

Determinants of Market Exclusivity for Prescription Drugs in the United States

SYNOPSIS

Government-granted patents and periods of market and regulatory exclusivity provide manufacturers of brand-name pharmaceuticals with monopolies that protect them against competition from generic drug companies. In total, most brand-name drug manufacturers have a 12-to-16-year window during which their products are free from competition from lower-cost generics.

THE ISSUE

High prices for brand-name prescription drugs have become an important political issue in the United States. Commonwealth Fund–supported researchers from Harvard Medical School reviewed the laws and regulations that establish the exclusivity periods that manufacturers currently enjoy, along with policy proposals for adjusting them.

KEY FINDINGS

- ▶ **The time remaining on a patent after the Food and Drug Administration (FDA) approves a brand-name drug usually provides most of its market exclusivity.** After discovering a new drug, manufacturers typically apply for a 20-year patent. However, after completing preclinical research and up to seven years of clinical trials, only part of this period remains. The drug manufacturers can extend the length of patent protection in several ways, including: applying for up to five additional years of patent-term restoration during the clinical trial period; receiving an additional six months of exclusivity for conducting trials in children; and obtaining secondary patents covering the drug's manufacturing methods.
- ▶ **Drug manufacturers also receive a concurrent period of regulatory exclusivity that begins at FDA approval and prevents generic entry.** Once a new drug is approved, the FDA provides a guaranteed period during which a generic version cannot be approved, regardless of the time remaining on the new drug's patent. This regulatory exclusivity typically runs for at least six years for new drugs. Certain drugs are eligible for 10 to 12 years of regulatory exclusivity, such as those approved to treat certain infectious diseases and newly approved biologic products used to treat conditions like rheumatoid arthritis and cancer.
- ▶ **The average market exclusivity period for newly approved drugs is more than 12 years.** Highly innovative, first-in-class therapeutics have been shown to garner additional exclusivity time, with one study of top-selling drugs showing that they average about 14.5 years.

September 11, 2017

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Journal *JAMA Internal Medicine*, Sept. 11, 2017

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THE BIG PICTURE

The duration of market exclusivity provides an incentive for manufacturers to invest in drug development, although the end of market exclusivity and entry of generic drugs after a reasonable time also provides incentives for manufacturers to find new sources of revenue. Some policymakers have tried to promote public health goals by adjusting market exclusivity periods in the hopes that will make certain fields — like development of new antibiotics for resistant infections — more attractive for private investment. But market exclusivity already may be sufficiently long that further extensions would have little impact.

Similarly, changing regulatory exclusivities may not affect drug development incentives, because patents may offer longer protection for brand-name drugs. Public policy must strike a balance between rewarding past investments while encouraging timely availability of low-cost generic drugs.

ABOUT THE STUDY

The researchers reviewed peer-reviewed medical and health policy literature published between 2006 and 2016 that was related to prescription drug market exclusivity periods, determinants of their length, and effects on drug costs, patient access, and health outcomes.

The goal of policy in this area should be to ensure that drug market exclusivity periods provide for fair return on investment but not block timely availability of lower-cost generic drugs.

THE BOTTOM LINE

Policymakers often propose ways to extend market exclusivity periods further to create incentives for investing in drug development. However, patents and regulatory exclusivity periods protect new drugs from competition and sustain the high prices charged for many brand-name prescription drugs.

A. S. Kesselheim, M. S. Sinha, and J. Avorn, "Determinants of Market Exclusivity for Prescription Drugs in the United States," *JAMA Internal Medicine*, published online Sept. 11, 2017.

This summary was prepared by Joel Dodge.