Restricted Access Drug Programs Impede Generic Drug Competition

The Problem

Companies are using Risk Evaluation and Mitigation Strategies (REMS) and other restricted access drug programs to deny generic drug firms access to samples of branded drug products.

Generic companies need these samples to conduct drug product development and bioequivalence studies necessary for FDA approval. Without access to these samples, the testing, review and approval of generic drugs cannot occur, which prevents generic competition for brand drugs in restricted access programs.

As the biosimilar market continues to develop, the inability of companies to obtain samples of brand biologics for early development testing purposes will also cause access delays and keep drug prices artificially high.

Cost to Federal Government and Patients

Access delays to affordable medicines can cost patients and the federal government billions of dollars. A recent study showed that using restricted access programs to limit generic competition costs the health care system $5.4 billion annually - $1.8 billion to the federal government alone[1]. According to the Congressional Budget Office (CBO), various bills designed to remedy the problem could save the federal government billions of dollars.

Dr. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, testified in a January, 2016 Senate HELP Committee hearing that "innovator companies feel it is their duty to their stockholders to delay completion as long as possible[2]" and more recently testified that these abuses are "a problem we struggle with a lot" and went on to note that they have "delayed [the] availability of generics.[3]"

Background

Traditionally, generic manufacturers have purchased the samples needed for a generic drug application, or Abbreviated New Drug Application (ANDA), from entities within the pharmaceutical supply chain, such as a wholesaler or from the brand manufacturer. The FDA put restricted access programs in place to "ensure that the benefits of [a] drug outweigh the risks of the drug". Certain elements of restricted access programs include additional medication guides or patient package inserts, prescriber training, communication plans, and/or restricted distribution networks that control the public distribution of certain drugs.

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[1] i Brill, Alex. Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry. July 2014. Retrieved from http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf

[2] Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs. Before S. Comm. on Health, Education, Labor and Pensions, 114th Congress (2016) (Comments by Janet Woodcock, MD, Director of Center for Drug Evaluation and Research at FDA). Available at: http://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs

[3] Testimony of Dr. Janet Woodcock Testimony "Examining FDA's Generic Drug and Biosimilar User Fee Programs." House Energy and Commerce Committee. March 2, 2017. https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-generic-drug-and-biosimilar-user-fee-programs

Generic manufacturers that would like to submit an ANDA for a product covered by a REMS must have the same medication guide (if there is one) and the same or comparable elements to assure safe use (ETASU). FDA strongly encourages companies to enter into a single-shared REMS program, in which the generic adopts the brand's REMS protocol. However, if there are proprietary issues or other burdens that preclude a single, shared-REMS, the generic manufacturer may receive a waiver from FDA and develop its own approved REMS/ETASU.

Certain drug companies are increasingly using these regulations to restrict distribution exclusively to pharmacies and registered patients, precluding distribution to generic firms. In response to such actions, generic companies have attempted to purchase the product directly from the brand manufacturer for testing, but these requests have gone unanswered, or in some cases, the brand company has denied them outright.

Legislative Intent and FDA

The Food and Drug Administration Amendments Act of 2007 (FDAAA) states specifically that companies may not use FDA regulations to delay generic competition[4]. In fact, when the House passed its version of the FDAAA in July 2007, it contained an even more explicit instruction that a sufficient amount of the drug must be made available for bioequivalence testing by generic manufacturers[5]. Unfortunately, the lack of an effective enforcement mechanism in the law created the loophole that companies are exploiting to delay generic entry.

Although FDA has issued guidance on this issue, it cautioned that the problem continues to worsen, that the guidance will have limited impact, and that the agency does not currently have the tools necessary to stop these abuses[6]

Legislative Proposal

Congress should pass the FAST Generics Act (H.R. 2051), the CREATES Act (S. 974/H.R. 2212) or similar language that concurs with the legislative intent in FDAAA to prohibit companies from using restricted access programs as a way to avoid generic competition.

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[4] Section 355-1(f)(8) states, "Limitation: No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under Section 355(b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) of this section to a drug that is the subject of an abbreviated new drug application."

[5] H.R.2900 passed July 16, 2007: "(6) BIOEQUIVALENCE TESTING. - Notwithstanding any other provisions in this subsection, the holder of an approved application that is subject to distribution restrictions required under this subsection that limit the ability of a sponsor seeking approval of an application under subsection 505(b)(2) or (j) to purchase on the open market a sufficient quantity of drug to conduct bioequivalence testing shall provide to such a sponsor a sufficient amount of drug to conduct bioequivalence testing if the sponsor seeking approval under section 505(b)(2) or (j) – (A) agrees to such restrictions on distribution as the Secretary finds necessary to assure safe use of the drug during bioequivalence testing; and (B) pays the holder of the approved application the fair market value of the drug purchased for bioequivalence testing. (7) LETTER BY SECRETARY – Upon a showing by the sponsor seeking approval under section 505(b)(2) or (j) that the sponsor has agreed to such restrictions necessary to assure safe use of the drug during bioequivalence testing, the Secretary shall issue to the sponsor seeking to conduct bioequivalence testing a letter that describes the Secretary's finding which shall serve as proof that the sponsor has satisfied the requirement of subparagraph (6)(A)."

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