manufacturers. They merely must allow the marketplace to work as it should – without limiting the ability of generic manufacturers to purchase samples at commercially-reasonable, market-based prices.