Anticompetitive Tactics Delaying Generic Drug Entry and Price Competition

A Rapid Review of Market Barriers and Delays, Costs, and Potential Reforms

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Executive Summary

When generic drugs enter the market, prices can decline by 80 percent or more relative to the brand-name drug price (Vokinger et al. 2017). Any tactic that delays generic entry therefore preserves brand-only pricing for as long as it succeeds, with potential consequences for health care spending, particularly patient affordability and resulting medication adherence. However, brand-name manufacturers use various strategies to delay generic competition, maintaining elevated drug prices for months or years and imposing billions of dollars in excess health care spending on patients, employers, and public programs. This report synthesizes the available evidence concerning seven such anticompetitive tactics in the US pharmaceutical market for small-molecule (nonbiologic) drugs.

Following established rapid-review methods, this study assessed 150 studies that met inclusion criteria, prioritizing peer-reviewed and government research published in 2019 and later. These studies were supplemented by selected earlier foundational studies and by additional sources identified through citation chaining from the included sources and through targeted searches designed to capture recent legislative developments and institutional policy updates.

The Seven Anticompetitive Tactics and Their Costs

1. **Patent thickets.** Manufacturers accumulate numerous secondary patents filed after the initial patent, encompassing features such as pill coatings, delivery devices, or dosing, rather than the active ingredient itself, which requires generic competitors to challenge each subsequent patent and ultimately resolve years of overlapping litigation before their products can enter the market. For four top-selling drugs, the resulting delays generated an estimated $3.5 billion in excess costs for commercial and Medicare Part D payers over a two-year period following generic competition, based on spending data from 2011 to 2021 (Hong et al. 2025).
2. **Product hopping.** Manufacturers transition patients to a modestly reformulated version of a medication before generics of the original formulation become available, leaving a diminished market share for the lower-cost generic version. For example, the shift to a new formulation of Copaxone delayed meaningful price competition by 2.5 years and was associated with an

estimated $4.3–$6.5 billion in excess health care spending across all US payers from 2015 to 2017 (Rome et al. 2020).

3. **Pay-for-delay settlements.** A brand manufacturer compensates a generic challenger in cash or other forms of payment to abandon its patent challenge and delay generic market entry. Such arrangements shifted from cash to harder-to-detect, noncash value transfers after a 2013 Supreme Court ruling. However, these tactics persist, as more than 1 in 4 of the 64 recent settlements showed evidence of such reverse-payment arrangements, costing payers and patients an estimated $12 billion annually from 2014 to 2023 (Drake and McGuire 2024).
4. **Sample denial.** Manufacturers decline to sell brand-name drug samples that generic developers must use to conduct the strict bioequivalence testing required by the US Food and Drug Administration (FDA) for generic approval. All generic firms interviewed by federal auditors reported that such refusals had delayed or deterred development of generic products (GAO 2019).
5. **Parking of 180-day exclusivity.** The first generic to challenge a brand's patents earns 180 days of market exclusivity, during which the FDA is not allowed to approve a competing generic product. A sole first filer can decline to launch, "parking" that exclusivity and blocking subsequent generic products until a settlement date. When exclusivity is instead shared among multiple generic first filers, which is a common occurrence for drugs with new ingredients, no single firm can park the exclusivity, and generic entry occurs more than three years earlier on average (Drake 2026).
6. **Authorized generics.** A brand may market its own product under a generic label; it can deploy this product, or pledge to withhold it, as leverage in settlement negotiations to delay the launch of independent generic competitors' products. On average, launch of an authorized generic reduces the probability of independent generic entry between 1999 and 2018 by 7.5 percentage points (Yao and Liu 2025).
7. **Citizen petitions.** Manufacturers file petitions with the FDA late in a generic's review, compelling the agency to pause and respond, and thereby postponing approval. Brands filed 92 percent of the citizen petitions examined, and the FDA denied 92 percent of these (Carrier and Minniti 2016).

What Evidence Shows

- **The anticompetitive tactics operate in combination.** Patent settlements, secondary patents, and gaps in FDA authority (e.g., FDA's limited role in verifying patents listed in its official registry, referred to as the Orange Book; its inability to compel sample sharing; and narrow triggers for exclusivity forfeiture or citizen petition review) recur across several tactics, allowing the practices to reinforce one another. As a result, narrow fixes tend to shift anticompetitive conduct rather than eliminate it.
- **Most are lawful in isolation.** Each tactic is generally legal and relatively modest in the delay it causes and the costs it imposes, which is why competition law alone has not resolved the problem.
- **Existing policy has helped but remains insufficient.** Enforcement against improper patent listings and nonmeritorious petitions has produced measurable gains. Statutes such as the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) of 2019 and the Medicare Prescription Drug, Improvement, and Modernization Act (Medicare Modernization Act) of 2003 have closed specific loopholes in sample access and exclusivity parking, respectively. But these remedies are case-by-case and reversible, and several tactics continue.

What Reform Requires

- **A small number of reform measures could address multiple anticompetitive tactics at once.** A statutory presumption against pay-for-delay settlements (i.e., a legal default that treats a brand-to-generic payment for delayed entry as anticompetitive unless the companies prove otherwise) would reach three tactics simultaneously (pay-for-delay settlements, 180-day exclusivity parking, and no-authorized-generic agreements). Congressional action to clarify FDA authority could reduce or resolve both sample denial and misuse of citizen petitions without reliance on litigation.
- **Two patent-based anticompetitive tactics require additional reform.** Patent thickets could likely be curbed by capping the number of related patents a brand can enforce against a generic and by tightening which patents qualify for FDA listing. Product hopping could be addressed by legislation supporting Federal Trade Commission challenges to anticompetitive switches, paired with market surveillance and payer tools that flag hops early and steer prescribing toward generic-available versions.

- **Gaps in the evidence remain.** Providing rigorous current evidence (i.e., after the incremental reforms implemented in recent years) on each tactic's distinct effect on prices is a priority for future research. In addition, the existing research on how high prices negatively affect patient access, adherence, and health should be updated to examine more recently introduced brand-name drugs.

In sum, timely generic competition is among the most reliable mechanisms available to US payers and patients for lowering prescription drug prices. Strengthening such competition will require new efforts pairing sustained enforcement with new legislation that reaches the shared mechanisms underlying these tactics. These efforts are set out, with specific recommendations, in the full report.

Anticompetitive Tactics Delaying Generic Drug Entry and Price Competition

Introduction

Prescription drugs account for a large share of US health care spending, at roughly 16 percent of national health expenditures in 2025, including $915.2 billion in retail and nonretail prescriptions (Tichy et al. 2026).[1] Generic competition is one of the most important mechanisms for lowering those costs once a brand drug's exclusivity period ends. Estimates from the generic and biosimilar pharmaceutical industry suggest that generic medicines make up roughly 90 percent of US prescriptions, but only about 12 percent of prescription drug spending, and the lower prices of generic and biosimilar medicines were reported to account for an estimated $467 billion in health care system savings in 2024.[2] These savings depend on generics reaching the market without undue delay: Once multiple generic manufacturers compete, prices commonly fall by 80 percent or more relative to the brand (Vokinger et al. 2017). The magnitude of this decline depends on the number of manufacturers that reach the market. More generic competitors tend to bring about greater price reductions, and the most substantial savings occur when several generics compete over time, rather than at the time of initial generic entry (CBO 2024). This dynamic runs through every tactic examined below. Brand-name manufacturers can use each of the seven anticompetitive tactics examined in this report to reduce the number of generic competitors or delay their arrival, and each therefore preserves brand-level prices and the excess spending that flows from them for as long as it succeeds.

The 1984 Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, established the regulatory framework for small-molecule (i.e., nonbiologic) generic drug competition in the US. Congress designed this legislation to balance two goals. First, incentivizing pharmaceutical innovation through a period of market exclusivity, and second, increasing generic competition and expanding patient access to these medications after the period of exclusivity (CRS 2016). Under this framework, a generic manufacturer may seek approval to enter the market through an abbreviated new drug application (ANDA) by demonstrating bioequivalence to the brand reference drug without repeating the brand's full clinical development program. The act also reduced the financial

risk of mounting such a challenge. Before 1984, a brand could bring a patent infringement suit only after a generic had launched, exposing the generic manufacturer to damages if it lost. The Hatch-Waxman Act instead treats the generic's application itself as an act of infringement, allowing the parties to litigate before the generic reaches the market and before any damages accrue.[3] To keep a challenge worthwhile despite its cost and risk, the Act granted the first generic firm to file such a challenge a 180-day period of marketing exclusivity.[4]

Under Hatch-Waxman, a new brand drug is granted a standard 20-year patent term from the date the patent application is filed, but some of this time is used for clinical development and review by the US Food and Drug Administration (FDA). In practice, first generic entry for a new small-molecule drug typically occurs about 12 to 14 years after brand approval, even without additional exclusivity-extending tactics (Beall, Darrow, et al. 2019; Kannappan et al. 2021). This average 12- to 14-year period reflects the baseline framework established under the Hatch-Waxman Act, representing the point at which generic competition would typically be expected. However, as detailed in this report, manufacturers have developed and implemented various additional strategies to prolong the brand's period of exclusivity beyond this baseline. These tactics can impose billions of dollars annually in excess spending on US patients and payers by delaying generic competition (Hong et al. 2025; Dave et al. 2020; R. Feldman 2022; Drake and McGuire 2024).

Evidence on these tactics and strategies is dispersed across the health economics, legal, and health policy literatures, which makes their mechanisms, scale, and costs difficult to compare. Cost estimates are particularly hard to compare because studies assess different payers and costs, such as Medicare, Medicaid and CHIP (the Children's Health Insurance Program), commercial insurance, patient out-of-pocket spending, or total federal budgetary effects. This report presents findings from a rapid evidence review commissioned to synthesize rigorous research on seven selected anticompetitive tactics (the principal tactics documented across the legal, economic, and regulatory literature): patent thickets, product hopping, pay-for-delay settlements, sample denial pathways, parking of 180-day exclusivity, authorized generics timed to the exclusivity window, and citizen petitions. This review covers the mechanism, scale, cost, and patient consequences of each tactic and identifies reform options. Because many of these strategies are lawful in isolation yet impede competition when used to delay generic entry, new policies, paired with more rigorous and consistent enforcement, are likely needed to bolster timely generic entry. This report concludes with recommendations.

Methods

This rapid review synthesizes evidence from peer-reviewed health economics and policy studies, legal and regulatory analyses, and high-quality gray literature on small-molecule drugs in the US market, informed by best-practice rapid review guidance (Haby et al. 2016, 2024). The seven anticompetitive tactics were selected because, together, they represent the principal anticompetitive strategies documented across the legal, economic, and regulatory literature on generic entry delay, drawing on taxonomies and prior syntheses, including that of Vokinger and others (2017), and corroborated by agency assessments from the Federal Trade Commission (FTC), US Government Accountability Office (GAO), and Congressional Budget Office (CBO), rather than being derived from the review's own literature search, which was instead structured to retrieve evidence on each prespecified tactic.

Between January and March 2025, the review team searched three platforms (Elicit, Google Scholar, and Perplexity), running one structured query per tactic across five outcome domains (time to generic entry, number of entrants, price and volume erosion, excess spending, and empirical effects of legal or policy reforms) and prioritizing publications from 2019 onward while retaining key historical sources. These AI-enabled tools were used to assist with literature identification, article summarization, and citation accuracy, and additionally supported drafting and editing for clarity and readability, consistent with Urban Institute guidelines regarding the use of these tools. The authors performed all analysis and interpretation and verified all AI-assisted text against the primary sources.

The team screened titles and abstracts, extracted data with a standardized template, and assessed study quality against a six-item checklist adapted from the *JBI Manual for Evidence Synthesis* (Aromataris et al. 2024), automatically rating studies as *high quality* if they met all four critical criteria: a clearly stated research question, an appropriate data source, a clearly described methodology, and conclusions supported by the analysis. These searches identified 196 unique records, of which 150 met the inclusion criteria. Supplementary references entered the synthesis where relevant; in particular, additional sources were identified through citation chaining from the included sources and through targeted searches designed to capture recent legislative developments and institutional policy updates. The review presents findings as a narrative synthesis, describing for each tactic the mechanism of delay, quantitative estimates of entry timing and price effects, consolidated cost estimates, and evidence on patient out-of-pocket exposure.

Cost estimates in this review are not always directly comparable across tactics, because studies differ in the payers and costs they include. A given estimate may reflect a single payer or program (for example, Medicare, Medicaid and CHIP, or commercial and employer-sponsored insurance), patients'

out-of-pocket spending, or total federal budgetary effects that account for offsetting changes to income such as tax revenue. As a result, the reported cost to the country for one tactic can differ substantially from an all-payer estimate to a federal budget–saving estimate. To aid interpretation, this report identifies the payer scope for each cost estimate so that figures can be reconciled consistently. Full methods, covering the complete search strategy, study selection rules, and quality assessment criteria, appear in the Appendix: Methods section.

Tactic 1: Patent Thickets

Pharmaceutical manufacturers have transformed the current US patent system's protection from a fixed window of time for a monopoly into an expanding window by layering secondary patents, regulatory exclusivities, and litigation strategies that can extend market exclusivity by years beyond any single drug's innovation, costing US payers and patients billions of dollars annually in excess spending (Dave et al. 2020; Hong et al. 2025; R. Feldman 2018).[5] This broad practice, known as "evergreening" or "life cycle management," operates chiefly through two distinct anticompetitive strategies: patent thickets, the subject of this section, and product hopping, addressed as Tactic 2. Patent thickets, clusters of overlapping secondary patents layered on top of a brand drug's core compound patent, are a strategy by which manufacturers extend effective market exclusivity beyond its originally intended duration. The evidence on this practice allows us to assess the degree to which it delays generic entry and to provide robust estimates of the associated costs.[6]

1.1 How It Works

Patent thickets are effective at generating years of additional market exclusivity for the brand drug because delays in generic entry result from litigation over the validity of secondary patents and are not contingent on those patents ultimately being upheld. Although the Hatch-Waxman Act originally intended to strike a clear regulatory balance between rewarding innovation and facilitating timely generic entry, its mechanics have increasingly been leveraged by brand-name manufacturers (CRS 2024; Jayeoba 2024). Under the traditional baseline life cycle, a brand-name drug's monopoly ran its course primarily based on its core active-ingredient patents, resulting in a predictable generic entry timeline of 12 to 14 years following FDA approval (Beall, Darrow, et al. 2019; Hong et al. 2025). Over recent decades, however, brand manufacturers shifted toward an aggressive "life cycle management" paradigm, tripling patenting intensity from an average of 1.86 patents per active ingredient in 2001 to nearly 6 patents per active ingredient by 2019 (Tu 2024).[7] This strategic behavior relies on

systematically accumulating a dense web of secondary patents covering new formulations, dosage strengths, delivery devices, metabolites, manufacturing methods, combinations of active ingredients, and methods of use, many of which are filed long after initial FDA approval to prolong the process for generic entrants via overlapping legal battles (Carrier and Tu 2024; Tu 2024; R. Feldman et al. 2026). These patents are then listed in the FDA's Orange Book, the official registry of patents that generic competitors must certify against before receiving marketing authorization. When a generic manufacturer challenges any listed patent, the brand need only file an infringement suit to trigger an automatic 30-month litigation stay, blocking FDA approval of the generic (CRS 2024).[8]

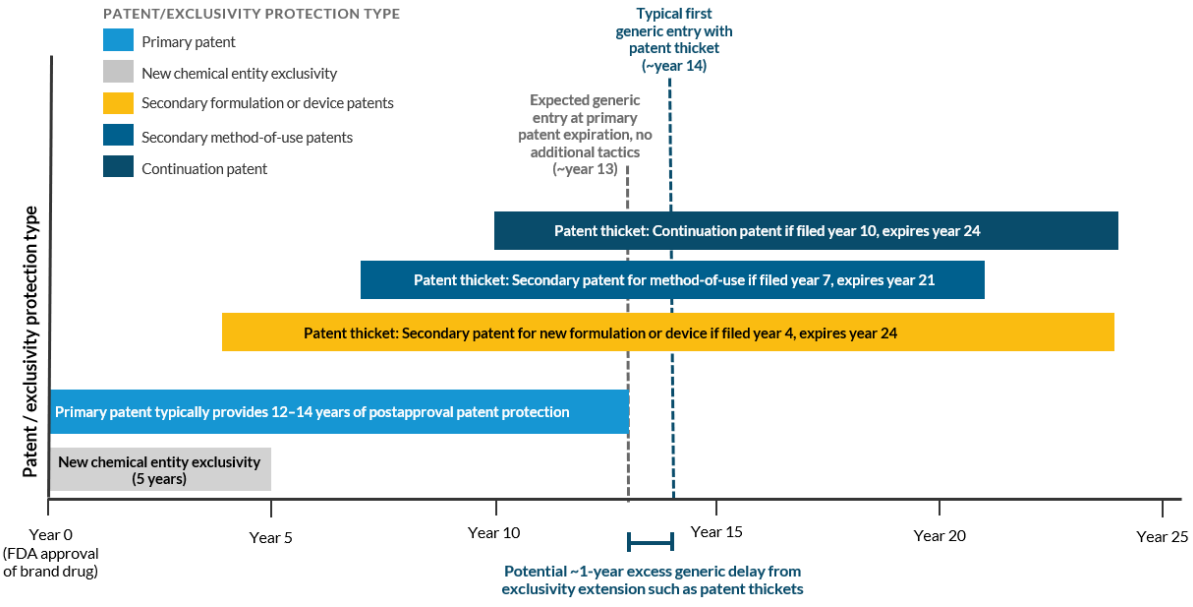
Several patent mechanisms drive thicket construction (figure 1). Regulatory exclusivity for a new chemical entity (NCE) begins with the primary patent on the novel active ingredient, which typically provides 12 to 14 years (represented by the darker blue bar) of effective patent-protected exclusivity after FDA approval under the standard regulatory pathway, that is, where the patent term accounts for the time lost during FDA review, including standard patent litigation and regulatory stays[9] but not employing any additional anticompetitive tactics, such as secondary patenting or other exclusivity-extending strategies. The primary patent runs in parallel with a 5-year NCE exclusivity (the lighter blue bar) that prohibits the FDA from receiving generic applications for the first 4 years and from approving them for the first 5 years, with whichever protection expires later serving as the binding constraint on generic entry (Beall, Darrow, et al. 2019). Manufacturers can also layer pediatric (6 months) and orphan (7 years) exclusivities that extend the primary patents (not shown in figure 1). A *patent thicket* is built on top of this primary foundation through secondary patents (the yellow, orange, and green bars), which are additional patents that do not cover the original active ingredient but nonetheless trigger litigation stays and delay generic entry. The thicket bars illustrate a hypothetical example of how long each secondary patent could remain nominally in force (for example, until years 21 through 24, well past the primary patent's expiration around year 13), but this does not reflect the delay that an average thicket imposes. Most secondary patents are eventually invalidated, carved out, or designed around, and a generic manufacturer only has to overcome the patents that block its own product, rather than every patent in the thicket, because many patents cover formulations, devices, or indications that the generic does not replicate. Because of this, the actual typical effect of a patent thicket is an incremental delay in the first generic entry, from approximately year 13 to year 14 (e.g., the 7-to-13-month excess delay shown in the figure) even though the underlying patents remain nominally in force for many additional years. However, the length of the delay is highly variable. In cases where secondary patents are difficult to overcome, for example, device patents on inhalers and injector pens, as described below, the actual delay can extend substantially longer.

Several secondary and additional patent-thicket strategies correspond to the three thicket bars in figure 1. Secondary formulation and device patents (the yellow bar) include reformulations and delivery components, such as inhalers and injector pens, rather than the active ingredient itself. Because a device's physical design can actually be substantially more difficult to copy than the small molecule itself, these types of patents are among the most durable and can delay competition well beyond the primary patent's expiration (Alhiary et al. 2023). A new-formulation patent (the yellow bar) can figure into both patent thickets and "product hopping," which is detailed in Tactic 2, bridging two related but mechanically distinct strategies.[10] Secondary method-of-use patents (the orange bar) claim particular indications or dosing regimens. Generics can sometimes sidestep these through "skinny label" carve-outs (i.e., marketing the generic only for indications not covered by the use patent by omitting the protected use from its labeling), but unresolved use patents can still deter or delay entry. Continuation patents (the green bar) are derived from an existing patent family late in the product life cycle, adding new claims timed with approaching generic challenges without disclosing any new invention (Tu 2024; R. Feldman 2018; Carrier and Tu 2024).

FIGURE 1

Anatomy of a Patent Thicket

Illustrative timeline for a hypothetical brand-name small-molecule drug for a single primary patent



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Sources: (1) New chemical entity exclusivity.[a] (2) Patent challenges triggering the automatic 30-month litigation stay were filed a median of 5.2 years (an interquartile range of 4.0–8.0 years) after brand approval.[b] (3) Top-selling new molecular entities average 12 to 14 years of effective patent-protected exclusivity after FDA approval, reflecting standard patent term restoration but assuming no other anticompetitive tactics are used,[c] and another study of generic entry timing through the standard Paragraph IV patent challenge pathway found that generic entry typically occurs between 12.5 and 14.5 years after brand-name drug approval,

again assuming no other anticompetitive tactics beyond standard patent litigation and regulatory stays.[b] (4) Patent continuations filed at least five years after the new molecular entity was first filed.[d] (5) Orange Book landscape.[e] (6) Exclusivity stacking.[f,a] (7) Market exclusivity extensions, which could include patent thickets or other tactics, delayed generic entry by 7 to 13 months beyond the primary patent expiration.[g]

Notes: FDA = Food and Drug Administration. Illustrative example only. For clarity, the illustration excludes details, including multiple secondary patents. Not to scale.

[a] CRS (Congressional Research Service, *The Role of Patents and Regulatory Exclusivities in Drug Pricing*, January 30, 2024.

[b] Sunand Kannappan, Jonathan J. Darrow, Aaron S. Kesselheim, and Reed F. Beall, "The Timing of 30-Month Stay Expirations and Generic Entry: A Cohort Study of First Generics, 2013–2020," *Clinical and Translational Science* 14 (5; May 2021): 1917–23, https://doi.org/10.1111/cts.13046.

[c] Reed F. Beall, Jonathan J. Darrow, and Aaron S. Kesselheim, "Approximating Future Generic Entry for New Drugs," *Journal of Law, Medicine & Ethics* 47 (1; January 2021): 177–82, https://doi.org/10.1177/1073110519840499.

[d] S. Sean Tu, "The Long CON: An Empirical Analysis of Pharmaceutical Patent Thickets," *University of Pittsburgh Law Review* 86 (1; 2024): 213–42.

[e] Jonathan J. Darrow and Daniel T. C. Mai, "An Orange Book Landscape: Drugs, Patents, and Generic Competition," *Food and Drug Law Journal* 77 (1; 2022): 51–77.

[f] Sanjay Kumar Patel, "Regulatory Exclusivity in the United States and European Union and Its Impact on Generic Entry," *Nirma University Journal of Pharmaceutical Sciences* 6 (2; December 2019): 3–10, https://doi.org/10.5281/.

[g] Dongzhe Hong, S. Sean Tu, Reed F. Beall, et al., "Estimating Costs of Market Exclusivity Extensions for 4 Top-Selling Prescription Drugs in the US," *JAMA Health Forum* 6 (8; August 2025): e252631, https://doi.org/10.1001/jamahealthforum.2025.2631.

1.2 Case Examples

Three well-studied cases illustrate the breadth and financial scale of patent thicket strategies (figure 2):

1. Revlimid (lenalidomide), used to treat multiple myeloma, illustrates how patent thicket–related litigation can force settlements that allow only limited early generic entry. By obtaining several secondary add-on patents around Revlimid (chiefly patents on alternative crystalline forms of the molecule and on methods of use, rather than on a delivery device as in many other cases) (I-MAK 2023), the manufacturer could extend its market monopoly and delay unrestricted generic competition from the 2019 expiration of the primary compound patent until 2026, with generic firms that settled limited to capped volumes beginning in 2022 (I-MAK 2022). Nearly one-third of Revlimid's cumulative US sales from 2006 through early 2022 occurred after its primary patents expired in late 2019, generating $19.6 billion in just the first two and a half years of that postexpiry window (I-MAK 2022). The Revlimid case also involved sample-denial tactics, which are addressed in Tactic 4 below.
2. Inhalers for asthma and chronic obstructive pulmonary disease (COPD) demonstrate device patent thickets at scale. Of the 53 brand-name inhalers approved by the FDA between 1986 and 2020, only 3 faced independent generic competition by the end of 2022 (Reddy et al. 2023). Device patents are particularly effective at blocking generic entry because FDA approval through a typical generic drug application (i.e., ANDA) requires pharmaceutical equivalence:

The generic must use the same dosage, form, and route of administration as the brand reference product. A generic manufacturer cannot simply offer the same active ingredient in a slightly different device and achieve automatic substitution at the pharmacy counter, and any listed device patent can independently trigger a 30-month litigation stay against generic applicants. Between 2000 and 2021, brand-name manufacturers earned $178.1 billion on inhalers in the US, with $110.3 billion (62 percent) earned after the primary patents on the active ingredients had expired, and 98 percent of that postprimary revenue accrued while secondary device patents continued to shield products from generic competition (W. B. Feldman et al. 2023).

3. GLP-1 receptor agonists now carry the longest documented patent protection period of any drug-device combination. Among GLP-1 receptor agonists regulated as small molecules, manufacturers listed a median of 19.5 patents per product, and the median expected protection after FDA approval was 18.3 years, which Alhiary and colleagues (2023) describe as the highest reported for a large class of drug device products. In this class, manufacturers have also listed 107 Orange Book device patents that make no mention of the active ingredient in their claims. These device-only patents expand the patent thicket that generic manufacturers must certify against and litigate, often triggering 30-month stays of FDA approval and in some cases extending the expected duration of patent protection by up to 2.6 additional years (Alhiary et al. 2024). Generic semaglutide (the active ingredient in Ozempic, Rybelsus, and Wegovy) is not expected before 2032 at the earliest, reflecting a broad thicket of follow-on patents on semaglutide-based products (derivatives, formulations, indications, devices), along with statutory extensions of semaglutide's patent term to compensate for regulatory and patent-office delays (I-MAK 2025). This expected generic delay does not include compounded semaglutide products prepared by pharmacies, which are not FDA-approved and are currently the subject of FDA safety warnings and enforcement actions.[11] I-MAK estimates this extended monopoly will generate the manufacturer, Novo Nordisk, an additional $166 billion in US revenue that would otherwise face generic competition (I-MAK 2025).

FIGURE 2

Key Case Statistics: Patent Thicket Case Examples

Selected statistics from documented patent thicket and device patent case examples

50 of 53

Number of brand-name inhalers approved between 1986 and 2020, and that had no generic competition by 2022[a]

62 percent ($110 billion)

Percent of US brand inhaler revenue ($110 billion of $178 billion) that was earned after active ingredient patents expired, 2000–21[b]

19.5

Number of patents per GLP-1 drug, of which 54 percent covered delivery devices[c]

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Sources: [a] Sanjay Reddy, Reed F. Beall, S. Sean Tu, Aaron S. Kesselheim, and William B. Feldman, "Patent Challenges and Litigation on Inhalers for Asthma and COPD," *Health Affairs* 42 (3; 2023): 398–406, https://doi.org/10.1377/hlthaff.2022.00873.
[b] William B. Feldman, S. Sean Tu, Rasha Alhiary, Aaron S. Kesselheim, and Olivier J. Wouters, "Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000–2021," *JAMA* 329 (1; 2023): 87–9, https://doi.org/10.1001/jama.2022.19691.
[c] Rasha Alhiary, Sarah Gabriele, Aaron S. Kesselheim, S. Sean Tu, and William B. Feldman, "Delivery Device Patents on GLP-1 Receptor Agonists." *JAMA* 331 (9; 2024): 794–6, https://doi.org/10.1001/jama.2024.0919; and Rasha Alhiary, Aaron S. Kesselheim, Sarah Gabriele, Reed F. Beall, S. Sean Tu, and William B. Feldman, "Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists," *JAMA* 330 (7; 2023): 650–7. https://doi.org/10.1001/jama.2023.13872.

1.3 Evidence of Delay

As described above, first generic entry for a new molecular entity typically occurs around 12 to 14 years after FDA approval without anticompetitive tactics. When exclusivity-extending tactics such as patent thickets are present, generic entry is delayed beyond the primary patent expiration by an estimated 7 to 13 months, representing excess spending that could have been avoided with timely generic competition (Hong et al. 2025). However, this estimate is not specific to patent thickets alone. The "7 to 13 months" delay estimate is the range observed across four top-selling case-study drugs, not an average, and likely a conservative estimate.[12]

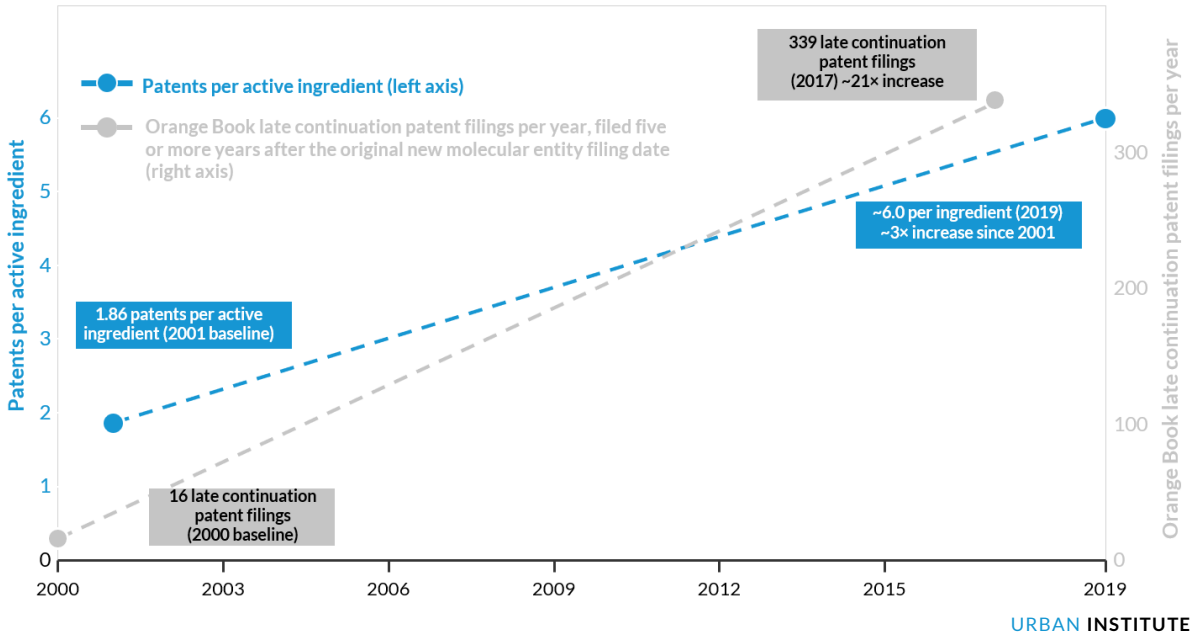
The average number of patents listed per drug in the Orange Book more than tripled over two decades, rising from 1.86 patents per active ingredient in 2001 to nearly 6 per active ingredient in 2019 (figure 3) (Tu 2024). This increase included a sharp increase in continuation patents, patents filed at least 5 years after the original new molecular entity filing, which grew from only 16 per year in 2000 to 339 per year in 2017 (Tu 2024). In a comprehensive 10-year study tracking 60,000 data points, 72 percent of the 106 top-selling drugs had their patent and exclusivity protections extended at least once, and 51 percent received multiple extensions (R. Feldman 2018). On average, four times as many patents are granted on top-selling drugs in the US as in Europe, where generic competition routinely enters the market years earlier (I-MAK 2022). A 2022 analysis of all FDA-approved prescription drugs found that only 8.6 percent had a patent covering their active ingredient, the type of patent considered hardest for

generic manufacturers to design around or invalidate, suggesting that the foundation for patent thicket construction is present in only a small share of drugs, most likely concentrated among high-revenue products (Darrow and Mai 2022).

FIGURE 3

Thicket Inflation: Average Patents per Active Ingredient, 2001–19

Continuation patents filed five or more years after original priority date for small-molecule drugs



Sources: S. Sean Tu, "The Long CON: An Empirical Analysis of Pharmaceutical Patent Thickets," *University of Pittsburgh Law Review* 86 (1; 2024): 213–42; and Jonathan J. Darrow and Daniel T. C. Mai, "An Orange Book Landscape: Drugs, Patents, and Generic Competition," *Food and Drug Law Journal* 77 (1; 2022): 51–77.

Notes: Filled dots mark values reported by Tu (2024); dashed lines are straight-line interpolations, and thus intermediate values do not correspond to measured data. Tu (2024) introduced this analysis for a subset of continuation patent applications filed *at least five years* after the original priority date. Continuation applications allow a patent holder to reenter prosecution and claim new variations of an already disclosed invention without adding new technical disclosure. The continuation patents filed at least five years after the original new molecular entity filing are typically late-generation derivatives of the original patent filed long after the core invention was disclosed and, Tu (2024) argues, are strategically timed to block or deter generic entry as primary patents approach expiration.

1.4 The Cost of Patent Thickets

The financial impact of delayed generic competition, particularly because of patent thickets, is measurable and substantial (figure 4). Among 69 small-molecule drugs expected to lose exclusivity between 2010 and 2015, 45 percent experienced delayed or absent generic entry (Dave et al. 2020).[13] Using administrative Medicaid data from 2010 through 2016, the authors estimated that these delays resulted in $761 million in excess postrebate Medicaid spending, or approximately $109 million per

year, in 2016 dollars. Patent litigation over later-issued or secondary patents was associated with generic-entry delays for 80 percent of the 15 drugs with the highest spending (Dave et al. 2020).

FIGURE 4

Key Cost Statistics: Delayed Generic Entry

Selected excess spending estimates associated with delayed generic entry, including delays attributable to patent thickets

$4.9 billion/3 years

Estimated excess commercial insurance and Medicare spending over three years caused by market exclusivity extensions for four top-selling drugs, measured over the extension period and the three years of postentry price recovery that followed, in 2022 US dollars[a]

$761 million/ 7 years

Excess Medicaid spending postrebate over seven years for 31 drugs, in 2016 US dollars[b]

$3 billion/ 10 years

Projected federal savings (Medicare, Medicaid, etc.) over 10 years from prohibiting a bundle of anticompetitive tactics including patent thickets, product hopping, and pay-for-delay[c]

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Sources: [a] Dongzhe Hong, S. Sean Tu, Reed F. Beall, et al., "Estimating Costs of Market Exclusivity Extensions for 4 Top-Selling Prescription Drugs in the US," *JAMA Health Forum* 6 (8; 2025): e252631, https://doi.org/10.1001/jamahealthforum.2025.2631.
[b] Chintan V. Dave, Michael S. Sinha, Reed F. Beall, and Aaron S. Kesselheim, "Estimating the Cost of Delayed Generic Drug Entry to Medicaid," *Health Affairs* 39 (6; 2020): 1011–7, https://doi.org/10.1377/hlthaff.2019.00673.
[c] CBO (Congressional Budget Office), "Alternative Approaches to Reducing Prescription Drug Prices," October 2024.

Across four top-selling drugs—imatinib (Gleevec), glatiramer acetate (Copaxone), celecoxib (Celebrex), and bimatoprost (Lumigan)—whose monopolies were extended by 7 to 13 months beyond the primary patent expiration, the delay generated an estimated $4.9 billion in excess national spending over the extended exclusivity period and the three years of postentry price recovery that followed, including excess spending of $2.5 billion in commercial plans and $2.4 billion in Medicare, based on monthly spending data from 2011 to 2021 (Hong et al. 2025). Measured over the shorter window of the exclusivity extension plus the first two years after generic entry, the same delays generated an estimated $3.5 billion in excess spending ($1.9 billion in commercial plans, $1.6 billion in Medicare), most of it in the first postentry year, with smaller incremental savings thereafter.

A seven-month exclusivity extension on the cancer drug imatinib (Gleevec) drove an estimated $1.4 billion in excess spending over three years, including $549 million in commercial plans and $854 million in Medicare, and because generic competition was weak, spending fell only modestly after generic entry (Hong et al. 2025).[14]

Legislative cost estimates from the CBO project that prohibiting anticompetitive tactics including patent thickets, product hopping, and pay-for-delay would reduce the federal deficit by $3 billion from 2024 to 2034. This figure is a conservative floor because it captures only federal savings and reflects a narrow methodology, but it includes both small-molecule and biologic drugs (CBO 2024).

1.5 Patient Consequences

Direct causal evidence linking thicket-induced generic entry delay to adverse health outcomes is limited and represents an important area for future research. However, it is known that patent thickets delay generic entry and help maintain high out-of-pocket patient costs associated with reduced medication adherence and worse clinical outcomes (Beall, Darrow, et al. 2019). For example, in the heavily thicketed inhaler market, among commercially insured COPD patients, those in high-deductible plans abandoned their initial prescription at nearly twice the rate of those in copay plans (17.7 percent versus 10.1 percent), and 39 percent of patients who abandoned treatment filled no further COPD prescriptions (B. Patel et al. 2022). Similarly, extensive device and secondary patents have delayed generic competition for GLP-1 drugs (such as Ozempic manufactured by Novo Nordisk), leaving Medicare Part D enrollees using these medications to face median annual out-of-pocket costs exceeding $1,500 in 2019, because of a lack of lower-cost generic alternatives (Alhiary et al. 2023).

1.6 Reforms

The FTC has recently challenged the validity of many drug patent listings, particularly those for inhalers and GLP-1 devices.[15] This regulatory pressure, paired with key judicial victories, has successfully led to the delisting of hundreds of these barrier patents from the FDA's Orange Book. This reform creates an ongoing natural experiment to see how removing these barrier patents speeds up generic entry and lowers prices.[16]

These delistings enforce existing law, and going further requires new policy. The remaining options fall into three related topics: limiting the use of patent lawsuits to delay generic competitors, limiting how many patents (or how many years of protection) a single drug can amass, and raising patent quality so weak patents are never issued in the first place (R. Feldman et al. 2026; W. B. Feldman 2025). On the litigation topic, proposed reforms include limiting the automatic 30-month delay on generic approvals to just one patent per drug and restricting the use of late-stage "continuation" patents. In a separate fix to the approval pathway, Congress could remove another structural barrier by explicitly granting the

FDA authority to approve generic drug-device combinations (such as inhalers) based on functional equivalence rather than requiring an identical physical design (FDA 2024).

On the patent quality topic, applying stricter examination standards at the US Patent and Trademark Office and making it easier to challenge weak patents could prevent dense "patent thickets" from forming in the first place. Similarly, the US Supreme Court could curb weak secondary patents by clarifying how the nonobviousness standard applies to them, an issue the court has not revisited in nearly two decades (R. Feldman et al. 2026). Some proposed legislation aims to cap the number of patents a brand can assert in court, which the CBO estimates could reduce the deficit by $1.8 billion over 10 years (CBO 2024). Legal experts caution, however, that litigation caps alone may have limited impact because manufacturers would simply cherry-pick their strongest, latest-expiring patents to sue over. The structural answer to that cherry-picking problem, which R. Feldman and others (2026) identify as the most promising legislative fix, is a "one-and-done" rule that limits each drug to a fixed number of patents or to a fixed total period of protection. Since the limit attaches to the drug's patent portfolio itself rather than to litigation conduct, it cannot be evaded by patent selection. Taken together, the quality reforms and a portfolio-level cap (such as "one-and-done") reach the problem at its source, while limiting the 30-month stay offers the most direct near-term relief. Larger savings for patients are likely to come from combining these levers rather than relying on any one reform.

1.7 Key Evidence Gaps

The evidence base on patent thickets has several notable limitations. Most studies are descriptive rather than causal, as they document the accumulation of secondary patents and listed protections but do not isolate the effect of that accumulation on the timing of generic entry (R. Feldman 2018; Alhiary et al. 2023). Simply counting patents listed with the FDA establishes how dense thickets have become but cannot by itself show how much entry was delayed as a result (Darrow and Mai 2022).

A second gap concerns deterrence. Cohort studies observe only drugs for which a generic firm filed a formal legal challenge to an existing patent (i.e., a "Paragraph IV" certification) or eventually launched, so thickets that discourage a challenge from being mounted at all are largely invisible, and the measured delay may therefore understate the true effect (Kannappan et al. 2021). Third, studies count listed patents without assessing how many would survive a validity challenge, leaving open how much of the documented protection reflects genuine innovation versus weak or likely obvious claims (Alhiary et al. 2023; R. Feldman et al. 2026). Fourth, the cost evidence remains thin and drug-specific. The most rigorous spending estimates cover only a handful of products, selected partly on data availability, and the estimates vary enormously across drugs, so they are better read as illustrative case figures than as a

population-wide average (Hong et al. 2025). No comprehensive estimate of the excess spending attributable to thickets across the small-molecule market currently exists. Finally, the mechanisms documented for specific drug-device classes, such as inhalers and GLP-1 receptor agonists, may not generalize, and patient-level consequences, such as out-of-pocket costs and nonadherence, are rarely measured directly in this literature (Alhiary et al. 2023).

Tactic 2: Product Hopping

Product hopping is a strategy whereby a brand drug manufacturer introduces a reformulated successor (e.g., a new dosage form, higher concentration, extended-release version, or modified delivery device) before the original compound loses patent exclusivity, then shifts the prescribing base to the new product before generic competition for the original can take hold. Product hopping is closely related to patent thicketing and often rests on the same secondary patents, and the two share the underlying objective of prolonging brand revenue. They are nonetheless distinct tactics because they obstruct competition through different channels. A patent thicket delays the generic's entry, multiplying the patents a competitor must clear before the FDA can approve and the generic can launch. In contrast, a product hop does little to delay that approval; instead, it diminishes the market the generic was positioned to capture. Because the reformulated product is not considered pharmaceutically equivalent to the original, automatic generic substitution by pharmacists is blocked, as the market that generics were positioned to enter has been structurally narrowed or eliminated. The tactic shrinks the commercial value of the original product's generic market and restarts a patent clock on the reformulation, extending brand-level pricing for years (Rome et al. 2020; Beall, Kesselheim, et al. 2019; Gowda et al. 2021; FTC 2022). Some types of product hops have been found to be potentially unlawful (Carrier 2021; FTC 2022).

2.1 How It Works

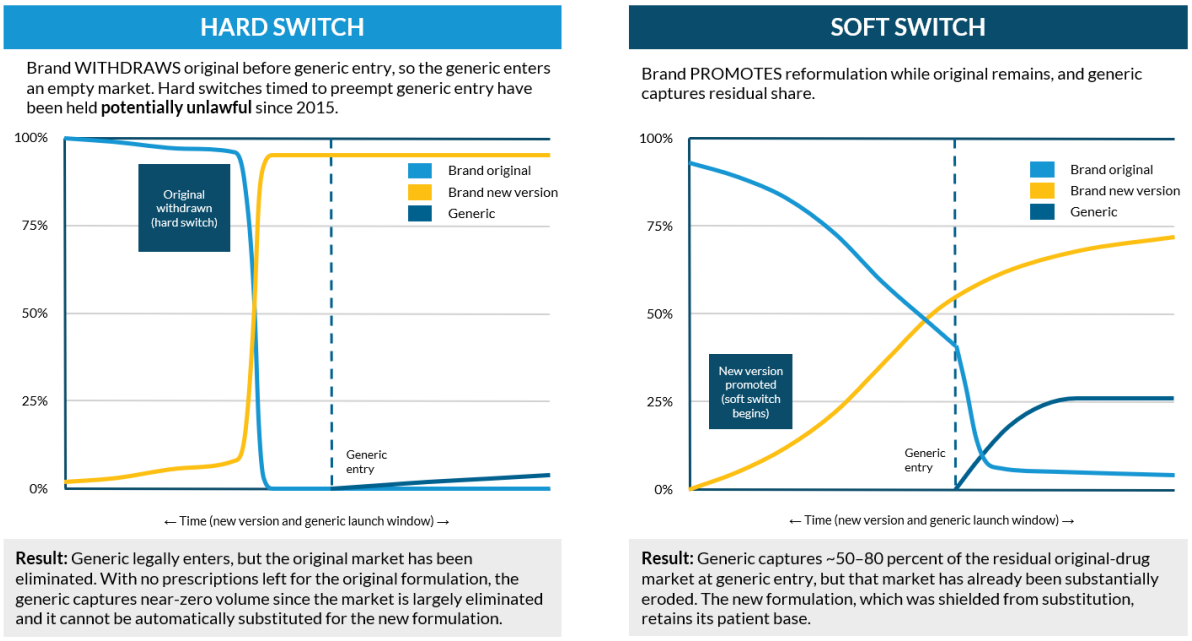
Product hops take advantage of a structural asymmetry in the Hatch-Waxman legal framework: Pharmacists can substitute a generic for a brand-name product only when the brand and generic are rated as pharmaceutically equivalent. A reformulated version using the same active ingredient at a different concentration, in a different dosage form, or in a different delivery device will not be rated as equivalent to the original; thus, the generic approved for the original product cannot be automatically substituted for the reformulation. Product hops occur in two structurally distinct forms (figure 5):

1. In a hard switch, the brand manufacturer discontinues the original product before lower-cost generics can enter the market, forcing prescribers and patients to use the newer formulation. The generic of the original still gains approval and may be sold, but with the original withdrawn, there is no longer a prescription base for which pharmacists can automatically substitute it—so it captures little volume, even at a lower price. Courts in *Abbott Laboratories v. Teva Pharmaceuticals* and *New York v. Actavis*[17] have recognized hard switches as potentially unlawful when the discontinuation is deliberately timed to eliminate generic substitution before patients have any opportunity to choose a lower-cost alternative (Carrier 2021; FTC 2022).
2. In a soft switch, the brand manufacturer retains the original product on the market but actively promotes the reformulation, using pricing differentials or structuring formulary rebates to migrate prescribers to the newer formulation (Gowda et al. 2021; Field 2023). In these cases, since the original product is still technically available, courts have been more reluctant to restrict soft switches under existing antitrust legal frameworks, even when the commercial effect on the generic market is similar to a hard switch (Carrier 2021; Shepherd 2020).

FIGURE 5

How Product Hopping Works: Hard Switch Versus Soft Switch

Illustrative timeline for a hypothetical brand-name small-molecule drug



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Sources: Benjamin N. Rome, Frazer A. Tessema, and Aaron S. Kesselheim, "US Spending Associated with Transition from Daily to 3-Times-Weekly Glatiramer Acetate," *JAMA Internal Medicine* 180 (9; 2020): 1165–72, https://doi.org/10.1001/jamainternmed.2020.2771; Vrushab Gowda, Reed F. Beall, Aaron S. Kesselheim, and Ameet Sarpatwari, "Identifying Potential Prescription Drug Product Hopping." *Nature Biotechnology* 39 (4; 2021): 414–7,

https://doi.org/10.1038/s41587-021-00877-9; FTC (Federal Trade Commission), *Federal Trade Commission Report on Pharmaceutical Product Hopping*, *October 2022*; and Michael A. Carrier, "A Simple Solution to the Problem of 'Product Hopping,'" *Harvard Health Policy Review*, December 2021, https://doi.org/10.56927/512292.
Notes: Illustrative schematic; timeline lengths are stylized. In a hard switch, the brand withdraws the original product before or around the time of generic launch, and thus the generic enters an emptied market. In a soft switch, the brand promotes the new formulation while the original remains nominally available, and thus the generic enters a market whose prescription base has been migrated.

2.2 Case Examples

Three cases illustrate the mechanisms and financial impact of product hopping strategies:

1. Glatiramer acetate (Copaxone) is a well-documented soft-switch product-hop case. Teva launched a three-times-weekly, higher-concentration version in 2014, raised the price of the original daily formulation while actively promoting the new product, and by December 2015 had converted more than three-quarters (77 percent) of patients to the new version. When the first generic daily glatiramer entered the market in 2015, uptake was minimal. Generic competition for the three-times-weekly version did not begin until 2017, after a federal court struck down Teva's reformulation patents (N. Patel and Kesselheim 2022). The resulting 2.5-year delay was associated with $4.3–6.5 billion in excess spending across all US payers (Rome et al. 2020).
2. Albuterol inhalers illustrate how a product hop can be structured around a regulatory transition. When the FDA phased out chlorofluorocarbon (CFC)-propellant inhalers beginning in 2009, brand-name manufacturers introduced hydrofluoroalkane (HFA)-propellant versions protected by new device and propellant patents, restarting patent clocks on a decades-old active ingredient. Annual brand-name sales in the US and Canada exceeded $1 billion in most years throughout the following decade, until the first generic HFA albuterol received FDA approval in 2020 (Wouters et al. 2022). Across inhaler product lines broadly, device hopping extended expected protection to a median of 28 years from originator product approval over the study period, 1986 to 2020 (W. B. Feldman et al. 2022).
3. Namenda (memantine), made by Actavis, is the subject of the leading federal appeals court ruling (*New York v. Actavis*)[18] establishing that hard-switch product hopping can violate antitrust law (Carrier 2021). In 2014, Actavis announced its intention to discontinue Namenda IR (immediate-release) before generic entry, which would have coerced the market into a newer XR (extended-release) version, for which pharmacists would not be able to automatically substitute generics (Carrier 2021). The New York attorney general brought suit to block the discontinuation and prevailed; the US Court of Appeals for the Second Circuit upheld the ruling

in 2015, finding that a drug company cannot force patients onto a newer, patent-protected version by withdrawing the original before lower-cost generics have a chance to enter (Carrier 2021). A rigorous, peer-reviewed study indicates the hop would have caused approximately $1.7 billion in excess consumer payments (R. Feldman 2018).

2.3 Evidence of Delay

The strongest systematic evidence of generic delays because of product hopping comes from a 15-year longitudinal cohort study of small-molecule drugs approved in 2002 (Beall, Kesselheim, et al. 2019). Of 17 reference products tracked, 9 (53 percent) were associated with 21 new formulations. In three cases—aripiprazole (Abilify), oxaliplatin (Eloxatin), and voriconazole (Vfend)—generic versions of new formulations arrived more than 2 years after the originals, leaving a gap that manufacturers leveraged by using strategies such as discontinuing original oxaliplatin to force patients onto the new formulation. The average additional exclusivity gained by new formulations beyond the original product's generic entry date was 1.2 years. A larger, 2026 analysis of 30 drugs sold in both standard (i.e., the original) and long-acting versions reinforces this pattern. The long-acting versions had roughly three times as many patents and a median of 11 additional years of nominal patent protection; 73 percent were launched before all the original version's patents had expired, and nearly half (47 percent) of the original versions were later discontinued, characteristic of a "hard switch" (R. Feldman et al. 2026).

Near-real-time surveillance studies confirm that product hopping is ongoing market practice. Gowda and others (2021) flagged 10 suspected product-hop cases in a 12-month period (August 2018 to July 2019), including 5 potential soft switches and 5 potential hard switches, which occurred three years after hard switches were first held potentially unlawful in federal court. Evidence also supports that product hopping diminishes the commercial incentive for generic entry by preemptively shrinking the available market. In the glatiramer (Copaxone) case, the generic captured only 38 percent of total sales because the prescribing base had already been migrated to the new formulation (Sertkaya et al. 2021).

Just a few months after the generic daily glatiramer entered the market, more than three-quarters of patients had already been converted to the new brand formulation—the generic entered a market that had already been largely vacated, severely limiting the competitive impact (N. Patel and Kesselheim 2022).

2.4 The Cost of Product Hopping

The most direct quantified cost estimate comes from the glatiramer acetate (Copaxone) case. Rome and colleagues (2020) estimated that the 2.5-year delay in robust generic competition, caused by Teva's transitioning of patients from daily to three-times-weekly Copaxone before generics for the reformulation could enter the market, was associated with $4.3–6.5 billion in excess US spending across all payers from 2015 to 2017, in 2019 US dollars. Quarterly national glatiramer spending on all formulations peaked at $962 million in the first quarter of 2015 and fell to $508 million per quarter by 2019, only after generics for the three-times-weekly formulation entered the market (Rome et al. 2020).

Broader portfolio-level estimates across five product hops found approximately $4.7 billion in estimated annual lost generic savings to patients and payers according to an industry-sponsored white paper (Brill 2020).[19] Device hopping generates similarly large costs: The shift from CFC-propellant to HFA-propellant albuterol inhalers generated approximately $15 billion in US brand-name albuterol inhaler sales between 2007 and 2021, a period when the transition effectively stalled generic competition (Wouters et al. 2022).

CBO's scoring of the product-hopping provisions of the Affordable Prescriptions for Patients Act (as reported by the Senate Judiciary Committee)[20] estimated $917 million in direct federal savings on program expenditures and $277 million in additional revenues over the period 2024 to 2034 from product–hopping–specific provisions alone—a conservative floor that captures only federal spending and excludes commercial payer and patient out-of-pocket savings (CBO 2024). Notably, these product-hopping provisions were ultimately removed from the version of the bill (S. 150, 118th Congress) that passed the Senate in July 2024. Key cost statistics for product hopping are summarized in figure 6.

FIGURE 6

Key Cost Statistics: Product Hopping

Selected estimates associated with product-hopping strategies

2.5 years

Delay in robust generic competition caused by the Copaxone (glatiramer) product hop; patients migrated to the three-times-weekly version before generic entry for the original formulation[a]

$4.3–$6.5 billion

Estimated excess US spending across all US payers, associated with delayed glatiramer generic competition, 2015–17, in 2019 US dollars[a]

38 percent

Share of total sales the generic captured in the glatiramer product-hop case study, as the brand manufacturer had already shifted much of the prescribing base to a new formulation[b]

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Sources: [a] Benjamin N. Rome, Frazer A. Tessema, and Aaron S. Kesselheim, "US Spending Associated with Transition from Daily to 3-Times-Weekly Glatiramer Acetate," *JAMA Internal Medicine* 180 (9; 2020): 1165–72, https://doi.org/10.1001/jamainternmed.2020.2771.

[b] Aylin Sertkaya, Andreas Lord, and Clara Berger, *Cost of Generic Drug Development and Approval*, Office of the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services, December 31, 2021.

2.5 Patient Consequences

Product hopping can maintain brand-level prices following generic entry, with documented consequences for patient out-of-pocket costs and medication access. Because a generic cannot be automatically substituted for the original of a reformulated product, patients who have been migrated to the new version of the drug face continued brand-level cost sharing, often hundreds of dollars per month, even after the original formulation faces generic competition (Brill 2020; N. Patel and Kesselheim 2022). For glatiramer, quarterly out-of-pocket exposure remained elevated throughout the 2015 to 2017 partial-competition period and decreased substantially only after generic three-times-weekly products entered the market to compete (Rome et al. 2020). N. Patel and Kesselheim (2022) documented a case where a patient depleted personal savings, was unable to fill Copaxone prescriptions, and experienced subsequent declines in cognitive function and short-term memory. Patients prescribed inhalers encountered similar barriers, with high cost sharing associated with treatment discontinuation, even among insured patients (Reddy et al. 2023).

2.6 Reforms

FTC antitrust enforcement has produced meaningful remedies in hard-switch cases, demonstrating that antitrust tools can work effectively, but their application remains uneven, and soft-switch enforcement is less developed under current law (Carrier 2021). The proposed Drug Competition Enhancement Act

(S. 1040, 119th Congress) is bipartisan legislation that would classify both hard and soft product hopping as antitrust violations enforceable by the FTC.[21] At the state level, policymakers and payers could deploy surveillance protocols using publicly available FDA formulation approvals and discontinuation notices as an early-warning tool to flag potential hops, giving regulators time to act before market share erodes (Gowda et al. 2021). Payers and health systems can also make policy changes at the point of prescribing. Because generic substitution operates only within a given formulation, formulary design and prescribing guidance can influence clinicians to prescribe generic products rather than the protected reformulation (Wouters et al. 2022). However, the "price disconnect," where prescribers select the drug but do not bear the costs, limits how effective such measures are (Carrier 2021).

2.7 Key Evidence Gaps

The evidence base describing the occurrence and impact of product hopping is weak, with several limitations that constrain its use in policy analysis. First, no systematic estimate exists of how often switching to new drug formulations delays or diminishes generic competition; the most rigorous prevalence work tracks only a single approval-year cohort or a one-year surveillance window (Beall, Kesselheim, et al. 2019; Gowda et al. 2021), and the most-cited spending figures rest on a handful of selected cases and simplified assumptions describing switching and generic discounting (Brill 2020). Second, isolating causality remains difficult because product hopping currently operates amid patent thickets, overlapping device patenting, and pay-for-delay settlements, which makes it difficult to attribute any given generic's delay to the switch itself (Carrier 2019; Reddy et al. 2023). Third, the excess financial cost to payers and patients has been estimated only for individual products or small groups of drugs rather than larger groups of products (Rome et al. 2020; N. Patel and Kesselheim 2022), and the leading reform benchmark, roughly $1.2 billion in projected federal savings, evaluates proposed legislation rather than actual outcomes (CBO 2024). Fourth, evidence on subsequent generic competition remains relatively sparse, as studies rarely report the number of generic entrants at 12 or 24 months. The clearest market-share finding related to product hopping, which shows a generic capturing only 38 percent of the market in the first year after entry, was developed from just three case studies (Sertkaya et al. 2021). Finally, patient-level consequences remain largely anecdotal and contextual rather than causally demonstrated (N. Patel and Kesselheim 2022), and the effects of recent policy shifts, such as Medicare's drug price negotiations under the Inflation Reduction Act, on manufacturer switching incentives remain unknown.

Tactic 3: Pay-for-Delay and Reverse-Payment Settlements

Pay-for-delay settlements, which are reverse-payment agreements in which a brand drug manufacturer compensates a generic patent challenger to end its lawsuit and postpone market entry, comprise another documented anticompetitive tactic in the pharmaceutical industry. The underlying economic motivation is simple. Since generic competition substantially erodes brand revenue once it enters the market and is taken up, brand manufacturers can gain far more from extending their period of exclusivity than they spend on a generic settlement, even if the settlement is very large. At the same time, generic challengers can secure guaranteed financial returns by agreeing to a settlement, avoiding the risk and cost of prolonged litigation (Drake et al. 2025).

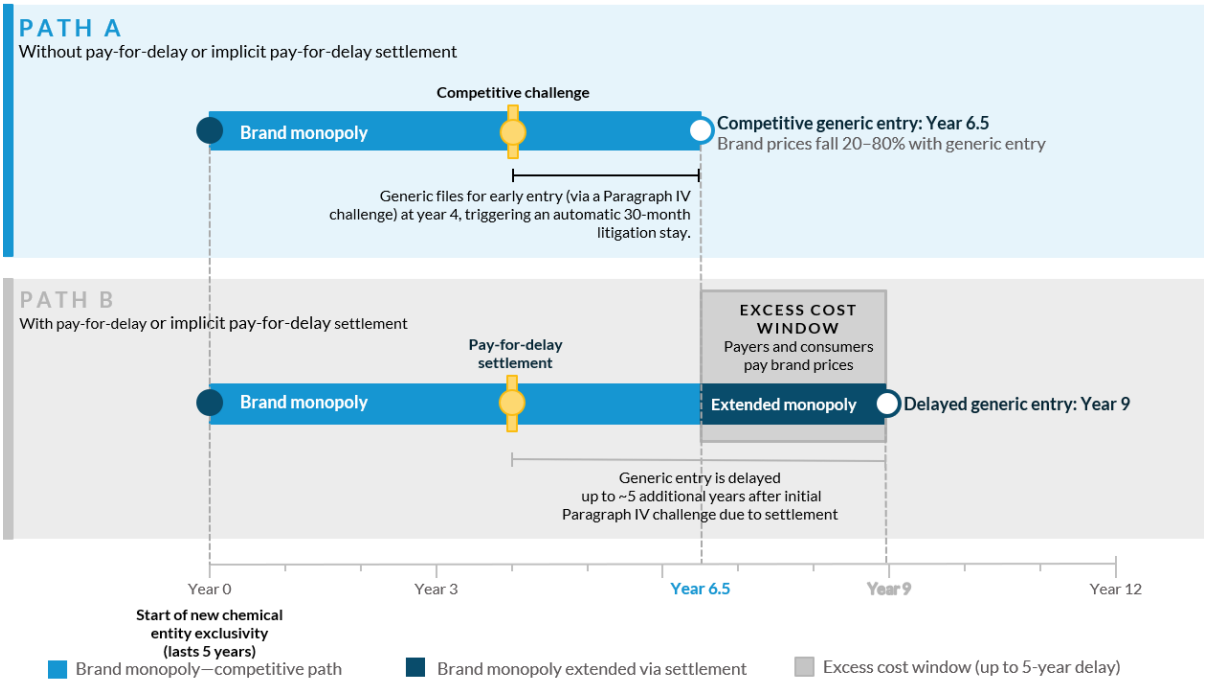
3.1 How It Works

Under the Hatch-Waxman Act, a generic manufacturer seeking to enter the market before a brand drug's patent expires must file a Paragraph IV challenge with the FDA, asserting that the relevant patents are invalid or would not be infringed by the generic (figure 7). This challenge is technically a patent infringement, giving the brand 45 days to file a patent-infringement lawsuit that triggers an automatic 30-month litigation stay, which blocks FDA approval of the generic. The resulting litigation does not typically produce a court-adjudicated winner and loser and typically ends in a settlement. These settlements have become a vehicle for compensating generic challengers to accept delayed entry. A settlement that delays the first filer can compound this effect because that filer holds the 180-day exclusivity, and an agreed entry date years in the future simultaneously "parks" the exclusivity period and also blocks later generics that are not parties to the settlement, linking the pay-for-delay tactic directly to the exclusivity parking examined below in Tactic 5.[22]

FIGURE 7

How Pay-for-Delay Settlements Work

Illustrative timeline for a hypothetical, typical brand-name small-molecule (nonbiologic) drug for a single primary patent



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Sources: Keith M. Drake and Thomas G. McGuire, "Using Stock Price Movements to Estimate the Harm from Collusive Drug Patent Litigation Settlements," Working Paper No. 33196, National Bureau of Economic Research, revised June 2025. https://doi.org/10.3386/w33196; CRS (Congressional Research Service), *The Role of Patents and Regulatory Exclusivities in Drug Pricing*, Report R46679, January 30, 2024; *Federal Trade Commission v. Actavis, Inc.*, 570 US 136 (2013); and Eric Helland and Seth A. Seabury, "Are Settlements in Patent Litigation Collusive? Evidence from Paragraph IV Challenges," *SSRN*, May 2022, https://doi.org/10.2139/ssrn.4120273.

Notes: Illustrative example for a hypothetical, typical brand-name small-molecule (nonbiologic) drug; timeline lengths are stylized based on literature. Causal econometric estimates indicate that a settlement suppresses generic entry for up to five years following the original Paragraph IV challenge.

The core structure of the pay-for-delay tactic is a reverse transfer of value in which the brand compensates the generic manufacturer in cash or by other means in exchange for the generic's agreement to stay out of the market until a negotiated entry date that is typically later than the generic's expected litigation time frame. The form of compensation changed after the Supreme Court's 2013 decision in *FTC v. Actavis*, which held that pay-for-delay agreements are subject to antitrust scrutiny.[23] Direct cash payments became legally risky, so brand and generic firms responded by using less visible structures, including side deals such as co-promotion or supply arrangements, no-authorized-generic (no-AG) pledges as examined below in Tactic 6, and complex royalty structures that

deter authorized-generic launches[24] (R. Feldman and Misra 2019; Drake and McGuire 2023; FTC 2016).[25]

3.2 Case Examples

Two cases illustrate the financial burden on patients and payers of pay-for-delay and reverse-payment strategies:

1. The Provigil (modafinil) case is one of the best-documented and most economically consequential pay-for-delay examples in academic literature. During 2005–2006, Cephalon paid more than $300 million to four generic first filers in exchange for agreements keeping all four out of the market until April 2012. Cephalon's chief executive described the outcome as producing six more years of patent protection and $4 billion in sales that no one expected (Carrier 2019). Event study analysis of stock prices found that Cephalon's market capitalization rose by roughly $1.1–$1.3 billion across the four settlement announcements (Hartman et al. 2019). Patients paid substantially elevated out-of-pocket costs throughout the six-year delay period, as generic modafinil was available at approximately half the brand's out-of-pocket cost once it entered in 2012 (R. Feldman 2022).
2. The Lidoderm (lidocaine patch) case illustrates noncash reverse payment. Rather than a direct cash transfer, Endo Pharmaceuticals' settlement with generic challenger Watson included a no-AG pledge during Watson's 180-day exclusivity period, functioning as the compensating value transferred without an explicit payment. R. Feldman (2022) includes Lidoderm in a Medicare Part D analysis demonstrating that generic competition would have saved payers an average of more than 50 percent of the rebated brand price during the delay interval.

3.3 Evidence of Delay

Pay-for-delay settlements can add delay on top of the standard 12-to-14-year baseline for generic entry. A Paragraph IV challenge is the primary mechanism generic manufacturers use to contest a brand drug's patents and enter the market early, but a settled challenge forfeits that opportunity entirely. Using historical data from the FTC, Drake and McGuire (2024) estimated an average delay of 17 months for pre–*FTC v. Actavis* settlements. However, rigorous instrumental variable econometric modeling indicates the true delay is far longer: Pay-for-delay agreements effectively reverse the procompetitive effects of patent challenges, suppressing generic entry for up to 5 years after the initial challenge (Helland and Seabury 2022). Drugs with a Paragraph IV challenge but no pay-for-delay settlement were

associated with a 68-percentage-point increase in the probability of generic entry, whereas a challenge with a settlement was associated with only an 8.3-percentage-point change, not significantly different from 0, indicating that the settlement offset the expected gain through generic entry from the challenge (Helland and Seabury 2022).

Following the 2013 *FTC v. Actavis* decision, pharmaceutical firms largely abandoned explicit cash payments and instead adopted harder-to-detect value transfers such as side business deals or commitments by brand manufacturers to refrain from launching authorized generics (Hemphill 2019).[26] Drake and McGuire (2024), applying stock price event studies to 64 publicly announced settlements during 2014 to 2023, found that 17 (more than one-quarter) showed indications of collusion or reverse payment. Noncollusive settlements produced no significant stock price reaction, while settlements with collusion indicators increased the brand firm's stock prices by approximately 3.5 percent. The total increase in brand-firm market capitalization across identified collusive settlements during this period was approximately $16.1–16.5 billion. Taken together, these findings suggest that pay-for-delay did not end with *Actavis*; instead, it evolved, and the financial gains captured by brand firms correspond to additional spending borne by drug purchasers paying monopoly prices during generic delays.

3.4 The Cost of Pay-for-Delay and Reverse-Payment Settlements

The most direct estimates of the cost of pay-for-delay settlements come from three studies that used two complementary methodologies. The three cost studies summarized here measure different combinations of payers over different periods, so their headline figures are not directly comparable. R. Feldman (2022), using a sample of Medicare Part D claims data paired with settlement agreements for 12 pay-for-delay cases, estimates that, extrapolated to the entire US population on a list-price basis, these settlements cost all US payers between $6.4 billion and $36.1 billion annually during the period 2006 to 2017, with the Medicare Part D costs ranging from $2.3 billion to $13.1 billion per year. The wide range reflects different assumptions about counterfactual entry timing (alternative delay length and patent expiration scenarios) rather than analytical weakness.

Drake and McGuire (2024), using stock price event studies to infer capitalized brand profit gains from delayed generic entry, estimate that the 17 settlements they identified as collusive increased spending by US drug purchasers, meaning the payers and patients who buy these medications, by $3.1–3.2 billion per year during 2014 to 2023. This figure is the additional amount purchasers paid for those drugs and does not include downstream effects such as lost federal tax revenue. Scaling up to account for settlements not captured in the event study sample (a factor of about 3.8), the authors estimate

industrywide annual costs of approximately $12 billion, also measured as spending by US drug purchasers.

Brake and others (2025) take Drake and McGuire's (2024) observed approximately $3 billion annual all-purchaser estimate (the 17 potentially collusive settlements, not the $12 billion industrywide figure) and allocate it across payers for a historical and a projected period.[27] For the federal budget, estimated costs attributable to these settlements totaled $16.1 billion over 2014 to 2023 (Medicare, $9.9 billion; federal Medicaid/CHIP, $3.5 billion; Affordable Care Act Marketplace subsidies, $0.5 billion; and lost federal tax revenue from higher employer-sponsored insurance premiums, $2.2 billion) and are projected to reach $27.4 billion over 2024 to 2033. Households (across all insurance types including uninsured) bore out-of-pocket costs exceeding $4.4 billion over 2014 to 2023, with $5.3 billion projected over 2024 to 2033. The private sector bore an estimated $12.2 billion in higher premiums over 2014 to 2023, projected at $17.9 billion over 2024 to 2033, the bulk of it for employer-sponsored insurance. Applying Drake and McGuire's (2024) larger industrywide estimate as an upper bound would more than double these federal cost projections.

These estimates do not conflict; rather, they include different payers, settlement samples, and time frames. The $3.1–$3.2 billion and $12 billion estimates are annual, all-payer amounts; the first estimate is for 17 observed settlements, and the second estimate is scaled to the full industry. The $16.1 billion and $27.4 billion figures are 10-year aggregates for the federal budget alone, derived from the $3 billion observed base rather than the $12 billion industry estimate. As a result, the $27.4 billion federal total should not be read as the federal share of a $12 billion-per-year all-payer cost. The federal share of that larger estimate would be several times higher. The cost estimates computed by Brake and colleagues (2025) and the related studies discussed above capture only the settlements identified as collusive or reverse-payment, not settlements generally; an industry-commissioned analysis found that a broader assessment of patent settlements in the post-*Actavis* period more often accelerated generic entry than delayed generic entry, so the figures from Brake and colleagues are best read as the cost of the anticompetitive subset rather than of settlement as a practice in general.[28] Key cost statistics for pay-for-delay settlements are summarized in figure 8.

FIGURE 8

Key Cost Statistics: Pay-for-Delay Settlements

Selected excess spending estimates associated with pay-for-delay and reverse-payment settlements

$12 billion per year

Estimated industrywide annual cost to US payers and patients, scaled from the 17 settlements with indications of reverse payment during 2014–23[a]

$4.4 billion for 10 years

Additional out-of-pocket costs borne by patients of all coverage types, including cost sharing and self-pay, because of pay-for-delay settlements, 2014–23[b]

More than 1 in 4

Of 64 publicly announced settlements during 2014–23, more than 1 in 4 (17) showed indications of reverse payment[a]

Sources: [a] Keith M. Drake and Thomas G. McGuire, "Using Stock Price Movements to Estimate the Harm from Collusive Drug Patent Litigation Settlements," Working Paper No. 33196, National Bureau of Economic Research, revised June 2025, https://doi.org/10.3386/w33196; and CRS (Congressional Research Service), *The Role of Patents and Regulatory Exclusivities in Drug Pricing*, Report R46679, January 30, 2024.
[b] Ryan Brake, Rodelle Williams, and Cathi Callahan, *Pay for Delay: Historic and Future Costs of Delayed Generic Entry*, Actuarial Research Corporation, April 8, 2025.

The Hatch-Waxman Act's patent challenges were meant to speed generic entry, but pay-for-delay settlements can suppress it for up to five years after the initial patent challenge, nearly reversing all the challenge's procompetitive benefits (Helland and Seabury 2022).

3.5 Patient Consequences

Pay-for-delay settlements impose substantial out-of-pocket costs on patients during periods of delayed generic competition. Multiple independent analyses have quantified these excess costs using claims data and actuarial methods. Adverse consequences for patients' medication adherence and health outcomes are plausible given the magnitude of these cost increases and general evidence that price sensitivity affects prescription-filling behavior, but direct causal links at the patient level have not yet been established. R. Feldman (2022) estimates that annual patient out-of-pocket costs attributable to pay-for-delay across 12 studied drug settlements ranged from $610 million to $2.8 billion nationally, with generic out-of-pocket costs averaging approximately 49 percent of brand costs in the postdelay period, implying that patients paid roughly twice as much as they would have had generic entry proceeded on a competitive timeline. Moreover, R. Feldman (2022) asserts that these high brand drug prices, prolonged by pay-for-delay settlements, can fall disproportionately on lower-income patients, threatening access to lifesaving treatments and widening equity gaps. Helland and Seabury (2022) confirm that settlements raise prices and suppress quantity across affected brand drugs for up to five

years, and their welfare simulations estimate that settling a Paragraph IV challenge reduces consumer surplus by approximately $471 million per affected drug in the settlement year, with a five-year cumulative consumer surplus loss of roughly $835 million per drug. Brake and others (2025) estimate that patient out-of-pocket costs attributable to 17 identified pay-for-delay settlements exceeded $4.4 billion from 2014 to 2023, with an additional $5.3 billion projected over 2024–2033. Delayed generic entry also raised private insurance premiums by an estimated $12.2 billion over the same historical period, spreading cost burdens beyond cost sharing to the broadly insured population.

> **Patients with prescriptions affected by pay-for-delay settlements paid, on average, twice what they would have paid for a generic during the period that generic entry was delayed (R. Feldman 2022).**

3.6 Reforms

The 2013 *FTC v. Actavis* decision established rule-of-reason review for pay-for-delay agreements and reduced the frequency of explicit cash settlements. However, policy reform remains warranted, as compensation has shifted to implicit arrangements, as described above. The proposed Preserve Access to Affordable Generics and Biosimilars Act (119th Congress) would create a presumption of illegality for broad categories of pay-for-delay agreements; the CBO estimated $1.5 billion in 10-year federal savings, though analysts argue this figure substantially understates the benefit because of grandfathering provisions (Brake et al. 2025). Any legislation based on such a presumption of illegality is best aimed at settlements in which a brand pays a generic to stay off the market, rather than at patent settlements in general. An industry-commissioned review of settlements reached after the 2013 *Actavis* decision found that many brought generic competition to markets well before the relevant patents would otherwise have expired, often by several years, rather than delaying generic entry. However, the analysis covered both generics and biosimilars and may not apply to generics to the same degree.[29] A rule written too broadly could discourage these ordinary early-entry agreements, while one focused on payments that keep a generic out of the market would deter the harmful settlements without chilling the beneficial ones.[30] In 2019, California enacted AB 824,[31] which presumes a patent settlement unlawful when a generic drugmaker both receives anything of value and agrees to delay or limit the generic's entry, with some exemptions (Wallentine 2020). The California law appears to be appropriately targeted, though it may still affect procompetitive early-entry licenses. Its real-world effects on market entry remain unevaluated, and since 2025 a federal court has barred its enforcement except for settlements connected to California, limiting its reach and potential impact.[32] From the regulatory perspective, R. Feldman (2022) proposes that greater transparency in FTC-filed settlement

disclosures, which are currently aggregated and not publicly drug-specific, could extend enforcement capacity to state attorneys general and private litigants, potentially deterring the types of implicit payment arrangements that have proliferated since *FTC v. Actavis (2013)*.

3.7 Key Evidence Gaps

The pay-for-delay literature includes more rigorous empirical studies compared with most tactics in this review, but several limitations remain. Because settlement terms are rarely disclosed, most estimates infer the practice of pay-for-delay from market signals rather than directly observing it. Drake and McGuire (2024) identify indications of these payoffs through stock price movements, and their industrywide figures are sensitive to these methods and their specifications, ranging across various methods from roughly $7 billion to $12 billion in annual excess spending. The actual frequency of settlements involving financial compensation has not been established, especially for the noncash deals that became more prevalent after *FTC v. Actavis* (2013). Tactics such as promises not to launch competing generic drugs, side deals, and tiered royalties are substantially more difficult to identify compared with direct cash payments, so these settlements are likely undercounted. Cost evidence is also inconsistently estimated. While patient out-of-pocket spending is well documented through claims and actuarial data (Brake and others 2025), the downstream consequences for medication adherence and health outcomes are hypothetical rather than established. In addition, estimates of generic delay length depend on modeling assumptions and instrument choice. Helland and Seabury (2022) find that settlements suppress generic entry for several years, but generalizing from litigated cases to the full settlement population is challenging. Although recent work has estimated how costs vary across payer types including Medicare and Medicaid, little is known about how these costs vary across drug classes or therapeutic areas for these payers. In addition, the "surplus-distribution" analysis, which estimates how much brand and generic firms each may gain from a patent challenge (Jacobo-Rubio et al. 2020), has not been extended to assess pay-for-delay settlements. Finally, whether stepped-up FTC enforcement since *FTC v. Actavis* has reduced the incidence of pay-for-delay or merely shifted it toward subtler forms of compensation remains empirically unresolved.

Tactic 4: Sample Denial and Related Restricted Distribution Pathways

Brand-name pharmaceutical manufacturers have used various legal and regulatory mechanisms to deny generic manufacturers access to the drug samples required for federally mandated bioequivalence

testing. Among these mechanisms are the FDA's safety-based Risk Evaluation and Mitigation Strategy (REMS) framework and voluntary restricted distribution programs. A REMS program is an FDA-mandated safety program for drugs whose risks are deemed to require controls beyond standard labeling. The most strict form of REMS, known as Elements to Assure Safe Use (ETASU), can confine distribution to certified prescribers and pharmacies to prevent serious harms related to use of the drug, such as the severe birth defects caused by teratogenic drugs like thalidomide. However, brand firms have invoked this restricted-distribution authority to withhold samples from legitimate generic developers, even though the products can be supplied for testing without compromising the safety controls the REMS program was designed to enforce. By withholding samples, brand firms stop or delay the abbreviated approval pathway that generic drugs use to enter the US market, and the FDA currently lacks the administrative authority to mandate sample provision to the generic manufacturer.[33] The sample denial pathway tactic thus operates as a choke point for generics. Without physical samples of the brand-name reference drug, a generic firm cannot complete the bioequivalence studies that are the legal prerequisite for ANDA approval, regardless of how quickly the generic manufacturer could bring a product to the market. Congress enacted legislation in 2019, known as the CREATES Act, intended to give generic manufacturers a litigation-based path to obtain samples,[34] a necessary yet insufficient solution. It is a case-by-case, litigation-driven remedy that leaves the underlying incentive structure and REMS-based obstruction mechanisms in place, and the net impact on drug costs and generic entry has not been empirically assessed.

4.1 How It Works

Under the Hatch-Waxman Act, a generic manufacturer seeking FDA approval must demonstrate bioequivalence using samples of the brand-name reference drug. These samples are not permitted to be substituted with foreign versions, self-manufactured copies, or synthesized comparators. The brand manufacturer's control over its own product thus creates a structural bottleneck for the generic. Any refusal or impediment to providing samples can stop generic development before any patent challenge is filed (Carrier 2018; CRS 2018). Brand manufacturers created this bottleneck through three distinct pathways (figure 9):

1. **Safety program–related sample denial** occurs when a brand manufacturer withholds from generic developers samples of a drug subject to a REMS with ETASU, which limits distribution to a closed network of certified pharmacies and settings, and does not allow distribution to commercial wholesaler channels. The FDA can issue a safety determination letter affirming that sample provision to the generic company would not violate the REMS, but this may have little

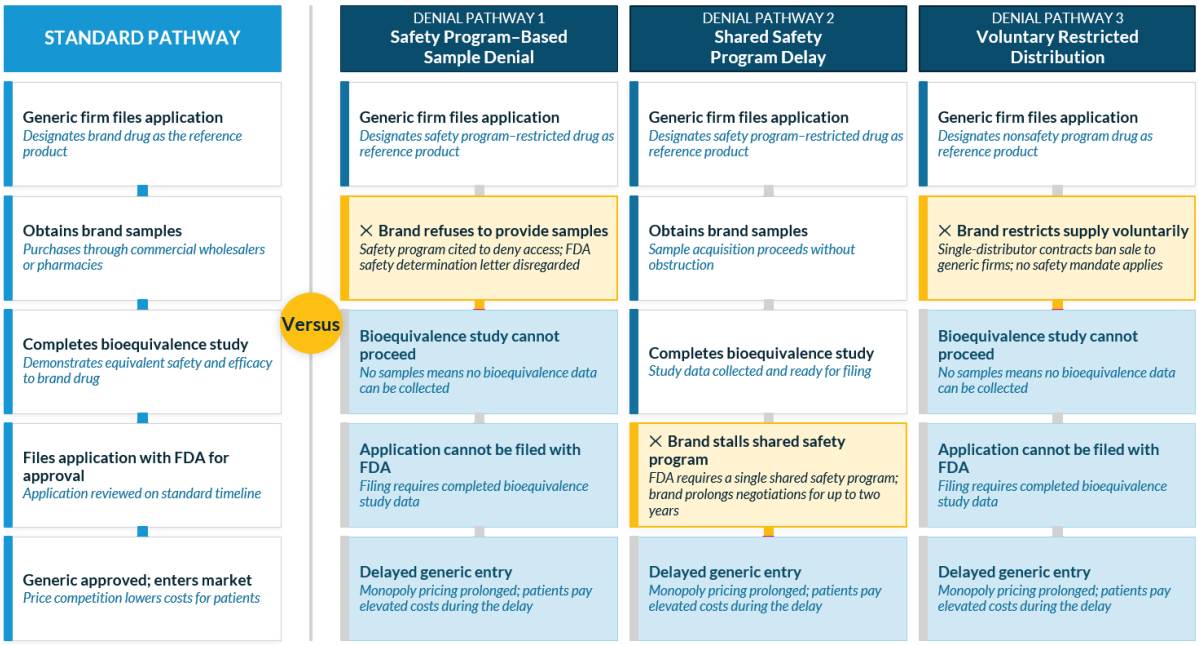
impact since the FDA lacks statutory authority to compel the brand to sell it. Brand manufacturers have declined sample requests even after the FDA has affirmatively cleared the generic's proposed testing protocols as safe (Carrier 2018; GAO 2019; CRS 2018). The generic developer must independently satisfy the same ETASU safety conditions, and the FDA reviews its proposed protocols before issuing this letter, so the safety determination is the step that separates a genuine safety concern from a pretextual refusal; a denial that persists after a favorable determination has no safety basis. In litigation over Revlimid (lenalidomide), Celgene was alleged to have refused samples even after the FDA indicated that supplying them would not create a safety risk (Waxman et al. 2018; Carrier 2018).

2. **Shared safety program delay** can arise when mandatory negotiations for a unified "shared system" REMS governing safe prescribing and dispensing for both brand and generic versions are prolonged by the brand manufacturer, which freezes the generic manufacturer's drug application even after bioequivalence testing is otherwise complete. The GAO has documented cases in which shared REMS system negotiations extended almost two years (GAO 2019). In these cases, since bioequivalence is already established and the generic must adopt the same safety conditions, the remaining barrier is the speed of negotiation of this agreement, which the brand controls, and does not involve unresolved safety questions. The FDA can also approve a separate comparable REMS for the generic instead of a single shared system, demonstrating that a prolonged single-system negotiation is not actually required for safety (GAO 2019). Reckitt Benckiser's conduct and delay around the Suboxone (buprenorphine-naloxone) shared REMS program is a documented example (Haffajee and Frank 2019).
3. **Voluntary restricted distribution** is a tactic where brand manufacturers voluntarily impose restricted distribution programs on products that are not otherwise subject to a REMS program (i.e., drugs for which the FDA has not established a REMS or ETASU safety requirement), limiting supply to a single distributor or specialty pharmacy and contractually restricting those channels not to sell the product to generic manufacturers. This mechanism replicates the REMS sample denial tactic without a determination that such restrictions are needed for safety (Carrier 2019; Sertkaya et al. 2021). Because no safety program applies, the brand cannot point to a REMS to justify the restriction, and the limited-distribution arrangement functions only to block sample access. For example, in the Daraprim (pyrimethamine) case, Turing moved a previously unrestricted drug to a single specialty channel, and Carrier (2019) concluded the arrangement lacked a clear safety rationale and served mainly to delay generic entry.

FIGURE 9

The Sample Denial and Related Restricted Distribution Pathways: Three Ways Brand Manufacturers Can Block Generic Drug Entry

Illustrative process pathways for a hypothetical brand-name small-molecule drug



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Sources: Michael A. Carrier, "Sharing, Samples, and Generics: An Antitrust Framework," *Law Archive*, April 3, 2018, https://doi.org/10.31228/osf.io/qrp36; Michael A. Carrier, "Higher Drug Prices from Anticompetitive Conduct: Three Case Studies." *Journal of Legal Medicine* 39 (2; 2019): 151–67, https://doi.org/10.1080/01947648.2019.1645540; Aylin Sertkaya, Andreas Lord, and Clara Berger, *Cost of Generic Drug Development and Approval*, Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services, December 31, 2021; and GAO (US Government Accountability Office), *Generic Drug Development: Stakeholders' Views of Risk Evaluation and Mitigation Strategies Differ*, 2019.
Notes: FDA = Food and Drug Administration. Illustrative example only.

4.2 Case Examples

The following three historical case examples primarily document conduct and market effects that occurred before the enactment of the CREATES Act (2019). The patterns of conduct remain directly relevant to litigation brought under the Act, but the scope of the Act's deterrent effect is uncertain:

1. Revlimid and Thalomid (manufactured by Celgene) represent the most financially consequential documented sample denial case. Multiple generic manufacturers spent approximately a decade attempting to obtain samples from Celgene despite FDA safety determination letters affirming that sample provision would not violate the REMS. Celgene repeatedly declined, citing safety requirements the agency had found inapplicable. Even when

the FDA issues a letter confirming a generic developer's testing protocols are safe, the agency lacks the statutory authority to compel sample sharing because current law does not explicitly require brand manufacturers to sell their products to competitors. By June 2018, no generic had been approved despite Revlimid's 2006 launch, and Medicare Part D spent approximately $2.7 billion on the product in 2016 alone (Bluhm 2019). When generic lenalidomide ultimately entered the market in 2022, it was governed by restrictive settlement agreements leveraging an extensive patent thicket. By capping initial generic volume at 7 percent, these terms ensure the brand manufacturer retains effective market exclusivity through 2026, prolonging its de facto monopoly to 20 years.[35]

2. Tracleer (bosentan), made by Actelion, is subject to a REMS with ETASU requiring dispensation through a certified specialty pharmacy network. Actelion refused to sell samples to generic manufacturers seeking to enter the generic bosentan market, invoking its REMS as justification. This refusal became the subject of antitrust litigation in which the generic manufacturer argued that REMS-based sample denial can constitute unlawful monopolization when a manufacturer is already commercially selling the product, and the FDA has cleared sample provision as safe (Carrier 2024). The litigation concluded with Actelion agreeing to a $65 million settlement to compensate these payers, settling allegations that the company's exploitation of REMS protocols unlawfully suppressed generic competition and sustained artificially high prices.[36]
3. Suboxone (a brand-name version of a buprenorphine-naloxone combination product), made by Reckitt Benckiser, illustrates the restricted distribution tactic as one element of a multitactic strategy in a clinically high-stakes market: The generic delay came largely from the shared safety program (REMS) delay and the tablet-to-film product hop, with citizen petitions playing a secondary role. The FDA deemed the refusal an exclusionary tactic that undermined the Hatch-Waxman Act, dismissing the company's safety justifications. Nevertheless, this delayed meaningful generic film competition and generated an estimated $1.6 billion in additional profits for Reckitt Benckiser, according to estimates by Feldman and Frondorf, cited in Haffajee and Frank (2019). The costs were borne primarily by public payers, with Medicare and Medicaid together accounting for 32 percent of $2.6 billion in broader buprenorphine market sales in 2017. The public health stakes were particularly high because buprenorphine is a first-line treatment for opioid use disorder during a period of high overdose mortality.

4.3 Evidence of Delay

Because sample denial operates at the generic development stage, before a generic application (i.e., ANDA) is even submitted, its effect is an upward shift of the entire development timeline, extending the period of brand-only pricing before any generic challenge can be formally filed. As of March 2019, the FDA's publicly posted list documented 164 separate inquiries from generic manufacturers about inability to obtain samples (GAO 2019). All four generic companies interviewed by the GAO for its 2019 report stated that inability to access ETASU-limited samples had either delayed or discouraged development of specific products. This developer attrition effect is particularly concerning because foreclosed projects are not recorded in a generic application's filing data; they disappear before the formal process begins (GAO 2019).

Several cases described above illustrate the severity of delay when sample denial materializes. Mylan attempted to obtain Celgene samples for Revlimid (lenalidomide) and Thalomid (thalidomide) for nearly a decade without success, despite the FDA's clarification that providing samples for the purpose of bioequivalence testing does not violate REMS safety protocols (Carrier 2018; Waxman et al. 2018). As mentioned above, in a shared-system REMS dispute over Suboxone for the treatment of opioid use disorder, which the manufacturer had transitioned from a tablet to a sublingual film, Reckitt Benckiser refused to cooperate with generic manufacturers on a shared REMS, even though the FDA could have quickly approved a separate comparable REMS rather than require a single shared system. The refusal delayed generic buprenorphine film competition by approximately nine months until the FDA granted a separate REMS pathway (Haffajee and Frank 2019).

4.4 The Cost of Sample Denial and Restricted Distribution Pathways

Direct cost estimates measuring the cost of sample denials are limited because the tactic often co-occurs with other strategies including patent thickets, pay-for-delay, and product hopping, which complicates the isolation of causal effects. The most policy-relevant estimates were computed in the CBO's scoring of the CREATES Act (2019), which projected a reduction in the federal deficit of more than $3.3 billion over 10 years, with the savings primarily due to accelerated generic entry for drugs subject to sample denial barriers (CBO 2019b). This estimate is almost certainly a lower bound for the cost of all strategies related to sample denials, as it covers only cases likely to be addressed through CREATES litigation and excludes non-REMS-restricted distribution and projects deterred before any lawsuit (CRS 2018; Waxman et al. 2018).

More specific cost estimates are unavailable. Existing figures capture program-level spending rather than delays attributable to sample denial in particular. Medicare and Medicaid collectively paid at least $11.8 billion in 2017 on drugs subject to active REMS ($8.5 billion in Medicare; $3.3 billion in Medicaid), though the GAO does not estimate what share reflects delayed generic competition attributable to sample denial specifically (GAO 2019). A 2014 industry estimate attributed approximately $5.4 billion annually in systemwide excess spending to misuse of REMS and other restricted distribution programs, with roughly one-third ($1.8 billion) borne by the federal government; that estimate was not peer-reviewed and should be interpreted cautiously (CRS 2018). Key cost statistics for sample denial pathways are summarized in figure 10.

FIGURE 10

Key Cost Statistics: Sample Denial Pathways

Selected cost estimates associated with REMS-based and other sample denial pathways

$3.3 billion

10-year federal deficit reduction projected under the CREATES Act from accelerating generic entry for drugs that had been subject to sample denial barriers[a]

$11.8 billion

Medicare and Medicaid spending in 2017 on reference-standard drugs subject to active REMS programs[b]

164

Number of inquiries from generic manufacturers between 2003 and 2019 to FDA about inability to obtain brand samples as of March 2019[b]

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Sources: [a] CBO (Congressional Budget Office), "Cost Estimate: H.R. 965, the CREATES Act of 2019," April 25, 2019.
[b] GAO (US Government Accountability Office), *Generic Drug Development: Stakeholders' Views of Risk Evaluation and Mitigation Strategies Differ*, October 2019.

4.5 Patient Consequences

Sample denial preserves brand-only pricing for extended periods, imposing direct out-of-pocket cost burdens on patients who would otherwise benefit from generic competition that can reduce prices by up to 80 percent or more once several generics compete. For patients taking Revlimid for multiple myeloma, Waxman and colleagues (2018) document individual monthly out-of-pocket exposures approaching $15,000 once manufacturer assistance programs end, with one documented patient facing out-of-pocket copayments that had increased by 600 percent since diagnosis. The consequences can extend beyond cost to access and clinical outcomes in high-stakes therapeutic areas. In the buprenorphine market, where prolonged shared-system REMS negotiation was a central element of the delay strategy, Haffajee and Frank (2019) document that sustained brand-only pricing constrained the volume of medication that public programs could purchase and make accessible to patients with opioid

use disorder, a condition for which medication treatment substantially reduces overdose risk. Direct causal evidence linking sample denial–specific delay to measurable adverse health outcomes remains limited and is a priority for future research.

> **At a time when opioid overdoses were at epidemic levels, estimated at 47,600 lives lost in 2017 (Wilson et al. 2020), Reckitt Benckiser's nine-month refusal to cooperate on a required shared drug safety program blocked generic Suboxone entry, limiting how much buprenorphine treatment public programs could purchase for patients with opioid use disorder and resulting in an estimated cost of $203 million annually in forgone Medicaid savings (Haffajee and Frank 2019).**

4.6 Reforms

Efforts to address sample denial have made progress, but enforcement currently relies on fragmented, case-by-case litigation; the CREATES Act (2019) narrowed the enforcement gap by establishing a private right of action, allowing generic manufacturers to sue brand companies for samples on commercially reasonable terms. Concurrently, the FTC has supported these efforts by filing amicus briefs in sample denial cases, arguing that refusing to sell needed samples constitutes illegal monopolization under antitrust law (Carrier 2024). However, because the CREATES Act functions through the courts rather than through a standing regulatory rule, it does not fully close the loophole. As the Congressional Research Service has identified (CRS 2018), the foundational problem is a statutory gap: The FDA still lacks the direct administrative authority to mandate sample provision.[37] The Congressional Research Service suggests that to resolve this bottleneck, broader legislation is likely required to explicitly grant the FDA the authority to compel sample sales when safety concerns do not justify a refusal, but such legislation has not yet been introduced.

4.7 Key Evidence Gaps

The evidence base on sample denial has several notable limitations. The only direct empirical measurement of how often the tactic occurs and how long it delays development comes from a Canadian survey commissioned by a generic-industry association that relied partly on imputed delay values. It found that roughly 16 percent of surveyed development projects had been delayed, with a median launch delay of six months (Grootendorst 2022). No comparable US estimate of prevalence or duration has been identified. The financial cost specific to sample denial has not been independently estimated for the US: The widely cited figure of $5.4 billion in annual national costs originates from a

generic industry–commissioned analysis (CRS 2018), and federal cost discussions rest on the CBO's projection of more than $3 billion in 10-year savings from the CREATES Act, rather than on a measured retrospective cost of the conduct itself (CBO 2019b). Because sample denial typically co-occurs with patent thickets, pay-for-delay settlements, and product hopping, existing spending studies cannot easily isolate its independent contribution. The most rigorous Medicaid analysis found that restricted sample access played an obvious role in only a few cases, with patent litigation acting as the dominant delay mechanism (Dave et al. 2020). Furthermore, the shared-system negotiation channel and the voluntary non-REMS-restricted distribution channel are far less documented than ETASU-based sample denial, and the evidence on voluntary restriction rests largely on a single case (Carrier 2019; Sertkaya et al. 2021), while the most comprehensive federal account is descriptive and interview-based rather than causal (GAO 2019). Notably, no study has yet evaluated whether the CREATES Act reduced the frequency or duration of sample denial after its passage in 2019, leaving the central reform question unanswered (Sertkaya et al. 2021). Finally, because these denials occur before a generic application is ever filed, foreclosed development projects leave no trace in FDA filing data, meaning that the true prevalence of the conduct may be understated by the available evidence (GAO 2019).

Tactic 5: Parking of 180-Day Exclusivity

The "parking" of a generic drug's 180-day exclusivity period, also called "exclusivity parking," is a tactic that occurs when the first generic manufacturer to legally challenge a brand-name drug's patent under the Hatch-Waxman Act (also known as a "Paragraph IV" patent challenge) withholds commercial launch after receiving FDA approval. This action prevents the generic's 180-day marketing exclusivity period from starting and blocks all subsequent generics from entering the market. The exclusivity period was established under the Hatch-Waxman Act to reward generic challengers for the high costs and risks of patent litigation; however, the 180-day exclusivity period can be used strategically when a first generic filer "parks" and does not launch during this period, often as part of a reverse-payment settlement with the brand manufacturer. This transforms what was supposed to be a competitive incentive into a barrier that extends the brand's monopoly pricing. The Medicare Modernization Act (MMA) of 2003 substantially addressed this "parking" strategy by introducing statutory forfeiture conditions (i.e., legal triggers that can revoke the generic's 180-day exclusivity period), yet empirical research confirms that parking persists in modified forms, particularly through settlement agreements that specify future entry dates outside the law's forfeiture triggers (Drake and McGuire 2020; Van de Wiele et al. 2021).

5.1 How It Works

Under the Hatch-Waxman Act, the first generic applicant (an Abbreviated New Drug Application [ANDA] filer) to submit a legal challenge asserting that a brand drug's patents are invalid or not infringed (i.e., a "Paragraph IV" challenge) earns a 180-day market exclusivity window. Originally, this 180-day clock began only with a commercial launch rather than FDA approval. Consequently, a first filer that chose not to launch could stall the market indefinitely, blocking all subsequent generics. Brand companies leveraged this noncompetitive situation by paying first filers through cash, no-AG pledges (i.e., promises whereby the brand company agrees not to launch its own competing authorized generic), or volume-limited licenses (i.e., permits that restrict the total amount of generic drugs sold) to delay their launch (FTC 2002, 2011; Van de Wiele et al. 2021). Through this mechanism, the first filer profited while keeping its exclusivity parked, the brand extended its monopoly pricing, and consumers paid high prices despite the approval of alternative generics (FTC 2002, 2011; Van de Wiele et al. 2021). Parking is structurally related to pay-for-delay (Tactic 3 above) because reverse-payment settlements routinely include a parking element. That is, the first filer accepts compensation in exchange for an agreed entry date years in the future, and its parked exclusivity acts as a legal barrier to all other generics, even those who are not part of the settlement (Drake and McGuire 2020). Relatedly, even when the first filer launches, settlement royalty terms can suppress competition within the 180-day exclusivity window due to a generic-to-brand royalty structure that declines if the brand introduces an authorized generic. This can deter the launch of an authorized generic, keeping a market with a single generic, and providing value to the generic company that may induce the first filer to accept a later entry date (Drake and McGuire 2023).

Congress addressed parking directly through the MMA of 2003, which added six forfeiture conditions: the first filer's 180-day exclusivity is forfeited if it fails to obtain tentative FDA approval within 30 months of its ANDA submission, or if it fails to market the drug within a specified time frame after a court finds the listed patents invalid or not infringed, or after the brand withdraws the listed patent, plus additional triggers. These provisions were found to substantially reduce the original form of parking behavior (Van de Wiele et al. 2021). However, exclusivity parking has been found to persist in at least two forms that the MMA restrictions did not fully eliminate. First, settlement agreements can specify an entry date far in the future, which can park exclusivity without triggering an MMA forfeiture condition. Second, when multiple ANDA filers share first-filer status, the shared exclusivity can be coordinated or effectively parked if none of the co–first filers launches. A third residual form of exclusivity parking involves regulatory delay. When FDA review standards change mid-prosecution, this

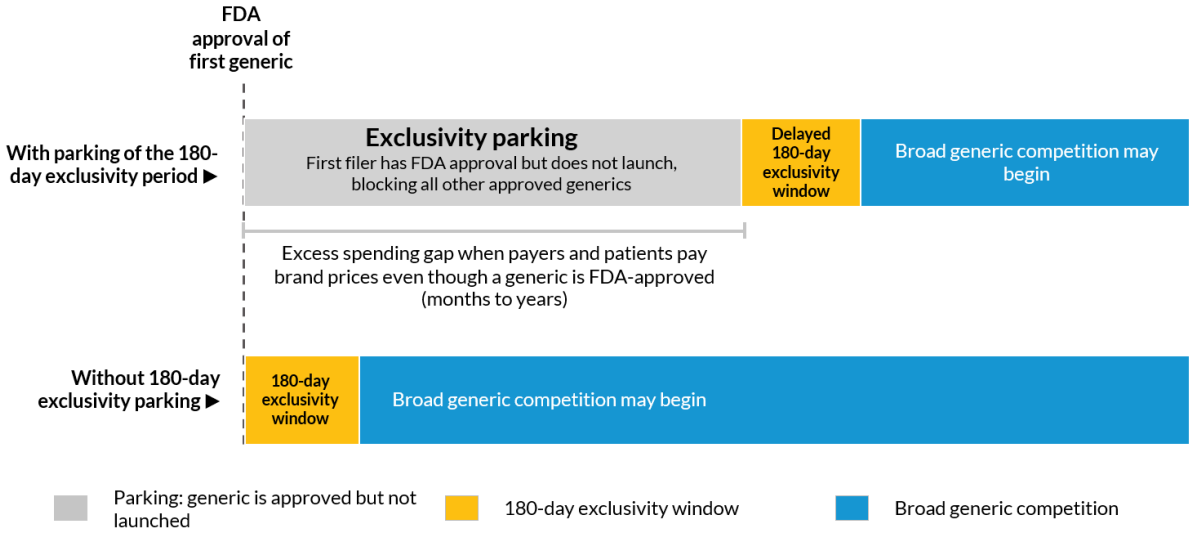
can prevent a first filer from obtaining tentative approval within 30 months, triggering forfeiture for reasons outside the filer's control (Van de Wiele et al. 2021; Gandhi et al. 2025).

Exclusivity parking does not threaten every drug equally. Whether parking can occur and how much it matters depend on the type of drug at issue, as described by Drake in a 2026 *Health Affairs Forefront* article.[38] The first type of drug that is vulnerable to this tactic is high-value NCEs. Because the FDA cannot accept generic applications for an NCE until four years after the brand's approval, many generic firms tend to file on the same first day for these drugs, so first-filer eligibility is frequently shared rather than held by a single firm. The blockbuster anticoagulant Xarelto, for example, had eight first filers sharing eligibility. The second type is top-selling drugs that contain a previously approved (non-NCE) active ingredient. Sole first-filer status, the configuration most exposed to exclusivity parking, is concentrated here, because no submission window applies and shared exclusivity is rare. The third type relates to low-sales drugs that are costly or difficult to manufacture, such as some injectables and topical formulations. These drugs typically attract fewer generic applicants, so a sole first-filer more often faces no later entrants regardless of the exclusivity period, and the exclusivity period does not have a substantial effect on encouraging generics or delaying competition. How a parked 180-day exclusivity can block later generic entry is illustrated in figure 11.

FIGURE 11

How 180-Day Exclusivity Parking Can Block Generic Entry

Illustrative timeline for a hypothetical brand-name small-molecule drug



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Sources: Keith M. Drake and Thomas G. McGuire, "Generic Entry Before the Agreed-On Date in Pharmaceutical Patent Settlements," *Journal of Competition Law & Economics* 16 (2; 2020): 188–219, https://doi.org/10.1093/joclec/nhaa007; Victor L.

Van de Wiele, Jonathan J. Darrow, and Aaron S. Kesselheim, "No Parking Here: A Review of Generic Drug 180-Day Exclusivity and Recent Reform Proposals," *Yale Journal of Health Policy, Law, and Ethics* 20 (1; 2021); Rachel Sachs, Marta Wosińska, Richard G. Frank, and Loren Adler, "The FDA Could Do More to Promote Generic Competition: Here's How," White paper, Brookings, 2024; and CBO (Congressional Budget Office), "Alternative Approaches to Reducing Prescription Drug Prices," October 2024.
Notes: FDA = Food and Drug Administration. Illustrative; not to scale. The first generic company to challenge a brand-name drug's patents earns 180 days of exclusive sales rights before other generics can enter the market. But when that company gets FDA approval and then waits to launch, "parking" its exclusivity, it blocks all other approved generics from selling. During this gap, patients and insurers keep paying brand-name prices, sometimes for months or years. The bottom half of the figure shows the scenario without such a tactic: The first generic launches promptly, its 180-day window runs, and broad generic competition can follow.

5.2 Case Examples

Although the MMA's 2003 forfeiture provisions eliminated most traditional cases of exclusivity parking, a small number of cases have involved such anticompetitive tactics (Van de Wiele et al. 2021):

1. Xyzal, a widely used allergy medication with US sales of approximately $224 million (Drake and McGuire 2020), illustrates how a manufacturer can evade the regulatory mechanisms of the MMA. The first-filing generic applicant experienced a five-month delay beyond the 30-month stay period, not because it chose to wait, but because the FDA changed the brand-name drug's approved age range from children "6 months to 5 years of age" to "children 2 years of age and older" plus some additional labeling revisions (Van de Wiele et al. 2021). Because these FDA-initiated changes did not meet any of the six enumerated MMA forfeiture triggers, the first filer's 180-day exclusivity remained intact throughout the delay, legally blocking other approved generics from entering the market for the entire extended period (Van de Wiele et al. 2021).
2. Xyzal was not an isolated case of a nontraditional case of exclusivity parking, as between 2007 and 2012, changes to FDA review standards were estimated to have caused delays in approximately 20 cases among more than 3,500 generic drug applications approved in those years (Van de Wiele et al. 2021). Thus, even after the MMA substantially curtailed the original form of strategic exclusivity parking, a residual category of delay remains. This is driven by both regulatory complexity and the safe harbors within the forfeiture conditions that neither Congress nor the FDA has fully closed. As a result, researchers have noted that strategic behaviors related to exclusivity parking may have become less transparent rather than less frequent (Van de Wiele et al. 2021).

The 2003 reforms curtailed the most overt forms of exclusivity parking, but "it is possible that strategic behavior has become less transparent, rather than less frequent" (Van de Wiele et al. 2021).

5.3 Evidence of Delay

The clearest direct evidence of delay because of generic exclusivity periods comes from Drake and McGuire (2020), which reviewed publicly disclosed settlements between first filers and brand companies. Of the 54 drugs for which a single first filer settled and kept its exclusivity, no other generic ever reached the market before the date set in the settlement, and the "acceleration clauses" meant to let a later challenger move that date up never actually did so. Earlier entry happened only when exclusivity was shared among several first filers or had been forfeited, and even then it was always another first filer, never a later challenger, that brought entry forward. The pattern is consistent: Once a sole first filer settles and retains its exclusivity, it reliably blocks earlier competition without being treated as having given up that exclusivity.

The exclusivity period is usually defended as a necessary reward for challenging brand patents, but recent work questions that premise. Examining drugs built on a new active ingredient that faced generic entry between 2015 and 2025, Drake (2026) found that firms kept filing challenges even when the reward was diluted, and most higher-selling drugs drew several challengers, including some that already knew they were ineligible for the exclusivity period. Drugs whose exclusivity was shared among multiple first filers reached the market about three years sooner, on average, than drugs left to a single first filer, and whether the exclusivity was forfeited made no difference to initial generic entry timing, even after accounting for sales and patent characteristics. In a related commentary, Drake draws out the implication: if a large, protected reward were what drove challenges, a weaker reward should slow entry, but it does not.[39] Instead, generic challenges are sustained by low litigation costs, the immense market value of blockbuster drugs, and a durable first-mover advantage. For these high-value products that dominate health care spending, the statutory 180-day exclusivity reward is largely redundant (Drake 2026).

When a top-selling drug has only one generic first filer, the 180-day exclusivity period often stops acting as a spur to competition and becomes a tool for delaying it, as argued in a 2026 commentary by Drake.[40]

That same evidence points to where the period does the most harm. Top-selling drugs built on an active ingredient the FDA had already approved almost always have just one first filer, because nothing

pushes competitors to file on the same day. These are exactly the products a single firm can settle and park, the situation Drake and McGuire (2020) found produces no early entry. The exposure is broad: A patent challenge now accompanies about 81 percent of new drugs facing their first generic competitor, rising to 93 percent of those selling more than $250 million a year (Sachs et al. 2022). Roughly a quarter of recent first-filer applications were approved, but not yet on the market, the position in which parking can occur, though not every application in that status has been parked, and initial challenge applications took an average of 4.8 years (57.6 months) to clear FDA review, a long and costly wait during which a settlement that delays entry can become more attractive (Gandhi et al. 2025).

5.4 The Cost of 180-Day Exclusivity Parking

Direct cost estimates specific to exclusivity parking are more limited than those for patent thickets or pay-for-delay, because parking is less common since the 2003 MMA reforms and is usually bundled with pay-for-delay settlements, which makes its separate effect hard to isolate. A rigorous government estimate is the CBO score for H.R. 938, the Bringing Low-Cost Options and Competition Although Keeping Incentives for New Generics (BLOCKING) Act of 2019 (116th Congress). CBO projected that the bill, which would allow FDA to approve a subsequent generic ANDA when the first applicant has not yet received final approval, would reduce the federal deficit by $442 million over the 2019–2029 budget window, including $374 million in reduced direct spending (primarily Medicaid and Medicare Part D) and $68 million in increased revenues reflecting macroeconomic feedback as lower premium costs shift into taxable employee wages (CBO 2019a). Because it is a net federal estimate, the CBO projection understates the total benefit, leaving out savings to commercial insurers and patients' out-of-pocket costs. Drake's 2026 commentary illustrates the stakes for the sole-first-filer drugs most exposed to parking. The commentary explains that if two later-filing firms could otherwise have launched alongside the first filer, the exclusivity period leaves one initial generic seller instead of three, and without it the initial generic price would have been roughly 50 percent lower. The same study cites a 2019 FDA estimate that such delays raised drug-purchaser spending by about $1.8 billion a year.

The CBO's broader 2024 analysis estimates that earlier-entry reforms would accelerate generic entry by roughly six months to two years for affected drugs. Prices for small-molecule drugs fall to roughly three-quarters below the pre-entry brand price by the fourth year after generic entry (CBO 2024), so even a one-year delay imposes substantial costs on payers and patients.

Sertkaya and others (2025) offer a countervailing data point: Aggressively restricting parking could weaken the very incentive meant to drive generic competition. Using sales data for 37 drug markets in which a generic launched after a patent challenge, they estimate that first-filer generic sales fall 13.0

percent on average from month six to month seven as exclusivity ends, and that adding 30 days would shrink that decrease to 3.1 percent, costing about $870,000 (in 2017 dollars) in month seven sales for the average first filer. This result suggests the exclusivity period may give some challengers an important chance to recoup their legal costs before competition from other generics erodes their sales. Reforms that curb parking by trimming this reward therefore need careful design so they do not discourage future patent challenges. Key statistics on exclusivity parking are summarized in figure 12.

FIGURE 12

Key Statistics: Exclusivity Parking

Selected estimates associated with 180-day exclusivity parking

0 of 54

Cases of early generic entry before the agreed settlement date when first filer retained sole 180-day exclusivity; acceleration clauses provided no real acceleration in sole-exclusivity cases[a]

$442 million

Projected federal deficit reduction over 2019–29 from the BLOCKING Act (H.R. 938), addressing first-filer parking of the 180-day exclusivity period[b]

27 percent

The share of patent-challenging generic drugs in "approved but unlaunched" status from 2020 to 2024, which can include both parked generics and other generics barred from entry[c]

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Sources: [a] Keith M. Drake and Thomas G. McGuire, "Generic Entry Before the Agreed-On Date in Pharmaceutical Patent Settlements," *Journal of Competition Law & Economics* 16 (2; 2020): 188–219, https://doi.org/10.1093/joclec/nhaa007.
[b] CBO (Congressional Budget Office), "Cost Estimate: H.R. 938, Bringing Low-Cost Options and Competition Although Keeping Incentives for New Generics Act of 2019," April 2019.
[c] Kajal Gandhi, Ramesh Joga, M. Sowndharya, et al., "Unlocking Generic Market Access: A Retrospective Analysis of USFDA Paragraph IV Filings (2020–2024)," *Therapeutic Innovation & Regulatory Science* 59 (6; 2025): 1380–93, https://doi.org/10.1007/s43441-025-00831-w.

5.5 Patient Consequences

When a first generic filer parks its 180-day exclusivity, patients and payers continue to pay brand-level prices for the duration of the parked window, even after the FDA has certified that generic versions are safe, effective, and ready to sell. For patients with coinsurance, high-deductible plans, or no coverage, that means continued out-of-pocket spending on brand-priced drugs while cheaper equivalents exist but are barred from the market. For chronic-condition drugs, where a monthly copay can be hundreds of dollars or more, even a six-month parking period can add up to thousands of dollars in excess spending. Still, no peer-reviewed study has yet measured nonadherence or poor health outcomes caused specifically by parking rather than by pay-for-delay or patent-thicket delays, because the effect of any one tactic is hard to isolate when several operate at once.

5.6 Reforms

The 2003 MMA forfeiture provisions, which revoke exclusivity if first generic filers delay marketing, are the most significant enacted reform aimed at exclusivity parking and are widely credited with sharply reducing the classic pre-2003 form of this tactic. Van de Wiele and colleagues (2021) document that a post-2003 form of parking still occurs in a small fraction of total approvals. However, it does not reach the level of parking achieved through settlement-set entry dates that did not trigger forfeiture. The proposed BLOCKING Act (H.R. 938) bypasses the bottleneck, as it allows the FDA to approve a later generic when the first applicant has not yet received final approval. This commercial approval forces a countdown by immediately triggering the start of a 180-day period (i.e., the no-parking period). Once this 180-day clock expires, the subsequent applicant can enter the market, bringing lower-priced generic drugs to consumers earlier than under current law, with the expected savings as noted above (CBO 2019a). However, Van de Wiele and others (2021) and Gandhi and others (2025) warn that the bill could reduce Paragraph IV challenge incentives by making exclusivity less predictable for first filers; further, they note that it targets a problem arising in a small fraction of generic drug approvals. Congress has not enacted H.R. 938.

Sachs and others (2022) recommend that any settlement that does not allow immediate generic entry should presumptively forfeit the first filer's exclusivity, which would directly address the overlap between exclusivity parking and pay-for-delay strategies. No enacted legislation currently implements this recommendation. Sertkaya and colleagues (2025) suggest that modestly strengthening the generic's rewards could improve incentives to launch, even at risk, though the link between reward size and actual launch behavior has not been empirically established. The argument is that, if the 180-day head start were made more valuable, for example by extending the period to 210 days, generic companies would have a stronger financial reason to launch their product rather than park their approval. In contrast, Drake's 2026 commentary argues that policymakers should tailor or even eliminate the exclusivity period rather than strengthen it. This perspective argues that the exclusivity period is not needed to motivate challenges for many drugs and that, for sole first-filer drugs, it mainly serves to delay later generics, so narrowing or removing it could expand competition and decrease spending for payers and patients. This question remains contested, depending on the extent to which the exclusivity reward drives firms' decisions to challenge patents and to initiate a market launch.

5.7 Key Evidence Gaps

The research describing exclusivity parking has several notable limitations. No updated empirical estimate of parking frequency or duration exists for the period after the MMA's 2003 forfeiture

provisions took effect, which restricted parking in its original form. The most comprehensive accounting identified approximately 20 cases attributable to changes in FDA review standards between 2007 and 2012, representing a small fraction of the more than 3,500 generic applications approved in that period (Van de Wiele et al. 2021). The financial cost of post-MMA parking to payers and patients has not been estimated, and the CBO's projection of $44.2 million per year in federal savings from the BLOCKING Act is the only available cost estimate (CBO 2019a). Whether shared exclusivity among cofirst filers functions as a coordination mechanism for delayed launch is also understudied (Drake and McGuire 2020). Little evidence exists to describe how exclusivity parking affects the total number of generic entrants beyond the first filer. A related gap is how many generics are sold during the exclusivity period even when the first filer launches, since terms that reduce the settlement royalty if the brand introduces an authorized generic can deter that launch and leave a single generic on the market. The evidence for this royalty pathway is also sparsely studied, as only eight of 47 qualifying settlements (over 2007–19) disclosed a brand royalty, and researchers found just three with a declining structure (Drake and McGuire 2023). Finally, as Van de Wiele and others (2021) caution, strategic behavior related to exclusivity parking may have become less transparent rather than less frequent after the MMA, meaning the true current prevalence of parking-like conduct may be understated by the available data. A further unresolved question, as described above, is how much the 180-day exclusivity period actually drives generic firms' decisions to challenge patents and to launch products, since recent analyses reach opposing conclusions about whether the reward is necessary to sustain generic challenges (Sertkaya et al. 2025; Drake 2026).[41] Resolving this question bears directly on whether reform should preserve, strengthen, or narrow the period.

Tactic 6: Authorized Generics Timed to the Exclusivity Window

Authorized generics are brand-name products marketed under a generic label by the brand manufacturer using the same FDA-approved NDA. Because the authorized generic is produced by the brand-name manufacturer using its own existing, approved NDA, its launch does not constitute a patent challenge, nor does it require a separate ANDA. Instead, it is a business strategy used by brand manufacturers to retain market share. Authorized generics have been found to be competitive in the short run by reducing prices, but potentially anticompetitive in the long run. During the 180-day first-filer exclusivity window, an authorized generic is the only competitor the patent-challenging first generic faces, reducing prices modestly for purchasers while decreasing the first filer's revenues. The

critical policy question is whether the strategic deployment of authorized generics, particularly through no-AG pledges embedded in patent settlement agreements, ultimately delays the entry of additional generics and raises systemic spending. As discussed in Tactic 3, no-AG commitments are now one of the primary noncash reverse-payment currencies following *FTC v. Actavis*, having largely replaced explicit cash transfers (Drake and McGuire 2023; Drake et al. 2025). This concern does not depend on the contested idea that the exclusivity reward is what motivates challenges, as described in related literature (Drake 2026).[42] Instead, a no-AG pledge works as a reverse-payment because the 180-day window is valuable to a sole first filer, a point Drake affirms in the journal article, not because that value is what prompted the challenge. The claim that authorized generics discourage firms from challenging at all is less supported than the claim that no-AG pledges function as reverse payments, since firms keep filing even when the reward is diluted, so any deterrent effect on patent challenges is likely confined to a narrow set of drugs.

6.1 How It Works

Under the Hatch-Waxman Act, the first generic manufacturer to file a successful Paragraph IV patent challenge earns 180 days of marketing exclusivity, during which the FDA will not approve any competing ANDAs—the standard regulatory filings required for independent generic drugs to enter the market. However, an authorized generic does not require a separate ANDA since it is the brand product itself distributed under a generic label by a subsidiary or licensee, and its launch during this 180-day window is permissible under existing law. Because the authorized generic is the only generic competitor for the first filer during these 180 days, the brand's launch decision materially affects the first filer's expected revenues (figure 13).

The potential competitive harm operates through two pathways:

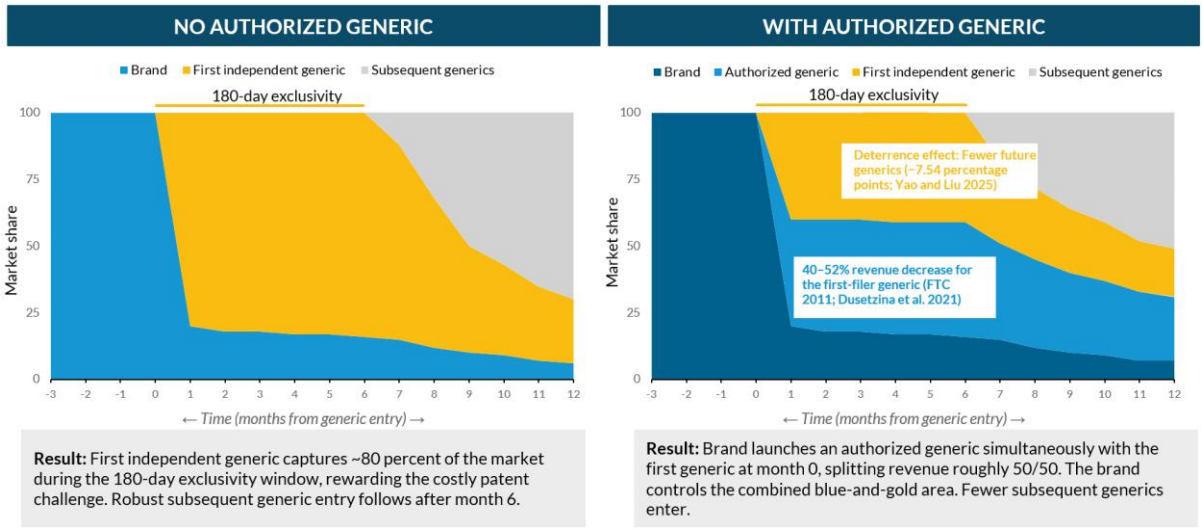
- In the first pathway, the brand launches an authorized generic during the 180-day exclusivity window, reducing market share and revenues for the first generic filer. Sertkaya et al. (2021) find that the dollar-sales market share of a first-to-file generic is on average 7 percentage points higher when no authorized generic is present, and that first-year revenues would be roughly 5 percent higher, translating to an average 10.9 percent increase in the expected net present value of a generic's Paragraph IV challenge. If expected returns from patent challenges are lower, fewer of these challenges will be filed by generics, resulting in entry deterrence.
- In the second pathway, the brand *withholds* an authorized generic, pledging not to launch one as consideration in a patent-settlement agreement. This no-AG promise increases the first generic

filer's expected revenues, making it rational for the generic to accept a later entry date in a settlement. Drake and McGuire (2023) demonstrate that declining royalty structures conditioned on the brand's authorized-generic launch are analytically equivalent to explicit no-AG pledges: A royalty rate that deters the brand from launching an authorized generic conveys net value to the generic and can induce delayed entry, functioning as an anticompetitive reverse payment. Bokhari and others (2020) show that restricting when a brand can launch an authorized generic can prevent pay-for-delay settlements from occurring, demonstrating that the right to launch an authorized generic is a key bargaining chip that enables these broader anticompetitive strategies.

FIGURE 13

No Authorized Generic Versus with Authorized Generic

Illustrative timeline and market share for a hypothetical brand-name small-molecule drug



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Sources: FTC (Federal Trade Commission), *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact: A Report of the Federal Trade Commission,* August 2011; Stacie B. Dusetzina, Nancy L. Keating, and Haiden A. Huskamp, "Authorized Generics and Their Evolving Role in Prescription Drug Pricing and Access," *JAMA Internal Medicine* 181 (4; 2021): 423–4, https://doi.org/10.1001/jamainternmed.2020.8450; Aylin Sertkaya, Andreas Lord, and Clara Berger, *Cost of Generic Drug Development and Approval,* Office of the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services, December 31, 2021; Annabelle C. Fowler, Ruben Jacobo-Rubio, and Jing Xu, "Authorized Generics in the US: Prevalence, Characteristics, and Timing, 2010–19," *Health Affairs* 42 (8; 2023): 1071–80, https://doi.org/10.1377/hlthaff.2022.01677; Rubaiyat Alam and Rena M. Conti, "Entry Delays and Fighting Brands: Evidence from Generics and Authorized Generics," *Journal of European Economic Association*, February 2025; Keith M. Drake, Gered Dunne, Aime Mason, Thomas G. McGuire, and Amie Price, "Trends in Authorized Generic Drug Launches and Their Effects on Competition in Oral-Solid Drug Markets in the US, 2016–23," *Health Affairs* 44 (6; 2025): 745–53, https://doi.org/10.1377/hlthaff.2024.01058; Lu Yao and Mengde Liu, "Strategic Behavior and Entry Deterrence by Branded Drug Firms: The Case of Authorized Generic Drugs," *The European Journal of Health Economics* 26 (4; 2025): 561–75, https://doi.org/10.1007/s10198-024-01721-y.

Notes: Illustrative example only. For clarity, the illustration excludes details. Not to scale; market share trajectories are illustrative, calibrated to published estimates. The 40 to 52 percent revenue reduction estimate is from FTC (2011) and covers the

exclusivity period 2003–08. The approximate 50/50 volume split reflects figures in Drake and colleagues (2025) for markets with a single Abbreviated New Drug Application. Having a second generic competitor in the form of an authorized generic decreases retail prices by an additional 4 to 8 percent during the 180-day exclusivity period (FTC 2011). The 7.54-percentage-point entry deterrence is from Yao and Liu (2025), instrumental variables estimation, N = 25,614 market-firm-year observations. Seventy percent of authorized generics launched before or during the 180-day window (Fowler, Jacobo-Rubio, and Xu 2023). Alam and Conti (2025) model the authorized generic as a "fighting brand," which the brand can launch at any time without Food and Drug Administration approval delays, reducing expected lifetime profits of independent generics and deterring entry.

6.2 Case Examples

Two cases illustrate the financial burden of authorized generics timed to the exclusivity window:

1. Entacapone (Comtan/Stalevo), the Parkinson's disease drug mentioned above, is a case involving excess costs related to an authorized generic. The primary patent expired in October 2013, but through settlements with three potential independent challengers, each launching as an authorized-generic supplier rather than a Paragraph IV challenger, the brand extended a period of weak competition. The first independent generic did not enter until 2015. Medicare spent $1.1 billion on entacapone-class products from 2011 through 2020, and Rome, Egilman, and colleagues (2023) estimate $137–$449 million of that amount was avoidable, as prices fell 62 percent rather than the 74 to 92 percent decline expected with eight or more independent competitors.
2. Albuterol inhalers, a rescue medication for asthma and other respiratory conditions, were the highest-volume authorized-generic product in Medicaid between 2014 and 2020. Two authorized generics for ProAir and Ventolin entered in 2019, at least a year before independent generic competition, and accounted for 17.1 million Medicaid prescriptions in 2019–20, which was 51 percent of all Medicaid albuterol inhaler prescriptions during those two years (Rome, Gunter, et al. 2023). The first independent generic albuterol inhalers did not enter until 2020. Thus, for at least a year, authorized generics captured a substantial share of a very high-volume market before independent competition emerged. The authors concluded that authorized generics introduced before independent generics, such as those described in this study, warrant scrutiny because they may delay or diminish the price competition and savings associated with independent generic entry.

6.3 Evidence of Delay

Authorized-generic launches were once common and strategically timed but have declined sharply as no-AG settlement pledges have increasingly replaced actual authorized-generic competition. A

comprehensive analysis identified 854 authorized-generic launches between 2010 and 2019, and in markets eligible for 180-day first-filer exclusivity, approximately 70 percent launched before or during that exclusivity period (Fowler et al. 2023). In Medicaid, more than 1,000 authorized-generic products accounted for 4 percent of all Medicaid prescriptions and 16 percent of use among products with an authorized generic available from 2014 to 2020. Nearly one-third were marketed at least one year before independent generic competition appeared, and 23 percent had no independent generic as of December 2020 (Rome, Gunter, et al. 2023).

Yao and Liu (2025), applying an instrumental variable framework to 207 generic manufacturers across 25,614 market-firm-year observations between 1999 and 2018, find that authorized-generic entry lowers the probability of independent generic entry by an average of 7.54 percentage points. Government spending is higher in authorized-generic markets than in comparable markets without authorized generics. Drake and others (2025) analyzed 146 common pill-form drugs that faced their first generic competition between 2016 and 2023. They found that brand-name companies are launching their own authorized generics far less often in more recent years. Although more than 60 percent of these markets had an authorized generic between 2016 and 2018, that number decreased to just 12.5 percent between 2021 and 2023. This large decline happened for two main reasons. First, a 2019 change in Medicaid pricing rules, and second, brand companies increasingly promising *not* to launch an authorized generic, which they did as an incentive to persuade generic competitors to delay entering the market. Evidence suggests fewer authorized generics are being launched because the *threat of* doing so has become a powerful deterrent to generics. Just threatening an authorized-generic launch, which could decrease an independent generic company's profits by roughly half (40 to 52 percent), gives brand companies substantial leverage to establish generic delay agreements. Drake and others (2025) identified eight potential agreements where brand-name manufacturers agreed not to launch an authorized generic, including drugs with combined annual sales exceeding $17 billion, before generic competition began during the years 2016 to 2023. When an authorized generic was present in the market, the actual prices pharmacies paid for generics were 13 to 18 percent lower than in markets with only one independent generic competitor and no authorized generic. Although this discount is measurable, it is substantially smaller than the 50 to 80 percent price decreases observed when multiple independent generics enter the market. Alam and Conti (2025) estimate a structural model confirming this trade-off, showing that banning authorized generics would increase long-run generic entry but raise prices in the initial post-patent-expiry period, for example, the first roughly 6 to 12 months after expiry.

6.4 The Cost of Authorized Generics Timed to the Exclusivity Window

The clearest evidence of the cost of authorized generics comes from Medicaid's drug rebate mechanics. A 2019 US Department of Health and Human Services Office of Inspector General (HHS-OIG) audit found that authorized-generic transactions to secondary manufacturers were being included in brand-drug AMP calculations, reducing the brand's reported AMP and thereby reducing Medicaid rebate amounts (HHS-OIG 2019). Recalculating AMP for nine sampled brand-name drugs in calendar year 2017, representing approximately 45 percent of Medicaid dollars for drugs with authorized generics, HHS-OIG estimated that Medicaid received $595 million less in rebates than it otherwise would have without the authorized generics (HHS-OIG 2019). Because HHS-OIG's sample covered only nine drugs, the total rebate shortfall across all affected brand drugs was likely substantially larger. Congress subsequently closed this loophole through Section 1603 of a bill known as the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019,[43] effective October 1, 2019, requiring separate AMP calculations for brand and authorized-generic products. The $595 million finding is therefore best understood as a historical measure of the fiscal stakes involved in authorized-generic arrangements rather than an estimate of ongoing harm: The AMP blending problem it documents has been legislatively resolved. The cost channel that remains active today is entry deterrence, causing fewer independent generics to enter a market and producing thinner competition and higher prices for a longer time, which are costs that have not been estimated in aggregate for Medicaid or any other payer.

Examining market entries between 2016 and 2023, Drake and colleagues (2025) frame the magnitude of potential harm in spending stakes: The eight identified possible no-AG agreements involve drugs with combined annual pregeneric sales exceeding $17 billion. For one drug in Medicare, Rome, Gunter, and others (2023) use data from 2011 to 2020 to estimate $137–$449 million over a decade in avoidable spending on the Parkinson's disease drug entacapone because of an authorized-generic licensing strategy that substituted for independent competition (see Section 6.2, Case Examples, for more detail). The CBO (2024) estimates that prohibiting reverse-payment settlements broadly, a category including no-AG pledges as well as direct cash payments, licensing agreements, and other tactics, would reduce the federal deficit by $1.5 billion over a 10-year budget window (2025–2034), though other analysts argue this substantially understates the true benefit (Brake et al. 2025). No published study provides a single aggregate estimate of nationwide excess spending attributable to authorized-generic strategy, reflecting both the tactic's dual nature and the difficulty of isolating its effects from concurrent tactics. Key statistics on authorized generics are summarized in figure 14.

FIGURE 14

Key Statistics: Authorized Generics

Selected cost estimates associated with authorized generic strategies

7.54 percentage points

The average decrease in probability of independent generic entry attributable to authorized-generic launch, across US drug markets between 1999 and 2018[a]

$17 billion

The annual pregeneric sales of just eight drugs currently tied up in suspected no-AG agreements based on 2016–23 data, showing the large scale of consumer and payer dollars currently locked behind these delayed-entry no-AG agreements[b]

From 61 to 13 percent

The decrease in authorized-generic launches among first-time generic markets from 2016–18 to 2021–23, as brands increasingly trade away their authorized-generic rights to secure delayed-entry settlements with generics[b]

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Sources: [a] Lu Yao and Mengde Liu, "Strategic Behavior and Entry Deterrence by Branded Drug Firms: The Case of Authorized Generic Drugs," *The European Journal of Health Economics* 26 (4; 2024): 561–75. https://doi.org/10.1007/s10198-024-01721-y. [b] Keith M. Drake, Gered Dunne, Aime Mason, Thomas G. McGuire, and Amie Price, "Trends in Authorized Generic Drug Launches and Their Effects on Competition in Oral-Solid Drug Markets in the US, 2016–23," *Health Affairs* 44 (6; 2025): 745–53, https://doi.org/10.1377/hlthaff.2024.01058.

6.5 Patient Consequences

When an authorized generic is launched during the 180-day exclusivity window for the first generic filer, which occurred in 12.5 percent of drug markets during the period 2021 to 2023, it reduces prices by 13 to 18 percent compared with a prescription drug market in which there is only one independent generic competitor available and no authorized generic (Drake et al. 2025), providing a short-term but measurable improvement for patients in deductible phases or without insurance. However, this benefit is concentrated in a specific, brief window and does not substitute for the 50 to 80 percent reductions that occur with multiple independent generics. The longer-run cost increases associated with the authorized generic strategy arise from entry deterrence against additional independent generics. Drugs for which authorized-generic strategies reduce the pipeline of independent generic challengers have higher prices for longer, with likely consequences for patients' cost-related nonadherence and access, similar to those documented for the other tactics reviewed here. Direct causal evidence linking authorized generic–specific entry deterrence to measurable adverse patient outcomes is unavailable.

> **Combined annual pregeneric sales exceeding $17 billion were tied up across just eight drug markets facing generic entry between 2016 and 2023 under suspected no-AG agreements, demonstrating the large scale of health care spending associated with these delayed-entry barriers (Drake et al. 2025).**

6.6 Reforms

The primary ongoing policy challenge in this area is the use of no-AG pledges as noncash currency in patent settlements, which effectively purchases delayed generic entry. Legislative and regulatory responses fall into two broad categories: strengthening antitrust enforcement against settlement agreements that embed no-AG provisions and directly restricting the timing of authorized-generic launches to eliminate the leverage that enables these settlements.[44]

On the antitrust enforcement side, *FTC v. Actavis* (2013) subjects reverse-payment settlements, including noncash consideration such as no-AG pledges, to rule-of-reason antitrust analysis. Drake and McGuire (2023) demonstrate that declining royalty structures conditioned on authorized-generic launch are analytically equivalent to explicit no-AG clauses and warrant the same scrutiny. Because no-AG pledges are now a primary noncash currency in reverse-payment settlements, the proposed Preserve Access to Affordable Generics and Biosimilars Act (119th Congress), which would presumptively bar reverse-payment agreements, including no-AG pledges, would directly reach authorized-generic-based delay. The CBO (2024) estimates $1.5 billion in 10-year federal savings, which other analysts argue substantially understates the benefit (Brake et al. 2025).

Alternatively or in addition, policymakers can focus on restricting the authorized-generic mechanism itself rather than just the settlement agreements. Bokhari and others (2020) demonstrate that legally restricting when a brand can launch an authorized generic, particularly prohibiting the brand from launching one during the first filer's 180-day exclusivity window, would eliminate the incentive for these pay-for-delay settlements. However, Alam and Conti (2025) caution that a full ban on authorized generics would raise initial postexclusivity prices even as it increases eventual independent entrants, underscoring that any restriction should target the strategic timing of deployment rather than the existence of authorized generics.

6.7 Key Evidence Gaps

The research on authorized generics shares the problem of isolating effects, which is a problem common to the literature addressing all seven tactics reviewed here. Because brand manufacturers frequently use authorized generics at the same time as patent thickets and pay-for-delay settlements, isolating the delay attributable specifically to authorized-generic deterrence is methodologically challenging (Drake et al. 2025; Yao and Liu 2025).

Evidence on the number of generic manufacturers entering within 24 months is underrepresented relative to price evidence and shorter time spans, which constrains what is known about the impact of

authorized generics. Most studies document short-run price erosion during the 180-day exclusivity window but do not systematically track how authorized-generic presence or no-AG settlement terms affect the total count of subsequent independent entrants (FTC 2011; Drake et al. 2025).

No published study has produced a spending estimate across multiple payers that accounts for both the short-run price reduction when an authorized generic competes during the 180-day exclusivity window and the long-run cost of deterred generic entry that follows. Available cost evidence is concentrated in Medicaid (Rome, Gunter, et al. 2023) and invoice price analyses, which are not a realistic reflection of payer cost; Medicare Part D and commercial net price impacts of authorized generics are rarely estimated. Finally, no published research has examined how the Inflation Reduction Act's Medicare drug price negotiation provisions may have changed brand manufacturers' incentives to use authorized generic strategies, nor do existing studies link authorized generic–attributable delay to patient adherence and health outcomes.

Tactic 7: Citizen Petitions

Brand-name drug manufacturers have used the FDA's citizen petition process, a regulatory channel originally designed to allow the public to raise legitimate safety concerns, as a strategic tool to delay approval of pending generic drug applications. With origins in the Administrative Procedure Act of 1946, the citizen petition process was included in FDA regulations after 1966 to allow pathways for public engagement in agency rulemaking (Schmitt and Malecha 2025). Brand companies have exploited this framework by filing specialized citizen petitions under Section 505(q) of the Federal Food, Drug, and Cosmetic Act (added in 2007) requesting that the FDA act against a pending generic application. These petitions generally argue that the FDA should require additional bioequivalence testing or impose other restrictions before approving the generic. The FDA must respond to these petitions within 150 days, diverting agency staff time and attention which might otherwise be used to review the generic application. Although the FDA's 2019 guidance appears to have successfully reduced the number of citizen petitions, the burden has not disappeared. In fact, the FDA is still "concerned about the resources required to respond to 505(q) petitions [i.e., citizen petitions] within the 150-day deadline at the expense of completing the other work of the Agency" (FDA 2023, 6; 2025, 7). Furthermore, because the FDA remains legally obligated to fully review even the most frivolous filings lacking merit, a baseless petition filed close to an expected approval date can effectively hold up generic entry until it is resolved (Carrier and Minniti 2016; Sachs et al. 2022). Meaningful reform likely requires further

expanding the FDA's statutory authority to address petitions that lack merit more directly (Schmitt and Malecha 2025).

7.1 How It Works

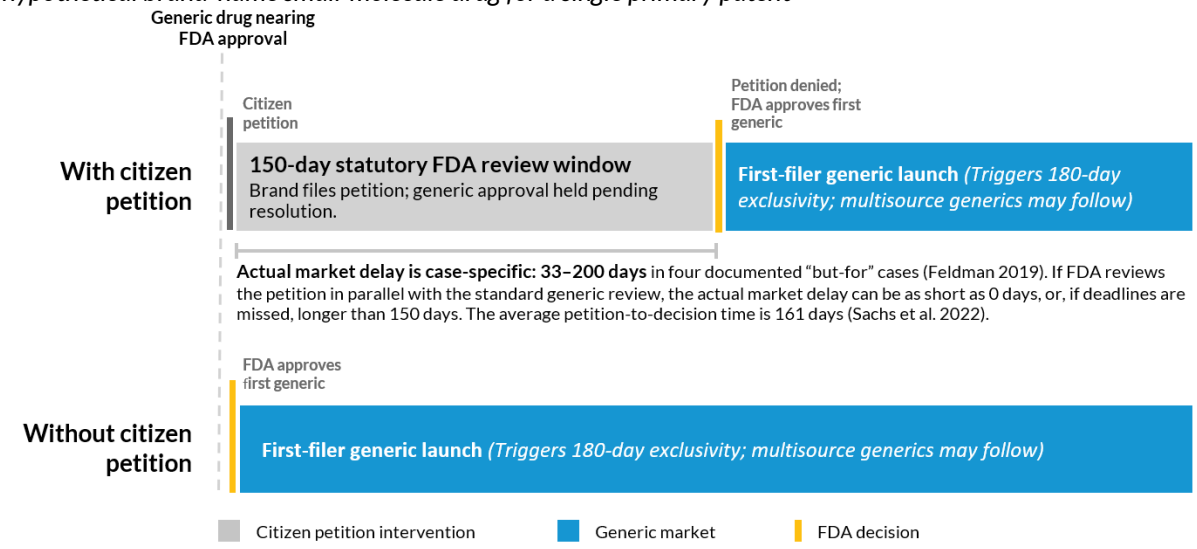
The citizen ("505[q]") petition mechanism exploits a structural asymmetry in the generic approval process. A generic manufacturer that has completed all scientific and regulatory requirements may nonetheless face a delay if a brand firm files a petition raising technical questions that the FDA must evaluate before finalizing generic approval. As figure 15 illustrates, the 150-day statutory review window creates a period in which generic approval can be withheld pending petition resolution, regardless of whether the petition has scientific merit. The actual market delay depends on whether the petition is the binding constraint on approval. If the FDA reviews the petition in parallel with the generic's remaining standard review, the delay can be as short as zero days; however, in documented cases where the petition was the sole obstacle, actual delays ranged from 33 to 200 days (R. Feldman 2019). Brand firms often file these petitions late in the review process (39 percent were filed within six months of patent expiration or the end of exclusivity), and the FDA ultimately denies 92 percent of these petitions, suggesting that the petitions' strategic value lies in the delay itself rather than the scientific content (Carrier and Minniti 2016; Vokinger et al. 2017).

Congress enacted Section 505(q) as part of the Food and Drug Administration Amendments Act of 2007, establishing the 150-day response deadline for these petitions, authorizing summary denial of delay-motivated petitions, and mandating annual reporting to Congress. In 2019, the FDA finalized guidance clarifying factors it considers in identifying delay-motivated petitions, including late timing and the absence of supporting scientific evidence (Schmitt and Malecha 2025). The FDA's 2019 guidance clarified criteria for identifying delay-motivated petitions, and these reforms appear to have contributed to declining petition volume: The FDA received only 4 new petitions in fiscal year 2023, down from an average of 23 per year during 2011–19, and reported no formal approval delays in both fiscal years 2021 and 2023 (Sachs et al. 2022; FDA 2023, 2025). Whether the 2019 FDA guidance has durably curtailed strategic petitioning has not been rigorously evaluated.

FIGURE 15

How Citizen Petition Tactics Delay Generic Drug Approval

The point in the approval timeline when a brand firm files an "11-hour" petition before generic approval for a hypothetical brand-name small-molecule drug for a single primary patent



Macro-lifecycle context: On average, generic drug applications subject to citizen petitions take 1,222 days (3.3 years) to approve versus 979 days (2.7 years) without, resulting in a difference of 243 days across the entire review process, not focusing only on a discrete end-of-process delay (Fahim and Ngorsuraches 2020).

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Sources: Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85 (2007); Michael A. Carrier and Carl Minniti, "Citizen Petitions: Long, Late-Filed, and At-Last Denied," *American University Law Review* 66 (2016): 305–62, https://aulawreview.org/blog/citizen-petitions-long-late-filed-and-at-last-denied/.
For case-specific delays: Robin Feldman, "The Burden on Society From Eleventh-Hour 'Citizen Petitions' Filed to Slow Generic Drugs," *Legal Studies Research* (355, 2019), University of California Hastings Law, https://doi.org/10.2139/ssrn.3404301.
For 161-day average: Rachel Sachs, Marta Wosińska, Richard G. Frank, and Loren Adler, "The FDA Could Do More to Promote Generic Competition: Here's How," White paper, Brookings, 2022, https://www.brookings.edu/articles/the-fda-could-do-more-to-promote-generic-competition-heres-how/.
For macro–life cycle data: Shahariar Mohammed Fahim and Surachat Ngorsuraches, "Did Citizen Petitions Prolong the Number of Approval Days of Generic Drugs?," *Research in Social and Administrative Pharmacy* 16 (9, 2020): 1282–4, https://doi.org/10.1016/j.sapharm.2019.12.015.
Notes: FDA = Food and Drug Administration. Illustrative schematic; timelines are stylized and not to scale. The 150-day window is a statutory regulatory clock, not a guaranteed market delay (which may be shorter if reviews run concurrently). The 243-day life cycle difference reflects total cumulative process time, not a single discrete delay at the end.

7.2 Case Examples

Three cases from the pre-2019 FDA reform period illustrate the range of strategic petition tactics:

1. **Vancocin** (vancomycin) illustrates how repeated citizen petitions can be used to delay generic competition. Shire ViroPharma filed 24 citizen petitions between 2006 and 2012 challenging

the approval of generic versions of oral vancomycin. The FTC brought an enforcement action against this serial petitioning strategy, and the FDA ultimately denied the petitions and approved generic vancomycin. The Vancocin case became the leading example of serial petition abuse and was cited and described in the FDA's 2019 guidance (Sachs et al. 2022; Vokinger et al. 2017).

2. **EpiPen** (epinephrine auto-injector) illustrates how a citizen petition can be used alongside other tactics as part of a broader strategy to delay generic competition. Mylan filed a citizen petition in January 2015 challenging Teva's pending generic EpiPen application, years after it likely knew details of Teva's generic device and just months before Teva's negotiated June 2015 entry date under a prior settlement. Research suggests that the petition was likely part of a broader anticompetitive strategy that also included a delayed-entry settlement and exclusive contracts. During the period of delayed generic competition, EpiPen prices increased more than 400 percent, from approximately $100 for a two-pack in 2009 to approximately $460 in 2016 (Carrier 2019).
3. **Copaxone** (glatiramer acetate) illustrates how citizen petitions can be combined with and interact with other tactics to delay generic competition. Teva filed eight citizen petitions, all ultimately denied, in response to anticipated generic competition for its multiple sclerosis drug, Copaxone. The last petition was denied on the same day that Sandoz's generic glatiramer was approved. At the same time as the citizen petition strategy, Teva pursued a product hop from daily formulation to a three-times-weekly formulation, addressed separately in Tactic 2 (Carrier and Minniti 2016; Sachs et al. 2022).

7.3 Evidence of Delay

Historical empirical evidence consistently shows that citizen petitions are overwhelmingly filed by brand manufacturers, rarely succeed on their merits, and are associated with measurable delays in generic approval. In an analysis of all 124 petitions filed under Section 505(q) from 2011 to 2015, Carrier and Minniti (2016) found that brand firms filed 92 percent of petitions and the FDA denied 92 percent overall. Among petitions filed within six months of patent or exclusivity expiration, the denial rate was 98 percent. Six generic drug applications (ANDAs) were approved on the same day the FDA resolved a relevant petition (meaning the final petition decision and the generic approval occurred on the same calendar day), and 17 were approved within one month of petition resolution, suggesting that the agency may have held approvals until petitions were denied. Sachs and colleagues (2022) extended these findings into the 2016–19 period, identifying 15 cases of same-day petition resolution and

abbreviated application approval, and in 14 of those 15, the petition was denied. Among these same-day resolutions, it took an average of 161 days from petition filing for the FDA to issue a decision, though the analysis does not isolate whether this time frame represents administrative processing, market delay, or both.

The most direct quantitative estimate of delay comes from Fahim and Ngorsuraches (2020), who compared approval time frames for 289 generic drug applications (ANDAs) filed between 2008 and 2014. Generic drug applications subject to at least one citizen petition took an average of 1,222 days to approve, compared with 979 days for those without petitions, a statistically significant difference of approximately 243 days. Even after excluding generic drug applications with imputed filing dates, the difference remained significant, at 191 days. Among the generic drugs studied, 63.7 percent had at least one citizen petition (Fahim and Ngorsuraches 2020).

FDA's own annual reports to Congress provide complementary data. Cumulatively through September 30, 2023, the FDA had resolved 265 petitions: 71 percent were denied, 22 percent were denied/granted in part, 4 percent were granted, and 3 percent were withdrawn. In both fiscal years 2021 and 2023, the FDA reported no formal approval delays attributable to 505(q) petitions, and petition counts have trended downward. However, the agency's narrow statutory definition of "delay" may not capture more subtle approval frictions, and FDA officials have acknowledged that petition review still diverts priority resources from other work (FDA 2023, 2025).

While the FDA's 2019 guidance successfully drove down citizen petition volumes, disruption continues behind closed doors, leaving the FDA "concerned about the resources required to respond to 505(q) petitions within the 150-day deadline at the expense of completing the other work of the Agency" (FDA 2023, 6; 2025, 7).

7.4 The Cost of Citizen Petitions

As with other tactics considered above, causal cost estimates attributable specifically to citizen petitions are limited because petitions are frequently pursued with other anticompetitive tactics. The most rigorous monetized estimate comes from R. Feldman (2019), who used a conservative "but-for" methodology to identify petitions that were highly likely the sole remaining obstacle to generic entry. Starting with 249 generic-related citizen petitions filed between 2000 and 2012, Feldman narrowed the list to four that met strict criteria: each was filed within six months of approval, was denied, resulted in generic approval within one business day of denial, and led to generic market entry within one week. The four drugs affected were felodipine (Plendil), ramipril (Altace), quetiapine (Seroquel), and tizanidine

(Zanaflex). Petitions delayed these four drugs' generic entry by a combined 521 days, at an estimated financial cost to society of $1.9 billion, or approximately $3.6 million per day, and the estimated cost to government insurance programs was approximately $782 million (R. Feldman 2019). These figures are likely to be biased downward because they exclude petitions that contributed to delay as one element of a broader, multitactic strategy. Because the underlying data predate the FDA's 2019 guidance on delay-motivated petitions, these estimates reflect the cost of the tactic during a period when it was more widely used. Whether similar costs are persisting under the current regulatory framework remains unknown, as it has not been evaluated.

Supporting evidence from individual cases suggests that costs may be even higher when citizen petitions are combined with other tactics. In the buprenorphine-naloxone (Suboxone) market, where citizen petitions were part of a strategy that also included product hopping and REMS abuses, Haffajee and Frank (2019) estimated that stronger generic competition could lower prices by about 37 percent, implying approximately $703 million in annual savings. For EpiPen, each day of petition-caused delay for a product with approximately $1 billion in annual revenue could represent roughly $3 million in preserved brand revenue (Carrier 2019). Selected historical estimates for citizen petitions are summarized in figure 16.

FIGURE 16

Key Statistics: Selected Historical Estimates Associated with Citizen Petition Tactics

Selected historical estimates associated with citizen petition tactics

~8 months

Additional approval time for generic drugs with citizen petitions versus those without, 2008–14[a]

$1.9 billion

Estimated societal cost of four "but-for" citizen petition delays filed between 2000 and 2012, which accumulated 521 total days of generic market exclusion; this total includes $782 million in excess costs imposed directly on government insurance programs[b]

92 percent

FDA denial rate for brand-filed 505(q) petitions, 2011–15; petitions filed within six months of exclusivity expiration were denied 98 percent of the time[c]

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Sources: [a] Shahariar Mohammed Fahim and Surachat Ngorsuraches, "Did Citizen Petitions Prolong the Number of Approval Days of Generic Drugs?," *Research in Social and Administrative Pharmacy* 16 (9; 2020): 1282–4. https://doi.org/10.1016/j.sapharm.2019.12.015.

[b] Robin Feldman, "The Burden on Society from Eleventh-Hour 'Citizen Petitions' Filed to Slow Generic Drugs," *Legal Studies Research* (355; 2019). University of California Hastings Law, https://doi.org/10.2139/ssrn.3404301.

[c] Michael A. Carrier and Carl Minniti, "Citizen Petitions: Long, Late-Filed, and At-Last Denied," *American University Law Review* 66 (2016): 305–62, https://aulawreview.org/blog/citizen-petitions-long-late-filed-and-at-last-denied/.

7.5 Patient Consequences

Direct causal evidence linking generic launch delays from citizen petitions specifically to adverse health outcomes has not been established and remains an area for future research. However, the financial mechanism is straightforward. Petitions that delay generic entry extend the period of brand-only pricing, and each additional day without generic competition and brand-only availability increases costs for patients, insurers, and public programs. R. Feldman (2019) notes that the $1.9 billion cost estimate, which isolates four "but-for" petition delays accumulating 521 total days of market exclusion for four drugs between 2000 and 2012, excludes public health harms because of patients' inability to afford treatment during the delay. In the buprenorphine-naloxone market, where a strategic citizen petition was used in addition to formulation changes to delay generic competition, the resulting extended period of brand-only pricing may have reduced access to this life-saving medication treatment for opioid use disorder, potentially exacerbating epidemic overdose mortality (Haffajee and Frank 2019). For EpiPen, where an eleventh-hour citizen petition was deployed to hold off generic entry, families faced subsequent monopoly price increases that rendered a potentially lifesaving product unaffordable without manufacturer coupons (Carrier 2019). More broadly, because generic entry can reduce out-of-pocket costs by half or more, tactics that preserve brand-only pricing may contribute to well-documented links between higher patient cost exposure and patients' cost-related nonadherence (Vokinger et al. 2017).

7.6 Reforms

As described above, the FDA's 2019 guidance clarified criteria for identifying delay-motivated petitions, an action that contributed to declining petition volume (Sachs et al. 2022; FDA 2023, 2025). However, FDA officials have acknowledged that their existing authority related to petitions is still insufficient. The agency cannot summarily deny a petition without first evaluating its scientific merits, effectively requiring full review before dismissal (Sachs et al. 2022). Proposed reforms address both the filing stage, by seeking to deter frivolous petitions, and the review and enforcement stage, by improving transparency and accountability after petitions are filed. Sachs and others (2022) recommend stronger FDA dismissal authority, financial penalties for delay-motivated filings, and a requirement that the FDA report which specific generic applications are delayed, enabling enforcement by state attorneys general and private litigants. Schmitt and Malecha (2025) propose a centralized petition status portal, written explanations when petition responses coincide with related agency actions, and administrative review mechanisms modeled on the US Patent and Trademark Office's Patent Trial and Appeal Board. The board is an expert body that conducts expedited challenges to questionable patents outside the federal

courts. Applied to citizen petitions, a comparable FDA panel could more quickly and efficiently determine whether a petition has scientific merit, rather than requiring the agency to conduct a full scientific review of every filing before it can be dismissed.

While recent guidelines have successfully curbed petition volumes, the FDA remains legally trapped into fully reviewing even the most frivolous filings. Meaningful reform requires immediate summary dismissal authority at filing to block bad-faith claims, alongside expedited expert panels to fast-track unavoidable scientific reviews (Schmitt and Malecha 2025).

7.7 Key Evidence Gaps

The most significant limitation of the citizen petition literature for informing future policy is that the strongest empirical evidence, including the most comprehensive empirical studies (Carrier and Minniti 2016; Fahim and Ngorsuraches 2020) and cost estimates (R. Feldman 2019) predate the FDA's 2019 guidance clarifying the criteria for identifying delay-motivated petitions. As mentioned above, petition volume has declined sharply since that point. The FDA received only four new petitions in fiscal year 2023, down from an average of 23 per year during 2011–19, and the agency reported no formal approval delays attributable to citizen petitions in both fiscal years 2021 and 2023 (Sachs et al. 2022; FDA 2023, 2025). Whether this decline reflects a durable deterrent effect, a shift to less visible strategies, or other market factors is unclear and requires rigorous evaluation.

Within the pre-2019 evidence base, additional methodological limitations weaken the strength of available estimates. Because citizen petitions frequently co-occur with patent litigation, pay-for-delay settlements, and product hopping, isolating the petition's independent causal contribution to delayed entry and excess spending is difficult. R. Feldman's (2019) "but-for" methodology addresses this limitation conservatively by selecting only petitions that appeared to be the final obstacle to generic entry, but this approach necessarily understates total petition-related costs. Similarly, the 243-day estimate of delay related to citizen petitions (Fahim and Ngorsuraches 2020) relies on a bivariate comparison that does not adjust for drug, firm, or market confounders, and many generic drug filing dates are imputed. More rigorous causal designs such as those using instrumental variables or regression discontinuity have not yet been applied to petition-specific delay. Finally, no study in this literature estimates the effect of petition-specific delay on patients' out-of-pocket spending, patients' cost-related nonadherence, or health outcomes.

Synthesis: A Map of Reform Evidence and Recommendations

Although no single policy would likely counter all seven anticompetitive tactics, several reforms could address multiple tactics, as these strategies often rely on the same underlying mechanisms. Table 1 consolidates the reform options identified across Tactics 1 through 7 into eight reform domains, grouping recommendations by the underlying market barrier they address rather than by individual tactic. For each recommendation, it identifies the tactic or tactics addressed and its current policy status, such as whether it has been enacted by a state, proposed in federal legislation, or established through enforcement or the courts. Five broader patterns and themes emerge.

First, the reforms fall into two broad categories, which are measures that enforce or extend existing law, and measures that require new statutory authority. Several enforcement actions have already had measurable effects, including the FTC's challenges to improper Orange Book patent listings, antitrust scrutiny of reverse-payment settlements following the Supreme Court's 2013 *FTC v. Actavis* decision, the FDA's 2019 citizen petition guidance, and litigation under the CREATES Act. But enforcement generally proceeds case by case, requires sustained agency resources, and leaves room for firms to change strategies in response. More durable, systemwide changes generally require legislation.

Second, because many of the tactics work through the same mechanisms, some reforms could address several at once. For example, patent settlements are the shared vehicle for pay-for-delay (Tactic 3), exclusivity parking (Tactic 5), and no-AG pledges (Tactic 6). Thus, a legal presumption against exclusionary settlements, combined with automatic loss of first-filer exclusivity when a settlement delays entry, could therefore reach all three tactics. Also, secondary and device patents are important components of patent thickets (Tactic 1), product hopping (Tactic 2), and authorized-generic dominance in device markets (Tactic 6) Improving patent quality, which would require action by the US Patent and Trademark Office and the courts rather than the FDA, together with congressional action allowing the FDA to approve generic drug-device combinations based on functional equivalence, could address several of these barriers. Finally, new administrative authority from Congress could allow the FDA to resolve both sample access disputes (Tactic 4) and nonmeritorious citizen petitions (Tactic 7) directly through rulemaking, reducing avenues for lengthy litigation.

Third, the evidence repeatedly shows that rules aimed at individual anticompetitive tactics can be circumvented as firms shift to another strategy.[45] This suggests that reforms are more effective as complements rather than substitutes, particularly when they target shared underlying mechanisms of delay.

Fourth, the evidence on exclusivity parking and authorized generics highlights an important tradeoff. The 180-day first-filer reward that several of these anticompetitive tactics leverage is also widely regarded as an important incentive for generic manufacturers to challenge patents in the first place. This suggests that reforms need to curb its strategic misuse without weakening it substantially (Van de Wiele et al. 2021; Sertkaya et al. 2025; Alam and Conti 2025). However, as discussed above, this reform caution has been questioned. A recent analysis argues that the first-filer reward may be less central to generic manufacturers' decisions to challenge patents and that, for several drug categories, the 180-day period delays later generic entrants more than it spurs challenges. If so, there may be room to narrow the exclusivity period without substantially reducing generic patent challenges (Drake 2026).

Fifth, greater transparency could strengthen several of these reforms at relatively low cost. Drug-specific disclosure of settlements and FDA reporting on the specific generic applications delayed by citizen petitions or other barriers could give enforcement capacity to state attorneys general and more information to private litigants, even without requiring any new substantive prohibitions (R. Feldman 2022; Sachs et al. 2022; Schmitt and Malecha 2025).

TABLE 1

A Map of Potential Legislative Reforms and Recommendations

Potential Legislative Action	Tactic(s) Addressed	Status and Notes
A. Pass legislation to improve patent quality and limit patent quantity before patents are issued		
Through legislation, direct the Patent and Trademark Office to raise examination standards and make weak secondary patents easier to challenge before they are issued. The Supreme Court could also reinforce this approach by applying the nonobviousness requirement more stringently to secondary patents and clarifying that routine reformulations and minor modifications generally do not warrant new patent protection.[a]	(1) patent thickets (also reduces the foundation for (2) product hopping and (6) authorized generics)	Proposed / judicial[b,c]
Through legislation, adopt a portfolio-level "one-and-done" cap that limits each drug to a fixed number of patents or a fixed total period of protection. Because the limit would apply to the full patent portfolio, manufacturers could not reserve weaker patents for later litigation, and patents beyond the cap would not be granted.[d] Identified as a particularly promising structural fix.	(1) patent thickets	Proposed; a one-and-done–style patent bill passed the Senate in 2023 but did not reach the House floor[e]
Cap the number of patents a brand may assert against a generic in court. This could reduce litigation-based delay but would have limited effect on its own because manufacturers could choose to litigate their strongest, latest-expiring patents.	(1) patent thickets	Proposed; CBO scores roughly $1.8 billion in federal savings over 10 years;[f] caution noted[c]

Potential Legislative Action	Tactic(s) Addressed	Status and Notes
B. Limit litigation-based blocking and improper patent listings		
Limit the automatic 30-month hold on generic approval to one stay per drug and restrict later-filed continuation patents from triggering additional stays as generic entry approaches.	(1) patent thickets	Proposed[b,c]
Have the FTC, acting under its own existing authority, continue and expand challenges to improper Orange Book patent listings, including device-only listings for inhalers and injector pens, and preserve resulting delistings. This would create an ongoing test of whether removing barrier patents speeds generic entry.	(1) patent thickets, (2) product hopping, (6) authorized generics in device markets	Enforcement, ongoing[g,h]
C. Give the FDA more authority to address barriers directly rather than case by case		
Congress can grant the FDA authority to require brand manufacturers to sell samples to generic developers when its safety review shows no basis for refusal, closing the gap the CREATES Act leaves open by relying on private litigation.	(4) sample denial/restricted distribution	Proposed; builds on the enacted CREATES Act[i,j,k]
Give the FDA authority to dismiss delay-motivated citizen petitions without conducting a full scientific review, impose financial penalties for frivolous petition filings, and create an expert review panel (modeled on the Patent Trial and Appeal Board) to review petitions more quickly.	(7) citizen petitions	Proposed; extends Food and Drug Administration Amendments Act of 2007 § 505(q) and the FDA's 2019 guidance[l,m]
Authorize the FDA to approve generic drug-device combinations such as inhalers on the basis of functional equivalence rather than on identical physical design.	(1) patent thickets, (2) product hopping, (6) authorized generics in device markets	Proposed[n]
D. Apply a presumption of illegality to exclusionary patent settlements		
Enact through legislation a presumption of illegality for reverse-payment settlements, broadly defining payment to include any transfer of value to a generic challenger, including no-authorized-generic (no-AG) pledges and other noncash compensation (Preserve Access to Affordable Generics and Biosimilars Act ,119th Congress).	(3) pay-for-delay settlements, (6) authorized generics	Proposed; would strengthen current rule-of-reason review under *FTC v. Actavis*[o] CBO scores roughly $1.5B in federal savings over 10 years;[f] a commissioned actuarial analysis argues this understates the benefit because of grandfathering.[p,q]
Apply the same standard to settlement structures such as reduced royalties in exchange for the brand withholding an authorized generic.	(3) pay-for-delay settlements, (6) authorized generics	Proposed; supported by analytical modeling[r]
Automatically forfeit the first filer's 180-day exclusivity period if a settlement delays generic entry.	(5) parking of 180-day exclusivity, (3) pay-for-delay settlements	Proposed; would extend the forfeiture conditions in the Medicare Modernization Act of 2003[k,l]

Potential Legislative Action	Tactic(s) Addressed	Status and Notes
At the state level, presume settlements involving explicit or implicit transfer of "anything of value" to a generic manufacturer are unlawful unless proven otherwise (modeled on California AB 824).	(3) pay-for-delay settlements, (5) parking of 180-day exclusivity	Enacted state law;[s] effects not yet evaluated[t]
E. Limit authorized generics during the 180-day exclusivity period		
Prohibit a brand manufacturer from launching an authorized generic during the first filer's 180-day exclusivity window, eliminating a bargaining tool used in no-AG settlements. Limit restrictions to the 180-day exclusivity period rather than banning authorized generics altogether, because a full ban would raise prices immediately after generic entry even if it leads to more independent generic competition later.	(6) authorized generics	Proposed[u,v]
F. Expand transparency to enable distributed enforcement		
Require public, drug-specific disclosure of patent settlements, which are currently reported only in aggregate, and require FDA to identify which generic applications are being delayed, so that state attorneys general and private litigants can challenge anticompetitive conduct.	(3) pay-for-delay settlements, (7) citizen petitions	Proposed[w,l]
Create a centralized database for citizen petition status and require the FDA to explain when petition decisions coincide with related agency actions such as approval of a generic.	(7) citizen petitions	Proposed[m]
G. Deploy market surveillance and payer tools		
Make hard- and soft-product hopping subject to FTC antitrust enforcement, reducing the evidentiary burden that has limited soft-switch cases under current law (Drug Competition Enhancement Act of 2025, S. 1040, 119th Congress).	(2) product hopping	Proposed[x,y]
Step up an early-warning surveillance system using public FDA data on formulation approvals and product discontinuations to identify potential product hops before market share shifts to the new product.	(2) product hopping	Proposed; the surveillance tool has been demonstrated using historical data[z]
Use formulary design and prescribing guidance to encourage prescribers to focus on generics when available.	(2) product hopping	Payer and health-system action[y,aa]
H. Preserve the first-filer launch incentive (a cross-cutting guardrail)		
When reforming exclusivity parking or restricting authorized generics, preserve first generic filer's incentives while limiting this anticompetitive conduct. Evidence is mixed on how important that reward is, so reforms can be targeted and their effects can be monitored.	(5) parking of 180-day exclusivity, (6) authorized generics	Design caution; contested[bb,cc,dd,ee]

Source: Authors' analysis and sources listed in table notes below.

Note: FDA = Food and Drug Administration; FTC = Federal Trade Commission; no-AG = no-authorized generic. Tactics referenced by number: (1) patent thickets, (2) product hopping, (3) pay-for-delay settlements, (4) sample denial and restricted distribution, (5) parking of 180-day exclusivity, (6) authorized generics, (7) citizen petitions. The Urban Institute and its employees

do not take positions or endorse legislation. The recommendations presented here reflect the authors' evidence-based assessments and should not be attributed to the Urban Institute, its trustees, or its funders.

[a] Under current law, an invention must be "new" and nonobvious to qualify for a patent, and this recommendation works by enforcing that existing standard more rigorously so that weak secondary patents are harder to obtain or defend. A pending bill would cut against that approach: The Patent Eligibility Restoration Act, introduced in Congress (S. 1546 and H.R. 3152, 119th Congress) mainly to clarify patent eligibility in contested fields such as biotechnology, diagnostics, and software, would, as drafted, remove the word "new" from Section 101 of the Patent Act and replace the courts' long-standing exceptions to patentability with a narrower statutory list. The Patent Eligibility Restoration Act is not an alternative to the reform recommended here but a separate measure, whose effect, if enacted as written, would lower the patentability bar this recommendation depends on, meaning that the weak secondary patents this reform aims to keep off the books, and to make easier to invalidate, would instead become easier to obtain and harder to challenge, so enacting the Patent Eligibility Restoration Act while pursuing this recommendation would push patent quality in opposite directions at once. See Robin Feldman, "Is Newness Necessary for Patenting?," *SSRN* (2026), https://doi.org/10.2139/ssrn.6178761.

[b] William B. Feldman, "Patent Thickets and Product Hops: Challenges and Opportunities for Legislative Reform," *Journal of Law, Medicine & Ethics* 53 (1; 2025): 158–63, https://doi.org/10.1017/jme.2025.54; and CBO (Congressional Budget Office), "Alternative Approaches to Reducing Prescription Drug Prices," October 2024.

[c] Robin Feldman, Ramy Alsaffar, Tanziuzzaman Sakib, Gideon Schor, Vaughn Goehrig, and Beatrice Goddu, "The Power of Secondary Patents: Measuring the Effect of Key Secondary Patent Types on Granted Protection Period and Generic Entry Time," *Seton Hall Law Review* 56 (5; 2026): 1, https://doi.org/https://doi.org/10.60095/GCAL6900.

[d] By contrast, a rule that only capped how many patents a brand could assert in court in the initial litigation would leave the remaining patents in existence and listed in the Orange Book, where each must still be addressed by generic challengers and continues to confront future entrants.

[e] Robin Feldman, "Is Newness Necessary for Patenting?."

[f] CBO, "Alternative Approaches to Reducing Prescription Drug Prices."

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[k] Michael A. Carrier, "Amicus Curiae Brief of 69 Professors of Law, Economics, Business, and Medicine in Support of Plaintiff," (March 28, 2024), District of Maryland court brief in *Government Employees Health Ass'n v. Actelion Pharmaceuticals Ltd., et al.*, SSRN, https://ssrn.com/abstract=4784604.

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[o] *Federal Trade Commission v. Actavis, Inc.*, 570 US 136 (2013).

[p] Ryan Brake, Rodelle Williams, and Cathi Callahan, "Pay for Delay: Historic and Future Costs of Delayed Generic Entry," Actuarial Research Corporation, 2025.

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[s] California State Legislature, AB 824, October 7, 2019.
[t] Kevin Wallentine, "Shifting the Burden on Pay-for-Delay Challenges: Analyzing AB 824's Effects on Reverse Payment Settlements and Drug Costs Developments in the Law," *Loyola of Los Angeles Law Review* 54 (1; 2020).
[u] Farasat A. S. Bokhari, Franco Mariuzzo, and Arnold Polanski, "Entry Limiting Agreements: First-Mover Advantage, Authorized Generics, and Pay-for-Delay Deals," *Journal of Economics & Management Strategy* 29 (3; 2020): 516–42, https://doi.org/10.1111/jems.12351.
[v] Rubaiyat Alam and Rena M. Conti, "Entry Delays and Fighting Brands: Evidence from Generics and Authorized Generics," *Journal of European Economic Association*, February 2025.
[w] Robin Feldman, "The Price Tag of 'Pay-for-Delay,'" *Columbia Science and Technology Law Review* 23 (1; 2022).
[x] "Grassley, Cornyn, Blumenthal, Durbin Introduce Bill to Spur Drug Pricing Competition," US Senate Committee on the Judiciary, March 17, 2025.
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[cc] Victor L. Van de Wiele, Jonathan J. Darrow, and Aaron S. Kesselheim, "No Parking Here: A Review of Generic Drug 180-Day Exclusivity and Recent Reform Proposals," *Yale Journal of Health Policy, Law, and Ethics* 20 (1; 2021).
[dd] Kajal Gandhi, Ramesh Joga, M. Sowndharya, et al., "Unlocking Generic Market Access: A Retrospective Analysis of USFDA Paragraph IV Filings (2020–2024)," *Therapeutic Innovation & Regulatory Science* 59 (6; 2025): 1380–93, https://doi.org/10.1007/s43441-025-00831-w.
[ee] Keith M. Drake, "Rethinking the Value of the 180-Day Exclusivity Period for Generic Drugs," *Health Affairs Forefront* (blog), June 15, 2026, https://www.healthaffairs.org/do/10.1377/forefront.20260610.346814/full/.

A Cross-Cutting Research Agenda

Across the seven tactics, the evidence gaps point to several common research priorities. The most consequential gap is causal attribution. Because these tactics are typically layered on the same product, few studies isolate any single tactic's independent effect on the timing of generic market entry or on spending, and much of the literature remains descriptive rather than causal. Closely related is the lack of reliable population-level, multi-payer cost estimates. The strongest estimates are based on relatively small sets of selected drugs, several widely cited national estimates come from industry-commissioned studies, and some of the leading benchmarks estimate the effects of proposed legislation rather than observed outcomes. A third recurring gap is the difficulty of observing deterred competition, competition that never occurs, such as thickets that eliminate a challenge, sample denials that stop generic development before any application is filed, and settlements that suppress a generic launch. Because these situations leave no observable trace in FDA data, observed and measured delays likely

understate the true effect of these tactics. The future research agenda also includes two more priorities, which are to systematically track the number of independent generic entrants at 12 and 24 months rather than short-run price erosion alone, and to evaluate whether recent reforms (e.g., the CREATES Act, the FDA's 2019 citizen petition guidance, and Inflation Reduction Act price negotiation) have reduced the use of these tactics or just shifted them into less observable forms. Answering these questions would be difficult but methodologically feasible.

A second set of research evidence gaps is conceptually distinct and considerably harder to address. These relate to measuring how delayed competition impacts patients' access to medicines and, in turn, patient health. Estimating this effect requires a more complex counterfactual because the affected drugs are often new and subject to coverage restrictions related to both their novelty and their high launch prices. The relevant question is therefore not only how much more patients paid, but also which patients were unable to obtain treatment, went untreated, and with what health consequences.

Conclusion

Timely generic competition is among the most reliable mechanisms the US has for lowering prescription drug prices, yet the seven anticompetitive tactics examined here show how readily that competition can be delayed. The financial stakes help explain why these strategies persist. Once several independent generics compete, the price of a small-molecule drug commonly falls by 50 to 80 percent, so each month of delay extends the period in which brand-level prices remain in place (Drake et al. 2025). Individually, most of these practices are lawful, and many appear to be somewhat modest in cost when viewed in isolation. However, together they form a layered system that can postpone competition for months or years and add billions in avoidable, excess spending for patients, employers, and public programs. The evidence also shows how interconnected the tactics are. Patent settlements, secondary patents, and gaps in regulatory authority recur across the strategies examined here, helping to explain why piecemeal responses tend to shift anticompetitive conduct rather than stop it. Progress is possible and, in places, already visible: Enforcement against improper patent listings and frivolous citizen petitions has produced measurable gains. But these wins are case-by-case and reversible. Durable relief will require legislation that reaches the shared mechanisms beneath the tactics. Two priorities stand out. First, policymakers can combine enforcement with structural reforms while preserving incentives for generic manufacturers to challenge patents. Second, researchers can address the field's major evidence gaps by producing rigorous and current evidence that accounts for the incremental reforms in recent years and measures how each tactic affects prices, costs, access to medicines, and patient health.

Appendix A. Methods

This rapid review synthesizes evidence from peer-reviewed health economics and policy studies, secondary legal and regulatory analyses, and high-quality gray literature. The review follows best-practice rapid review guidance emphasizing focus, transparency, and reproducibility (Haby et al. 2016, 2024) and is restricted to small-molecule drugs in the US market.

Search Strategy

This analysis identified literature through a three-platform sequential search conducted between January and March 2025. The primary search was restricted to publications from 2019 to the present to ensure the currency of market and policy data; however, some foundational or key historical research or reports published before this date were included. First, Elicit (an AI-assisted research tool querying the Semantic Scholar database of more than 200 million papers) was used to execute seven structured natural-language queries, one per tactic, focusing on five outcome domains: time to generic entry, number of entrants, price and volume erosion, excess spending, and empirical effects of legal or policy reforms. For each query, a minimum of the top 20 semantically ranked results were screened. Second, Google Scholar Boolean searches (top 50 results per tactic) captured gray literature, legal scholarship, and government reports not indexed by the Semantic Scholar platform. Third, Perplexity was used for targeted retrieval of government and gray literature from sources including the CBO, GAO, FTC, US Department of Health and Human Services Assistant Secretary for Planning and Evaluation, and similar agencies to address gaps identified after the first two searches. Finally, the reference lists of key papers were also screened.

Study Selection and Quality Assessment

Studies were eligible if they addressed small-molecule drugs in the US market and reported on at least one outcome domain. Titles and abstracts were screened for inclusion. Data were extracted using a standardized template. Study quality was assessed using a six-item checklist adapted from the *JBI Manual for Evidence Synthesis* (Aromataris et al. 2024) and tailored to the mixed methods of this literature. Four study quality criteria were designated as critical: (1) clear research question or policy objective, (2) appropriate data source or evidence base, (3) transparent methodology, and (4) conclusions supported by the analysis. Studies meeting all four critical criteria were rated as *high quality*, while those failing or remaining unclear on one or more critical items were categorized as *moderate* or *low quality* but were not automatically excluded. Where relevant, supplementary information, including

references to subsequent generic market entry occurring after the publication of included studies and citations to applicable statutes and proposed legislation, was incorporated to ensure the currency and comprehensiveness of the evidence base.

Throughout the synthesis, cost figures are reported with their payer scope and time frame because the underlying studies measure different things. Some estimate spending for a single program or payer (for example, Medicare Part D, the federal and state shares of Medicaid and CHIP, or commercial and employer-sponsored insurance), others capture patient out-of-pocket spending, and still others report net federal budgetary effects that net out offsetting changes such as tax revenue. A single-payer figure for one tactic is therefore not comparable to an all-payer or net-federal figure for another, and the text notes the relevant scope alongside each estimate.

Studies Included and Synthesis Approach

The initial review identified 196 unique records across all seven searches; 150 were included in the evidence synthesis, with 46 excluded primarily for focusing exclusively on biologics, reporting no US market outcomes, or lacking sufficient methodological transparency. Along with these initial studies, supplementary references were incorporated where relevant, including citations to information about subsequent generic market entry, applicable statutes, and proposed legislation. Across the seven tactics, the numbers of included studies were 46 for patent thickets, 28 for product hopping, 35 for pay-for-delay, 23 for sample denial pathways, 12 for parking of 180-day exclusivity, 23 for authorized generics, and 14 for citizen petitions; studies may appear in more than one tactic-specific synthesis. Supplementary references entered the synthesis where relevant; in particular, additional sources were identified through citation chaining from the included sources and through targeted searches designed to capture recent legislative developments and institutional policy updates. Findings are presented as narrative synthesis, consistent with rapid review norms. For each tactic, the review summarizes (1) the mechanism of delay; (2) quantitative estimates of entry timing, entrant counts, and price or volume effects; (3) consolidated cost estimates with methodological caveats; and (4) evidence on patient out-of-pocket exposure and cost-related nonadherence.

AI assistance was also used as a drafting and revision aid, including organizing author-supplied findings, improving grammar, clarity, and readability, and assisting with citation checking. AI tools were not used to generate analytic conclusions or to interpret the evidence; those judgments were made by the authors. The authors reviewed, edited, and verified all AI-assisted text against the primary sources, confirming that every quantitative estimate and characterization traces to the cited source.

Notes

[1] Authors' calculation based on Tichy and others' (2026) estimate of $915.2 billion in total US prescription drug spending in 2025 and Centers for Medicare & Medicaid Services projections of approximately $5.6 trillion in total national health spending in 2025 ("National Health Expenditure (NHE) Fact Sheet," Centers for Medicare & Medicaid Services, June 24, 2026, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet).

[2] Association for Accessible Medicines, "2025 Generic and Biosimilar Medicines Savings Report Highlights Value and Vulnerability," AAM blog, September 5, 2025, https://accessiblemeds.org/resources/blog/2025-generic-and-biosimilar-medicines-savings-report-highlights-value-and-vulnerability/.

[3] Keith M. Drake, "Rethinking the Value of the 180-Day Exclusivity Period for Generic Drugs," *Forefront* (blog), Health Affairs, June 15, 2026, https://www.healthaffairs.org/do/10.1377/forefront.20260610.346814/full/.

[4] Drake, "Rethinking the Value."

[5] The cost estimates cited here isolate spending attributable to delayed generic entry and extended market exclusivity driven by manufacturer patent and litigation strategies, and do not incorporate separate pricing or formulary dynamics introduced by pharmacy benefit managers or other factors.

[6] The term "patent thicket" is used throughout this review to refer to the accumulation of secondary and tertiary patents on features beyond a drug's primary active ingredient. The broader practice of extending exclusivity through such secondary patenting is commonly called "evergreening" in the academic literature (and "life cycle management" in industry usage). Following R. Feldman and colleagues (2026), this review treats evergreening as the umbrella practice and patent thicketing as one of its two principal anticompetitive strategies, the other being product hopping (Tactic 2). Where a finer distinction is drawn, "evergreening" tends to emphasize the manufacturer's strategic intent to sequentially file such patents to extend exclusivity, while "patent thicket" tends to emphasize the resulting structural condition of overlapping patent protections that generic entrants must navigate. Because the sources cited here do not apply these labels consistently, we use "patent thicket" for the thicketing strategy specifically and reserve "evergreening" for the overall practice, rather than treating the two as synonyms.

[7] The increase has been driven largely by "secondary" and continuation patents rather than patents on the active ingredient (Darrow and Mai 2022); the broader intensification of post-approval patenting has been linked in part to incentives created by Medicare Part D beginning in 2006 (Sanzenbacher and Wettstein 2019). Specifically, by heavily subsidizing prescription drug costs for seniors, Part D created a substantial positive demand shock that increased the financial value of maintaining long-term market monopolies, thereby incentivizing manufacturers to secure secondary patents on high-volume medications.

[8] "Brief of Arnold Ventures, The National Center for Health Research, and Certain Medical Doctors as Amicus Curiae in Support of Respondents." Amgen, Inc., et al. v. Sanofi, et al., 598 U.S. 594 (2023).

[9] "Standard patent litigation and regulatory stays" refers to the Paragraph IV certification process under the Hatch-Waxman Act, in which a generic manufacturer notifies the FDA of its intent to market a generic copy of a brand-name drug by challenging the validity or applicability of listed patents. If the brand-name manufacturer responds with patent litigation within 45 days, a 30-month regulatory stay is triggered that bars the FDA from approving the generic application until the stay expires or litigation is resolved. This process and its typical timing are described in Kannappan and others (2021).

[10] A thicket blocks generic approval by forcing competitors to litigate numerous patents and navigate multiple 30-month stays while the brand continues selling the original product. Product hopping, conversely, suppresses generic uptake after approval by aggressively shifting the market onto a reformulated version prior to generic entry.

[11] "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize," FDA (US Food and Drug Administration), April 1, 2026, https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[12] Derived from Hong and colleagues' (2025) four small-molecule case studies, this range reflects a conservative floor for market exclusivity extensions. The study measured total delay without isolating patent thickets from other nonpatent factors and excluded drug-device combinations (some of which are included in this report) as well as biologics (which are excluded from this report), both of which routinely experience longer, multiyear generic entry delays related to patents.

[13] Dave and others (2020) is a peer-reviewed *Health Affairs* study supported by mixed funding. The authors received industry grants (from, e.g., PCMA Foundation) alongside independent funding (from, e.g., Arnold Ventures and Harvard-MIT Center for Regulatory Science).

[14] Appearing in eTable 11 of Hong and others' (2025) online supplement, the three-year, per-drug national figures show excess spending for imatinib of $1.40 billion (95 percent confidence interval, $1.14–1.67 billion), comprising $549 million in commercial plans (95 percent confidence interval, $405–707 million) and $854 million in Medicare Part D (95 percent confidence interval, $639–1,064 million); the main text reports only the two-year per-drug breakdown. Excess spending is measured over the extended exclusivity period plus the three years following generic entry (Supplement eMethods 4) and is expressed in 2022 dollars. Imatinib's weak generic competition is visible in two ways: Monthly spending fell only to 93 percent (commercial) and 85 percent (Medicare) of pre-entry levels at generic entry, and incremental excess spending stayed high in years two and three ($145 million and $129 million, respectively, in commercial plans; $255 million and $254 million in Medicare), whereas for celecoxib it collapsed after the first year ($66 million and $54 million in commercial plans in year one and two, respectively; $52 million and $8 million in Medicare) (Supplement eTable 12) (Hong et al. 2025).

[15] *Federal Trade Commission v. Actavis, Inc.*, 570 U.S. 136 (2013).

[16] Aiseosa Osaghae, "Recent Developments in Orange Book Litigation: How Patent Disputes Shape Prescription Drug Affordability," O'Neill Institute for National and Global Health Law, November 6, 2025, https://oneill.law.georgetown.edu/recent-developments-in-orange-book-litigation-how-patent-disputes-shape-prescription-drug-affordability/; "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, FTC (Federal Trade Commission), April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[17] *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408 (District of Delaware 2006); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (Second Circuit 2015).

[18] *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (Second Circuit 2015).

[19] The Brill paper is an industry-sponsored white paper commissioned by the Coalition for Affordable Prescription Drugs (an advocacy group representing pharmacy benefit managers, employers, and unions). Brill's estimates are derived from a simplified counterfactual rather than an empirical measurement. For each hop (Prilosec, TriCor, Suboxone, Doryx, and Namenda), the author begins with peak pre-hop brand sales and assumes that, absent the hop, generics would reach 90 percent market share at an 80 percent price discount, whereas the hop restricts generic uptake to 18 percent of the original product's market, yielding lost savings of roughly 57.6 percent of pre-hop brand sales per drug. The $4.7 billion sums one-year estimates drawn from hops occurring between 2001 and 2014 and is not inflation-adjusted, so unlike the Rome and others (2020) glatiramer estimate (which is derived empirically from national claims data and reported in 2019 dollars) the Brill estimate is not expressed in a common dollar year. Brill also notes the figure covers only five illustrative cases and excludes the 180-day first-generic exclusivity period and any post-hop growth in brand sales. Both Brill's and Rome colleagues' estimates, however, reflect costs across all payers.

[20] "Grassley, Cornyn, Blumenthal, Durbin Introduce Bill to Spur Drug Pricing Competition," US Senate Committee on the Judiciary, March 17, 2025, https://www.judiciary.senate.gov/press/rep/releases/grassley-cornyn-blumenthal-durbin-introduce-bill-to-spur-drug-pricing-competition); Congressional Budget Office, *Cost Estimate: S. 150, Affordable Prescriptions for Patients Act of 2023*, as reported by the Senate Committee on the Judiciary on March 1, 2023, June 13, 2024, https://www.cbo.gov/publication/60412; Drug Competition Enhancement Act, S. 1040, 119th Cong. (2025), https://www.judiciary.senate.gov/download/drug_competition_enhancement_act.

[21] This stand-alone bill serves to revive the product-hopping provisions originally proposed under the Affordable Prescriptions for Patients Act (S. 150, 118th Congress) in 2023, which would have created a statutory FTC cause of action for both hard and soft switches once the FDA receives a pending generic ANDA, lowering the evidentiary burden that has limited soft-switch cases to date. However, these product-hopping provisions were removed before S. 150's July 2024 Senate passage, prompting lawmakers to reintroduce them as a stand-alone measure via S. 1040 in 2025 ("Grassley, Cornyn, Blumenthal, Durbin Introduce Bill to Spur Drug Pricing Competition," US Senate Committee on the Judiciary, March 17, 2025, https://www.judiciary.senate.gov/press/rep/releases/grassley-cornyn-blumenthal-durbin-introduce-bill-to-spur-drug-pricing-competition).

[22] Drake, "Rethinking the Value."

[23] *Federal Trade Commission v. Actavis.*

[24] In a "no-authorized-generic" agreement, a brand-name manufacturer secures delayed market entry by promising not to launch its own competing generic version during the first challenger's 180-day exclusivity period. Antitrust authorities characterize this pledge as a substantial "reverse payment" because it protects the generic firm from competition, effectively transferring monopoly-level profits to the challenger as compensation for dropping its patent challenge. See also "FTC Report on Drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court's Actavis Decision," press release, FTC (Federal Trade Commission), January 13, 2016, https://www.ftc.gov/news-events/news/press-releases/2016/01/ftc-report-drug-patent-settlements-shows-potential-pay-delay-deals-decreased-substantially-first.

[25] "FTC Report on Drug Patent Settlements."

[26] "FTC Report on Drug Patent Settlements"; "Pay-for-Delay: When Drug Companies Agree Not to Compete," FTC (Federal Trade Commission), n.d., https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay.

[27] This report cites Drake and McGuire's current industrywide estimate of approximately $12 billion per year, from the revised working paper (NBER Working Paper No. 33196, November 2024, rev. June 2025), which scales the observed estimate of $3.1 to $3.2 billion per year up by a factor of about 3.8. Brake and others (2025) reference an earlier version of the same paper, which reported a smaller industrywide figure of about $7 billion per year, reflecting a lower scale-up factor. This difference does not affect Brake and others' primary federal cost estimates, which are built on Drake and McGuire's observed estimate of $3.1–3.2 billion per year across the 17 identified settlements, rather than on the industrywide figure. The industrywide scale-up affects only the upper-bound sensitivity analysis, which Brake and colleagues report separately. They report that the $7 billion figure would raise federal costs to $37.7 billion (2014 to 2023) and $63.9 billion (2024 to 2033). Drake and McGuire's revised $12 billion figure would imply a higher upper bound still, on the order of four times the primary federal estimates; that larger scaling is our own extrapolation and is not reported by Drake and others.

[28] IQVIA Institute for Human Data Science, "Assessment of the Impact of Settlements: Analysis Results," PowerPoint presentation, June 2025, Association for Accessible Medicines, https://accessiblemeds.org/wp-content/uploads/2025/06/202506-AAM-Impact-of-Patent-Settlements-IQVIA-Study.pdf.

[29] IQVIA Institute, "Assessment of the Impact of Settlements."

[30] IQVIA Institute, "Assessment of the Impact of Settlements."

[31] California State Legislature, AB 824, October 7, 2019, https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB824.

[32] Kristen O'Shaughnessy, Daniel Grossbaum, and Kelsey Greenagel, "Dreamin' of Entering a Patent Settlement Agreement in California? What to Know About California's Reverse Payment Law," White & Case LLP, February 25, 2025, https://www.whitecase.com/insight-alert/dreamin-entering-patent-settlement-agreement-california-what-know-about-californias.

[33] "Access to Product Samples: The CREATES Act," FDA (US Food and Drug Administration), November 28, 2022, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act.

[34] "Access to Product Samples: The CREATES Act."

[35] "How Celgene and Bristol Myers Squibb Used Volume Restrictions to Delay Revlimid Competition," I-MAK (Initiative for Medicines, Access, and Knowledge), April 4, 2025, https://www.i-mak.org/2025/04/04/how-celgene-and-bristol-myers-squibb-used-volume-restrictions-to-delay-revlimid-competition/.

[36] "Cohen Milstein Sellers & Toll PLLC and Hagens Berman Sobol Shapiro LLP Announce a Settlement in a Class Action If You Purchased, Paid for, or Provided Reimbursement for Tracleer or Bosentan," PRNewswire, April 3, 2026, https://www.prnewswire.com/news-releases/cohen-milstein-sellers--toll-pllc-and-hagens-berman-sobol-shapiro-llp-announce-a-settlement-in-a-class-action-if-you-purchased-paid-for-or-provided-reimbursement-for-tracleer-or-bosentan-302730549.html.

[37] "Access to Product Samples: The CREATES Act."

[38] Drake, "Rethinking the Value."

[39] Drake, "Rethinking the Value."

[40] Drake, "Rethinking the Value."

[41] Drake, "Rethinking the Value."

[42] Drake, "Rethinking the Value."

[43] Public Law No. 116-59 (09/27/2019)

[44] Brands deploy authorized generics for more than one reason, and a 2019 change to Medicaid law removed one of them. Previously, by blending an authorized generic's lower prices into the brand's reported average manufacturer price (AMP), a manufacturer could reduce the rebates it owed to Medicaid under the Medicaid Drug Rebate Program. Section 1603 of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (H.R. 4378, 116th Congress; enacted as Pub. L. No. 116-59) closed that avenue, requiring authorized generic sales to be excluded from the brand's AMP. This required brand and authorized-generic AMP to be calculated separately, ending a practice that had cost Medicaid an estimated $595 million in reduced rebates for just nine drugs in a single year (HHS-OIG 2019).

[45] Examples include brand manufacturers bypassing litigation caps by selectively asserting only their strongest patents in successive lawsuits to trigger repeated 30-month FDA approval stays; brand manufacturers circumventing the *Actavis* rule by shifting from direct cash payments to harder-to-detect transfers of value; and companies avoiding the requirements of the CREATES Act by continuing to rely on the protracted, case-by-case litigation burden.

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