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How do data exclusivity periods affect pharmaceutical innovation?

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Pharmaceutical companies and generic drug manufacturers have long been at odds over regulations about "data exclusivity," the period of time before generic manufacturers can make use of valuable clinical trial data.

A new study in the January 2011 issue of Health Affairs is the first to calculate the financial and social costs of limiting access to trial data — and finds that extending the term of exclusive access will lead to higher drug costs in the short term but also to more than 200 extra drug approvals and to greater life expectancy in the next several decades.

"Elected officials are unlikely to embrace legislation that would result in higher drug prices, but our research suggests that legislation to extend data exclusivity would spur innovation that would benefit future generations," explained Dana Goldman, lead author, director of the Schaeffer Center for Health Policy and Economics at USC and Norman Topping Chair in Medicine and Public Policy at USC.

The pharmaceutical companies that introduce new drugs are currently granted five years of exclusive access to the clinical trial data they submit during the approval process. An extension of three years is available if new applications arise and a six month extension is granted if the drug is approved for use in pediatric populations.

In 2007, the National Academies Committee on Science, Engineering and Public Policy called for extending this "data exclusivity" term to the

longer period used in Europe, ten to 11 years. But generic manufacturers have argued for shorter limits so that they can bring less expensive versions of drugs to patients sooner.

"Unfortunately, the health policy literature contains no information about the effects such a policy would have on innovation, population longevity and social welfare," said Darius Lakdawalla, research director at the Schaeffer Center at USC and associate professor in the USC School of Policy, Planning and Development.

In the first study to directly address these issues, the researchers estimate that extending the term of data exclusivity to 12 years would increase the lifetime revenue of a drug by 5 percent, on average.

With empirical evidence that profits drive drug innovation, this longer term would lead to an additional 228 drug approvals over the next fifty years and an increase of 1.7 months in average life expectancy, according to the study.

John Romley, an economist with the Schaeffer Center at USC and research assistant professor at the USC School of Policy, Planning and Development, acknowledged the trade-off between current and future generations: "Americans in the early 2020's would bear the cost of increasing drug spending. However, people turning 55 in 2060 could expect increased life expectancy as a result of innovation in the interceding years — that is, new drugs brought to market because of lengthier data exclusivity."

More information: Goldman et al., "The Benefits from Giving Makers of Conventional 'Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data." *Health Affairs*: January 2011.