

Addressing Out Of Control Prescription Drug Prices

Federal and State Strategies

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COMMUNITY CATALYST



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Community Catalyst is committed to improving prescription drug policies to ensure that consumers have access to safe, affordable and appropriate drugs. Prescription drug pricing, utilization and quality are part of the overall reforms that must be made to the delivery system to increase the value of health care.

Since 2001, Community Catalyst has been a leading independent consumer voice on a wide range of prescription drug issues. Unlike many other consumer organizations, we do not get support from the industry. Our Prescription Access Litigation (PAL) project supported class action lawsuits by the private bar that challenged illegal industry practices, resulting in \$1 billion in awards to consumers and health plans, including union health and welfare funds.

In 2007, Community Catalyst, with the support of the Pew Charitable Trusts, launched the Prescription Project, which led state and federal public policy campaigns to pass pharmaceutical marketing transparency laws in several states, culminating in the Physician Payment Sunshine Act included as part of the Affordable Care Act. The project's efforts to expose conflicts of interest between prescribers and the pharmaceutical and medical device industries also compelled dozens of academic medical centers across the country to revise and strengthen their conflict-of-interest policies. The work of the Prescription Project also drove passage of state legislation and federal programs to increase unbiased physician education on drug effectiveness.

Community Catalyst has built a state consumer health advocacy infrastructure with a strong track record of success in achieving policy and system changes that improve access and quality of care for all consumers, especially vulnerable populations. State advocates effectively operate at the local and federal levels, bringing their grounded experience and informed consumer voice to key health care decision-making arenas. Changes in the organization and financing of medical care since the Affordable Care Act have created new opportunities to address current deficiencies in the delivery of medical care. In this context, Community Catalyst and its Center for Consumer Engagement in Health Innovation are working to build the voice of consumers and communities, to achieve better health for all.

Acknowledgement

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Executive Summary

The practice of granting patent monopolies to pharmaceutical companies to spur innovation is arguably a flawed approach to advancing continuous innovation of safe, effective and affordable medicines. Even in the context of this flawed paradigm, the United States (U.S.) does poorly relative to other countries at making prescription drugs affordable for its population. Prescription drug prices and spending are consistently much higher in the U.S. than in other high-income countries. Studies show Americans pay at least three times more for prescription drugs than residents in other high-income countries.

High prescription drug prices are a growing concern for many Americans: One in four of those taking a prescription drug reported skipping doses or cutting pills in half due to costs. For millions of Americans with chronic conditions, access to needed medications has been a persistent issue.

The majority of Americans across the political spectrum are demanding that Congress and the Trump administration take action to lower prescription drug costs. Federal policymakers are better positioned than those at the state level to drive down drug prices. However, it is unclear whether Congress and the current administration are willing to tackle the problem in an effective way at any time soon. Therefore, to make progress on prescription drug affordability, states need to lead the way.

This brief highlights four key factors contributing to the high cost of prescription drugs in the U.S. including:

- **Problem 1: Pharmaceutical monopoly power over drug pricing** that is not counterbalanced by a strong coordinated purchasing strategy as it is in most high-income countries.
- **Problem 2: The opaque pharmaceutical supply chain** that allows various intermediary players to maximize their profits.
- **Problem 3: Manipulative marketing tactics** that drug manufacturers use to lure providers and consumers toward high-cost medications.
- **Problem 4: Insurers shifting costs to consumers** that leads to unaffordable medications millions of people depend on.

In addition, we include a policy framework that can guide actions at the federal and state levels to tackle each of the identified problems. Depending upon the political environment and resources in each state, consumer advocates, policymakers and stakeholders can work together to adopt a variety of measures that help curb unfair drug pricing. We hope our recommendations are valuable to consumer advocates and other stakeholders with a shared interest in taking practical steps to ensure equitable access to affordable and effective medicines for all. While this work requires challenging a strong pharmaceutical lobby, effective advocacy strategies and strong grassroots support can put victories within reach.

Explaining the Sky-High Cost of Prescription Drugs

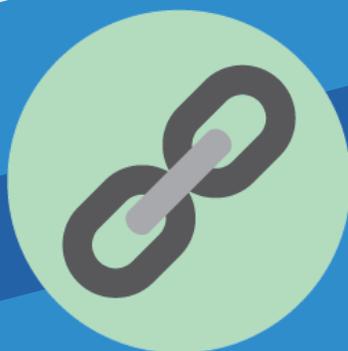
Rx Reform

Cost for Consumers



Pharmaceutical Monopoly Power

- Patent and market exclusivity rights
- Anticompetitive practices
- Lack of federal and state authority to negotiate lower drug prices



Lack of Transparency in the Supply Chain

- Opportunities for profit-taking among various intermediary players (including wholesalers, pharmacy benefit managers, retailers and insurers)



Insurers Shifting Costs to Consumers

- Placing most or all drugs that treat a specific condition on the highest cost-sharing tiers to discourage sick people from enrolling
- High coinsurance and copays



Manipulative Pharmaceutical Marketing

- Targeting physicians with gifts and other incentives
- Heavily investing in prescription drug advertising & marketing to steer patients away from lower-cost medications
- Strategic granting to influence disease-specific patient groups

The Results?

- 1** Rising costs of prescription drugs disproportionately harm low-income people and people living with chronic conditions
- 2** One out of five Americans taking prescription drugs either skips doses or cuts pills due to costs

A policy framework for federal and state actions

- **Solution 1: Enact legislation and leverage existing federal authorities that aim to reduce pharmaceutical monopoly power over drug pricing.** Policymakers should put in place policies that enable vigorous and effective competition that will bring down drug prices.

Level	Policymakers	Approach	Policy strategies	Specific recommendations	Selected examples
Federal	HHS	Regulation	Leverage March-In Rights (35 U.S.C. §203)	<ul style="list-style-type: none"> • Force patent manufacturers that receive federal grants for research and development to allow generic drugs to enter the market. 	
	HHS	Regulation	Leverage Patent & Copyright (28 U.S.C. §1498)	<ul style="list-style-type: none"> • License generic versions of high-cost medications at low prices. 	Early 2017, LA's Department of Health considered using 28 U.S.C. § 1498 to by-pass Gilead's patents on Sovaldi and Harvoni, two of the new, highly effective hepatitis C drugs, to treat people with hepatitis C in the state's Medicaid program, prison system, and its uninsured
	Congress	Legislation	Amend Hatch-Waxman Act , the Orphan Drug Act , the Biologics Price Competition and Innovation Act , and the Generating Antibiotic Incentives Now Act .	<ul style="list-style-type: none"> • Shorten patent and market exclusivity periods and eliminate patent extensions for drugs that have no demonstrated added value compared to those already on the market; • Amend 'March-In Rights' (35 U.S.C. §203) to set limits on introductory prices for new innovative drugs and annual price increases for existing drugs that have received federal funding for research and development; and • Increase FTC resources to monitor, oversee and investigate drug manufacturers engaging in anticompetitive practices and empower the FDA to terminate market exclusivity on any product found to be in violation. 	
	Congress	Legislation	Eliminate the 'noninterference' clause in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003	<ul style="list-style-type: none"> • Allow Medicare to directly negotiate drug price with drug manufacturers; and • Allow HHS to limit what Medicare pays for drug based on price of another therapeutically equivalent drug. 	

Level	Policymakers	Approach	Policy strategies	Specific recommendations	Selected examples
State	Legislature	Legislation	Enact legislation that prohibits price gouging for all drugs	<ul style="list-style-type: none"> Require drug manufacturers to justify price increases or face substantial penalties. 	MD's price gouging law authorizes the state AG to prosecute drug manufacturers that engage in excessive price increases in noncompetitive off-patent or generic drug markets. A three judge panel of the U.S. Court of Appeals for the Fourth Circuit recently ruled 2-1 that MD's anti-price gouging law unconstitutionally violates the "Dormant Commerce Clause," because, in their view, it would affect transactions in other states. Maryland AG has appealed the ruling to the full Fourth Circuit Court of Appeals.
	Department of health or relevant agencies	State plan amendment	Establish multistate and/or in-state collaborative	<ul style="list-style-type: none"> Establish multistate purchasing pools of high cost medications to negotiate reduced prices; and Operate as a PBM to represent in-state participants that use unified formularies for all covered members across state and local programs. 	More than half of the states are currently participating in at least one of four multistate purchasing pools . In addition to the federally required rebate, drug manufacturers offer these states supplemental rebates.

- **Solution 2: Enact legislation that mandates public disclosure on drug pricing, investment in drug development, manufacturing and marketing to create transparency within the pharmaceutical supply chain.** Detailed information on drug pricing and clinical efficacy should be available to the public in a clear, straightforward and timely manner.

Level	Key players	Approach	Policy strategies	Specific recommendations	Selected examples
State	Legislature	Legislation	Create a drug price review commission	<p>A drug price review commission should:</p> <ul style="list-style-type: none"> • Include at least 2 members representing patients and health care consumers as well as representatives from health care providers, public-employer-and-commercial payers and researchers; • Have the authority to approve or reject drug price setting; and • Offer public input opportunities during review periods. 	MD has filed a bill based on NASHP's Model Drug Price Transparency Act to evaluate the affordability of certain drugs and impose limits on how much the state and commercial health plans will pay.
	Legislature	Legislation	Enact drug price transparency legislation	<p>Require department of health or relevant agencies to set a price cap for a particular drug at a fixed percentage above the average price for that drug sold in OECD countries.</p> <p>Require drug manufacturers to:</p> <ul style="list-style-type: none"> • Submit justifications for all drugs that have a 10% price increase above the previous price and to undergo a price review process; • Provide advance notices of price hikes to give time for purchasers to adjust formularies, negotiate price concessions or seek other alternatives; and • Publicly disclose detailed information on prescription drug pricing as well as development, manufacturing and marketing costs on a drug-by-drug basis and grants to non-profit groups. <p>Require PBMs and nonprofit groups to submit reports of their financial arrangements with pharmaceutical manufacturers.</p> <p>Require insurers to show how increase in prescription drug prices affect premiums.</p>	<p>NV requires diabetes drug manufacturers to disclose information about the costs of making and marketing drugs where prices increase by a certain amount. PBMs and nonprofit groups receiving pharmaceutical grants are also required to submit annual reports to the state department of health and human services of their financial arrangements with drug manufacturers.</p> <p>NY requires the state Department of Health to establish a Medicaid spending cap with year to year spending targets and to review drug expenditures quarterly. If expenditures exceed the department's spending cap, the commissioner identifies and refers specific drugs to a drug utilization board for recommended supplemental rebates.</p> <p>In addition to public disclosure requirements, CA requires drug manufacturers to provide a 60-day advance notice of price increases for most prescription drugs.</p> <p>OR requires drug manufacturers to report research and development and marketing costs, profits and other factors that contribute to a specific drug's price increase of more than 10%. OR also requires insurers to show how high drug prices affect premiums.</p>

- **Solution 3: Enact legislation that prohibits manipulative marketing practices that draw providers and consumers toward more expensive alternatives.** In addition, public funding should be available for academic detailing programs and consumer education about new treatment options including their indications, contraindications and prices.

Level	Policymakers	Approach	Policy strategies	Specific recommendations	Selected examples
Federal	Congress	Legislation	Amend Revenue Code of 1986 to eliminate tax deduction for advertising and promotional expenses for prescription drugs	<ul style="list-style-type: none"> • Ban DTCA or eliminate tax deduction for DTCA. 	S.2623 - Protecting Americans from Drug Marketing Act 114th Congress (2015-2016) would amend the Internal Revenue Code to eliminate the tax breaks that drug makers can take to offset their spending on prescription drug ad campaigns.
	Legislature	Legislation	Enforce and expand the Physician Sunshine Act	<ul style="list-style-type: none"> • Limit or ban drug manufacturers from offering gifts to physicians. 	VT prohibits manufacturers from offering gifts, including “any payment, food, entertainment, travel, subscription, advance or service,” to health care professionals, other providers and Green Mountain Care Board.
State	Legislature	Legislation	Establish public funding for evidence-based academic detailing programs	<ul style="list-style-type: none"> • Provide guidance on potential benefits and possible harms of specific drugs. 	Academic detailing programs in PA, MA, NY, VT, ME, SC and DC have shown to be the most effective means to improve physician practices and patient outcomes. Economic analysis has also shown that they are cost-effective.

• **Solution 4: Enact legislation that aims to reduce cost-sharing and prohibit discriminatory formulary designs to ensure equitable access to affordable prescription drugs.**

Level	Policymakers	Approach	Policy strategies	Specific recommendations	Selected examples
State	Legislature	Legislation	Enact legislation to reduce cost-sharing for prescription drugs	<ul style="list-style-type: none"> Prohibit the use of coinsurance; Cap monthly copayment at no more than \$150 per prescription drug; and limit the total monthly out-of-pocket spending for prescription drugs at a specific threshold or perhaps at no greater than 1/12 of the annual out-of-pocket maximum; and Limit cost-sharing on prescription drugs for people with income at or below 150% of FPL. 	<p>DE, LA and MD set the monthly limit copayment at \$150 per specialty drug.</p> <p>CA caps out-of-pocket prescription drug costs at no more than \$250 for a 30-day prescription for most coverage. However, this copay cap will sunset at the end of 2019 unless legislation is enacted to make it permanent.</p>
	Legislature DOI	Legislation Regulation	Enact legislation and/or regulations that prohibit discriminatory formulary design (adverse tiering)	<ul style="list-style-type: none"> Reduce the number of drug tiers through standardized plans; Prohibit insurers from placing all or most drugs that threat a specific condition in a specialty tier; and Work closely with various stakeholders including ombudsmen, providers and consumer health advocacy groups to identify specific examples of discriminatory design and put into place policies that prohibit insurers from using these practices. 	<p>DE prohibits insurers from placing all drugs in a given class on a specialty tier.</p> <p>CA and CO prohibit plans from designing formularies in the way that discourages enrollment of individuals with health conditions.</p> <p>FL creates a drug-specific chronic conditions template to help identify adverse tiering—that requires plans to identify the number, name and tier of covered drugs used to treat certain conditions.</p>

Introduction

The current practice of granting patent monopolies to pharmaceutical companies to spur innovation is arguably a flawed approach to advancing continuous innovation of safe, effective and affordable medicines.¹ Even in the context of this flawed paradigm, the United States (U.S.) lags far behind other countries at making prescription drugs affordable for its population. Prescription drug prices and spending are consistently much higher in the U.S. than in other high-income countries.²

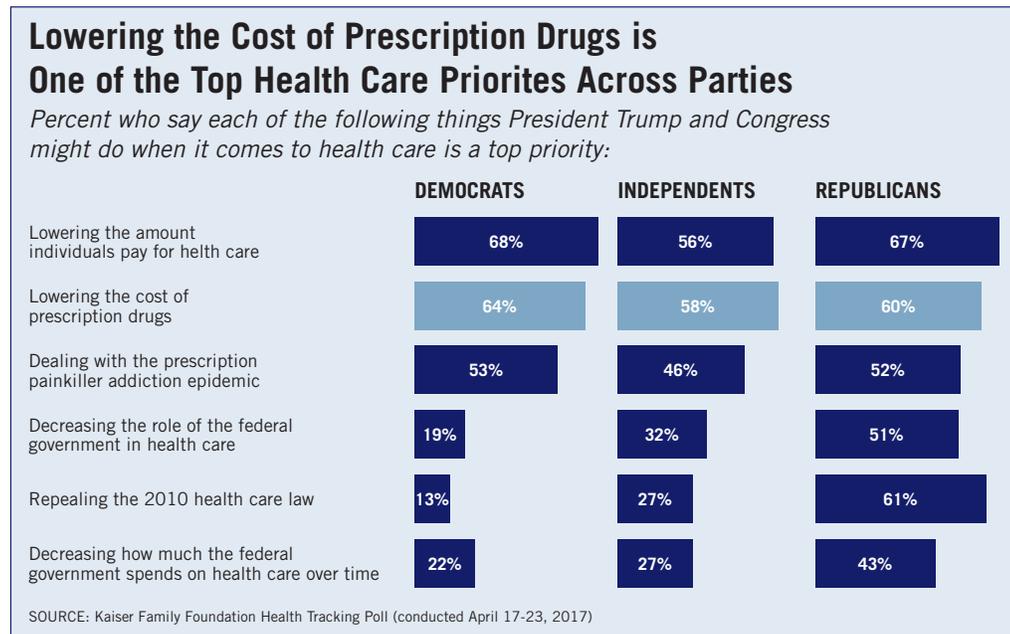
In 2016, national expenditures on prescription drugs reached \$328.6 billion, or 10.3 percent of overall national health expenditures.³ A recent study found that the price for four medications (Crestor, Lantus, Advair, and Humira) used to treat common conditions is nearly three times higher in the U.S. than in other high-income countries.⁴ The Center for Medicare and Medicaid Services (CMS) projected that among the major categories of health spending, prescription drugs would experience the fastest average growth of 6.3 percent per year over the next decade.⁵ Moreover, while population growth and greater use of prescription drugs among all age groups contribute to the rise in prescription drug spending, a shift in prescribing toward higher price products and price increases (especially for specialty medications) are the main factors driving average increases in drug prices.⁶

Federal policymakers are in a better position than those at the state level to drive down drug prices as existing laws on patent rights and market exclusivity protections rest at the federal level. However, it is unclear whether Congress and the current administration are willing to tackle the problem in an effective way at any time soon. Therefore, to make progress at improving prescription drug affordability, states need to lead the way.

This brief seeks to provide a policy framework to support consumer advocates in their efforts to make prescription drugs more accessible and affordable for their state residents. It begins with an overview of key factors contributing to the high costs of prescription drugs in the U.S., followed by policy strategies that the federal government and states can and should take to lower drug costs. We hope our recommendations are valuable to consumer advocates and other stakeholders with a shared interest in taking practical steps to ensure equitable access to affordable and effective medicines for all. While this work requires challenging a strong pharmaceutical lobby, effective advocacy strategies and strong grassroots support can put victories within reach.

Impact of Rapidly Increasing Prescription Drug Costs on Consumers and the Government

High drug prices are a growing concern for many Americans. A majority of Americans across the political spectrum find that prescription drug costs are unreasonable, and want “lowering the cost of prescription drugs” to be the “top health care priority” for the Trump administration and Congress.⁷



Insurers have responded to increasing drug prices by imposing coinsurance and high copayments and restricting access. Average out-of-pocket spending on prescription drugs has decreased as a result of the implementation of the Affordable Care Act (ACA).⁸ However, people with chronic conditions (such as cancer, digestive disease or mental illness) are likely to spend in excess of \$1,000 or more in 2014 despite having insurance coverage.⁹ While the rise in copayments and coinsurance reflect rather than cause an increase in the underlying price of prescription drugs, they directly contribute to lack of affordability for consumers. In a recent survey, the Kaiser Family Foundation found that one in four of those taking a prescription drug skipped doses or cut pills in half due to costs.¹⁰ For millions of Americans with chronic conditions, access to effective medications has been a persistent problem. For instance, one-third of Medicare patients with leukemia failed to fill prescriptions within six months of diagnosis when the cost of the life-saving drug, Gleevec, went up to \$146,000 a year.¹¹

The effects of high prescription drug costs are not limited to the health of individual patients. Not taking needed medications can lead to increased costs to the health care system in the form of unnecessary hospitalizations, emergency services and physician visits.¹² Escalating drug prices are also straining state budgets. Between 2013 and 2014, Medicaid prescription drug spending rose more than 24 percent.¹³ This large increase in spending creates a challenge for policymakers. With few tools for addressing spending growth, a number of states have taken harmful measures such as cutting prescription drug benefits, imposing prescription drug copays and curtailing the use of new medicines that many people depend on.¹⁴

Key Factors Contributing to Rapidly Increasing Prescription Drug Costs and the Lack of Affordability for Consumers

Broadly speaking, there are four key factors contributing to the high cost of prescription drugs and the lack of affordability for consumers: (1) the monopoly power of pharmaceutical manufacturers over drug pricing; (2) the opaque pharmaceutical supply chain that allows various intermediary players to maximize their profits; (3) manipulative pharmaceutical marketing campaigns affecting consumers and providers' decisions; and (4) insurers shifting costs to consumers by imposing high copayments and coinsurance in response to growing prescription drug prices. This section discusses each of these factors in more detail.

- **Problem 1: Pharmaceutical Monopoly Power Over Drug Pricing**

The fundamental cause of high prescription drug prices in the U.S. is the failure to counterbalance the monopoly power of pharmaceutical manufacturers with a strong coordinated purchasing strategy. This monopoly power is conferred via federal patent laws as well as rules that diminish federal and state authority to negotiate drug prices or implement measures to lower drug costs.

Patent and market exclusivity rights

Various federal patent laws, including the Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), the Orphan Drug Act, the Biologics Price Competition and Innovation Act, and the Generating Antibiotic Incentives Now Act give pharmaceutical manufacturers patents and market exclusivity rights as incentives for research and development of innovative products. Depending on the drug type, market exclusivity¹⁵ periods vary between five to 20 years. During the period of multiyear market protection, manufacturers of patented drugs are free to set market entry prices—often at high levels—and annually increase drug prices.¹⁶ At the same time, pharmaceutical manufacturers are often able to leverage federal funds for drug development as well as testing, marketing and commercialization. The combination of federal funding and the absence of generic competition enable brand-name drug manufacturers to develop and sell new drugs, recoup their development costs and gain a high return on investment. According to the U.S. Government Accountability Office, the pharmaceutical industry was the most profitable industry in 2015 with an average profit margin of 17.1 percent.¹⁷

Anticompetitive practices

Once a drug reaches the end of its exclusivity period, a generic version of the drug is allowed to enter the market, usually at a much lower price than the branded price. Typically, the price reduction is about 55 percent of the original brand name cost if there are two generics on the market, 33 percent with five generics, and 13 percent with 15 generics.¹⁸ As a result, generic drugs quickly capture the majority of the sales in the market formerly dominated by the brand-name pharmaceuticals.¹⁹ Facing a significant loss of revenue, many brand-name companies engage in anticompetitive practices (such as pay-for delay, product-hopping, sham citizen petitions, authorized generics and denying access to testing samples) to limit the effect of generic competition on drugs for which the patent is expiring.²⁰ These anticompetitive practices cause substantial harm to consumers as they prevent affordable medications

from entering the market. According to the most recent available data released by the Federal Trade Commission (FTC), Americans pay \$3.5 billion more for prescription drugs each year because of pay-for-delay deals between brand-name drug manufacturers and patent challengers.²¹

Lack of federal and state authority to negotiate lower drug prices

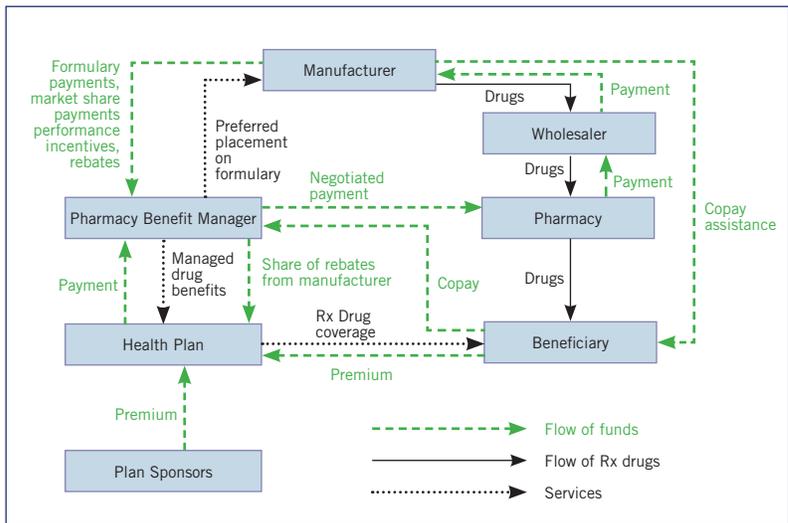
Although federal and state governments, through Medicare and Medicaid, are the largest purchasers of prescription drugs in the United States, they are limited in their ability to negotiate for lower prices. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 includes a ‘noninterference’ provision that explicitly prohibits the Secretary of the U.S. Department of Human and Health Services (HHS) from involvement in price negotiations with pharmaceutical manufacturers.

• Problem 2: The Opaque Pharmaceutical Supply Chain

Over time, the supply chain for retail drugs has become increasingly complex and lacking in transparency. Prescription drugs flow from manufacturers to various intermediaries (including wholesalers, pharmacy benefit managers, retailers, and private and public health insurance entities) before reaching patients. The complex web of financial arrangements between these players creates opportunities for profit taking at each transaction point.

Lack of transparency and granularity of information on drug pricing decisions

Because financial arrangements among players within the pharmaceutical distribution system often occur privately with no public records, it is difficult to determine how large these payments are and how they are distributed. A study conducted by the Leonard D. Schaeffer Center for Health Policy and Economics found that consumers enrolled in high deductible health plans sometimes pay more for a prescription drug than the insurer’s cost of acquiring the drug.²² While insurers acquire drugs at discount prices, consumers who have not used up their deductible have to pay the full average wholesale price until they reach their deductible.



Source: The Leonard D. Schaeffer Center for Health Policy and Economics (2017). [The Flow of Money through the Pharmaceutical distribution System](#)

Pharmacy benefit manager game-playing

Pharmacy benefit managers (PBMs), the third party administrators of prescription drug programs for private and public health insurance plans, are responsible for developing and maintaining the formulary, contracting with pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims. In the past few years, some critics have accused PBMs of driving up drug prices and interfering with patients' access to medications. Because some PBMs receive greater returns based on the size of the discounts achieved, they may have little incentive to oppose high market entry prices.²³ In addition, they may restrict access to drugs based on the rebates they receive rather than clinical efficacy or overall cost.²⁴

- **Problem 3: Manipulative Marketing Tactics**

Drug manufacturers are spending far more on marketing than research. According to a 2012 published on BMJ, for every dollar on “basic research,” pharmaceutical companies invested \$19 toward marketing and promotion.²⁵ In 2015, nearly two thirds of the top 100 pharmaceutical manufacturers by sales spent twice as much on marketing and sales than on research and development.²⁶ Pharmaceutical manufacturers focused much of their marketing expenses on targeting physicians to influence their prescribing practices. For instance, the industry spent more than \$3 billion on advertising to consumers, and at least \$24 billion on promoting drugs to health care professionals.²⁷ Tactics used include but are not limited to:

- *Detailing*, where pharmaceutical representatives visit doctors to pitch their products, take them out for meals or give them gifts or free medication samples. A new research published in JAMA found that doctors who received free meals and other kinds of payments from pharmaceutical companies tended to prescribe more opioid painkillers to their patients over the course of a year those who did not get such freebies.²⁸
- *Direct-to-consumer advertising (DTCA)*, which has increased nearly fourfold since the 1997 Food and Drug Administration guidance allowing the DTCA expansion into broadcast and electronic media.²⁹ The U.S. and New Zealand are the only countries in which drug manufacturers can advertise prescription drugs directly to consumers. Common DTCA tactics include: providing financial assistance (e.g. copay coupons) to patients, promoting prescription products on television, radio, print (magazines, newspapers), the Internet, and other forms of mass media (billboards and direct mailings). Research shows that providing copay coupons effectively steers patients away from lower-cost generic alternatives.³⁰ In addition, patients are more likely to speak to their doctors about a brand-name drug if it had been promoted on television.³¹
- *Grants to disease-specific patient advocacy groups*, which drug manufacturers see as allies to help build demand for new treatments and facilitate the U.S. Food and Drug Administration (FDA) approval of experimental therapies. According to a study published in the New England Journal of Medicine, more than 80 percent of patient-advocacy groups accept donations from drug and medical-device companies. For some groups, these donations accounted for more than half of their annual revenue; and nearly 40 percent of these groups have industry executives that sit on their governing board.³²

- **Problem 4: Insurers Shifting Costs To Consumers**

Prescription drug affordability is important, especially for millions of Americans living with chronic conditions, many of whom rely on more than one costly medications. However, insurers have responded to high drug prices in at least two ways that exacerbate affordability problems for consumers: (1) imposing high cost-sharing through deductibles, coinsurance or copayments; or (2) adopting discriminatory formulary designs (also known as adverse tiering) where high-cost medications are placed in the most expensive drug tier to deter sick people from enrolling.

High out-of-pocket cost sharing

To discourage enrollees from using high-cost drugs, many health plans assign different levels of cost sharing to as many as four different categories of prescription drugs: generic drugs (tier 1), preferred-brand drugs (tier 2), non-preferred-brand drugs (tier 3), and specialty drugs (tier 4). Health plans generally consider specialty drugs medications used to treat complex conditions, and they are the most expensive among these four tiers. However, the term specialty drug lacks a precise definition and drugs are sometimes assigned to the specialty tier just based on price. The out-of-pocket cost for medications to treat conditions like cancer, multiple sclerosis, hepatitis C or rheumatoid arthritis, if excluded from prescription drug plans, can reach more than \$50,000 a year.³³ More than half of commercial health plans require enrollees to pay coinsurance rather than copayments.³⁴ Because coinsurance costs are based on a percentage of the drug's price, they can be far more costly than copays and vary significantly over time, which makes it challenging for consumers to budget for their treatments.³⁵

Discriminatory formulary designs (adverse tiering)

Despite significant consumer protections under the ACA,³⁶ there is evidence insurers are resorting to other tactics to dissuade high-cost patients from enrolling, and these tactics increase prescription drug costs for people with chronic conditions. For instance, health plans have placed most or all drugs that treat a specific condition on the highest cost-sharing tiers and have refused to cover commonly prescribed treatments (such as single-tablet drug regimens).³⁷ Avalere Health found that some marketplace health plans place all drugs used to treat complex diseases (such as HIV, cancer, and multiple sclerosis) on the highest drug formulary cost-sharing tier—known as the 'specialty' tier.³⁸ As a consequence, regardless of which drugs they take, people living with those high-cost chronic conditions enrolling in those plans will incur significant out-of-pocket costs. A 2015 study found that consumers living with HIV enrolling in plans with discriminatory designs had an average annual cost per drug of \$4,892, compared to \$1,615 for enrollees in other plans, and that the disparity persisted even for patients taking generic medications.³⁹

A Policy Framework for Federal and State Actions

As a result of public demand for affordable medicines, policymakers have started turning their attention to finding solutions that help lower prescription drug costs.

Members of Congress have filed a number of bills. Among those, the Improving Access to Affordable Prescription Drugs Act (S.771) is the most comprehensive proposal designed to lower drug costs while increasing innovation and promoting transparency.⁴⁰ CMS has also taken some action, proposing to allow Medicare beneficiaries to pay coinsurance based on the discounted drug prices paid by insurers rather than the higher retail prices.⁴¹ Recently, the Trump administration released a blueprint for lowering high prescription drug prices in the U.S. While the plan identifies some of the factors causing skyrocketing costs — high list prices, a lack of negotiation tools for federal programs, and rising out-of-pocket costs for consumers — the fundamental factor contributing to sky-high prescription prices, the pharmaceutical monopoly power over drug pricing, is not addressed.⁴² While there are modest steps in the right direction, the Trump administration's action plan leaves drug corporation's monopoly power largely untouched.

At the state level, in 2017 state policymakers introduced at least 80 bills focusing on price transparency, unfair price increase and lowering out-of-pocket cost sharing on prescription drugs for people with chronic conditions.⁴³ Despite strong pushback from the pharmaceutical industry, five states—**California, Maryland, Nevada, New York and Oregon**—have enacted groundbreaking legislation that targets excessive drug pricing. In addition, at least eight states—**California, Colorado, Delaware, Louisiana, Maryland, Montana, New York and Vermont**—have leveraged their authority to regulate health insurance to lower prescription drug cost-sharing.⁴⁴ This year also started out strong: within the first three weeks of 2018, lawmakers in 20 states introduced 43 bills designed to rein in prescription drug costs.⁴⁵

Addressing prescription drug costs requires actions at both the federal and state level. We use the following policy framework to address each of the four problems contributing to the fast-growing drug costs discussed above. Specifically, we recommend policymakers to:

- **Solution 1: Enact Legislation And Leverage Existing Federal Authorities To Reduce Pharmaceutical Monopoly Power Over Drug Pricing**

At the federal level, Congress should:

- *Leverage existing laws, such as 'March-In Rights' (35 U.S.C. §203) and 'Patent & Copyright' (28 U.S.C. §1498), to force down prescription drug prices.* For instance, in case of supply shortage or exorbitant price hikes, HHS has the right under 35 U.S.C. §203 to force patent manufacturers that used taxpayers' dollars to develop their innovations to allow drugs to enter the market at cheaper prices. HHS can also invoke the government use of patented interventions under 28 U.S.C. §1498 to license generic version of high-cost medications at low prices.⁴⁶ This approach was used in the 1950s and 1960s to procure cheaper drugs.⁴⁷ Early this year, the State of **Louisiana** Department of Health was considering using 28 U.S.C. §1498 to bypass Gilead's patents on Sovaldi and Harvoni, two of the new, highly effective hepatitis C drugs, to treat people with hepatitis C in the state's Medicaid program, prison system, and its uninsured.⁴⁸

- Amend the Hatch-Waxman Act, Orphan Drug Act, the Biologics Price Competition and Innovation Act and the Generating Antibiotic Incentives Now Act to:⁴⁹

- (1) *Shorten patent and market exclusivity periods and eliminate patent extensions.* For instance, the U.S. is the only country that allows a 12-year exclusivity period for biologics, which discourages the development of biosimilars. Experts suggest it would make more sense to grant brand-name drug manufacturers only up to seven years of market exclusivity for biologics.⁵⁰ In addition, to rebalance innovation incentives and competition, Congress should eliminate patent extensions for drugs that have no demonstrated added value compared to those already on the market.
 - (2) *Amend ‘March-In Rights’ (35 U.S.C. §203) to set limits on introductory prices for new innovative drugs and annual price increases for existing drugs that receive federal funding for research and development.* Under 35 U.S.C. §203, the federal government has the authority to “march-in” in the event that high price is preventing a drug developed with federal funding for research and development from being available or affordable. The proposed amendment is to allow federal government to prospectively review the launch price of a drug developed with federal support.
 - (3) *Prohibit anti-competitive practices (such as pay-for-delay, product-hopping, sham citizen petitions, and authorized generics) that lead to high drug prices.* Congress should increase FTC resources to monitor, oversee and investigate drug manufacturers engaging in anticompetitive practices. In addition, the FDA should be empowered to terminate market exclusivity on any product found to be in violation. All patent claims (including biologics) should be disclosed in the Orange Book at the time of originator drug registration—not years later when the originator is trying to block the generic manufacturers from market entry.
- Remove the ‘non-interference’ clause in the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003](#), so Medicare could directly negotiate Part D drug prices with pharmaceutical manufacturers. According to a 2007 analysis conducted by the Congressional Budget Office, savings for Medicare could occur if the HHS Secretary has the authority to negotiate lower prices for a broad set of drugs or drug types (including many of today’s high-priced specialty drugs and biologics) on behalf of Medicare beneficiaries.⁵¹ In addition, Congress should allow HHS to limit what Medicare pays for a drug based on the price of another therapeutically equivalent drug.

At the state level, states should:

- Establish multistate and/or in-state collaborative

- (1) *Establish multistate purchasing pools to negotiate reduced prices of high cost medications.* States could seek state plan amendment approvals to establish collaborations among states to purchase large quantities of high-cost medications in exchange for favorable rebates. This strategy can limit annual price increases, eliminate differences in costs between participating states and ensure access to critical medications for low-income people.

Currently, there are four multistate purchasing pools in which more than half of the states are participating.⁵² In addition to the federally required rebate, which is approximately 50 percent of initial payments, drug manufacturers offer these states supplemental rebates.

- (2) *Operate as PBMs to broaden purchasing and negotiating power.* Similar to multistate purchasing pools, states can pool in-state participants and use unified formularies for all covered members across state and local programs.
- *Enact legislation that requires pharmaceutical manufacturers to (1) justify excessive price increases for both generic and brand name drugs or face penalties; or (2) provide rebates when prices exceed a specific threshold.*⁵³ Maryland passed into law price-gouging legislation, [HB 631](#), which authorizes the state attorney general to take legal action to stop drug manufacturers from engaging in unconscionable price increases in noncompetitive off-patent or generic drug markets. Despite limitations within HB 631, which is focusing only on generic drugs and is lacking public disclosure of information collected by the state attorney general, Maryland's law presents a new tool to hold drug manufacturers accountable and deter price hikes in the state.⁵⁴ A three judge panel of the U.S. Court of Appeals for the Fourth Circuit recently ruled 2-1 that Maryland's anti-price gouging law unconstitutionally violates the "Dormant Commerce Clause," because, in their view it would affect transactions in other states.⁵⁵ Maryland Attorney General Brian Frosh has appealed the ruling to the full Fourth Circuit Court of Appeals.⁵⁶ State advocates are hopeful that the Attorney General will prevail and get the anti-price gouging law reinstated. Interestingly, a few days after the court decision on Maryland's law, the **Illinois** House of Representatives passed a similar legislation, [HB4900](#), that would give the Illinois attorney general the power to stop price gouging of essential off-patent or generic drugs. The Illinois State Senate is expected to vote on that bill in May.
 - *Create an independent committee to review price setting and annual price increases for prescription drugs.* To ensure consumers are protected from unreasonable prescription drug costs, state agencies should have the authority to evaluate the reasonableness of drug prices. Specifically, for a prescription drug that triggers criteria for a review, state agencies should be able to approve or reject a proposed price before it is allowed to be sold in the state. **Maryland** introduced a drug cost review bill to evaluate the affordability for certain drugs. The proposed bill establishes a Drug Cost Review Commission and an advisory board to closely evaluate high cost drug prices and set the rates at which Marylanders would pay for those drugs, based on a drug's cost and affordability.
 - *Offer public input opportunities.* Consumers should have opportunities to provide input through either a comment period, a public hearing, or formal appeals process.

- **Solution 2: Enact Legislation That Mandates Public Disclosure On Drug Pricing, Investment In Drug Development, Manufacturing And Marketing In Order To Break Down The Opaque Pharmaceutical Supply Chain**

The following policy strategies can be undertaken at the state level.

- *Require department of health or relevant agencies to set a price cap for a specific drug and require drug manufacturers to submit justifications for all drugs with a price cap.* The price cap could be set at a fixed percentage above the average price for that drug sold in the country members of the Organization for Economic Co-operation and Development (OECD). For example, **Maryland** has proposed to cap the amount that the state and commercial health plans would pay for certain drugs rather than the amount drug manufacturers would charge for them. Specifically, the legislation, based on NASHP's Model Drug Price Transparency Act,⁵⁷ requires drug manufacturer to justify their price setting for certain drugs, with an annual cost above \$30,000. **New York** enacted legislation, [S.2007B/A.3007B](#), that requires the state Department of Health to establish a Medicaid spending cap with year-to-year spending targets and to conduct drug expenditure reviews quarterly. If expenditures exceed the department's spending cap, the commissioner identifies and refers specific drugs to a drug utilization board for recommended supplemental rebates. At least 30 drugs were under review after the law was implemented, and the state asked for supplemental rebates from 12 manufacturers—most complied.⁵⁸
- *Require drug manufacturers to submit justifications for all drugs that have a 10-percent price increase above the previous price and to undergo a price review process.* Pharmaceutical manufacturers should be required to publicly disclose detailed information on prescription drug pricing as well as development, manufacturing and marketing costs on a drug-by-drug basis, and grants to non-profit advocacy groups. **Nevada** enacted legislation, [SB 539](#), targeting two specific groups of drugs that are used to treat diabetes, insulin and biguanides. Diabetes drug manufacturers are now required to disclose information about the costs of making and marketing drugs when prices increase by a certain amount. Nevada's law also requires PBMs and nonprofit groups receiving grants from pharmaceutical companies to submit annual reports to the state department of health and human services of their financial arrangements with drug manufacturers. Recently, **Oregon** enacted legislation, [HB 4005](#), to require pharmaceutical manufacturers to compile a report on a prescription drug if the price was \$100 or more for a one-month supply (or course of treatment lasting less than 1 month) and if the net price increased by 10 percent or more. In addition, Oregon's Department of Consumer and Business Services is required to post a list of high drug price increases. Furthermore, insurers are required to show how these drug price increases affect premiums.
- *Require pharmaceutical manufacturers to provide advance notices of price hikes to give time for purchasers to adjust formularies, negotiate price concessions or seek other alternatives.* **California** passed into law a bill, [SB 17](#), which aims to increase transparency in prescription drug pricing through advance notice and public information about the costs of prescription drugs. Drug manufacturers are required to disclose information about drug pricing to the Office of Statewide Health Planning and Development. SB 17 also requires a 60-day advance notice of price hikes for most prescription drugs. Insurers are also required to publicly disclose, through rate review, the percentage of the premium attributable to prescription drug costs.

- **Solution 3: Enact Legislation That Prohibits Manipulative Marketing Practices That Lure Providers And Consumers Toward More Expensive Alternatives**

At the federal level, Congress should:

- *Enact legislation that bans DTCA or eliminates the tax deduction for DTCA.* It is irresponsible to promote unnecessarily expensive drugs to consumers lacking medical knowledge to make smart informed decisions. The American Medical Association has called for a ban on advertising prescription drugs and medical devices directly to consumers.⁵⁹ In 2016, a group of Democratic senators (including Al Franken (D-Minnesota), Sheldon Whitehouse (D-Rhode Island), Sherrod Brown (D-Ohio) and Tom Udall (D-New Mexico)) introduced the Protecting Americans from Drug Marketing Act to amend the Internal Revenue Code of 1986 to eliminate the tax breaks that drug makers can take to offset their spending on ad campaigns.⁶⁰ Savings generated from the elimination of these tax breaks should be used to fund academic detailing programs⁶¹ and educate consumers about how to review prescription drug ads.

At the state level, states should:

- *Limit or ban physician gifts.* The Physician Payment Sunshine provisions under the ACA require drug and medical device manufacturers to publicly report gifts and payments made to physicians and teaching hospitals. However, the law does not limit financial relationships between these entities. **Vermont's** law goes beyond the Physician Payment Sunshine Act to prohibit manufacturers from offering gifts, including “any payment, food, entertainment, travel, subscription, advance or service,” to health care professionals, other providers and Green Mountain Care Board.⁶²
- *Establish public funding for evidence-based academic detailing programs.* Located in medical schools or schools of pharmacy, academic detailing programs operate independently from drug manufacturers. These programs provide prescribers with reliable guidance on potential benefits and possible harms of specific drugs. These programs have shown to be the most effective means to improve physician practices and patient outcomes. Several states, including **Pennsylvania, Massachusetts, New York, Vermont, Maine, South Carolina, and the District of Columbia,** have established academic detailing programs, which have proven to be cost-effective. Studies of existing state programs found that every \$1 invested in these programs results in a \$2 return on investment.⁶³

- **Solution 4: Enact Legislation And Regulations That Aim To Reduce Cost Sharing And Prohibit Discriminatory Formulary Designs (Known As Adverse Tiering) To Ensure Equitable Access To Affordable Medications**

States should enact legislation to:

- *Reduce cost-sharing on prescription drugs by:*

- (1) *Reducing the number of drug tiers through standardized plans* that limit the number of specialty brand name, and generic tiers. **Massachusetts, New York and Vermont** have limited plans to three formulary tiers.

- (2) *Prohibiting the use of coinsurance and capping monthly copayments at no more than \$150 for prescription drugs.* No states have prohibited the use of coinsurance, but at least eight states have limited monthly out-of-pocket payments of patients in private health plans. **Delaware, Louisiana and Maryland** set the monthly limit at \$150 per specialty drug. **California** caps out-of-pocket prescription drug costs at no more than \$250 for a 30-day supply of a prescription drug for most coverage.⁶⁴ Note that the co-pay caps for prescription drugs in California will sunset at the end of 2019 unless the state enacts legislation to make this requirement permanent. In addition, states should consider capping the total annual out-of-pocket spending for prescription drugs at a specific dollar threshold or perhaps no greater than one-twelfth of the annual out-of-pocket maximum. For consumers who rely on multiple prescription drugs a month, this could significantly increase improve affordability.
- (3) *Limit cost-sharing on prescription drugs for people with income at or below 150 percent of the federal poverty level.* For people with this income level who likely have less disposable income, any spending on health insurance premiums or cost-sharing would come not from discretionary income, but rather at the expense of the ability to afford food, clothing, shelter and other necessities. Therefore, states should consider requiring only nominal amounts of cost sharing on prescription drugs or eliminate it altogether.
- *Prohibit discriminatory formulary designs (also known as adverse tiering) by:*
- (1) *Prohibiting insurers from placing all or most drugs that treat a specific condition in a specialty tier.* **Delaware** prohibits insurers from placing all drugs in a given class on a specialty tier. Similarly, **California and Colorado** prohibits plans from designing formularies in the way that discourages enrollment of individuals with health conditions. **Florida** creates a drug-specific chronic conditions template—a tool to help identify adverse tiering—that requires plans to identify the number, name and tier of covered drugs used to treat certain conditions.⁶⁵
- (2) *Working closely with various stakeholders including ombudsmen, providers and consumer health advocacy groups to identify specific examples of discriminatory formulary design and putting into place policies that prohibit insurers from these practices.*

Conclusion

The fast-growing cost of prescription drugs has become a top health care concern for many Americans. Unless policymakers come up with effective strategies to drive down drug prices, many people, especially those living with chronic conditions, will continue to struggle to pay for their medications and end up skipping doses or deciding to not fill their prescription at all. This leads to poorer health and higher health care costs. Consumer advocates, policymakers at both the federal and state levels, and stakeholders can work together to adopt measures that help curb unfair drug pricing and improve affordability for consumers. The work often seems overwhelming given the power and resources of the pharmaceutical lobby. However, with political will, effective advocacy strategies and strong grassroots support, victories are within reach.

Glossary

Authorized generics: are not generic but branded products sold under generic names. Brand-name drug companies often use this tactic to compete with generic companies. By law, the first generic company is granted an exclusivity period of 180 days to market a new generic product. During this time, the FDA might not approve any additional generic competitors. However, the 180-day exclusivity does not preclude a company with the expiring patent from launching an authorized generic. This means by selling a drug they are already making under a different name, brand-name drug companies are drawing revenue away from generic companies during the 180-day exclusivity, thus effectively extending their monopoly for another six months.⁶⁶

The Biologics Price Competition and Innovation Act (BPCIA) (Public Law 111-148) was signed into law as part of the Affordable Care Act in 2010 to create an approval pathway for drugs that are highly similar (biosimilar) to or interchangeable with biological products (drugs made from human and/or animal materials). The BPCIA establishes a 12-year data exclusivity for new biological structures and a one-year exclusivity for biosimilars. The law also creates a patent dispute resolution process that requires the biosimilar sponsor to disclose information about its manufacturing process to the relevant patent holder. A series of informational exchanges then occur in which the biosimilar sponsor and the original patent holder identify a list of patents that are in question. The validity of the claims of infringement can then be adjudicated.⁶⁷

Sham citizen petition: Brand-name drug companies file “sham” citizen petitions to ask the FDA to delay action on a pending generic application. Many of these petitions are submitted near the date of patent expiration, effectively limiting potential competition for another 150 days. According to the FDA, brand-name drug companies submit 92 percent of all citizen petitions.⁶⁸

The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417) commonly known as the Hatch-Waxman Act, was enacted in 1984 with two main goals: (1) to grant brand-name drug companies extensions in market exclusivity as incentives for innovation in pharmaceutical research and development; and (2) to create price competitions by helping low-cost and high-quality generic drugs enter the market quickly. At first, the Hatch-Waxman Act had a positive record of success with a robust generic drug market. By 2012, generic drugs became the standard of care for many common diseases as they were less expensive than branded drugs and were available in nearly every therapeutic class. However, after 30 years of success, numerous problems have emerged. Some were the results of deliberate manipulation of the law by the pharmaceutical industry to maximize their profits, others involve interpretation of the statute by the Supreme Court in a way that unintentionally limits the liability of generic drug companies when patients are harmed by their drugs, which may disincentive future uses of generic drugs.⁶⁹

The Federal Medicaid Rebate Program was created by the Omnibus Budget Reconciliation Act of 1990 to help lower Medicaid spending on outpatient prescription drugs by ensuring states receive discounts similar to those provided to private purchasers. Under this program, participating drug manufacturers are required to enter into a national rebate agreement with the HHS secretary in exchange for state Medicaid coverage of most of their products. Approximately 600 drug manufacturers and all 50 states are in the program. The program has generated significant revenue for the states (and the federal government) and helped offset Medicaid prescription drug expenditures. However, states, payers and drug manufacturers are considering whether the program is an effective approach to lower drug costs and improve access to therapies.⁷⁰

The Generating Antibiotic Incentives Now (GAIN Act) provisions ([Public Law 112–144](#)) was signed into law in 2012 as part of the Food and Drug Administration Safety and Innovation Act. The GAIN Act extends an additional five years of exclusivity for new antibiotics that are qualified as infectious disease products—antibacterial or antifungal drugs to treat serious or life-threatening infections. This extra five years of market protection is in addition to any existing exclusivity, including that which may be applicable under Hatch-Waxman, orphan drug or pediatric exclusivity.⁷¹

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ([Public law 108 -173](#)) also called the Medicare Modernization Act includes the Medicare Part D prescription drug benefit plan. Under Part D, private plans negotiate drug prices with drug manufacturers and structure benefits (including formularies, cost-sharing, utilization management policies and preferred pharmacies). While creating an opportunity for Medicare beneficiaries to purchase drug coverage—a choice they had not have before, the Medicare Modernization Act has effectively expanded the role of private plans in Medicare and prohibited any interference by HHS with respect to drug prices.⁷²

The Orange Book (Approved Drug Product with Therapeutic Equivalence Evaluations). Required by the Hatch-Waxman Act, FDA publishes the Orange Book that lists drug products approved on the basis of safety and effectiveness under the [Federal Food, Drug, and Cosmetic Act](#). The Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. Inclusion of products in the Orange Book is independent of any current regulatory actions through administrative or judicial means against a drug product. In addition, therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the Federal Food, Drug, and Cosmetic Act.⁷³

The Orphan Drug Act ([Public Law 97-414](#)) was enacted in 1983 to stimulate the development of orphan drugs—drugs for rare diseases (such as Huntington’s Disease, myoclonus, ALS, Tourette syndrome and muscular dystrophy) that affect fewer than 200,000 Americans. Prior to its passage, the pharmaceutical industry had little incentive to invest money in the development of treatments for small patient populations, because the drugs were expected to be unprofitable. The law provides seven-year market exclusivity to sponsors of approved orphan products, a tax credit of 50 percent of the cost of conducting human clinical testing, and research grants for clinical testing of new therapies to treat orphan diseases. These incentives have encouraged the pharmaceutical industry to accelerate research and development of these drugs allowing patients with orphan diseases access to treatment. However, many drugs that have gained the orphan drug status are not entirely new. According to a *Kaiser Health News* investigation, more than 70 percent of these drugs were first approved by FDA for mass market use. These medicines were later approved as orphans.⁷⁴

Pay-for-delay: In a pay-for-delay deal, a brand-name drug company pays off a would-be competitor to delay it from selling a generic version of the drug. Without any competition, the brand-name company can continue demanding high prices for its drug.⁷⁵

Product-hopping: is a tactic by which brand-name drug companies can try to obstruct generic competitors and preserve monopoly profits on a patented drug by making modest reformulations that offer little or no therapeutic advantages. Product-hopping is also called ever greening.⁷⁶

Risk evaluation and mitigation strategy (REMS): In 2007, Congress enacted the Food and Drug Administration Amendments Act (FDAAA) that require generic sponsors of drug applications to submit a proposed REMS if the FDA determines that it is needed to ensure a drug's benefits outweigh its risks. Six factors considered for REMS include: (1) the population size likely to use the drugs; (2) the seriousness of the disease; (3) the drug's expected benefit; (4) the expected duration of treatment; (5) the seriousness of adverse effects; and (6) the drug's novelty. The FDA can require a REMS before a drug enters the market based on known risks or after the drug has been approved based on new evidence of risk. Brand-name manufacturers have use this regulatory strategy to block generic companies from getting testing samples.⁷⁷

Endnotes

- ¹ Joseph E. Stiglitz. Prizes, Not Patents. *Project Syndicate*, March 6, 2007. <https://www.project-syndicate.org/commentary/prizes--not-patents?barrier=accessreg>. Accessed April 27, 2018.
- ² D. O. Sarnak, D. Squires, G. Kuzmak, and S. Bishop, Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? *The Commonwealth Fund*, October 2017. <http://www.commonwealthfund.org/publications/issue-briefs/2017/oct/prescription-drug-costs-us-outlier>. Accessed April 27, 2018.
- ³ Micah Hartman, Anne B. Martin, Nathan Espinosa, Aaron Catlin, and The National Health Expenditure Accounts Team. National Health Care Spending In 2016: Spending And Enrollment Growth Slow After Initial Coverage Expansions. *Health Affairs* 37, No. 1 (2018): 150–160. doi: 10.1377/hlthaff.2017.1299. Accessed April 27, 2018.
- ⁴ Papanicolas I, Woskie LR, Jha AK. Health Care Spending in the United States and Other High-Income Countries. *JAMA*. 2018; 319(10):1024–1039. doi:10.1001/jama.2018.1150. Accessed April 27, 2018.
- ⁵ Gigi A. Cuckler, Andrea M. Sisko, John A. Poisal, Sean P. Keehan, Sheila D. Smith, Andrew J. Madison, Christian J. Wolfe, and James C. Hardesty. National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Affairs* 37, NO. 3 (2018): 482–492. doi: 10.1377/hlthaff.2017.1655. Accessed April 27, 2018.
- ⁶ The Department of Health and Human Services. Observations on Trends in Prescription Drug Spending. *ASPE Issue Brief*. March 2016. <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>. Accessed April 27, 2018.
- ⁷ Henry J Kaiser Family Foundation. Public Opinion on Prescription Drugs and Their Prices: Poll Findings from 2015-2018. *KFF Health Tracking Polls*. <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>. Accessed April 27, 2018.
- ⁸ Andrew W. Mulcahy, Christine Eibner, and Kenneth Finegold. Gaining Coverage Through Medicaid Or Private Insurance Increased Prescription Use And Lowered Out-Of-Pocket Spending. *Health Affairs* 35, NO. 9 (2016): 1725–1733. doi: 10.1377/hlthaff.2016.0091. Accessed April 27, 2018.
- ⁹ Cynthia Cox, Anthony Damico, Gary Claxton and Larry Levitt. Examining High Prescription Drug Spending For People With Employer Sponsored Health Insurance. Henry J Kaiser Family Foundation. October 2016. <https://www.healthsystemtracker.org/brief/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/#item-start>. Accessed April 27, 2018.
- ¹⁰ Bianca DiJulio, Ashley Kirzinger, Bryan Wu, and Mollyann Brodie. Data Note: Americans’ Challenges with Health Care Costs. Henry J Kaiser Family Foundation. March 2017. <http://www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/>. Accessed April 27, 2018.
- ¹¹ Liz Szabo. As Drug Costs Soar, People Delay Or Skip Cancer Treatments. *NPR Shots*. March 15, 2017. <http://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments>. Accessed April 27, 2018.
- ¹² Jane E. Brody. The Cost of Not Taking Your Medicine. *The New York Times*. April 17, 2017. https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html?_r=0. Accessed April 27, 2018.
- ¹³ Medicaid and CHIP Payment and Access Commission (MACPAC). Medicaid Spending for Prescription Drugs. *MACPAC*. January 2016. <https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf>. Accessed April 27, 2018.
- ¹⁴ The Kaiser Family Foundation. State Health Facts: Medicaid Benefits: Prescription Drugs. 2012. <https://www.kff.org/medicaid/state-indicator/prescription-drugs/>. Accessed April 27, 2018.
- ¹⁵ The term “market exclusivity” can be confusing as there are three forms of extended protection for monopoly pricing: (1) patents; (2) data exclusivity where one can still submit independently clinical trial data, just not rely on data from already registered originator drug; and (3) market exclusivity where one is precluded from submitting for registration of a follow-on product.
- ¹⁶ Naren P. Tallapragada. Off-Patent Drugs At Brand-Name Prices: A Puzzle For Policymakers. *Journal of Law and the Biosciences*. 2016; 3(1):238-247. doi:10.1093/jlb/lsw008. Accessed April 27, 2018.

- ¹⁷ U.S. Government Accountability Office. Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals. November 2017. <https://www.gao.gov/assets/690/688472.pdf>. Accessed April 27, 2018.
- ¹⁸ Aaron S. Kesselheim, MD, JD, MPH; Jerry Avorn, MD; Ameet Sarpatwari, JD, PhD. The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform. *JAMA*. 2016; 316(8): 858-871. doi: 10.1001/jama.2016.11237. Accessed April 27, 2018.
- ¹⁹ David Balto. Removing Obstacles to Generic Drug Competition: A Critical Priority for Health Care Reform. Center for American Progress. June 2009. <https://www.americanprogress.org/issues/economy/reports/2009/06/23/6281/removing-obstacles-to-generic-drug-competition/>. Accessed April 27, 2018.
- ²⁰ Cynthia Koons and Robert Langreth. The Loopholes Drug Companies Use to Keep Prices High. *Bloomberg*. December 20, 2017. <https://www.bloomberg.com/news/features/2017-12-20/the-loopholes-drug-companies-use-to-keep-prices-high>. Accessed April 27, 2018.
- ²¹ Federal Trade Commission. Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. 2010. <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>. Accessed April 27, 2018.
- ²² Neeraj Sood, PhD; Tiffany Shih, PhD; Karen Van Nuys, PhD; Dana Goldman, PhD. The Flow of Money through the Pharmaceutical distribution System. *The Leonard D. Schaeffer Center for Health Policy and Economics*. June 2017. http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf. Accessed April 27, 2018.
- ²³ Kevin A. Schulman, MD; and Barak D. Richman, JD, PhD. The Evolving Pharmaceutical Benefits Market. *JAMA*. April 2018. doi:10.1001/jama.2018.4269. Accessed April 27, 2018.
- ²⁴ David Dayen. The Hidden Monopolies That Raise Drug Prices: How Pharmacy Benefit Managers Morphed From Processors To Predators. *The American Prospect*, March 28, 2018. <http://prospect.org/article/hidden-monopolies-raise-drug-prices>. Accessed April 27, 2018.
- ²⁵ Donald W Light, professor 1, Joel R Lexchin. Pharmaceutical Research And Development: What Do We Get For All That Money? *BMJ* 2012; 345:e4348. <https://doi.org/10.1136/bmj.e4348> Accessed April 27, 2018.
- ²⁶ Institute for Health and Socio-Economic Policy. The R&D Smokescreen: The Prioritization of Marketing & Sales in the Pharmaceutical Industry. October 2016. <http://nurses.3cdn.net/e74ab9a3e937fe5646afm6bh0u9.pdf>. Accessed April 27, 2018.
- ²⁷ The Pew Charitable Trust. Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients. November 2013. <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients>. Accessed April 27, 2018.
- ²⁸ Scott E. Hadland, MD, MPH, MS; Magdalena Cerdá, DrPH, MPH; Yu Li, MD, PhD; et al Maxwell S. Krieger, BS; Brandon D. L. Marshall, PhD. Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing. *JAMA*. May 2018. doi:10.1001/jamainternmed.2018.1999. Accessed May 21, 2018.
- ²⁹ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM). Guidance for Industry Consumer-Directed Broadcast, Advertisements, Questions and Answers. August 1999. <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM122825.pdf>. Accessed April 27, 2018.
- ³⁰ Leemore Dafny, Christopher Ody, Matt Schmitt. When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization. *UCLA Anderson School of Management*, October 4, 2016. http://www.hbs.edu/faculty/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf. Accessed April 27, 2018.
- ³¹ John Henning Schumann. Those TV Drug Ads Distract Us From The Medical Care We Need. *NPR Shots*, April 29, 2017. <https://www.npr.org/sections/health-shots/2017/04/29/525877472/those-tv-drug-ads-distract-us-from-the-medical-care-we-need>. Accessed April 27, 2018.

- ³² Matthew S. McCoy, Ph.D., Michael Carniol, M.B.A., Katherine Chockley, B.A., John W. Urwin, B.S., Ezekiel J. Emanuel, M.D., Ph.D., and Harald Schmidt, Ph.D. Conflict of Interest for Patient-Advocacy Groups. *The New England Journal of Medicine* 2017; 376: 880-885. <http://www.nejm.org/doi/pdf/10.1056/NEJMs1610625>. Accessed April 27, 2018.
- ³³ Alisan Kodjak. Specialty Drugs Can Prove Expensive Even With Medicare Coverage. *NPR Shots*, December 3, 2015. <https://www.npr.org/sections/health-shots/2015/12/03/458216778/specialty-drugs-can-prove-expensive-even-with-medicare-coverage>. Accessed April 27, 2018.
- ³⁴ Sandy Ahn and Sabrina Corlette. State Efforts to Lower Consumer Cost-Sharing for High-Cost Prescription Drugs. *Urban Institute*. August 2017. <https://www.urban.org/sites/default/files/publication/93071/2001491-state-efforts-lower-rx-cost-sharing.pdf>. Accessed April 27, 2018.
- ³⁵ Ibid. footnote 32.
- ³⁶ A number of consumer protections under the ACA include: guaranteed issue, bans on preexisting condition exclusions and lifetime/annual limits, new rating reforms, essential health benefits and prohibiting discrimination based on a variety of factors including health status. However, these protections could be undercut if short-term health insurance that don't meet the ACA requirement become more widely available.
- ³⁷ Michelle Andrews. 7 Insurers Alleged To Have Discriminated Against HIV Patients. *NPR Shots*, October 18, 2016. <http://www.npr.org/sections/health-shots/2016/10/18/498427561/7-insurers-alleged-to-have-discriminated-against-hiv-patients>. Accessed April 27, 2018.
- ³⁸ Avalere PlanScape®. Prescription Drug Tier Placement and Cost Sharing in Health Insurance Exchange Plans. Avalere. February 2015. http://go.avalere.com/acton/attachment/12909/f-017c/1/-/-/20150211Avalere%20Planscape%202015_Class%20Tiering%20Analysis.pdf. Accessed April 27, 2018.
- ³⁹ Douglas B. Jacobs, Sc.B., and Benjamin D. Sommers, M.D., Ph.D. Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace. *The New England Journal of Medicine* 2015; 372:399-402. doi: 10.1056/NEJMp1411376. Accessed April 27, 2018.
- ⁴⁰ S.771 - Improving Access To Affordable Prescription Drugs Act. 115th Congress (2017-2018). <https://www.congress.gov/bill/115th-congress/senate-bill/771>. Accessed April 27, 2018.
- ⁴¹ CMS-4182-P: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (Proposed Rule). <https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-25068.pdf>. Accessed April 27, 2018.
- ⁴² Department of Health and Human Services U.S.A. American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-Of-Pocket Costs. May 2018. <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> Accessed May 21, 2018.)
- ⁴³ Aaron Berman, Theodore Lee, Adam Pan, Zain Rizvi, Arielle Thomas. Curbing Unfair Drug Prices: A Primer for States. The Yale Global Health Justice Partnership. August 2017. https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf. Accessed April 27, 2018.
- ⁴⁴ Ibid. footnote 27.
- ⁴⁵ Jane Horvath. State Legislatures Start Out Strong in 2018 with Bills to Curb Rx Drug Costs. *NASHP Blog*, January 23, 2018. <https://nashp.org/state-legislatures-start-out-strong-to-curb-rx-costs-in-2018/> Accessed April 27, 2018.
- ⁴⁶ Hannah Brennan, Amy Kapczynski, Christine H. Monahan, and Zain Rizvi. A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health. *Yale J.L. & Tech* 2016; 275(18): 275- 354. https://www.yjolt.org/sites/default/files/kapczynski_18yjolt275_gk_0_0.pdf. Accessed April 27, 2018.
- ⁴⁷ Katherine Young and Rachel Garfield. Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control. Henry J Kaiser Family Foundation. February 2018. <http://files.kff.org/attachment/Issue-Brief-Snapshots-of-Recent-State-Initiatives-in-Medicaid-Prescription-Drug-Cost-Control>. Accessed April 27, 2018.

- ⁴⁸ Between May 8 and June 7, 2017, Louisiana Department of Health was reviewing public comment received on using 28 U.S.C. §1498 to buy generic versions of Hepatitis C drugs. While there were a number of powerful statements from patients, family members, health care professionals, other Louisiana residents, and national advocacy groups highlighting the burden of Hepatitis C and expressing their support for this approach, the LDH also received opposing statements from the pharmaceutical industry and other stakeholders without offering an alternative approach. LDH is continuing to consult with additional stakeholders for next steps moving forward. <http://ldh.la.gov/index.cfm/newsroom/detail/4227>. Accessed April 27, 2018.
- ⁴⁹ Henry Waxman, Bill Corr, Kristi Martin, Sophia Duong. Getting to the Root of High Prescription Drug Prices Drivers and potential solutions. *The Commonwealth Fund*. July 2017. http://www.commonwealthfund.org/~media/files/publications/fund-report/2017/jul/waxman_high_drug_prices_drivers_solutions_report.pdf. Accessed April 27, 2018.
- ⁵⁰ Aaron S. Kesselheim, MD, JD, MPH; Michael S. Sinha, MD, JD, MPH; Jerry Avorn, MD. Determinants of Market Exclusivity for Prescription Drugs in the United States. *JAMA Intern Med*. 2017;177(11):1658-1664. doi:10.1001/jamainternmed.2017.4329. Accessed April 27, 2018.
- ⁵¹ Juliette Cubanski and Tricia Neuman. Searching for Savings in Medicare Drug Price Negotiations. *Henry J Kaiser Family Foundation*. April 2018. <http://files.kff.org/attachment/issue-brief-searching-for-savings-in-medicare-drug-price-negotiations>. Accessed April 2018.
- ⁵² National Conference of State Legislature (NCSL). Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans. November 2017. <http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx#SSDC>. Accessed April 27, 2018.
- ⁵³ *ibid.* footnote 36
- ⁵⁴ Lucas Allen. Demanding Affordable Medicines: Lessons from Maryland's Law against Price Gouging. *Truthout*, September 18, 2017. <http://www.truth-out.org/news/item/41966-demanding-affordable-medicines-lessons-from-maryland-s-law-against-price-gouging>. Accessed April 27, 2018.
- ⁵⁵ Association For Accessible Medicines v. Brian E. Frosh, in his official capacity as Attorney General for the State of Maryland; Dennis R. Schrader, in his official capacity as Secretary of the Maryland Department of Health. U.S. Memorandum Of Law In Support Of Plaintiff's Motion For Preliminary Injunction. Court Of Appeals For The Fourth Circuit. Appeal from the United States District Court for the District of Maryland, at Baltimore. Marvin J. Garbis, Senior District Judge. (1:17-cv-01860-MJG). 2018. <http://www.ca4.uscourts.gov/Opinions/172166.P.pdf>. Accessed April 27, 2018.
- ⁵⁶ Association For Accessible Medicines v. Brian E. Frosh. Petition For Rehearing En Banc. On Appeal from the United States District Court for the District of Maryland (Marvin J. Garbis, District Judge) http://www.marylandattorneygeneral.gov/news%20documents/AAMvFrosh_Petition_for_Rehearing.pdf. Accessed April 30, 2018
- ⁵⁷ The National Academy for State Health Policy. Model Act: An Act to Promote Prescription Drug Price Transparency and Cost Control. 2017. <https://nashp.org/wp-content/uploads/2017/03/Transparency-Model-Legislation.pdf>. Accessed April 27, 2018.
- ⁵⁸ Jason A. Helgerson. Medicaid Drug Cap Webinar. New York Department of Health. August, 2017. https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/docs/2017-8-29_medicaid_drug_cap.pdf. Accessed April 27, 2018.
- ⁵⁹ American Medical Association. AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices. Statement released on November 17 2015. <https://www.ama-assn.org/content/ama-calls-ban-direct-consumer-advertising-prescription-drugs-and-medical-devices>. Accessed April 27, 2018.
- ⁶⁰ S.2623 - Protecting Americans from Drug Marketing Act. 114th Congress (2015-2016). <https://www.congress.gov/bill/114th-congress/senate-bill/2623/text>. Accessed April 27, 2018.
- ⁶¹ Community Catalyst. Fact Sheet: Academic Detailing: Evidence-Based Prescribing Information. Pew Prescription Project. April 2009. https://www.communitycatalyst.org/doc-store/publications/Academic-Detailing_Fact_Sheet.pdf. Accessed April 27, 2018.
- ⁶² Wendy Goldstein, Sarah K. Giesting and Amy Dow. Vermont Bans Gifts and Expands Disclosure

- Requirements for Payments to Health Care Providers. *Epstein Becker Green*. October 2009. https://www.ebglaw.com/content/uploads/2014/06/32060_HealthAlertVermont.pdf. Accessed April 27, 2018.
- ⁶³ National Conference of State Legislatures. NCSL Briefs for State Legislature: Health Cost Containment and Efficiencies. May 2011. <http://www.ncsl.org/documents/health/introandbriefscc-16.pdf>. Accessed April 27, 2018.
- ⁶⁴ Ibid. footnote 34
- ⁶⁵ Consumer representatives to the NAIC. Promoting Access to Affordable Prescription Drugs: Policy Analysis and Consumer Recommendations for State Policymakers, Consumer Advocates, and Health Care Stakeholders. August 2016. http://consumersunion.org/wp-content/uploads/2016/08/Promoting-Access-to-Affordable-Prescription-Drugs_Aug-2016.pdf. Accessed April 27, 2018.
- ⁶⁶ Federal Trade Commission. Authorized Generic Drugs: Short-Term Effects and Long-Term Impact. August 2011. <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>. Accessed April 27, 2018.
- ⁶⁷ Claire Laporte. Manufacturers of Biosimilar Drugs Sit Out the 'Patent Dance'." *Health Affairs Blog*, March 10, 2017. 10.1377/hblog20170310.059143. Accessed April 27, 2018.
- ⁶⁸ Sarah Zhang. How Pharma Companies Use 'Citizen Petitions' to Keep Drug Prices High. *The Atlantic*, March 8, 2017. <https://www.theatlantic.com/health/archive/2017/03/pharma-citizen-petitions-drug-prices/518544/>. Accessed April 27, 2018.
- ⁶⁹ Aaron S. Kesselheim and Jonathan J. Darrow. Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era? *Yale Journal of Health Policy, Law, and Ethics*. 2015: Vol. 15: Issue 2, Article 2. <http://digitalcommons.law.yale.edu/yjhple/vol15/iss2/2>. Accessed April 27, 2018.
- ⁷⁰ Ramsey Baghdadi. Health Affairs Policy Brief: Medicaid Best Price. *Health Affairs*, August 10, 2017. doi: 10.1377/hpb2017.8. Accessed April 27, 2018.
- ⁷¹ The Pew Charitable Trusts. Issue Brief: GAIN: How a New Law Is Stimulating the Development of Antibiotics. November 07, 2013. <http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2013/11/07/gain-how-a-new-law-is-stimulating-the-development-of-antibiotics>. Accessed April 27, 2018.
- ⁷² Health Policy Alternatives, Inc. Prescription Drug Coverage for Medicare Beneficiaries: An Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Henry J. Kaiser Family Foundation. January 2004. <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/prescription-drug-coverage-for-medicare-beneficiaries-an-overview-of-the-medicare-prescription-drug-improvement-act-2003.pdf>. Accessed April 27, 2018. Marsha Gold. Medicare Part D's Importance Extends Far Beyond the Drug Benefit It Provides. *Health Affairs Blog*, January 15, 2016. doi: 10.1377/hblog20160115.052694. Accessed April 27, 2018.
- ⁷³ U.S. Food & Drug Administration. Orange Book Preface: Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Equivalence Evaluations. Preface to the 38th Edition. <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>. Accessed April 27, 2018.
- ⁷⁴ Sarah Jane Tribbe and Sydney Lupkin Drugmakers Manipulate Orphan Drug Rules To Create Prized Monopolies. *Kaiser Health News*, January 17, 2017. <https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/>. Accessed April 27, 2018.
- ⁷⁵ Community and U.S. PIRG. Top Twenty Pay-For-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers. July 2013. <https://www.communitycatalyst.org/doc-store/publications/top-20-pay-for-delay-drugs.pdf>. Accessed April 27, 2018.
- ⁷⁶ Michael Carrier and Steve Shadowen. Pharmaceutical Product Hopping: A Proposed Framework for Antitrust Analysis. *Health Affairs Blog*, June 1, 2017. doi: 10.1377/hblog20170601.060360. Accessed April 27, 2018.
- ⁷⁷ Michael A. Carrier. Sharing, Samples, and Generics: An Antitrust Framework. *Cornell Law Review*, Volume 103: Issue 1. November 2017. <https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=4742&context=clr>. Accessed April 27, 2018.



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