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How can improved competition lead to lower drug prices?

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“We will have tougher negotiations, more competition and much lower prices at the pharmacy counter and it will start to take effect very soon,” Donald J. Trump said in his speech describing his *Blueprint to Lower Drug Prices and Reduce Out-Of-Pocket Costs*.

The Department of Health and Human Services (HHS) has taken a number of actions to increase competition and end the gaming of regulatory processes that may keep drug prices artificially inflated or delay generic, branded, or biosimilar competition. These efforts, which were in motion before announcement of the blueprint, include increasing the number of generic drugs and accelerating approval of generic drugs.¹

Studies show that greater generic competition is associated with lower prices. Based on a study in 2017, the relative price of a generic medication to the branded medication decreases appreciably when there are 3 or more manufacturers of the generic version. The researchers found that the relative generic-to-brand price was 87%, 77%, and 60% when there were 1, 2, and 3 generic manufacturers, respectively. With each additional manufacturer, the relative prices decreased at a slower rate.²

Over 1,000 generic drugs were approved in 2017, the highest annual total in FDA's history. While these generic approvals saved American consumers nearly \$9 billion in 2017, there are still drugs with inadequate generic competition. To that end, the Food and Drug Administration (FDA) is publishing the names of drugs that have no competitors to motivate manufacturing and bring prices down.¹ In fact, the FDA has highlighted potassium chloride oral solution, for instance, as one of the drugs that could benefit from competitors.³

Based on the FDA's Drug Competition Action Plan in 2017, the agency is focusing on different ways to enable patients to access more affordable medications. These techniques include "improving the efficiency of the generic drug development, review, and approval process; maximizing scientific and regulatory clarity with respect to complex generic drugs; and closing loopholes that allow brand-name drug companies to "game" FDA rules in ways that forestall the generic competition Congress intended".¹ Generic EpiPen is an example of a new generic that has emerged in the market recently with lower prices for patients.⁴ In one of the latest updates in September this year, the FDA issued 54 product specific guidance to promote generic drug access and drug price competition.⁵

Furthermore, the Blueprint proposes steps to prevent manufacturer gaming of regulatory processes such as Risk Evaluation and Mitigation Strategies (REMS). Historically, the FDA may impose REMS requirements on a drug to ensure its benefits outweigh its risks, and a REMS program may require restrictions on distribution of the drug, as well as mandated education for providers and patients. Although current law already prohibits use of REMS to "block or delay" approval of a generic drug, the Blueprint suggests the FDA will consider additional steps intended to prevent innovators' use of REMS requirements to impede generic entry.¹

The Blueprint also explains that the FDA will issue policies to improve "the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics." The Blueprint notes that FDA will continue its educational efforts directed at clinicians, patients, and payers about biosimilar and interchangeable products. Like non-biologic drugs, biologics are regulated by the FDA and are used to prevent, and treat diseases, for example, many cancers, rheumatoid arthritis, diabetes, and multiple sclerosis. However, the costs of these products have continued to increase, as has their share of U.S. drug spending.

The Biologics Price Competition and Innovation Act (BPCI) was enacted in 2010 with the intent of "balancing innovation and consumer interests" by creating an abbreviated pathway for the approval of biologics demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed reference product. In contrast to most drugs that are chemically synthesized and their structure well-characterized, most biologics are complex proteins or other by-products of living cells. Their safety and effectiveness can be affected by small changes in manufacturing, packaging, or

storage. FDA standards for evaluating proposed biosimilar incorporate new tools for assessing a biosimilar's structural and functional properties relative to the reference product. The agency continues to look for ways to ensure reference product manufacturers are not using FDA requirements to unfairly delay the entry of biosimilars.^{1,6}

Hopefully, these proposals and new actions to increase competition will change our current drug market and help patients access medications at a lower cost.

Next month, our pharmacists will take a closer look at how better negotiation can improve drug prices.

[Read the previous blog in this series from Bonnie Greenwood, PharmD, BCPS,](#) who gives an overview of the Trump Administration's blueprint to tackle rising drug costs.

¹American Patients First: The trump Administration Blueprint to Lower Drug Prices and Reduce Out of Pocket Costs. May 2018. Available from:

<https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>

²Dave CV, Hartzema A, Kesselheim AS. Prices of Generic Drugs Associated with Numbers of Manufacturers. N Engl J Med. 2017;377(26):2597-2598.

³FDA Approves First Generic Drug under New Pathway Aimed at Enhancing Market Competition for Sole Source Drugs. Aug 2018. Available at:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm616167.htm>

⁴FDA Approves First Generic Version of EpiPen. Aug 2018. Available at:

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM617173.htm?utm_campaign=08162018_PR_FDA%20approves%20first%20generic%20version%20of%20EpiPen&utm_medium=email&utm_source=Eloqua

⁵FDA In Brief: FDA Issues 54 Product-specific Guidances to Promote Generic Drug Access and Drug Price Competition. Sep 2018. Available at:

https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm620398.htm?utm_campaign=09132018_FiB_FDA%20issues%20guidances%20to%20promote%20generic%20drug%20access%20C%20price%20competition&utm_medium=email&utm_source=Eloqua&elqTrackId=B23838DCC05F52D5D24B67E378B494EB&elq=ffc05e5c612d492a9222fb400069f1b3&elqaid=5046&elqat=1&elqCampaignId=4027

⁶Biosimilars Action Plan: Balancing Innovation and Competition. Jul 2018. Available at:

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