

Testimony of Rachel E. Sachs, JD, MPH
Associate Professor of Law, Washington University in St. Louis

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Committee on Ways and Means
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Hearing on the Cost of Rising Prescription Drug Prices

Chairman Neal, Ranking Member Brady, and members of the House Ways & Means Committee,

My name is Rachel Sachs and I am an Associate Professor of Law at Washington University in St. Louis, where my research focuses on both innovation into new healthcare technologies, primarily pharmaceuticals, and access to those same technologies. I also serve as a Faculty Scholar with the University's Institute for Public Health and a Faculty Fellow with the University's Cordell Institute for Policy in Medicine and Law. Thank you for the opportunity to testify before you today about the high prices of prescription drugs, the impact those prices have on both patients and our public payers, chiefly Medicare, and how this committee might take steps toward solving these problems.

This committee should consider reforms in three main areas:

1. This committee should seek to lower patients' out-of-pocket costs.
2. This committee should aim to fix misaligned incentives in the pharmaceutical payment system.
3. This committee should strive to reduce overall pharmaceutical spending.

Because there are interactions between these reforms as detailed below, the committee should prioritize bills that choose and unite options from each category of intervention.

I. THE HIGH PRICE OF PRESCRIPTION DRUGS

Today, prescription drug prices in the United States are indeed high — and typically, they are rising. Individual drug prices are rising: over the first seven months of 2018, there were 96 price increases on existing medications for every price decrease.¹ System-wide spending is also rising, particularly for public payers: Between 2007 and 2014, Medicare Part D spending rose from \$46.2 billion to \$73.3 billion, for an average annual growth rate of about 6.8%.² By 2016, Part D spending had risen to \$99.5 billion.³ Medicare Part B spending may be increasing even more quickly, rising from \$15.4 billion in 2009 to \$29.1 billion in 2016, with a 12.9% increase in spending from 2015 to 2016 alone.⁴ A report from the Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation concluded that prescription drug spending in 2015 totaled about \$457 billion, 16.7% of overall personal health care services.⁵ Estimates also suggest that at current rates, over time even larger shares of total health spending will go toward retail prescription drugs.⁶

In the long term, these trends are not sustainable for our public payers, particularly Medicare. But in the short term, these trends are intolerable for patients. About one in four people taking prescription drugs have difficulty affording their prescriptions,⁷ and they may respond by skipping doses, by taking less medication per dose, or by delaying filling the prescription entirely.⁸ Patients

have died as a result of these impossible financial choices.⁹ Although it is common for the pharmaceutical industry to push back on criticisms of its price hikes by noting that they are increasing the *list* price of a drug, even as a patient's insurer may have negotiated a lower *net* price, patients' out-of-pocket expenditures are often based on these inflated list prices, including in Part D.¹⁰ At a time of partisan division on many issues, a full 80% of Americans now believe that prescription drug costs are "unreasonable."¹¹

These problems are far more severe in the United States than they are in other countries. The average price for a month's supply of the best-selling drug in the world, Humira, is \$2,669 in the United States — but just \$1,362 in the United Kingdom and \$822 in Switzerland.¹² First approved in the United States in December 2002 for the treatment of rheumatoid arthritis, in 2018 Humira began to face competition in Europe — but it is currently not scheduled to face such competition in the United States until 2023.¹³

II. LEGAL DRIVERS OF THIS PROBLEM

Pharmaceutical companies' ability to charge these high prices is driven largely by our system for providing exclusive rights to pharmaceutical manufacturers and our system for providing insurance reimbursement for their products. The United States Patent & Trademark Office (PTO) grants exclusive rights to companies for their new, nonobvious, and useful innovations, and pharmaceutical companies typically begin assembling robust patent portfolios around their potential drug compounds even before clinical trials in humans begin.¹⁴ Companies must start filing patent applications early due to doctrinal requirements that may prevent patents from being filed much later in the development process.¹⁵ Patents last twenty years from the date of filing,¹⁶ and although the early-starting patent clock means that companies' patents typically begin to run before they obtain Food & Drug Administration (FDA) approval and can market their products, the Hatch-Waxman Act restores patent time lost during the approval process. As a result, companies typically have effective patent lives on the order of 12 years,¹⁷ or 14-15 years for first-in-class drugs.¹⁸

Once a drug is approved by the FDA, its sponsor is then typically legally entitled to an FDA exclusivity period. Depending on the type of drug approved, companies will normally receive either five years (for small-molecule drugs without a Paragraph IV filing), seven years (under the Orphan Drug Act), or twelve years (for biologic drugs) of exclusivity to market their product.¹⁹ These exclusivity periods do differ legally, in terms of the type of exclusivity they confer and when and how that exclusivity functions.²⁰ To date, though, these exclusivity periods have often behaved functionally interchangeably. These exclusivity periods typically run in parallel with the patent life remaining on a drug after FDA approval,²¹ and in some ways they offer even stronger protection than can be gained with patents. FDA exclusivity periods are automatically enforced against other companies, who need FDA approval before coming to market, whereas patents require pharmaceutical companies to invest resources in enforcing their patents against potential violations. Further, FDA exclusivity periods are not meaningfully subject to challenge and invalidation in either the courts or administrative bodies the way patents are.²²

However, too often companies have sought to abuse these well-intentioned programs to extend their monopoly periods beyond what the drafters of these programs would have envisioned.

Professor Michael Carrier has identified six anticompetitive practices engaged in by brand pharmaceutical companies, as follows:²³

1. Brand companies have engaged in “pay for delay” settlements, paying potential generic competitors to stay off the market and thereby delaying competition for their products.²⁴
2. Brand companies have engaged in “product hopping,” where the company switches to a new version of its existing product to delay generic competition on the older version.²⁵
3. Brand companies have filed frivolous citizen petitions with the FDA in an effort to forestall the agency’s approval of a generic competitor. Carrier’s analysis showed that 98% of petitions filed within the six months preceding the expiration of a patent or exclusivity period (which he suggests is likely to be an effort to delay generic entry) are denied.²⁶
4. Brand companies have used FDA-required Risk Evaluation and Mitigation Strategy protocols to prevent generic companies from obtaining sufficient samples to perform FDA-required bioequivalence testing.²⁷
5. Brand companies have imposed closed distribution restrictions on their product, similarly to prevent generic companies from obtaining the samples they need to complete bioequivalence testing, but in cases in which the FDA has *not* requested the restriction.²⁸
6. Brand companies have engaged in bundling and manipulation of the rebate process to encourage insurers to cover a more expensive branded product even when a less-expensive generic or biosimilar is available.

Members of Congress in both parties²⁹ have also expressed concern about abuses of the Orphan Drug Act, designed to provide additional incentives to companies bringing drugs to market for conditions affecting a small number of Americans. Scholars have similarly proposed changes to that Act’s incentive structure.³⁰

At the same time, our public payers are limited in their ability to push back against monopoly pricing for these products. Medicare Part B coverage of prescription drugs is governed largely by the same standard that governs coverage of services under Part B: whatever is “reasonable and necessary for the diagnosis or treatment of illness or injury.”³¹ Although Part B drug coverage is limited by the structure of the program (in the sense that it is restricted to drugs which are provided in the course of a physician’s service),³² Part B cannot decline to cover an effective FDA-approved drug simply because it is expensive.³³ By law, Medicare Part D plans must cover at least two FDA-approved drugs per therapeutic class.³⁴ And for six protected classes of drugs — anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants — Part D must cover essentially all FDA-approved drugs.³⁵

State Medicaid programs are not required to cover outpatient prescription drugs, but all states have chosen to do so.³⁶ That choice comes with legal obligations. Essentially, states must provide reimbursement for all FDA-approved drugs with a few classes of exceptions, such as drugs used for cosmetic purposes.³⁷ But unlike Medicare, Medicaid’s coverage requirements come with preferred-pricing benefits. By law, innovator pharmaceutical companies must remit to Medicaid substantial rebates for each unit of a drug they sell to the program: at least 23.1% of a drug’s Average Manufacturer Price (AMP),³⁸ on top of which states may seek supplemental rebates. If the company offers an even bigger discount to a selected group of other payers, Medicaid is entitled by law to that “best price” for the drug.³⁹ Also unlike Medicare, Medicaid is insulated from price increases in existing drugs that outpace the inflation rate,⁴⁰ and more than half of Medicaid rebates

are estimated to be due to this provision.⁴¹

To be clear, there are very good reasons why our intellectual property laws and our system of reimbursement have been structured in the way that they have. The process of bringing a new drug to market is expensive,⁴² lengthy,⁴³ and risky.⁴⁴ Particularly coupled with the low costs of imitation (especially for small-molecule generics),⁴⁵ it is not a surprise for scholars to conclude that “[s]trong patent rights are necessary to encourage drug companies to expend large sums of money on research years before the product can be released to the market”⁴⁶ — and for policymakers⁴⁷ and industry⁴⁸ to agree. Similarly, Part D’s coverage requirements (particularly the protected class rules) serve important purposes. CMS wanted to prevent discrimination against beneficiaries with these conditions, as might be expected for patients with high-cost preexisting conditions.⁴⁹ CMS also aimed to “mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”⁵⁰

And yet, the combination of the two systems — exclusive rights plus often-guaranteed reimbursement — has driven our problem of high drug prices. If our payers cannot walk away from the drug price negotiation table if they do not like the deal a branded company with market power is offering, they cannot hope to obtain lower prices on these products. Other countries typically have similar intellectual property systems to our own, but it is far less common for them to guarantee reimbursement in the way that we do. Instead, they use a variety of tools in the negotiation process to drive down prices, ranging from pricing based on the clinical value of the product, to reference pricing within a class of drugs, to international reference pricing, to formulary exclusion.

III. ADDRESSING PROBLEMS WITHIN THE JURISDICTION OF THIS COMMITTEE

This committee has an important role to play in responding to the problem of high prescription drug prices, both by making changes to the way Medicare pays for prescription drugs and through use of this committee’s taxing powers. In light of the ways in which patent law and FDA regulation also drive the current prescription drug pricing situation, Congress should also work to identify solutions involving both of those doctrinal areas. Comprehensive reform will be most effective at addressing not only the immediate problem, but its drivers in the long term.

This committee can make significant change in at least three key areas: lowering patients’ out-of-pocket costs, fixing misaligned incentives primarily within the Medicare program, and reducing overall pharmaceutical spending within Medicare. As noted below, many proposed changes may have both benefits and costs, and advancing bills that choose and unite options from each category below may help maximize those benefits and minimize those costs.

A. Lowering Patients’ Out-of-Pocket Costs

Lowering patients’ out-of-pocket costs, either directly or indirectly, is a necessary step not only to relieve the financial pressures facing many patients, but also to address the health consequences that come with those financial pressures. Patients who are more adherent to the medications their physicians have prescribed may have better health outcomes and may even create partially

offsetting savings elsewhere in the healthcare system.⁵¹ The committee ought to consider at least three different options for assisting patients with these costs:

1. As the National Academies recently recommended, Congress could authorize CMS to limit patients' cost-sharing for particular classes of drugs, "when there is clear evidence that treatment adherence for a particular indication can reduce the total cost of care."⁵² This recommendation builds on the spirit of the Affordable Care Act's requirement that private insurance plans cover preventive interventions without cost-sharing.
2. As MedPAC has proposed,⁵³ Congress might eliminate Part D beneficiaries' cost-sharing above the out-of-pocket threshold. More than a million Part D beneficiaries have total drug spending above this threshold but do not receive low-income subsidies,⁵⁴ and they would be particularly benefited by such a change.
3. Congress might cap Medicare beneficiaries' out-of-pocket spending on prescription drugs on a per-month basis, similar to what a recent bill proposed.⁵⁵ Even if patients' overall out-of-pocket costs were reduced less substantially than under other proposals, smoothing those costs over the course of a year might provide other benefits for patients.

These proposals and others like them would provide relief to the millions of Medicare beneficiaries who have difficulty affording their medications due to high out-of-pocket costs. Given that the goal of insurance in general and Medicare specifically is to pool risks more broadly, the high costs borne by these individuals are a problem that ought to be solved. However, attempting to lower patients' out-of-pocket costs in isolation may result in increased burdens on other patients (as with increased utilization, their premiums may rise), on Medicare itself, which subsidizes these payments, and on taxpayers. As such, reforms to patients' out-of-pocket costs should be paired with reforms in the below categories, which would have the effect of lowering prices more directly and would more likely result in spending decreases overall.

B. Fixing Misaligned Incentives

Both Medicare Part B and Part D include a set of misaligned incentives for different actors which function to drive up both the cost of individual prescription drugs and overall drug spending, for reasons that cannot be explained by increased therapeutic value. The committee ought to consider rectifying each of these problematic incentives.

1. As each of the previous two administrations⁵⁶ has proposed, Congress should reform Part B's average sales price (ASP) reimbursement system for physician-administered drugs. The ASP+6% system financially rewards physicians for prescribing more expensive drugs than would otherwise be therapeutically justified.⁵⁷ This committee could investigate whether a lower percentage plus a flat fee or a flat fee alone would be preferable.
2. Congress might require pharmaceutical companies to reimburse Medicare Part B and Part D when the relevant price of a covered drug rises faster than a specified threshold. At present, companies are typically able to garner greater reimbursement by raising their prices. The HHS Office of Inspector General has suggested that extending Medicaid's inflation-adjusted clawback to the Part D program would help control price increases in Part D.⁵⁸ Alternatively, this committee might consider imposing a more punitive tax on companies that raise prices without an offsetting business justification.
3. As the National Academies recently recommended,⁵⁹ Congress could remove the tax deductibility of direct-to-consumer advertising of prescription drugs. To the extent that

direct-to-consumer advertising may drive inappropriate prescribing and utilization, Congress might wish to treat advertising less favorably than tax-favored research and development activities.

4. Congress could remove existing incentives for pharmacy benefit managers (PBMs) to place drugs with high list prices and large rebates in preferred placements on formularies, relative to drugs with lower net prices but smaller list-to-net spreads. Scholars have discovered that many Part D plans offer more favorable formulary placement to branded drugs than to lower-priced generics,⁶⁰ which not only may be harmful to patients whose out-of-pocket costs are based on the list price, but also which may drive up overall spending. A recent government report suggested that Part D plans spent nearly \$9 billion a year on brand-name drugs for which there was a generic available, \$3 billion of which could have been avoided.⁶¹ Another recent study demonstrated that Medicare spent almost \$1 billion in 2016 on brand-name drugs that are combinations of existing generics, the vast majority of which could have been saved if the generic components had been prescribed instead.⁶²

The above proposals would help to remedy distortions in our current system that provide incentives to prescribe higher-priced drugs, to raise list prices year-over-year, to invest in advertising rather than R&D, and to reimburse higher-priced drugs when lower-priced ones are available. However, they would not fundamentally address the underlying problems of high drug prices and little government leverage over those prices.

C. Reducing Overall Pharmaceutical Prices and Spending

Particularly for those specialty drugs in both Part B and Part D that have little or no competition, the above reforms will not enable Medicare to obtain lower prices on these products. The committee ought to consider reforms that would strengthen Medicare's hand from a negotiation perspective or that would shift payments from higher-cost systems to lower-cost ones.

1. Congress should give Medicare Part D the authority to negotiate directly prescription drug prices, particularly in the case of high-cost drugs with limited competition, coupled with the authority to enforce lower prices in those situations. Given the scale of the Part D program, it is not likely to be possible for the Secretary to negotiate for each drug in the program individually, but negotiation that begins by focusing on these cases (for which rebates may be low or non-existent at present) would be most beneficial. The authority to enforce lower prices could be administered in multiple ways. Three sets of policies the committee ought to consider are:
 - a. Binding arbitration. In the event that the Secretary and pharmaceutical company cannot reach a negotiated agreement, HHS might seek to use binding arbitration, often referred to as baseball-style arbitration.⁶³
 - b. Value-based pricing. The Secretary might benchmark reimbursement to the clinical value of the drug.⁶⁴
 - c. External reference pricing. The Secretary might benchmark prices to an external reference basket of prices charged in other countries, a strategy which can be implemented in many different ways.⁶⁵
2. Congress should also give Medicare Part B the authority to negotiate for and enforce lower prices on prescription drugs. The above-listed strategies (and many others) have the potential to be equally as applicable to Part B as they are to Part D, although the details of

their implementation would likely differ, depending on other reforms Congress chooses to make in the Part B program. Further, given the slow uptake of biosimilars in the Part B program relative to the rapid penetration of small-molecule generic drugs in Part D, these tools may have an even greater impact on certain classes of products in Part B.

3. As the previous administration⁶⁶ proposed, Congress might consider applying Medicaid payment rates for low-income subsidy beneficiaries rather than the currently-applied Part D rates. When Part D was created, it increased the prices pharmaceutical companies could expect to recoup for drugs sold to beneficiaries who had previously only been eligible for Medicaid.⁶⁷ Returning to Medicaid rates for the low-income subsidy population of more than 12 million Americans⁶⁸ could have large cost savings,⁶⁹ although those savings may be reduced if Congress also selects an inflation-adjusted clawback as suggested above.

When adopted together with reforms from the first two categories above, reforms in this category have the greatest potential to lower spending system-wide. Lowering patients' out-of-pocket costs and lowering the prices Medicare pays for many medications will both help patients with the largest financial burdens and will ensure our public payers are being responsible stewards of taxpayer dollars far into the future.

IV. MAINTAINING THE IMPORTANCE OF INNOVATION

When faced with the possibility of legislative or regulatory actions that would promote access in the short term by lowering drug prices, a common argument made in response is that pharmaceutical innovation will be reduced as a result, meaning that patients may lack new treatments in the future. This concern is not unfounded, as there is a relationship between increased prescription drug reimbursement and increased R&D into new therapeutic candidates.⁷⁰ However, this threat cannot be an absolute bar to changes within the system. Although this is true for several reasons, two are key to mention at this time.

First and most importantly, the kind of innovation we receive, not only the amount, is important to keep in mind. The goal of the proposals listed above is to align drug prices with the value we receive from those drugs. If Medicare pays more for drugs that provide better clinical value and less or not at all for drugs that are no better than existing treatments or that are not cost-effective, pharmaceutical companies might choose to invest in a different set of innovative projects — but that set of projects is likely to prove more beneficial for society.⁷¹ Scholars have argued that under our current system of incentives, pharmaceutical companies are discouraged from investing into certain kinds of pharmaceuticals, such as those that would treat early-stage cancers⁷² or diseases that are more prevalent among low-income Americans,⁷³ even if the social value of doing so might be quite large. Reflexively focusing on the innovation-access tradeoff masks these important innovation-innovation tradeoffs.

Second, these claims assume a whole host of other conditions, including that there are no other opportunities to obtain savings within pharmaceutical companies' current business models. It is not clear that this is the case, leading HHS Secretary Alex Azar — himself a former pharmaceutical company executive — to push back strongly against claims of lower innovation, calling them “mathematically unbelievable.”⁷⁴ There is room within the system as it exists today to realign

incentives and lower drug prices without the dire impacts on innovation that pharmaceutical companies threaten.

V. CONCLUSION

Congress has a critical role to play in helping solve the problem of high drug prices, both for patients and for our public payers. This Committee in particular has the ability to help lower patients' high out-of-pocket costs, fix misaligned incentives in the system as it exists today, and reduce pharmaceutical prices through negotiation tools. Chairman Neal, Ranking Member Brady, and Members of the Committee, I applaud your leadership in choosing to focus on this very important issue and I thank you for the opportunity to testify before you today. I look forward to answering your questions.

¹ Linda A. Johnson & Nicky Forster, *AP Investigation: Drug Prices Going Up Despite Trump Promise*, ASSOCIATED PRESS (Sept. 24, 2018), <https://apnews.com/b28338b7c91c4174ad5fad682138520d>.

² MEDICARE PAYMENT ADVISORY COMM'N (hereinafter MEDPAC), REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 168 (June 2016), <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.

³ THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS, 2017 ANNUAL REPORT 10, 99 (2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>.

⁴ MEDPAC, A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 147 (June 2018), http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf?sfvrsn=0 147.

⁵ U.S. DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, ASPE ISSUE BRIEF: OBSERVATIONS ON TRENDS IN PRESCRIPTION DRUG SPENDING 1 (Mar. 8, 2016), <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>.

⁶ Rabah Kamal et al., *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, PETERSON-KAISER HEALTH SYSTEM TRACKER (Dec. 10, 2018), <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/>.

⁷ *Id.*

⁸ Robin A. Cohen & Maria A. Villarroel, *Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013*, NCHS DATA BRIEF NO. 184, at 1 (Jan. 2015), <https://www.cdc.gov/nchs/data/databriefs/db184.pdf>.

⁹ Bram Sable-Smith, *Insulin's High Cost Leads to Lethal Rationing*, NPR (Sept. 1, 2018), <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>.

¹⁰ Stacie B. Dusetzina et al., *Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending*, 177 JAMA INTERNAL MED. 1185, 1186 (2017).

¹¹ Ashley Kirzinger et al., *Kaiser Health Tracking Poll – March 2018: Views on Prescription Drug Pricing and Medicare-for-all Proposals*, KAISER FAMILY FOUND. (Mar. 23, 2018), <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-march-2018-prescription-drug-pricing-medicare-for-all-proposals/>.

¹² Kamal, *supra* note 6.

¹³ Ned Pagliarulo, *Humira Biosimilars Launch in Europe, Testing AbbVie*, BIOPHARMA DIVE (Oct. 19, 2018), <https://www.biopharmadive.com/news/abbvie-humira-biosimilars-launch-europe/539938/>.

¹⁴ Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 539 (2009).

¹⁵ 35 U.S.C. § 102(a) (2012).

¹⁶ 35 U.S.C. § 154(a)(2) (2012).

¹⁷ C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 336 (2012).

¹⁸ Bo Wang et al., *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 JAMA INTERNAL MED. 635, 636 (2015).

¹⁹ 21 U.S.C. § 355(j)(5)(F)(ii) (2012) (Hatch-Waxman Act, conferring five years of exclusivity for small-molecule drugs); 21 U.S.C. § 360cc(a) (2012) (Orphan Drug Act, conferring seven years of market exclusivity); 42 U.S.C. § 262(k)(7)(A) (2012) (Biologics Price Competition and Innovation Act, conferring twelve years of data exclusivity).

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- ²⁰ Hatch-Waxman exclusivity runs from the approval of the innovator product until the *filing* of the generic application, 21 U.S.C. § 355(j)(5)(F)(ii), while the Biologics Act exclusivity runs from the approval of the innovator product until the *approval* of the follow-on biosimilar. 42 U.S.C. § 262(k)(7)(A); *see also id.* § 262(k)(7)(B) (noting that an application may not be filed for four years).
- ²¹ Hemphill & Sampat, *supra* note 17, at 330.
- ²² Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 431–32 (2012).
- ²³ Michael A. Carrier, *High Prices & No Excuses: 6 Anticompetitive Games (Presentation Slides), Testimony for FTC Workshop on “Understanding Competition in Prescription Drug Markets”* (Nov. 8, 2017), <https://ssrn.com/abstract=3066514>.
- ²⁴ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1557 (2006); *FTC v. Actavis, Inc.*, 570 U.S. 136, 141 (2013).
- ²⁵ Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016).
- ²⁶ Michael A. Carrier, Carl Minniti, *Citizen Petitions: Long, Late-Filed, and at-Last Denied*, 66 AM. U. L. REV. 305, 323 (2016).
- ²⁷ Jordan Paradise, *REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?*, 15 HOUS. J. HEALTH L. & POL’Y 43, 47 (2015).
- ²⁸ James Surowiecki, *Taking on the Drug Profiteers*, THE NEW YORKER (Oct. 12, 2015), <https://www.newyorker.com/magazine/2015/10/12/taking-on-the-drug-profiteers>.
- ²⁹ Sarah Jane Tribble, *GAO Will Investigate Skyrocketing Prices For Orphan Drugs*, NPR (Mar. 22, 2017), <https://www.npr.org/sections/health-shots/2017/03/22/521081742/gao-will-investigate-skyrocketing-prices-for-orphan-drugs>; Yasmeen Abutaleb, *Senator Sanders Asks Why Drug, Once Free, Now Costs \$375k*, REUTERS (Feb. 4, 2019), <https://www.reuters.com/article/us-usa-healthcare-catalyst/u-s-senator-sanders-asks-why-drug-once-free-now-costs-375k-idUSKCN1PT0ZJ>.
- ³⁰ Nicholas Bagley et al., *It’s Time to Reform the Orphan Drug Act*, NEJM CATALYST (Dec. 19, 2018), <https://catalyst.nejm.org/time-reform-orphan-drug-act/>.
- ³¹ 42 U.S.C. § 1395y(a)(1)(A) (2012).
- ³² MEDPAC, *supra* note 2, at 121.
- ³³ 42 U.S.C. § 1395y(a)(1)(A) (2012).
- ³⁴ 42 C.F.R. § 423.120(b)(2)(i) (2012).
- ³⁵ 42 U.S.C. § 1395w-104(b)(3)(G)(iv) (2012).
- ³⁶ Julia Paradise, *Medicaid Moving Forward*, KAISER FAMILY FOUND. (Mar. 9, 2015), <https://www.kff.org/health-reform/issue-brief/medicaid-moving-forward>.
- ³⁷ 42 U.S.C. § 1396r-8(k)(2), § 1396r-8(d)(2)(C) (2012).
- ³⁸ *See id.* § 1396r-8(c)(1)(B)(i)(VI).
- ³⁹ *Id.* § 1396r-8(c)(1)(A)(ii)(I).
- ⁴⁰ *Id.* § 1396r-8(c)(2)(A).
- ⁴¹ DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OEI-03-13-00650, MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 8 (2015).
- ⁴² The cost of pharmaceutical development is a topic of intense debate, but most estimates put the cost at well over a billion dollars. *See, e.g.*, Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016).
- ⁴³ Hemphill, *supra* note 17, at 1564.
- ⁴⁴ Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40, 47 (2014).
- ⁴⁵ Henry Grabowski et al., *Does Generic Entry Always Increase Consumer Welfare?*, 67 FOOD & DRUG L.J. 373, 390 (2012).
- ⁴⁶ Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1617 (2003); *see also, e.g.*, Rebecca S. Eisenberg, *The Problem of New Uses*, 2 YALE J. HEALTH POL’Y L. & ETHICS 717, 720–21 (2005).
- ⁴⁷ FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, at 14 (2003).
- ⁴⁸ *See, e.g.*, Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not) 2*, 12 (Nat’l Bureau of Econ. Research, Working Paper No. 7552, 2000), <http://www.nber.org/papers/w7552>.

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- ⁴⁹ See CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUMAN SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL ch. 6, § 30.2.5 (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.
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