A New Agenda for the FDA

Fostering Competition To Bring Down Drug Costs

COMMENTARY
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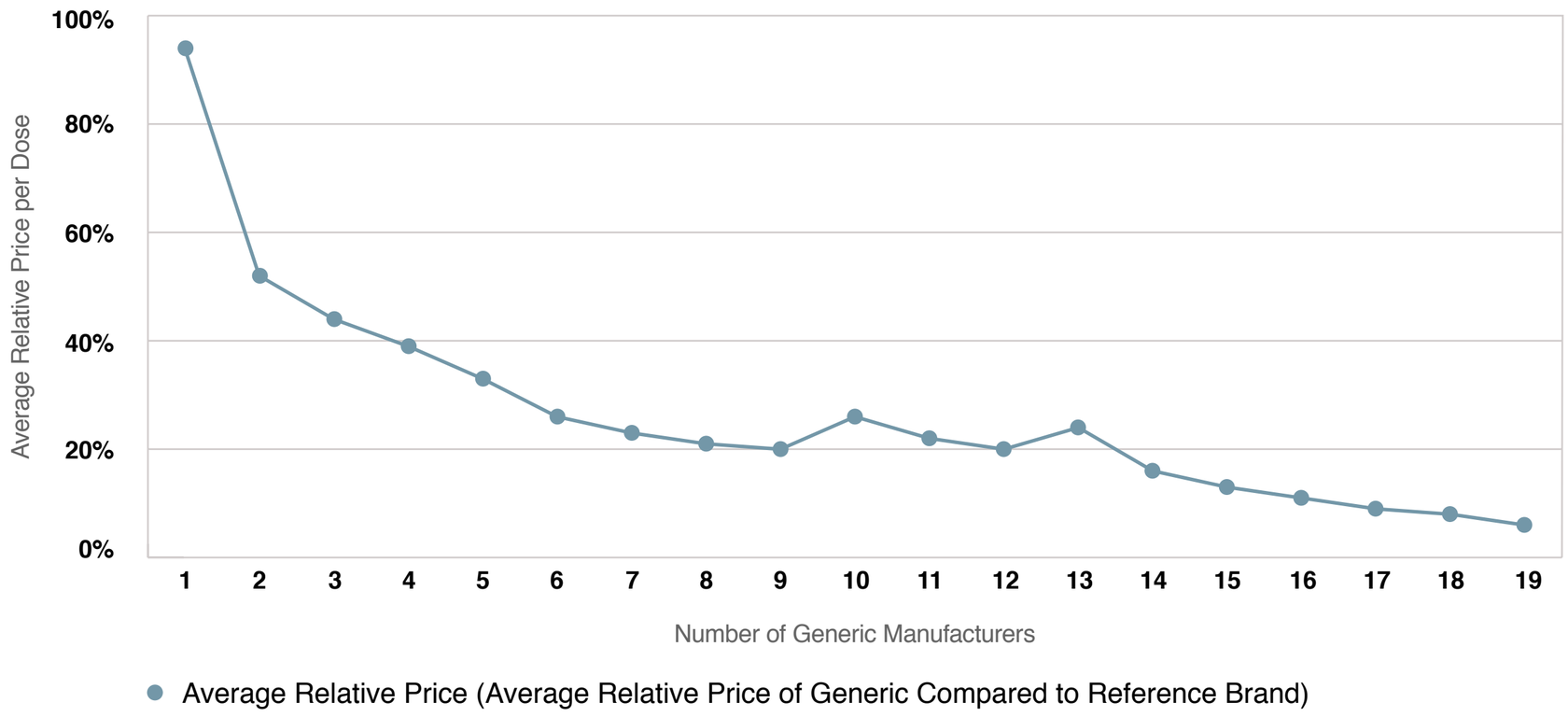
In a recent interview, the new head of the U.S. Food and Drug Administration (FDA), Scott Gottlieb, M.D., said the agency was taking aim at the high cost of prescription drugs and would prioritize the approval of competing treatments, including generics. He also said the FDA would plan to eliminate its backlog of generic-drug applications within a year. The goal, Gottlieb said, was to have at least three generic manufacturers for each drug.

This is welcome news. CVS Health has long advocated for expedited review of generic applications and priority review for those drugs that only have one alternative available. While drug prices are not squarely in the purview of the FDA, the agency has a direct influence on market competition.

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective™, 1999-2004, extracted from 2005.

For traditional branded medications, the first generic for any drug is typically priced only slightly lower than the brand drug according to analysis by the FDA. Upon entry of a second generic, the generic manufacturer reduces the price to almost half the brand name price. Having multiple generic competitors ultimately results in prices falling to about 20 percent of the original brand drug.

Factors Impacting Generic Approvals

By facilitating an efficient approval process, the FDA can encourage competition and innovation, which has a downstream impact on patient access and cost. At the beginning of the year, there were more than 4,000 generic applications pending review (including those back with manufacturers awaiting resubmission). This despite the fact that there has been a significant slowdown in generic drug applications being submitted to the FDA.

After reaching a high of nearly 1,500 in 2014, applications were down 43 percent in 2016.* There currently are more than 180 off-patent drugs without any generic competition. Of those, 150 are drugs for which the agency has never received a generic drug application for review. The agency is considering publishing the list of such drugs because, in Gottlieb's words, it may "create a more compelling business opportunity." We are pleased that Gottlieb recognizes that the approval process needs to improve. As of July 2016, the median time for a generic to reach approval was 47 months, compared to 10 months for the standard review of a new drug application and eight months for priority review.

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Among the respondents to a recent CVS Health/Morning Consult poll of nearly 2,200 registered voters, 47 percent felt that there isn't enough competition in the pharmaceutical market. The U.S. is also lagging, by nearly a decade, in bringing biosimilars to market and only created a pathway for biosimilar approval in 2010. Since then, only five biosimilars have been approved, while the European Union (EU) has 22 approved biosimilars. The first biosimilar was introduced in the U.S. in 2015. In the EU, it was in 2006. This matters because we know competition improves affordability. In 2016 alone, generic drugs saved Americans $253 billion. Over the last decade generics have resulted in more than $1 trillion in savings.

Six in 10 respondents to our poll supported proposals to speed up FDA approval of biosimilars. The just-issued Supreme Court decision in the Sandoz v. Amgen case over the biosimilar Zarxio, will hopefully help reduce the time it takes to bring biosimilars to market and provide some cost relief.

Key Policy Changes

If implemented, the focus on prioritizing generics would be a change in FDA policy. Historically, the agency has only prioritized the first generic application for a branded drug. The agency is also prohibited by law from taking drug prices into account when deciding whether to approve a new drug.

Another policy area Gottlieb has suggested revisiting is the Risk Evaluation and Mitigation Strategies (REMS) program, which some brand drug manufacturers have used to prevent potential generic manufacturers from having access to the pills they need – often up to 3,000 – to develop a generic. Roughly 40 percent of FDA-approved medications are subject to REMS. Abuse of the REMS program is estimated to cost $5.4 billion in annual lost savings.

These, and other proposals, are expected to be discussed at a public hearing in the next several months. CVS Health supports these efforts by the FDA and will continue to advocate for sensible policy changes that can help bring down the cost of prescription drugs for payors and their plan members.

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* Woodcock, J. (2017, March 2). Testimony before the United States House of Representatives Committee on Energy and Commerce Subcommittee on Health.