Biotechnology Innovation Organization

HATCH-WAXMAN: CAREFULLY BALANCING THE NEED FOR INNOVATION AND DRUG COMPETITION

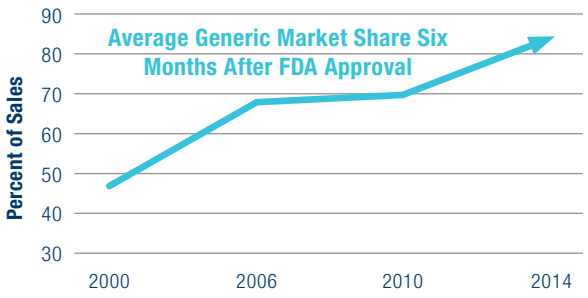
The Hatch-Waxman Act has been highly successful at balancing innovation and competition, as Congress intended, by providing up to 14 years of market protection through the combination of data exclusivity and patent term restoration for drug innovations, followed by robust generic competition. Anecdotal allegations of "evergreening" and "delay" tactics by brand drug companies are belied by overwhelming and consistent data that show record-levels of generic approval and market share penetration, and stable innovator exclusivity periods.

Fact: The time it takes for a generic medicine to come to market has remained steady at approximately 13.5 years for over two decades. And, once entering the market, generics are acquiring greater market share, faster than ever before.

Myth vs. Fact: Patent Evergreening

Despite allegations of over-patenting, data shows that there are only a few Orange Book listed patents on new drugs, and on average only 2.5 "secondary" patents per drug. The vast majority of these secondary patents — more than 75% — are filed **BEFORE** the original drug is approved by FDA. These are not "new patents on old drugs," as critics allege.

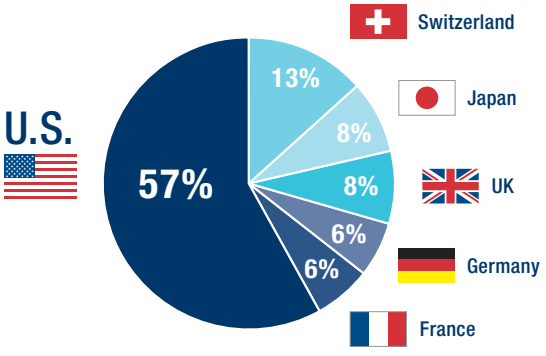
GENERIC ENTRANTS GAIN MARKET SHARE QUICKER AND TO A GREATER EXTENT THAN EVER BEFORE



Source: Henry Grabowski, Genia Long, Richard Mortimer & Ani Boyo (2016): Updated trends in U.S. brand-name and generic drug competition, Journal of Medical Economics

Fact: The U.S. leads the world in innovation AND has the most robust generic market in the developed world.

THE U.S. PRODUCES MORE NEW DRUGS THAN THE REST OF THE WORLD COMBINED



Percentages do not add up to 100% due to rounding.

Source: Milken Institute; Xconomy, "Which Countries Excel in Creating New Drugs? It's Complicated" 2014; Kneller, Nature Biotechnology, 2012

GENERIC SHARE OF TOTAL PRESCRIPTIONS DISPENSED IN THE U.S.

89%

Source: 2017 Association for Accessible Medicines *Generic Drug Access & Savings in the U.S.* report

UK 83% **Germany 81%** **Canada 73%**
OEDC 52% **France 30%** **Japan 34%**

Source: OECD Health Statics 2017

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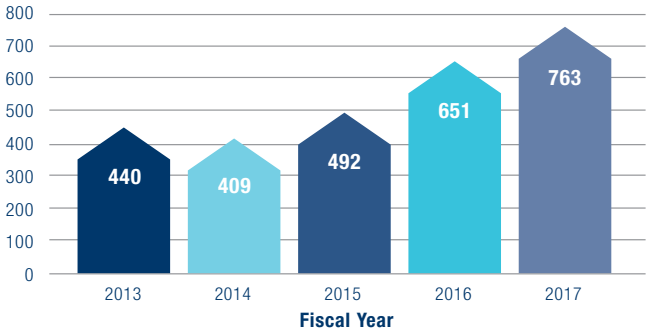
BIO Supports FDA Reform Efforts to Incentivize and Speed Generic Entry

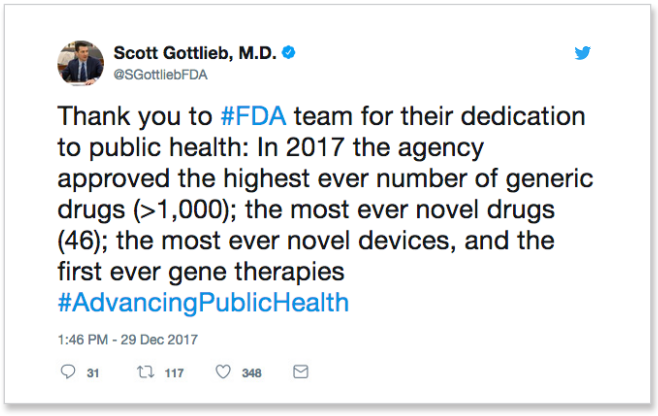
BIO supports ongoing reforms to incentivize and speed generic and biosimilar entry, including provisions in the 21st Century Cures Act and FDA Reauthorization Act of 2017, as well as continued FDA administrative actions to eliminate the generic application backlog.

These new reforms are leading to historic levels of new generic approvals:

GENERIC DRUG APPLICATIONS APPROVED BY YEAR



Source: FDA Commissioner Scott Gottlieb, M.D.



The FDA Is Addressing Individual Abuses, But Improvement in Poor Quality of Generic Applications Is Key to Spurring More Competition

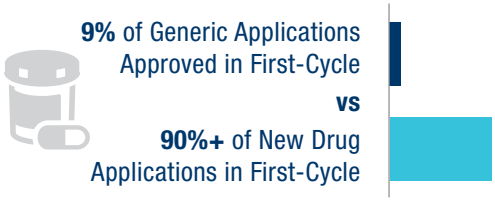
The FDA has prioritized for 2018 improved guidance to address egregious business activities designed to prevent or delay generics from entering the market. BIO supports this effort, but believes the best way to improve competition is to build upon existing initiatives to accelerate first-cycle FDA approval of generic medicines.

The FDA will:

"continue to take steps aimed at making it harder for brand companies to sometimes adopt tactics that prevent generics from coming to market in the time frame that the law intended."

— FDA Commissioner Scott Gottlieb, MD, January 3, 2018

THE MAIN CHALLENGE FOR GENERIC DRUG MAKERS IS POOR FIRST-CYCLE APPROVAL RATES



Source: Regulatory Affairs Professionals Society: Main Challenge for Generic Drugmakers? First Cycle Approvals, FDA Says, April 2017

BIO supports continued FDA initiatives to improve first-cycle generic approval rates, as this problem is the biggest barrier to more generic entry.