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The Benefits From Giving Makers Of Conventional `Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data

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Abstract

Pharmaceutical companies and generic drug manufacturers have long been at odds over “data exclusivity” regulations. These rules require a waiting period of up to eight years before generic drug companies can access valuable clinical trial data necessary to bring less expensive forms of innovative drugs to market. Pharmaceutical companies want the data exclusivity period lengthened to protect their investment. Generic manufacturers want the period shortened so they can bring less expensive versions of drugs to patients sooner. We examine the long-term effect of extending the data exclusivity period for “conventional” small-molecule drugs to twelve years – the same exclusivity period already extended to large-molecule biologic drugs under the Affordable Care Act. We conclude that Americans would benefit from a longer period of data exclusivity.

Data exclusivity refers to the period of time after approval of a new drug and before a generic manufacturer can access the clinical trial data that was submitted by the drug's originator during the approval process. Given the high cost of conducting clinical trials, data exclusivity provides strong intellectual property protection to pharmaceutical innovators. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, establishes the process by which generic drug manufacturers can seek approval from the Food and Drug Administration (FDA) to manufacture and market conventional drugs. Conventional drugs are created through chemistry, whereas the term biologics refers to drugs created from living organisms.

The Hatch-Waxman Act provides originators of new conventional drugs with five initial years of data exclusivity, and three extra years for supplemental applications, for uses other than the one[s] for which the drug was originally approved. In addition, the Food and Drug Administration Modernization Act of 1997 provides a six-month extension for previously approved drugs when such drugs are subsequently approved for use in pediatric populations.

By comparison, the data exclusivity period in Europe is ten years for both conventional drugs and biologics, plus an additional year if a new indication is added for which the drug provides significant clinical benefits compared to existing therapies.¹ In the United States, biologic drugs were granted a 12-year exclusivity period under the Affordable Care Act. We are not aware of any pending legislation to lengthen data exclusivity for conventional drugs in the US.

In 2007, the National Academies of Science and Engineering called for the United States to “adopt the European [data exclusivity] period” of 10–11 years and recommended that research be conducted to determine whether even that period of time is adequate, “given the complexity and length of drug development today.”² The pharmaceutical company GlaxoSmithKline has proposed fourteen years of data exclusivity for conventional drugs.³ Unfortunately, the health policy literature contains no information about the effects such a policy would have on innovation, longevity, and social welfare. We believe our study is the first to address these issues.

Data exclusivity provides intellectual property protection that is distinct from patent protection. In the United States, a patent becomes effective at the date of filing—typically long before clinical trials start—whereas data exclusivity begins on the date a drug is approved for marketing by the FDA.

In addition, a patent is subject to challenge. The Hatch-Waxman Act allows a would-be generic competitor to contest the validity of a patent in court. Such litigation now occurs for the vast majority of new drugs, and typically commences shortly after FDA approval.¹ Data exclusivity, by contrast, cannot be legally challenged.

The duration of the data exclusivity period entails a trade-off between current and future generations. A longer period delays competition from generic drug companies, effectively extending the originator's exclusive position in the marketplace. The prospect of higher profits gives drug companies a stronger incentive to innovate—both to create new drugs and to find new indications for existing products. An increase in innovation, in turn, benefits future generations of consumers. At the same time, however, a delay in generic competition imposes a greater spending burden on current consumers. So an increase in the length of data exclusivity benefits future generations, but at the expense of today's drug consumers.

Although some have questioned whether profits drive innovation, empirical evidence strongly supports this relationship. The Orphan Drug Act of 1983, which provides pharmaceutical companies with incentives to develop drugs for treating rare diseases or conditions for which there are small patient populations, was followed by a sharp increase in the number of drugs approved for this market.⁴ Higher profits from vaccines have been associated with a significant increase in the number of clinical trials to develop new vaccines.⁵ There is also evidence that manufacturers have delayed new drug launches rather than accept a lower anticipated price.⁶

Daron Acemoglu and Joshua Linn⁷ concluded that a 1 percent increase in the potential market size for a drug class leads to a 3–4 percent growth in the entry of new drugs.⁷ To our knowledge, this is the only study that estimates this relationship for the entire drug market. As Darius Lakdawalla and colleagues observe,⁸ the relationship identified by Acemoglu and Linn presumes that increases in the number or share of the aged population (60+ years old) driven by past baby booms or busts also increase innovation in drug classes targeted toward the aged. Moreover, it presumes that pharmaceutical innovation does not drive historical trends such as baby booms or busts; there is no evidence that contradicts this presumption. Applying this relationship between market size and innovation to average sales within a drug class, innovators produce one additional drug for every additional \$97.5 million of

annual potential revenue. Because the cost of a new conventional drug is estimated to be \$800 million,⁹ innovators require a 12 percent annual return on their investment—within accepted boundaries for the return on capital in the drug industry.

In this paper we analyze the effect of a longer period of data exclusivity for conventional drugs on both current and future generations. We do not consider the effects of a change in the data exclusivity period for biologics. We focus on a twelve-year duration because, as noted above, this is data exclusivity period recently approved by Congress for biologics. As such, it serves as a natural benchmark for extended data exclusivity for conventional drugs.

We address three specific policy questions: How would extending the initial five years of data exclusivity for new conventional drugs in the United States affect innovation? How would a longer period of data exclusivity affect the health of current and future generations? What is the dollar value of a longer period of data exclusivity to US society?

STUDY DATA AND METHODS

Our analysis has two main components. First, we estimated the effect of a longer period of data exclusivity on revenues to pharmaceutical companies. We used retrospective data from the drugs@FDA database¹⁰ and the FDA Electronic Orange Book¹¹ of approved drug products to construct a representative profile of protection from generic competition during a drug's life cycle.

Second, we feed that result into our global pharmaceutical policy model⁸ to determine the effect of increased pharmaceutical revenues on drug innovation and consumers' longevity. The model is a set of dynamic interactions that link present health and innovation to their future values. For example, next year's health status depends on today's health, on the drug treatments that are available, and on a set of random health “shocks” that vary with an individuals' own risk-factors such as age, health behaviors, and current disease conditions. An example of a shock would be exposure to an infection.

Following Joseph Lipscomb and colleagues,¹² we assume a real (inflation-adjusted) “social” discount rate of 3 percent in our baseline analysis. This discount rate captures the manner in which society discounts benefits in the future compared to benefits today. It is distinct from companies' cost of capital – the amount of interest they need to pay to borrow money – which is typically higher than 3 percent.⁹

For our baseline analysis, we assume an innovation elasticity of 3.0, meaning that a 1 percent increase in expected drug revenue leads to a 3 percent increase in the number of drugs approved within the class each year. This assumption is slightly conservative and understates changes in innovation, longevity, and welfare, relative to the findings of Acemoglu and Linn.⁷

Increased innovation in turn affects population health. The global pharmaceutical policy model uses the health benefits documented in the clinical literature as a result of recent drugs for seven major conditions (heart disease, hypertension, diabetes, cancer, lung disease, stroke and mental illness). The model also accounts for the increased likelihood of treatment associated with drug innovation. As innovation expands because of greater data exclusivity, the life expectancy of older Americans improves; this improvement results mainly from the increased likelihood of treatment, not the health benefits of new drugs. With longer life expectancy, the population of potential drug users grows, further increasing revenues and stimulating innovation over time. We model innovation and health through 2060.

The monetary value of increased longevity, that is, the amount consumers are willing to pay for longer life spans, has long been a subject of debate. An analysis by Richard Hirth and colleagues of attitudes and behavior related to mortality risk showed that the median value of a life-year ranges from \$110,200 to \$505,400 (in 2004 US dollars).¹³ Research by Kip Viscusi and Joseph Aldy implies that the value of a life-year ranges from \$150,000 to \$360,000.^{8,14}

In our baseline analysis, we assign a monetary value for increased longevity of \$200,000 per life-year, though in sensitivity analyses we consider a range of values for this and other parameters. Additional details about our methods, data, and assumptions are provided in a technical appendix.¹⁵

Limitations

Simulations of this sort have certain limitations. Because laws, regulations, science, and medicine are likely to change in unforeseen ways, the retrospective data we relied on may not characterize the future. Some plausible changes, for example, an increase in the number of successful challenges to patent validity,¹ may cause us to understate the effects of longer data exclusivity. Other changes such as government price controls, which would reduce potential profits available to drug companies, may cause us to overstate effects. Still other changes, such as advances or setbacks in science and medicine that are impossible to anticipate, could lead to either understated or overstated effects.

We do not model behavioral responses to a longer period of data exclusivity due to the technical complexity and lack of good evidence. For example, a generic drug company might attempt to bypass lengthier data exclusivity periods in the United States by conducting clinical trials of a generic version of an already-approved drug. If drug developers believe that generic manufacturers would behave in this way, our results overstate the long-term effects of longer data exclusivity.

We do not model non-mortality benefits, for example, treatments for mental health conditions, pain, and rheumatoid arthritis. Such benefits account for much of the value of many drugs, yet there was insufficient evidence on the non-mortality benefits of new drugs. If these benefits are important, our estimates of the benefits of longer data exclusivity are conservative.

Finally, we do not calculate the potential benefits of a data exclusivity period shorter than the current Hatch-Waxman provisions.

STUDY RESULTS

Applying our findings about increased revenues over a drug's life cycle, we found that extending data exclusivity to twelve years would increase lifetime drug revenues by 5.0 percent on average.

Exhibit 1 explains how we reached this result. The exhibit shows the proportion of conventional drugs that had protection against generic competition under existing law—arising from either patents or data exclusivity—and the proportion of such drugs that would have had protection if data exclusivity had lasted twelve years. The drugs in our sample began facing generic competition eight years after launch. With a twelve-year period of data exclusivity, by contrast, all the drugs would have faced no generic competition for at least twelve years after launch.

We also determined that expanding data exclusivity to twelve years would result in 228 extra drug approvals between 2020 and 2060, relative to the number of approvals that we

project under the current Hatch-Waxman data exclusivity provisions. We lay out these data in Exhibit 2, which illustrates the impact of increasing the period of data exclusivity to twelve years on the number of conventional drug approvals in the United States.

We found that a twelve-year data exclusivity period has little beneficial effect on longevity at age fifty-five. Americans in the early 2020s will bear the cost of increased drug spending with relatively little increased innovation and therefore relatively little benefit in terms of longevity. However, people turning fifty-five in the year 2060 can expect increased life expectancy of 1.44 years as opposed to 1.30 years under the status quo (Exhibit 3). The difference—1.7 months—is a result of innovation in the interceding years—that is, the new drugs brought to market because of lengthier data exclusivity. As a point of comparison, the elimination of obesity in the United States could increase life expectancy at birth by 2.5 to 13.0 months.¹⁶

By 2060, these Americans would spend \$3,400 per capita (in 2009 US dollars) over their remaining lives on drugs developed as a result of longer data exclusivity (Exhibit 4). Given the substantial value of a life-year, the benefit of increased longevity would be \$13,800, or \$10,400 when you calculate benefits minus costs. The increase in “welfare” or well-being is smaller, but still positive, between 2020 and 2060.

Sensitivity Analyses

The baseline model implies that a longer period of data exclusivity would be of value to future generations of Americans. How sensitive are these results to our assumptions? To answer this question, we varied the value of a life-year (\$50,000 to \$300,000), the innovation elasticity (0.5 to 4.0), the social discount rate (2 percent to 4 percent), and the revenue impact of a twelve-year period of data exclusivity (base case plus or minus 25 percent).

In most of these scenarios, the net benefit of a twelve-year period of data exclusivity to people age fifty-five was positive from 2020 through 2060. The costs exceeded the benefits—and so longer data exclusivity was harmful—only for the lowest levels of the innovation elasticity (0.5–1.0) and the value of a life-year (\$50,000). These parameter levels are much smaller than the best available evidence (described earlier). Hence, even though there is uncertainty about model parameters, a lengthier data exclusivity period would likely be beneficial overall.

DISCUSSION AND POLICY IMPLICATIONS

Recent discussions about the appropriate length of data exclusivity for new drugs have focused on biologics,¹ but as noted above, the National Academies Committee on Science, Engineering, and Public Policy² and the pharmaceutical company GlaxoSmithKline³ have proposed increasing the data exclusivity period for conventional drugs, as several European countries have done.

Unfortunately, there has been no quantitative analysis of the effects of a longer data exclusivity period on innovation, longevity, and societal welfare. To our knowledge, this is the first study to provide such estimates. Our analysis suggests that Americans would benefit in the long term from a longer period of data exclusivity.

This finding is robust with respect to plausible assumptions about the effect of revenues on innovation and other factors. Nevertheless, there is uncertainty regarding potential changes in regulations, science, and medicine that were not incorporated into our model.

The idea of extending data exclusivity for conventional drugs has not garnered much political support. It appears that elected officials are unlikely to embrace legislation that would result in higher drug prices. Our research suggests such legislation would spur innovation that would benefit future generations.

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NOTES

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EXHIBIT 1.

Effect Of A Twelve-Year Data Exclusivity Period On Introduction Of Competition From Generic Drugs

SOURCES: drugs@FDA database, FDA Electronic Orange Book, authors' calculations

EXHIBIT 2.

Effect Of A Twelve of a twelve-year period of data exclusivity On Number Of Conventional Drug Approvals In The United States

SOURCE: Authors' calculations

EXHIBIT 3.
 Effect Of A Twelve-Year Data Exclusivity Period On Life Expectancy Of Americans Age
 Fifty-Five
 SOURCE: Authors' calculations

EXHIBIT 4.

Incremental Benefits And Costs (In 2009 US Dollars) Of Twelve-Year Data Exclusivity to Americans Age Fifty-Five

SOURCE: Authors' calculations