COMMENTARY

How Obama's FDA Keeps Generic Drugs Off the Market

A flurry of new regulations is raising production costs and reducing competition for branded drugs.

The Food and Drug Administration's headquarters in White Oak, Md. PHOTO: CQ-ROLL CALL/GETTY IMAGES

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One of the biggest factors fueling the angst over drug prices in the U.S. is that some older medicines that should be sold cheaply as generics are still priced very high, often owing to a dwindling number of generic competitors and the rising cost of producing these drugs. Bernie Sanders and Hillary Clinton like to blame generic-company mergers and greedy drugmakers. But a closer look reveals that a series of regulatory policy blunders is at fault.

The modern generic-drug industry emerged after the 1984 Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman. The law created a cheaper and faster path for bringing generic copies of branded drugs to the market. By keeping regulatory barriers low, Hatch-Waxman enabled vigorous competition from multiple firms, each one vying to sell drugs for close to the cost of manufacturing.

Yet in recent years the Food and Drug Administration has imposed on generic firms many of the same costly requirements that the agency applies to branded-drug makers. For example, in a push to reduce the risk of contamination, the agency in 2009 forced generic-drug makers to retool their sterile manufacturing plants and make production lines less intricate. The abruptness of the change caused many facilities to be shut down, creating drug shortages and driving up prices.

The complexity and cost of completing a generic-drug application has also grown enormously. In 2003, when I began working at the FDA, we estimated that it cost less than $1 million for a firm to file a generic-drug application. A drug would have to fetch about $10 million in annual revenue before it would be subject to generic competition. Today, filing a generic application requires an average of about $5 million and can cost as much as $15 million. This means that a drug may not face brisk generic competition until it exceeds $25 million in annual revenue. Thanks to these changes, infrequently used generics—such as clomipramine for major

When the price of a drug rises, it becomes profitable and the target of new competition. The FDA recently committed to review new generic-drug applications in a 15-month cycle, an improvement over a median of more than two years for applications submitted in 2013. For generics filed in 2009, the median review time exceeds three years. Yet generics launched in 2015 took about four years for the FDA to approve, since less than 2% of applications were approved on their first submission. The agency has committed to improve first-cycle approvals, but it still rejects most applications before demanding resubmissions, further stymieing competition.

The key to the generic-drug economic model is to keep entry prices low enough to attract multiple competitors. One FDA study estimated that consumers pay 94% of the branded drug's price for a generic if there is only one generic entrant. But the price falls to about 40% if there are four competitors, and 20% when there are eight.

Yet of the more than 1,300 branded drugs on the market, about 10% have seen patents expire but still face zero generic competition, according to the Department of Health and Human Services. New regulations have, in many cases, made it no longer economically viable for more than one generic firm to enter the market.

The FDA should prioritize applications for generic categories where competitors are exiting. Companies that pursue copies of "abandoned" generics could receive a voucher that gives them expedited review of another generic drug. The value of this voucher would give firms more incentive to market copies of low-volume generics.

It gets worse. Generic-drug makers usually manufacture dozens of different drugs on each production line and hundreds of drugs in a single plant. The FDA is now trying to require production lines to be dedicated to one or two drugs, citing potential safety hazards. But generic-drug makers say this can triple manufacturing costs. While brand companies typically run only one or two products on each manufacturing line, generics run 30 to 50 products. The FDA's safety concerns could be addressed through better quality controls and improving its inspection capabilities.

Things may get worse before they get better. A new FDA draft regulation is artfully crafted to expose the generic-drug industry to the same kind of costly product liability suits that plague branded-drug makers. This political sop to the trial bar would force the generics to clutter their drug labels with defensive advisories to avoid "failure to warn" lawsuits. Legal fees stemming from the regulation would add over $5 billion to annual health-care costs, rising to $8.6 billion by 2024, according to the American Enterprise Institute's Alex Brill . The FDA should scrap this draft rule immediately.

ObamaCare's political architects blame its high costs on the rising price of prescription drugs. Yet the biggest drug-price increases come from a small number of very old medicines that would be cheap if not for careless policy-making.

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