



Next Generation Healthcare™

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Consumers Need Access to Low Cost Generic Drugs

Consumers, employers, insurers, and policymakers are all grappling with how to manage annual double-digit increases in the cost of prescription drugs. One clear answer is to increase competition in the drug marketplace by making more affordable generic medicines available to consumers.

Yet, today, an FDA approval pathway for bringing to market generic versions of an entire class of life-saving drugs called biopharmaceuticals (also biologics) -- drugs that are derived from living sources -- does not exist. And, these drugs are very expensive. As a result, programs such as Medicare -- a significant payer for the biopharmaceuticals used to treat a growing number of chronic conditions like hepatitis, leukemia and diabetes affecting older Americans -- must pay higher costs on all biologics. In fact, the Medicare Part B program spent more than \$5 billion on biologics in 2006, and these expenditures are expected to increase substantially during the next 10 years. According to a recent study by Engel & Novitt, the availability of biogenerics could conservatively save Medicare Part B \$14 billion over the next 10 years. The FDA needs a clear process for facilitating the development and approval of biogenerics that would give patients affordable alternatives to the brand drugs they need.

Congress also should pass legislation such as S. 2300, the Lower PRICED Drugs Act, a bipartisan bill sponsored by Senators Stabenow and Lott in the 109th Congress. This legislation would close legal loopholes used by brand-name drug manufacturers to extend the life of their patents and prevent or delay generic drugs from coming to the market. The Stabenow-Lott bill would close these loopholes and, in the process, save consumers and businesses billions of dollars by ensuring proper use of the current pediatric exclusivity provision, allowing generic versions of certain antibiotics, preventing delays in the generic drug approval process and preventing abuse of the citizen petition process.

In addition, insufficient funding for the Office of Generic Drugs (OGD) is slowing the process of getting generic drugs to market. Since the patents on numerous brand-name drugs are set to expire in the next few years, reducing the backlog of generic drug applications at OGD is more critical than ever. This backlog has grown steadily in recent years, while funding for the review and approval of generic applications has remained flat. The FDA expects to receive record numbers of new applications for generic drugs in the coming years. Thus, substantially increasing resources for OGD is critical to reduce the current backlog and increase competition in the pharmaceutical market.

What Washington Should Do

First, the FDA needs a clear process for facilitating the development and approval of biogenerics that would give patients affordable alternatives to the brand drugs they rely on to battle such illnesses as hepatitis, leukemia, growth hormone deficiency, and diabetes. Second, our lawmakers should not allow brand-name pharmaceutical companies to unfairly extend brand drug patents. Finally, Congress should increase funding for the Office of Generic Drugs (OGD) to speed the review of generic drug applications and bring these life-saving drugs to market.