Gamesmanship and Other Barriers to Drug Competition

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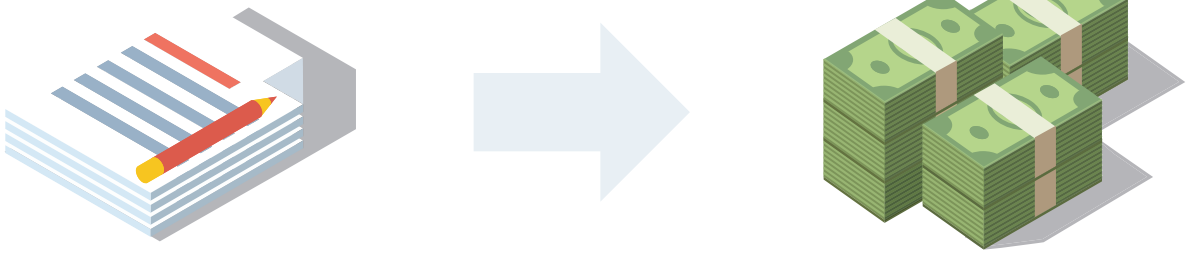
Executive Summary

Thirty-five years ago, Congress created a framework for the U.S. prescription drug market that struck a balance between innovation and competition — rewarding new drug development with market exclusivity for an appropriate time before fostering generic competition and the savings it brings. Over the decades, brand drug companies have found ways to tilt this balance in their favor, delaying competition for longer and longer periods. Some of this gamesmanship has caught the attention of policymakers, who have proposed incremental reforms targeting certain behaviors. But the problem is bigger than most realize — and it has resulted in substantial lost savings for patients, commercial insurers, and government payors.

Brand drugs earn their profits during the years they are on the market by themselves. The period of time before generic entry has increased on average 2.2 years, from 10.3 years in 1995 to 12.5 in 2013–2014, according to research by Duke University economist Henry Grabowski. This paper estimates that reversing this trend and accelerating generic entry would save the U.S. health care system approximately $31.7 billion.

Drug Firms' Gamesmanship Earns More Market Exclusivity for Brand Drugs



ACCELERATE GENERIC ENTRY BY
2.2 years

$31.7 B
IN DRUG SAVINGS

The tactics that brand firms use to extend market exclusivity beyond the initial period prescribed by law are wide-ranging and often intertwined, exploiting opportunities related to patents and exclusivity, litigation, regulatory oversight, and market dynamics. Some tactics — like the misuse of Risk Evaluation and Mitigation Strategy programs — have already garnered public attention, but others are not well understood.

The accompanying table summarizes some of the gamesmanship that brand firms engage in to keep generic drugs off the market.

Recent legislative proposals, while welcome, are relatively modest considering the increase in average exclusivity for brand drugs. Further efforts — in Congress and elsewhere — are needed to curtail the growth of brand market exclusivity and facilitate generic entry.

Brand Gamesmanship to Thwart Generic Competition

PATENT/EXCLUSIVITY STRATEGIES	
Patent Thickets	Filing overlapping patents and new patents, typically relating to drug formulation or delivery, late in the drug development cycle
"Orphan" Drugs	Obtaining orphan drug exclusivity, intended to encourage development of drugs to treat rare diseases, for products that treat large populations

MARKET STRATEGIES	
Evergreening/Product Hopping	Making inconsequential changes to a drug and moving patients to the "new" version with longer market exclusivity
Authorized Generics	Releasing an authorized generic to undercut the generic market by reducing the incentive for a generic firm to enter

REGULATORY STRATEGIES	
Orange Book Deficiencies	Delaying or withholding updates to the Orange Book about which drugs are being marketed and their associated patents
Citizen Petitions	Using citizen petitions, which require FDA review, to raise unfounded concerns and delay generic applications

LITIGATION STRATEGIES	
Legal Limbo	Employing a multitude of litigation tactics — and even the threat of these tactics — to add risk to generic challenges
Multiple 30-Month Stays	Using multiple 30-month stays on generic regulatory approval where allowed, after legislative fix to correct this problem

Introduction

A pillar of pharmaceutical cost containment in the United States is robust competition among generic drug manufacturers following a period of market exclusivity for a brand (innovator) product. As designed, market exclusivity allows brand drug companies to recoup the costs associated with new drug development. But brand drug manufacturers have found ways to extend exclusivity beyond its intended duration, allowing these firms to reap outsized economic profits at the expense of patients, commercial insurers, and government payors. Policymakers, aware of some of this behavior, have proposed incremental reforms targeting certain tactics. But the problem is bigger than most realize — and it has resulted in substantial lost savings.

In 1984, the Hatch-Waxman Act established the legal framework that governs small-molecule drug competition in the United States.[1] Hatch-Waxman was intended to strike a balance between ensuring appropriate market protections for new drugs and creating incentives for generic competition, but it unintentionally created an environment that is ripe for anticompetitive behavior by brand drug firms. In short, the nature of competition in the pharmaceutical industry and complex regulations associated with drug entry have been noted to promote unusual levels of "mischief" compared to other industries (*Bulow, 2004*). This mischief is characterized by wide-ranging and often intertwined tactics that exploit opportunities related to patents and exclusivity, litigation, regulatory oversight, and market dynamics.

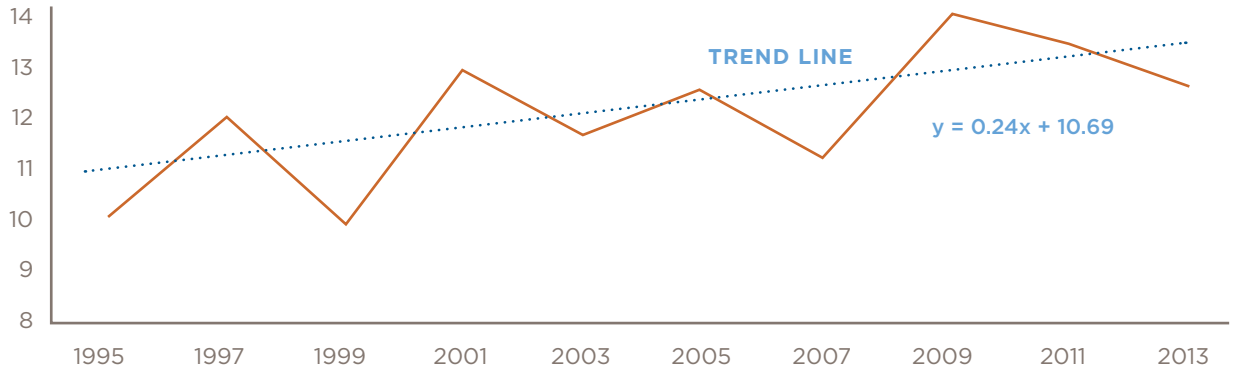
Collectively, the consequences of these tactics can be loosely measured by the upward trend over the past two decades in the duration of market exclusivity for brand drugs. This paper estimates the savings the U.S. health care system could realize by reversing the observed increase in brand market exclusivity beyond the period prescribed by law. After enumerating the array of tactics that brand drug companies use to artificially extend exclusivity, the paper discusses policy reforms to address this behavior. The paper focuses exclusively on small-molecule drugs. While biologic competition is of great importance to the health care system, the regulatory pathway for biosimilars of these complex drugs was created less than a decade ago, and innovator firms' established strategies to restrict competition are largely transferable to biologics.

The Cost of Brand Drug Gamesmanship

A recent study by Duke University economist Henry Grabowski and coauthors (*2016*) finds that the average market exclusivity for new drugs with annual sales greater than $250 million increased by 2.2 years between 1995 and 2014, from 10.3 years to 12.5 years — an increase of more than 20 percent

[1] *Formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, the bill is commonly referred to as "Hatch-Waxman" after its primary authors, Senator Orrin Hatch (R-UT) and Congressman Henry Waxman (D-CA).*

CHART 1. TREND IN AVERAGE BRAND DRUG EXCLUSIVITY DURATION



Source: *Author's calculations based on Henry Grabowski et al., "Updated Trends in US Brand-Name and Generic Drug Competition,"* Journal of Medical Economics *19, no. 9 (2016): 836–44.*

(**see Chart 1**).[2] A simple trendline analysis predicts that this duration will creep up 3 months per year, on average.

Delayed generic entry means delayed health care savings. For this analysis, I use savings generated by generics approved in 2017 as a proxy for the annual gain generics bring to payors and patients. I estimate that the U.S. health care system could save approximately $31.7 billion if the trend in brand market exclusivity were reversed and generic entry were accelerated by 2.2 years.

The estimate of savings from generic drugs approved in 2017 was calculated in a recent analysis by the Food and Drug Administration (FDA) using drug price data from IQVIA (*Conrad et al., 2018*). This analysis captured the savings from both first-time generics and subsequent Abbreviated New Drug Application (ANDA) approvals.[3] The FDA analysts estimate that these generics generated a total of $16 billion in savings over the 12 months following market entry.

The 2.2-year average increase in market exclusivity that Grabowski et al. (*2016*) calculate applies to brand drugs with sales greater than $250 million. I assume these smaller-market products represent approximately 10 percent of total sales and adjust the Conrad et al. (*2018*) savings estimate accordingly. This yields an estimate of approximately $31.7 billion in savings ($16 billion * (1–0.1) * 2.2 years).

Several limitations to this analysis should be noted. First, the sales data that Conrad et al. (*2018*) use in their analysis do not include manufacturer rebates. Second, there may be instances where an increase in brand market exclusivity is not the result of anticompetitive behavior. However, the Conrad et al. (*2018*) analysis likely underestimates the annual savings because generics that earned a 180-day exclusivity period would be priced higher during half of the observed period than they would subsequently. In addition, Grabowski et al. (*2016*) measure the average market exclusivity only of products for which a generic has been approved. There could be many more brand drugs that continue to hold monopoly power that would drive up this average had they been included.

[2] *Grabowski et al. (2016) also explore the trend in average duration of market exclusivity for drugs with less than $250 million in annual sales and observe that there is virtually no increase over time. This could be interpreted as evidence of rational behavior — given fixed costs associated with engaging in anticompetitive strategies, brand drug manufacturers only pursue these aggressive tactics for their most profitable drugs.*

[3] *While most barriers to generic entry relate to the first generic approval, subsequent generic approvals are contingent on the first approval. For this reason, it is appropriate to include the savings generated from first generics and subsequent approvals.*

Hatch-Waxman Framework

Market Protections for Innovators

In the United States, a patent lasts 20 years. Given the lengthy drug development process, including clinical testing and Food and Drug Administration (FDA) review, a new drug could be left with a decreased period of patent protection when it enters the market. The Hatch-Waxman Act gives the FDA the ability to lengthen the patent term for a new drug for up to five years. Beall et al. (*2019*) find that nearly 50 percent of top-selling brand drugs received patent term restoration, leading to a median extension of 2.75 years.

Hatch-Waxman also gives brand drug companies selling a new chemical entity five years of market exclusivity beginning from the date of marketing approval by the FDA. This exclusivity period cannot be challenged in court for the first four years.

Some new drugs — for example, antibiotics, drugs treating rare diseases, and drugs that are a new use of a previously approved chemical entity — are eligible for additional market exclusivity.

In addition, if a generic drug company files what is known as a Paragraph IV certification to challenge the validity of a brand drug's patents, the brand firm can trigger a 30-month stay on regulatory approval of the generic by filing a patent infringement lawsuit within 45 days. In short, brand drugs can often easily achieve at least seven and a half years of market exclusivity.

Incentives for Generic Competition

To balance the protections it affords innovators, Hatch-Waxman encourages competition by allowing generic drug firms to file an Abbreviated New Drug Application (ANDA) that demonstrates a generic's bioequivalence with the already approved reference drug. Hatch-Waxman gives generic manufacturers safe harbor from patent infringement claims in the process of submitting an ANDA.

Generic firms can win a 180-day period of market exclusivity for an ANDA with a Paragraph IV certification, which challenges the validity of a brand drug's patents. A successful generic challenger can then earn a temporary economic profit in the ensuing duopoly period, when they are alone on the market with the brand. This creates an incentive for generic companies to police the patent protection claimed by innovators and rewards generic firms for creating a competitive marketplace. Paragraph IV ANDAs can be submitted after just four years for a new chemical entity, rather than the five years required for other ANDAs.

Brand Drug Strategies to Thwart Competition

In the 35 years since Hatch-Waxman was enacted, brand drug manufacturers have learned to exploit the framework for their own gain, and at the cost of consumers. As the profitability of a new drug depends on the period of time in which the brand manufacturer is a monopolist, brand firms look for ways to extend the exclusivity period and prevent generic competitors from demonstrating bioequivalence and profitably entering the market. To identify brand manufacturers' strategies vis-à-vis generic competitors, it is essential to understand certain Hatch-Waxman provisions. These are described in the accompanying box.

For ease of comprehension, the various tactics that innovator firms use to thwart competition are divided below into four categories: 1) patent and exclusivity strategies, 2) litigation strategies, 3) regulatory strategies, and 4) market strategies. But these strategies are not siloed, and their net effect is significant, as demonstrated by the analysis presented above.

1. Patent and Exclusivity Strategies

One of the most problematic tactics that brand firms employ is creating patent "thickets" around their products. Brand firms have also been known to seek the extended market exclusivity reserved for orphan drugs on existing products that treat large populations.

Patent Thickets

One set of tactics that drug companies use to maintain monopoly power is to establish a patent thicket, or shield, around a product. This involves filing overlapping patents and new patents later in the drug development cycle. Most brand drug companies seek patent protections beyond the active ingredient in a drug. These so-called secondary patents cover the formulation of the drug, method of use, and minor modifications to the chemical compound that occur later in the drug development process (*Kapczynski et al., 2012*). Whereas the primary patent is generally filed early in the development of a new drug, secondary patents are commonly filed at more advanced stages in development or even after the drug is approved by the FDA.

When a generic firm files an ANDA in order to enter a new market, it must either file a Paragraph IV certification or attest that it is not violating any of the patents claimed by the brand company in the "Orange Book," the publication where the FDA lists approved drugs and their associated patents. As each new patent attached to a brand drug has a 20-year term, brand drug manufacturers strategically file secondary patents as late as possible. A recent study of brand drugs approved between 1985 and 2005 estimates that secondary patents extended patent protection by approximately seven years, on average; further, 40–50 percent of secondary patents were issued after FDA approval (*Kapczynski et al., 2012*).

Orphan Drug Exclusivity

Orphan drugs, which treat conditions impacting fewer than 200,000 people in the United States, are eligible for seven years of market exclusivity, as well as subsidies, tax credits, and waivers. This is intended to incentivize drug companies to develop treatments for rare diseases, but brand firms have been obtaining orphan drug exclusivity for drugs that ultimately treat larger populations. A recent study by Johns Hopkins researchers describes one example of this behavior:

> Rituximab was originally approved for a very narrow indication: the treatment of patients with relapsed or refractory low-grade or follicular, B-cell non-Hodgkin's lymphoma. Soon after FDA approval, rituximab was utilized to treat lymphomas and leukemias and was soon being used widely to treat rheumatoid arthritis, an inflammatory condition that affects almost 1.3 million Americans. (*Daniel et al., 2016*)

In fact, the study finds that 7 of the 10 bestselling drugs in the world in 2015 were approved by the FDA as orphan drugs. According to one of the coauthors, "The industry has been gaming the system by slicing and dicing indications so that drugs qualify for lucrative orphan status benefits" (*Johns Hopkins Medicine, 2015*).

2. Litigation Strategies

While Hatch-Waxman built legal challenges into its framework, brand firms have devised ways to keep generic firms continuously in court and thus out of the market.

Legal Limbo

As explained above, Hatch-Waxman offers 180 days of market exclusivity for a generic firm that files a Paragraph IV ANDA, and the brand firm can trigger a 30-month stay on generic approval by filing a patent infringement lawsuit within 45 days. The number of Paragraph IV challenges is increasing, as is the share of generic entry resulting from Paragraph IV ANDAs, and the vast majority of Paragraph IV challenges end in litigation (*Helland and Seabury, 2016; Grabowski et al., 2016*).

While Paragraph IV challenges have certainly limited the ability of brand drugs to extend exclusivity lifetimes by reference to dubious patents, they also create an opportunity for brand manufacturers to use the uncertainty associated with subsequent legal proceedings to keep potential generic entrants out of the marketplace. Once the 30-month stay expires, the FDA can approve a Paragraph IV ANDA, but this does not preclude brand companies from continuing patent infringement litigation. While the generic manufacturer can enter the market, they have to launch "at risk" — that is, knowing they could owe damages if the brand firm prevails in litigation.

The uncertainty created by brand manufacturers' ability to pursue such late-stage delays to generic entry serves no benefit other than the potential for windfall gain to the brand manufacturer.

Multiple 30-Month Stays

Under the original Hatch-Waxman legislation, generic entrants were required to file separate Paragraph IV certifications for each patent listed in the Orange Book. This led to the potential for multiple 30-month stays because brand drugs could list new patents after the original ANDA application was submitted. This problem was rectified by the 2003 Medicare Modernization Act, which stipulated that ANDA applicants certify only patents listed at the time of the original filing. However, in certain cases, multiple 30-month stays can still be triggered, such as when a Paragraph IV ANDA application is amended by the original applicant during the approval process. A 30-month stay is effectively an extension of market exclusivity for the brand drug. A change in an ANDA application that is already subject to a 30-month stay does not warrant an extension of market exclusivity equal to the period afforded the brand for the initial patent challenge.

3. Regulatory Strategies

Brand manufacturers use regulatory tactics to create obstacles to entry for new generics. Policymakers are generally aware of brand manufacturers' use of FDA safety protocols, known as Risk Evaluation and Mitigation Strategy (REMS) programs, to make it difficult for generic firms to demonstrate bioequivalence. But brand firms also use the citizen petition process to slow generic approval with unfounded concerns and intentionally delay submitting updates to the Orange Book.

Citizen Petitions

Brand manufacturers restrict generic entry through the use of citizen petitions, particularly 505(q) petitions that request FDA review of a pending ANDA over concerns about drug safety or bioequivalence. Because the FDA is required to thoroughly review each petition, even failed petitions provide significant value to brand drugs by delaying generic entry. According to a recent

study, 92 percent of 505(q) petitions were filed by brand firms, and nearly 40 percent of petitions were filed within six months of a drug's patent expiration; only 8 percent of petitions were eventually granted (*Carrier and Minniti, 2016*). While citizen petitions can be a valuable tool for bringing safety concerns to the attention of the FDA, the fact that they are used primarily by brand manufacturers, often near the time when a generic is trying to enter, and are rarely granted strongly suggests that they are being misused.

Orange Book Deficiencies

Another barrier to generic entry is generic firms' inability to get accurate and timely information from the Orange Book about which drugs are being marketed and their associated patents. Some improvements to Orange Book reporting were introduced in 2017, including standardizing the process through which manufacturers report their intention to discontinue selling drugs. However, incomplete or delayed information about the intellectual property protections associated with a brand drug can make it difficult for a generic entrant to evaluate the risks associated with developing a generic. And brand firms have been accused of intentionally delaying Orange Book updates.

REMS

The most well-known example of brand firms' regulatory tactics to thwart generic entry is their use of REMS programs to keep potential generic entrants from accessing the 1,500–5,000 drug samples necessary to test for bioequivalence. A common element of REMS programs is the requirement that providers obtain the drug through a specific distribution channel or that prescribers have special training or certification. Brand drug manufacturers use these distribution restrictions to justify refusing to share samples with potential generic entrants. Further, manufacturers of a brand with no REMS program in place have been known to refuse to share samples or place restrictions in contracts with distributors that limit distributors ability to sell samples to potential generic entrants.

For a brand drug with a REMS program, generic manufacturers are required to develop a shared set of safety protocols or receive an FDA waiver prior to approval. This requirement gives the brand firm another avenue for delaying generic competition by not cooperating. Since Congress created the REMS system in 2007, there is only one case of a generic successfully negotiating a shared set of safety protocols with a brand competitor. In some cases, brand drug firms simply drag out negotiations in order to protect their monopoly. In other cases, lengthy negotiations give brand manufacturers time to employ other tactics.

4. Market Strategies

Brand drugs also rely on market strategies to make it unprofitable for generic manufacturers to enter. Two examples of ways that brand firms manipulate the market are "evergreening" products and releasing their own authorized generics to undercut the generic market.

Evergreening

Evergreening, or "product hopping," involves moving customers from a drug nearing the end of its exclusivity to a similar drug with longer exclusivity. For example, when the Alzheimer's drug Namenda IR, which is taken twice a day, was about to lose patent protection, the manufacturer pulled it from the market so that patients would be moved to the extended-release version of the drug, which still had 14 years of its patent term remaining (*Carrier and Shadowen, 2017*). Although the New York State Attorney General successfully sued to keep Namenda IR on the market, less blatant versions of this tactic are commonplace among high-revenue drugs. A 2018 analysis of more than 60,000 drugs on the market between 2005 and 2015 found that 78 percent of drugs associated with new patents were reformulations of existing drugs, a pattern that has grown more pronounced over time (*Feldman, 2018*). While reformulations can improve a product

in a meaningful way, they are increasingly used to protect brand drug monopolies, with little or no benefit to patients.

Health policy experts concerned about this behavior detail just one example in Abbott Laboratories' formulations of the drug fenofibrate:

> The branded reformulations [of fenofibrate], which had no demonstrated incremental benefit on surrogate or patient outcomes (actually, none of the formulations have been shown to improve patient outcomes), obtained significant market share, while generic drugmakers sought to resolve the patent litigation with Abbott that was delaying the approval of their products. Small differences in dose prevented substitution of newer branded reformulations with older generics. As soon as direct generic competition seemed likely with the latest formulation, where substitution would be allowed, Abbott would launch another reformulation, and the cycle would repeat. (*Downing et al., 2012*)

Authorized Generics

Because of the cost and uncertainty associated with developing a generic drug, potential entrants are sensitive to tactics used by brand firms to introduce competition themselves. A common tactic is for the brand firm to release its own authorized generic (AG). It may seem counterintuitive for a firm to genericize its own brand drug, but AGs can be brought to market immediately, thus reducing the potential profits of a generic entrant. Even during a generic's 180-day exclusivity period, a brand manufacturer is free to introduce an AG. As health policy experts recently noted, "The threat of AG creation can serve as a coercive tool because the introduction of AG competition reduces first-filer revenues by (on average) 40% to 52% during the exclusivity period, and by 53% to 62% in the 30 months following the period" (*Jones et al., 2016*). It may be particularly valuable for brand manufacturers to develop a reputation for slashing prices when faced with generic competition so that potential generic competitors will fear that the costs associated with gaining regulatory approval will not be recouped upon entry.

Policy Reforms

As this paper has detailed, brand firms have devised many ways to stymy generic drug competition, but policymakers fail to fully appreciate the broad scope of the problem. In recent years, attention has focused on misuse of REMS programs by brand drug companies. Congress has considered legislation to address REMS abuse, and the Congressional Budget Office (CBO) has estimated significant federal health care savings from enactment of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. Specifically, the CREATES Act would save the federal government $3.3 billion in 2019–2029, primarily in reduced Medicare spending, while yielding an increase in federal revenues of $600 million over the same period (*CBO, 2019*). Commercial payors (not considered in the CBO analysis) would also save significantly from this reform.[4] But REMS is only part of the problem.

The House of Representatives recently passed H.R. 987, the Strengthening Health Care and Lowering Prescription Drug Costs Act, which included three provisions intended to promote generic entry and competition: the CREATES Act and two smaller, more controversial reforms. The first addresses generic drug manufacturers who may "park" their 180-day generic exclusivity and effectively delay generic competition for a period of time. The second prohibits "pay-for-delay" settlement agreements

[4] *My own research estimates that REMS misuse results in $13.4 billion in lost savings to the U.S. health care system as a whole, and the severity of the problem is worsening (Brill, 2018).*

between brand and generic manufacturers, a matter of legitimate concern prior to the Supreme Court's decision in *FTC v. Actavis*. Taken together, these proposals would, through reduced outlays and additional revenues, save the federal government nearly $5 billion over the 10-year budget window.

The Senate Committee on Health, Education, Labor and Pensions recently approved S. 1895, the Lower Health Care Costs Act of 2019, on a bipartisan basis. The bill, which includes a myriad of health policy proposals, would take specific actions to reduce the price of prescription drugs, including modernizing the Orange Book, preventing the abuse of citizen petitions, ending misuse of REMS, and other reforms to facilitate competition and limit brand market exclusivity. The Senate Judiciary Committee also recently considered legislation, S. 1224, to curb "sham" citizen petitions, and S. 1416, which would reduce the ability of drug manufacturers to use patent thickets or product hopping to thwart competition.

Policymakers' interest in and commitment to addressing these challenges is welcome, but the bills that have earned bipartisan support are relatively modest. For example, H.R. 987, as passed by the House, would save the federal government less than $500 million per year. Though commercial payors and patients also stand to gain considerably from reforms to promote drug competition, these savings pale relative to the large-scale consequences of the gain in brand drug average market exclusivity discussed above.

In short, this level of policymaker energy and focus is needed on all anticompetitive strategies identified in this paper. Reforms may need to include regulatory changes within the FDA and additional efforts by the FTC, as well as statutory changes, including amendments to Hatch-Waxman or patent law.

Conclusion

Brand drug firms have worked assiduously to tilt the balance between innovation and competition in their favor. The average number of years from the launch of a brand drug to the market entry of its first generic competitor has increased significantly in the last two decades. This raises important policy concerns, particularly in light of the strong interest among lawmakers in curbing drug spending. Policymakers seeking to improve drug competition and realize the associated health care savings need to understand what is causing the increase in exclusivity duration for brand drugs and to identify policies, big and small, that could reverse this trend and keep the gamesmanship in check.

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ABOUT MGA

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