Policy Brief

The Impact of Intellectual Property Protection on Post-Approval Innovation

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Abstract

This policy brief quantifies how changes in intellectual property protections shape post-approval pharmaceutical innovation and patient health for small-molecule drugs. Using available FDA approval data, we examine the effects on the 317 new small-molecule drugs approved between 2015 and 2024. Using existing evidence, we calibrate that a one-year increase in exclusivity is associated with approximately 6.34 post-approval new uses developed from drugs initially approved over the previous ten years. Accordingly, a fourteen-year effective patent life, which corresponds to the median market exclusivity period observed over the years for small-molecule drugs, is associated with approximately 89 post-approval treatments in total. This post-approval innovation is associated with an estimated gain of 218 million life-years, equivalent to approximately 2.8 million full lives. This implies that shortening the exclusivity period by 5 years would mean a loss of 31.7 post-approval treatments, corresponding to 1 million full lives lost. Our findings highlight the importance of reliable market exclusivity to incentivize continued development of medicines to identify new uses that lead to improvements in long-run health outcomes.

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Section 1: Introduction

Patents and other forms of intellectual property provide a period during which investments in R&D can be recouped before generic competition can occur, providing researchers in the pharmaceutical industry with the certainty needed to invest in biopharmaceutical markets. But beyond the development of new drugs, these protections also encourage investment in post-approval innovation, defined here as the expansion of therapeutic uses or indications for drugs that have already received FDA approval rather than the discovery of entirely new products. These post-approval developments require additional research investment and typically rely on the remaining period of market exclusivity to generate sufficient returns.

While these incentives promote efficiency by ensuring the greatest value is extracted from existing medicines that have already been established to be safe and effective, they also promote broad competition prior to generic entry as brands within product classes compete for market share by investing in research to demonstrate greater benefits to patients in the market through expanded uses. Payers, in turn, are able to leverage these differential benefits among product choices to negotiate manufacturer discounts on the prices of medicines as they control patient access to medicines through formularies.

Over the years, market exclusivity periods have averaged 14 years. This timeframe aligns with what was intended by the crafters of the Hatch-Waxman Act, which established the abbreviated regulatory pathway for generic products in 1984, while maintaining incentives for pharmaceutical innovators. Congress carefully considered the 14-year period in the context of establishing the patent term restoration policy under the Hatch-Waxman Act and was determined to provide research-intensive companies with the necessary incentive to increase R&D activities and earn a return on investment. While this period of market exclusivity has consistently been observed for small-molecule drugs over the past several decades, policy proposals have been advanced that would effectively curtail this period.

For example, the Inflation Reduction Act of 2022 (IRA) empowers Medicare to set prices for selected high-revenue brand-name drugs. For small-molecule drugs, the IRA exempts products from Medicare price setting for 9 years following FDA approval. Although the IRA does not explicitly address patent reform, its drug pricing provisions substantially shorten the exclusivity period during which manufacturers can earn revenues from innovative products, thereby weakening existing incentives and patent-based strategies within the pharmaceutical industry. In practice, the IRA's pricing provisions curtail the revenue window for brand-innovator companies by introducing earlier price setting, even when legal patent or FDA exclusivity remains in place. As a result, incentives to invest in post-approval innovations are weakened, since their economic returns depend critically on a sufficient period of revenue-generating market exclusivity before prices are eroded.

Prior research emphasizes that post-approval innovation can generate meaningful patient benefits by expanding therapeutic options and improving the match between treatments and patient needs. In oncology, post-approval development has been shown to deliver substantial clinical value by targeting earlier stages of disease, and a significant share of innovation occurs after initial approval (Philipson et al., 2025; Grabowski, DiMasi, and Long, 2024). Similarly, for orphan drugs, post-approval indications often broaden therapeutic reach and generate additional social value (Chambers et al., 2023). Research has shown that post-approval indications are used twice as often as a medicine's initial approved indication. Evidence from real-world utilization shows that approximately 65 percent of use for small-molecule drugs reflects post-approval indications, compared with 35 percent for the initial approved use (Employee Benefit Research Institute, 2025). Because these post-approval indications frequently account for the majority of real-world utilization and typically emerge years after initial approval, sustaining incentives for post-approval research is critical to realizing their full clinical and social value.

In this policy brief, we examine more generally and broadly how changes in effective patent lives translate into post-approval pharmaceutical innovation and the resulting impact on downstream patient health. We examine the total of 317 novel small-molecule approvals over the period 2015 to 2024. Drawing on the results from Budish et al. (2025), we estimate that each additional year of exclusivity generates approximately 6.34 post-approval indications over this ten-year sample. Accordingly, we find that an effective market exclusivity of fourteen years corresponds to 89 post-approval drugs among the novel drugs examined over the study period. This implies an estimated health outcome of 218 million life-years, equivalent to approximately 2.8 million full lives. Conversely, reducing effective exclusivity yields losses: a one-year reduction is associated with 6.34 fewer post-approval treatments and roughly 15.6 million life-years foregone or 200,000 full lives, while a five-year reduction implies a loss of 31.7 post-approval drugs and approximately 78.0 million life-years or 1 million full lives. These findings highlight an important but often overlooked channel through which changes in market exclusivity shape long-run health outcomes by strengthening incentives for post-approval innovation.

Section 2: Evidence Linking Exclusivity Length to Post-approval Innovation

Recent empirical research provides direct evidence on how the enforceability and duration of market exclusivity affect investment in post-approval drug innovation. In particular, new work by Budish et al. (2025) examines how incentives for developing new therapeutic uses change as effective patent protection weakens.

Using data on FDA-approved small-molecule drugs between 1985 and 2014, Budish et al. (2025) document a clear relationship between remaining exclusivity and post-approval research activity. They show that post-approval innovation declines sharply as drugs approach the end of their enforceable exclusivity period and nearly ceases once generic entry occurs, indicating a strong causal link between exclusivity length and continued post-approval investment.

These findings are informative for understanding the potential effects of the IRA. By allowing earlier Medicare price negotiation, the IRA effectively shortens the revenue-generating exclusivity window in a manner that mirrors key incentive effects of earlier generic entry. Consistent with this interpretation, recent investor interviews suggest that firms are already adjusting development strategies in response to the IRA by shifting away from projects with shorter effective exclusivity horizons (Canestaro, Patterson & Campbell, 2025). Empirical research also shows that following passage of the IRA, the average monthly number of industry-sponsored trials on post-approval drugs decreased by 47.3% for small-molecule medicines (Zheng, Patterson, & Campbell, 2025). This decline is concentrated in industry-sponsored trials, with no statistically significant change in government-funded post-approval trials, suggesting that the observed reduction reflects disproportionate changes in private development incentives.

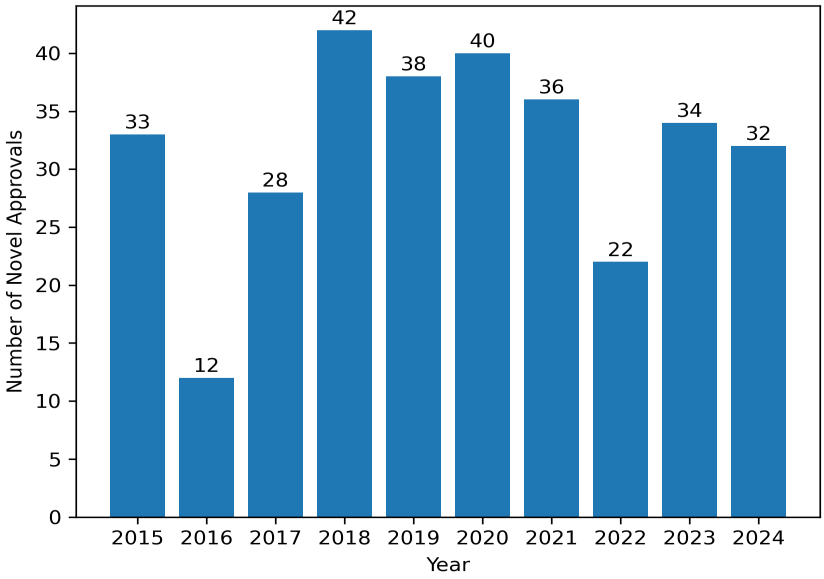
Together, this evidence provides the empirical foundation for calibrating how effective market exclusivity shapes post-approval treatment advances. In the next section, we use these estimates to quantify the relationship among market exclusivity, post-approval innovation, and associated patient health outcomes for each year that market exclusivity exists.

Section 3: Calibrating the Impact of Market Exclusivity on Post-approval Innovation

This section calibrates the relationship between effective market exclusivity and post-approval innovation using the results from the NBER paper (Budish et al., 2025). The goal is to provide a transparent mapping from changes in market exclusivity to downstream innovation and health outcomes.

Figure 1 documents the flow of novel small-molecule drug approvals by the FDA over the past decade. Between 2015 and 2024, annual approvals ranged from 12 to 42, with an average of approximately 32 small-molecule drugs per year. Accordingly, we adopt a ten-year calibration window and set $N_{sm} = 317$, reflecting the cumulative number of novel small-molecule drug approvals by the FDA over the 2015-2024 period.

Figure 1: FDA Approvals of Novel Small-Molecule Drugs (2015-2024)



Source: FDA, Nature, and ScienceDirect

To translate effective patent life into post-approval innovation, we rely on evidence from the *Missing Markets for Innovation (NBER)* study, which estimates a positive relationship between effective market exclusivity and the generation of post-approval drugs. Specifically, each additional year of effective market exclusivity generates 0.02 additional post-approval drugs per innovator small-molecule. This relationship is modeled as linear and anchored at zero in our analysis. Meanwhile, Rome et al. (2020) indicated that the median effective market exclusivity for new small-molecule drugs is approximately 14 years, which we therefore adopt as the upper bound in our calibration. Let E denote the number of years of effective market exclusivity. The total number of post-approval drugs induced by the exclusivity of length E is given by

$$Follow-on\ Drugs(E) = N_{sm} \times 0.02 \times E, \text{ for } E \text{ ranging from 0 to 14 years.}$$

In a previous study, Philipson and Durie (2021) found that the foregone innovation of 135 drugs would result in a loss of 331.5 million life-years in the United States, equivalent to approximately 2.46 million life-years lost per missing drug. Given this relationship and the U.S. life expectancy of 78.4 years, we estimate the corresponding health outcomes as follows:

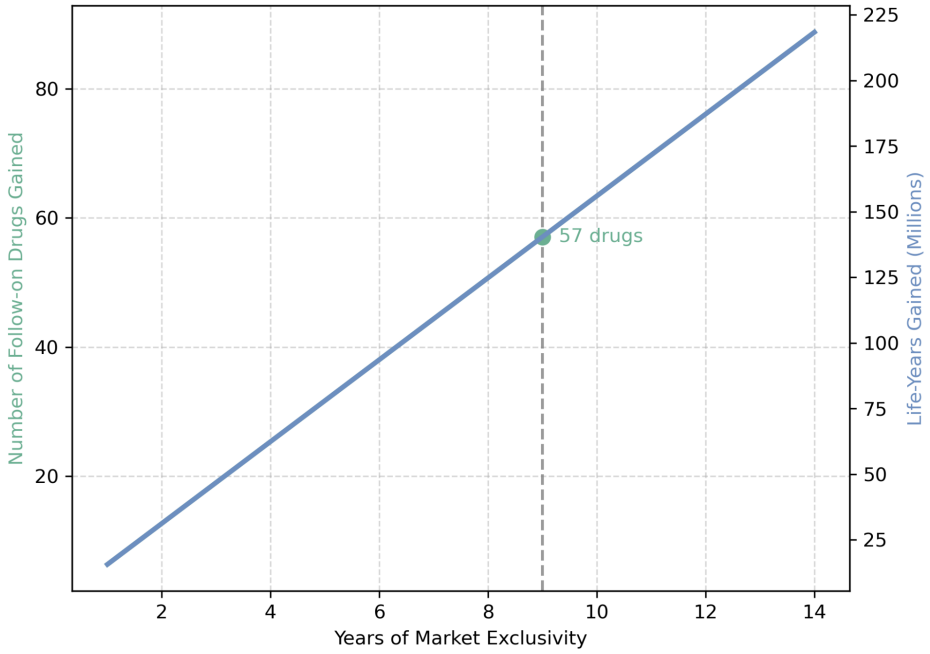
$$Life\ Years\ Gained = Follow-on\ Drugs(E)\ \times 2.46\,million,$$

$$Full\ Lives\ Gained = \frac{Life\ Years\ Gained}{78.4}.$$

Although the marginal effect of exclusivity may appear modest, the cumulative implications are substantial. As illustrated in Figure 2, extending effective patent life by nine years generates approximately 57 additional post-approval drugs, while a fourteen-year extension yields nearly 89 post-approval drugs. These post-approval innovations subsequently translate into meaningful

health gains. Using the existing evidence, each additional year of exclusivity corresponds to roughly 15.6 million life-years gained. At the nine-year reference point, this amounts to approximately 140 million life-years, or about 1.8 million full lives saved. At fourteen years, the implied gains rise to 218 million life-years, equivalent to nearly 2.8 million full lives. These results highlight the substantial long-term health benefits associated with changes in market exclusivity periods for innovative drugs, underscoring the importance of balancing affordability policies with incentives for continued medical innovation.

Figure 2: Market Exclusivity Length and Downstream Innovation and Health Outcomes



The evidence in this brief underscores that effective intellectual property protection, as reflected in market exclusivity, plays a central economic role in post-approval innovation. Quantitatively, we estimate that each additional year of effective exclusivity generates approximately 6.34 post-approval indications, corresponding to roughly 15.6 million life-years gained or 200,000 full lives. By allowing firms to recoup the large, upfront, and inherently risky investments required for drug development, the period of protected market returns serves as an economic mechanism through which research and clinical development costs are recovered, and the expected returns necessary to finance future innovation are generated. By sustaining these returns, the IP framework enables firms to undertake subsequent long-term post-approval research that expands therapeutic value well beyond initial approval. Policies that prematurely erode this revenue-generating window, particularly through poorly designed pricing interventions, risk weakening these dynamic incentives and reducing both post-approval innovation and the long-run flow of new therapies. A durable policy approach must therefore balance affordability objectives with the need to preserve the incentive structure that underpins continued medical progress and long-term patient health gains.

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