



Enough Is Enough

The Time Has Come to Address Sky-High Drug Prices

By Topher Spiro, Maura Calsyn, and Thomas Huelskoetter

September 2015

Center for American Progress



Enough Is Enough

The Time Has Come to Address Sky-High Drug Prices

By Topher Spiro, Maura Calsyn, and Thomas Huelskoetter

September 2015

Contents

- 1 Introduction and summary**
- 4 Life cycle of a prescription drug**
- 9 Spending on prescription drugs**
- 13 How we pay for prescription drugs**
- 21 Policy recommendations**
- 35 Conclusion**
- 37 Endnotes**

Introduction and summary

In any given month, about half of all Americans—and 90 percent of seniors—take a prescription drug.¹ These medications help millions of patients fight illnesses and recover from injuries; they also shorten the duration of common illnesses, alleviate pain, and treat life-threatening illnesses. Simply put, prescription drugs save lives and can prevent costlier, more invasive treatments.

Yet not all drugs offer the same value, and too often, patients and insurers pay exorbitant prices for their medications, even for products that are no more effective than cheaper options. In 2014, more than half a million Americans took at least \$50,000 worth of prescription drugs each.² Americans pay out of pocket for a much greater share of prescription drug costs than hospital costs.³ Not surprisingly, almost three-quarters of the public thinks that drug costs are too high.⁴ And while drug prices keep going up, a significant percentage of new prescription drugs are designed to treat the same conditions and offer little clinical advantage over existing drugs.⁵

Spending on prescription drugs is now growing at a faster rate than spending on any other health care item or service.⁶ Furthermore, drug prices are rising at a rapid enough rate that they are affecting the overall rate of health care cost growth.⁷ For example, Medicare's costs per beneficiary increased by 2.3 percent during 2014, after two years of no growth, due in large part to the almost 11 percent increase in drug costs for the program.⁸

There are numerous reasons why patients and health care payers pay such exorbitant prices for prescription drugs. Unlike other nations, the United States does not directly regulate the prices that drug companies can charge for their products. In addition, patent protection and market exclusivity shield drug manufacturers from normal market competition, giving manufacturers significantly greater bargaining power than insurers. Without any competition or additional regulation of prices, the price is simply what the manufacturer sets for its monopoly product.

All consumers end up paying more for health care because of these high prices. Patients in need of expensive medications often will pay thousands of dollars per month. But it is not just patients who need these products who help pay these costs. Rising drug costs also increase premiums and cost sharing for all consumers.⁹ These costs also will continue to squeeze federal and state budgets as Medicare, Medicaid, and other health care programs pay for these treatments. At the same time, drug company profits continue to increase at a faster pace than any other sector of the health care industry.¹⁰

This growing crisis is not sustainable. In a previous report, the Center for American Progress recommended several policies that the nonpartisan Congressional Budget Office, or CBO, estimates would reduce federal spending on drugs by more than \$140 billion over 10 years.¹¹ The focus of this report is a package of new, additional ideas that will:

- Lower drug costs across the board
- Ensure that relative drug prices reflect the benefits to patients
- Address drug costs paid for by both public programs and private insurance

The table on the following page summarizes the proposed package.

Together, these reforms will broaden the impact of research, lower costs for prescription drugs throughout the system, and offer greater financial protection for those Americans whose lives and health depend on prescription medications.

Integrated package of reforms

Encourage true innovation

- Provide transparency on research and development costs.
- Categorize new drugs by their comparative effectiveness. Using a private, independent organization, categorize new drugs by whether they provide no added benefit, minor added benefit, or significant added benefit compared with existing drugs.
- Provide star ratings of comparative effectiveness in drug labeling and marketing.
- If drug companies do not invest a minimum amount of money in R&D, require them to pay a refund to the National Institutes of Health.

Ensure that the system pays for value

- Develop voluntary recommendations of payment ranges to inform negotiations between payers and drug companies by using a private, independent organization.
- Incentivize drug companies to charge reasonable prices. If negotiated prices fall outside the recommended range, require public justifications and license patents that result from federally funded research to competitors.
- Level the playing field for private-sector negotiations by aggregating the purchasing power of pharmacy benefit managers and payers.
- Reform Medicare payment for physician-administered drugs.
- Allow payers to pay for success.
- Vary Medicaid drug rebates based on the comparative effectiveness of drugs.

Lower out-of-pocket costs for individuals

- Limit cost sharing in marketplace plans and employer plans.
- Provide cost-sharing information for specific drugs to consumers and physicians and allow insurers to have more flexibility in designing their drug formularies.

Life cycle of a prescription drug

The majority of spending on prescription drugs in the United States is for brand-name drugs during their exclusivity periods. Brand-name drugs make up only 20 percent of all prescriptions in the United States but account for 80 percent of spending on drugs.¹² Within the brand-name market, a limited number of very high-cost biologics—drugs made from living cells—and other specialty drugs that treat complex, chronic, and life-threatening conditions are driving prices even higher. This trend will continue: The majority of prescription medications are still chemically synthesized small-molecule drugs, but biologics are becoming more common and comprise about 40 percent of all drugs currently under development.¹³

Manufacturers are able to set extraordinarily high prices during a brand-name drug's exclusivity period—a 5-year period for chemical products and a 12-year period for biologics.¹⁴ After the exclusivity period ends, generic versions may enter the market, which in turn drives down prices.

Drug manufacturers defend their high prices by citing their research and development, or R&D, costs and the time it takes for the Food and Drug Administration, or FDA, to approve a new product. Yet manufacturers charge prices that not only allow them to recoup their significant R&D expenses but also to enjoy the highest profit margins of any part of the health care system.¹⁵

New drug development and approval

When developing new drugs, most pharmaceutical companies rely on basic research—funded in large part by the federal government and conducted by researchers at the National Institutes of Health, or NIH, and in academic laboratories—that studies the mechanisms of diseases. Pharmaceutical and biotechnology companies then use these findings as a jumping-off point for their applied R&D efforts.

Industry-sponsored laboratory and animal testing first tests a potential drug or biologic to determine if its investigational use in people is reasonably safe.¹⁶ Companies then conduct clinical, or human, testing, which usually occurs in a number of phases on increasingly larger groups of patients. The FDA monitors these clinical trials, which study the product's effectiveness and safety in people and consider side effects; dosing; and interactions with other drugs, food, and beverages. These studies do not, however, compare the drug's safety and effectiveness with other medications or treatments used to treat the same illness.

When the company believes it has compiled enough evidence to show that its product is safe and effective, it will seek FDA approval. The FDA approves a drug for marketing and sale if the data show that its benefits outweigh the known risks for its proposed use. The Tufts Center for the Study of Drug Development¹⁷ estimates that it takes eight years for a drug to move from the start of clinical trials through FDA approval.¹⁸

While the FDA's standard review time once a manufacturer seeks approval for a new drug is about 12 months, there are expedited approval pathways available to products that show early signs of promise or that offer new treatments for severe conditions with few existing therapeutic options.¹⁹ Some of the expedited approval programs offer rolling FDA review or a shorter clock for review, while others also authorize FDA approval based on more-limited clinical trial data.²⁰ In those cases, the drug is generally subject to postapproval testing, which is particularly important because, as one study has noted, "Drugs that are approved after a shortened premarket period or based on ... [limited data] may later be found to have greater risks or less certain benefits than was initially believed to be the case."²¹ These postapproval studies do not, however, include comparing the new treatments with existing therapies.²²

Costs to bring a new drug to market

The cost of developing new prescription drugs is a highly contested topic. Pharmaceutical companies commonly cite estimates from the industry-funded Tufts Center, which in 2014 updated its analysis to conclude that the development costs for a new prescription drug average \$2.6 billion.²³ Previously, in 2001, Tufts estimated the cost to be \$800 million, or about \$1 billion in 2013 dollars.²⁴

Then and now, the Tufts estimates feature a number of questionable methodological assumptions, leading many other experts to dispute the findings.²⁵ Most notably, \$1.2 billion of the \$2.6 billion estimate represents not actual costs but instead the hypothetical return on investment that a pharmaceutical company could have received by investing the money instead of using it in the development of a drug. As Aaron Carroll—a well-known health care policy expert and physician—has pointed out, however, research is an essential expense for a drug company, not an optional investment, and “if at some point it doesn’t invest in research and development, it won’t be a drug company anymore.”²⁶

In addition to this, the remaining \$1.4 billion of the Tufts estimate has its own flaws. It assumes that the average drug represents a new molecular entity, or NME, and is developed entirely with pharmaceutical company funding. For the majority of approved drugs, neither of these assumptions is true. Most approved drugs are not NMEs; in 2013, the percentage of new drug approvals that were NMEs was 28 percent, with the percentage rising to 37 percent in 2014.²⁷ Moreover, most new drugs are at least partially funded by the federal government at the basic research stage.²⁸ Finally, the Tufts analysis does not factor in the effects of federal R&D tax credits.

Given these concerns, the Tufts figure must be considered an inflated and imperfect yardstick. Unfortunately, however, there has been little transparency around actual pharmaceutical company costs, so it is not possible to identify a more reliable average cost.

Comparing R&D to other pharmaceutical expenditures

According to the Pharmaceutical Research and Manufacturers of America, or PhRMA—the pharmaceutical industry trade group—its member companies spent \$51.2 billion on R&D in 2014, representing 17.9 percent of total domestic and international sales.²⁹ This includes both preapproval and postapproval spending; a PhRMA breakdown shows that about 14 percent of R&D spending in 2012 involved additional research on drugs that had already received FDA approval, rather than on the development of new drugs.³⁰ The creation of biologic drugs generally requires a larger investment in R&D: According to one industry analysis, large biotechnology companies spent an average of 46 percent of sales on R&D in 2012.³¹

Pharmaceutical R&D funding is focused on the clinical trials and applied research that develop promising discoveries into market-ready medicines. According to National Science Foundation data, only 7.7 percent of pharmaceutical R&D spending goes to the basic research that leads to the discovery of NMEs.³² By some estimates, about four-fifths of basic research is funded by the federal government and other public sources.³³ Similarly, a recent study in *Health Affairs* that looked specifically at the development of the most truly innovative drugs over the past two-and-a-half decades found that the majority of them originated from discoveries made by publicly funded basic research, rather than from basic research funded by the pharmaceutical industry.³⁴

Although PhRMA argues that high prices are necessary to recoup its large investment in R&D, profit margins among the top 10 drugmakers ranged from 10 percent to 43 percent in 2013, with five of these companies racking up profit margins of 20 percent or higher.³⁵ On average, the pharmaceutical sector has significantly higher annual net profit margins than almost any other industry—more than double the average net profit margin for Standard & Poor's, or S&P, 500 companies.³⁶

Furthermore, an analysis by GlobalData found that 9 of the 10 largest pharmaceutical companies in the United States spend more on marketing than on R&D.³⁷ Although direct-to-consumer advertising, which is not permitted in most other countries, is the most visible form of drug advertising here, the bulk of pharmaceutical marketing is targeted at physicians. ProPublica, the independent non-profit investigative newsroom, analyzed a new federal database of drug company payments to doctors and found that the most heavily marketed drugs offered little to no added benefit over alternative therapies; several, in fact, were later discovered to have major side effects.³⁸ Genuine breakthroughs and innovations, on the other hand, had considerably lower levels of marketing, since they were considered to “sell themselves” without the need for significant promotion to doctors or patients.³⁹ Thus, unlike in most industries, pharmaceutical marketing often may be inversely related to innovation rather than complementary.

‘Me-too’ drugs and ‘evergreening’ drive up costs

Me-too drugs imitate a drug that another company has already put on the market, with little to no real improvement. In some cases, the newer drug’s path to approval may have overlapped with that of the pre-existing drug.⁴⁰ And these products may be improvements over earlier, similar prescription drugs. For example, they may have fewer side effects than existing drugs.

But in other cases, me-too drug development follows in the footsteps of other drugs and is a safer, less risky investment for pharmaceutical companies. Investment in these types of products diverts R&D resources from genuine innovations and delays the proliferation of generic alternatives, which increases costs throughout the health system.

While some argue that the addition of functionally similar drugs can reduce prices through competition, studies have found that these price reductions are generally marginal or even nonexistent.⁴¹ Moreover, in certain cases, pharmaceutical companies take advantage of shifting market dynamics to price their me-too drugs higher than the original drugs.⁴²

In addition to me-too drugs, a related practice known as evergreening also drives up costs. In this practice, pharmaceutical companies faced with expiring patents will make slight, cosmetic tweaks to an existing product. The tweaked drug then receives a new period of market exclusivity, delaying generic competition—despite the fact that there is no real clinical difference between the tweaked drug and the older version.

For example, Abbott Laboratories managed to get three separate patent extensions for its cholesterol-reducing drug Tricor-1, which it renamed Tricor-2, Tricor-3, and Tri-lipix.⁴³ None of these subsequent versions improved the clinical efficacy of the drug; rather, Abbott merely tweaked the dosage of the drug and switched it first from capsules to tablets and then to delayed-release capsules.⁴⁴ By delaying generic competition, this single case of evergreening drives up overall U.S. health care spending by an estimated \$700 million every year.⁴⁵

Spending on prescription drugs

In 2014, spending on prescription drugs totaled \$374 billion in the United States, an increase of 13 percent in one year. Prescription drug spending is now 15.9 percent of total health care spending for an average family of four.⁴⁶ These costs grew significantly in the past year; between 2014 and 2015, the cost of prescription drugs grew by 13.6 percent, compared with average growth over the previous five years of 6.8 percent.⁴⁷

The health care system is spending more on prescription drugs for a number of reasons. Some of the increase reflects new drugs entering the market that offer significant new benefits to patients with serious conditions, but pharmaceutical companies are also setting high prices for drugs that do not offer greater value than existing products.⁴⁸ In addition, companies also increase prices for brand-name products already on the market at rates that outpace inflation.⁴⁹

As media attention on the rising costs of prescription drugs has grown, the pharmaceutical industry has downplayed these costs by noting that retail prescription drugs have consistently accounted for about 10 percent of total health spending in the United States.⁵⁰ This figure comes from the official National Health Expenditures, or NHE, estimates, which in 2013 found retail prescription drugs to represent 9.3 percent of total spending.⁵¹ However, the NHE figure does not include drugs administered by physicians, hospitals, and nursing homes rather than sold through retail outlets. Many expensive drugs, such as those used to treat cancer, fall under these categories and thus are not accounted for in the 10 percent figure. For example, drug spending under Medicare Part B, which covers physician-administered drugs, totaled \$19 billion in 2013, without even accounting for private insurance spending on these drugs.⁵² Consequently, the 10 percent figure understates the true amount of prescription drug spending in the U.S. health system.

Rise in specialty drugs

Specialty drugs generally treat complex, chronic, or life-threatening health conditions and are commonly biologics or complex, large-chemical molecules. Many specialty drugs have transformed care for serious illnesses, such as the widely publicized drugs that offer a cure to most patients with Hepatitis C. Yet other specialty drugs enter the market with high prices but offer little improvement over existing treatments. The cancer drug Zaltrap, for example, was initially priced at double the price of the pre-existing standard treatment, despite not offering any clinical improvement.⁵³ When New York's Memorial Sloan Kettering Cancer Center refused to use the drug, the manufacturer cut the price in half.⁵⁴

There is no standard definition of specialty drugs, except that they are extraordinarily costly. Medicare uses a \$600-per-month threshold for this designation, but many cost significantly more. The transformative Hepatitis C drugs, for instance, can cost more than \$1,000 per day during the 12-week course.⁵⁵

Other than their cost, specialty drugs usually meet one or more of the following criteria:

- Complex to manufacture
- Require special handling or administration
- Treat complex medical conditions
- Require ongoing monitoring and clinical support

There are many ways to quantify the cost of these products for consumers, insurers, and employers. They cost a staggering 37 times more, on average, than traditional prescription drugs, and in 2013, the health care system spent more than \$80 billion on these products.⁵⁶ Specialty drugs make up only 1 percent of all U.S. prescriptions by volume but more than 31 percent of prescriptions by cost.⁵⁷

All parts of the health care system face increasing costs for these drugs. The Medicare program—whose beneficiaries are more likely to need these products—saw its costs for these drugs increase by more than 45 percent in 2014.⁵⁸ Commercial spending for specialty drugs increased by more than 30 percent in 2014, and Medicaid's costs for these drugs increased by more than 35 percent in the same year.⁵⁹

In the next two years, the share of specialty drugs by cost is expected to increase to 44 percent of all prescription drug spending.⁶⁰ By 2020, spending on specialty drugs could quadruple, reaching about \$400 billion, or 9.1 percent of national health care spending.⁶¹

These estimates reflect several trends. First, more specialty drugs are entering the market. Today, specialty drugs make up about 40 percent of all drugs currently under development and will represent about 60 percent of new drugs entering the market in the next few years.⁶² Of the specialty drugs currently under development, about half are oncology drugs.⁶³

Second, more patients are using these products. Millions of Americans currently take specialty drugs to treat conditions that include Hepatitis C and autoimmune and inflammatory disorders such as rheumatoid arthritis. And as the Federal Drug Administration continues to approve these products, millions more people may start to take specialty drugs to treat far more conditions.

For example, the FDA recently approved the first two products in a new class of drugs to treat high cholesterol, and experts expect more in the coming months.⁶⁴ The first two of these drugs—known as PCSK9 inhibitors—are priced at about \$1,200 per month, even higher than anticipated.⁶⁵ These medications should help millions of Americans who cannot tolerate or do not respond to statins, the class of drugs most commonly used to treat high cholesterol. But the drugs' costs will place added financial pressure on insurers, employers, and patients.

High cholesterol is far more common than other conditions treated with drugs with similar price tags. Today, there are about 70 million patients with high cholesterol.⁶⁶ Even though the majority of these consumers can continue to take statins, millions of patients will qualify for the costly new PCSK9 inhibitors. Moreover, patients must continue to take these drugs indefinitely, unlike the new treatments for Hepatitis C, which cure most patients after the 12-week treatment period. As a result, this new class of drugs alone could add \$150 billion to system-wide costs.⁶⁷

Increasing prices after market entry

Most media attention on the rising costs of prescription drugs is focused on the entry of blockbuster specialty drugs—such as the new Hepatitis C treatments—to the market. But this is not the only reason that drug spending is accelerating so

quickly. Companies are also increasing prices for existing products far in excess of inflation. A recent AARP Public Policy Institute study found that retail prices for brand-name prescription drugs increased by nearly 13 percent in 2013, which is more than eight times the general inflation rate.⁶⁸

For example, the prices for certain forms of some brand-name insulins—such as Humulin and Lantus—rose by up to 160 percent between 2007 and 2014, compared with a 12 percent increase in the Consumer Price Index over the same time period.⁶⁹ Similarly, in 2013, the average annual cost of one brand-name medication used to treat a chronic health condition was nearly \$3,000, compared with nearly \$1,500 in 2006.⁷⁰

This trend is also present in the market for specialty drugs, and it contributes to rising prices. For instance, the manufacturers of two specialty drugs that treat rheumatoid arthritis—Enbrel and Humira—both raised prices for these products by about 17 percent in 2014.⁷¹ These price increases followed a previous 15 percent bump in 2013.⁷² Constant price increases add to the burden of paying for these already expensive drugs—especially for patients who need these products to treat chronic conditions. Another example is Novartis' drug Gleevec, which was a huge breakthrough in treating chronic myeloid leukemia. After the drug's price more than tripled between 2001 and 2012, a coalition of more than 100 leukemia experts decried these increases in a medical journal.⁷³

In some instances, these price spikes were the result of a new company buying the rights to the drug. For example, when Horizon Pharma acquired the pain medication Vimovo, it increased the price by 597 percent on the first day.⁷⁴ As a result, Horizon earned more than eight times as much for the drug in 2014 as the drug had earned in the year before the price increase, despite the fact that fewer patients actually received it.⁷⁵ In 2015, Horizon increased the price again by another 75 percent, bringing the cumulative price markup under Horizon's ownership to more than 1,000 percent of the original price—despite the fact that no clinical improvements to the drug had been made.⁷⁶

How we pay for prescription drugs

There is no one price for a drug: Medicare, Medicaid, and different private payers all pay different amounts for the same product, and depending on a patient's source of insurance, the patient's share of the drug cost will also differ. Federal law sets broad parameters for how much the Medicare and Medicaid programs pay for prescription drugs, and payment by private payers varies depending on discounts and rebates that those insurers and employers negotiate with drug manufacturers.

In addition, depending on the type of drug—and especially on how the drug is administered—the payment methodology will differ, even for drugs taken by the same patient. For example, drugs that patients take at home fall under a plan's prescription drug benefit. For these products, a pharmacy benefit manager, or PBM, or specialty pharmacy usually negotiates the price, and when the patient purchases the drug at a pharmacy—or by mail order—he or she pays specific cost-sharing amounts set by the plan.⁷⁷ (See “Supply chain” text box)

Drugs administered by doctors or other health care providers—including most cancer drugs—are usually covered by health plans not as prescription drugs but instead as part of the plan's medical benefit.⁷⁸ For these drugs, doctors and other health care providers will generally purchase the drug, and insurers will pay them for the medication, along with a separate fee for administering the drug.⁷⁹ Cost sharing for these products will differ from cost sharing for self-administered drugs as well.⁸⁰

Because drug prices differ significantly depending on the type of drug and the payer, and because for each drug there could be multiple rebates and discounts paid at various points in its distribution, lowering system-wide spending for prescription drugs will require a variety of reforms. The following overview sections offer specifics on Medicare and Medicaid methodologies for certain parts of the health care system. These descriptions are not comprehensive but instead are intended to provide sufficient context to understand the policy recommendations presented later in this report.

Pharmacy benefit managers

PBMs administer pharmacy benefits for insurers and employers in both the public and the private sector, which collectively provide health insurance for about 210 million people, which is roughly two-thirds of the U.S. population.⁸¹ These entities not only process claims but also essentially help create the plan's drug benefit. They negotiate with drug companies to obtain discounts, rebates, or other price concessions. For example, the manufacturer may give rebates to encourage the use of certain drugs, such as an additional discount if the manufacturer's drug is the most commonly prescribed drug from a class of similar medications.⁸² Patients do not directly benefit from these discounts when they purchase the drug from the pharmacy; if their out-of-pocket costs are 20 percent of the price of the drug, they will pay 20 percent of the negotiated retail price, not 20 percent of the price after rebates are counted.⁸³ But rebates may reduce health care premiums if they end up back with the insurer or employer and are used to lower health care costs.

PBMs also set up pharmacy networks that channel patients to preferred pharmacies that have lower cost sharing for patients. Most also have their own mail order and specialty pharmacy businesses that provide lower-priced prescriptions to patients. They also review clinical data to evaluate new drugs, allowing them to make contracting and coverage decisions based on this information, including lists of preferred drugs, and to create incentives to encourage the use of generics.⁸⁴

PBMs regularly face a variety of allegations about their business model, especially the lack of transparency about rebates from drug companies. For example, lawsuits have alleged that PBMs pocket rebates from manufacturers that should be passed along to plan sponsors.⁸⁵ The Affordable Care Act, or ACA, increased transparency for PBMs who administer Medicare Part D benefits and in the new marketplaces, but other arrangements between PBMs, pharmacies, and pharmaceutical manufacturers continue to be secret. Given that more than 200 million Americans are covered by health plans that use PBMs, and that these entities play a role in almost two-thirds of all prescriptions dispensed in the United States,⁸⁶ greater transparency is critically important to make sure that these organizations pass along savings and function as counterweights to drug companies.⁸⁷

Supply chain

The pharmacy supply chain adds additional complexity to the issue of drug prices. If the flow of prescription drugs were similar to that of nonhealth care-related consumer goods, it would be easy to track the drug and its costs from the manufacturer to a wholesaler, then to a pharmacy, where the patient would purchase the drug. But the prescription drug market differs in a number of ways.⁸⁸ First, various players throughout the system negotiate various direct or indirect discounts. Health plans or PBMs, for example, negotiate discounts and rebate amounts directly with the manufacturer at the top of the supply chain, and retail pharmacies will negotiate discounts or rebates separately with manufacturers.⁸⁹ Wholesalers also will offer separate prompt-pay or volume discounts.⁹⁰

In addition, insured consumers only pay for a portion of the cost of a drug; their health plan covers the rest of the cost. This means that each person who arrives at the pharmacy to purchase a drug will pay an amount that is based on insurance coverage and their cost-sharing requirements, and the pharmacy will receive the rest of the payment from a third party.

Medicare

Like other parts of the health care system, Medicare does not have one method of paying for prescription drugs. Traditional Medicare pays for certain categories of prescription drugs—including drugs administered in doctors' offices or hospital outpatient departments—based on the drug's average sales price plus 6 percent of that price, or ASP plus 6. The ASP is essentially an average of the prices—net of rebates, discounts, and other price concessions—charged by the manufacturer in the commercial market, and when a drug is administered to a patient, the provider receives the Medicare payment directly, regardless of how much the provider paid for the drug. In 2013, Medicare and beneficiaries paid more than \$19 billion for Part B-covered drugs paid for under ASP plus 6.⁹¹

This price structure encourages physicians and hospitals to negotiate lower prices for specific drugs, but it also creates a stronger financial incentive for providers to prescribe higher-cost drugs when lower-cost alternatives may be just as effective.⁹² As the Medicare Payment Advisory Commission, or MedPAC—an independent commission that advises Congress on Medicare payment issues—has explained:

Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs.⁹³

For extraordinarily expensive specialty drugs, this 6 percent margin can generate significant revenues for the physician practice or hospital. This incentive is further magnified for hospitals that participate in the federal 340B Drug Pricing Program intended to lower drug prices for so-called safety-net hospitals and other health care providers that serve higher-need and lower-income patients. Hospitals in the program can purchase most outpatient drugs at very steep discounts while continuing to receive the usual ASP plus 6 payment amount.

In addition to the ASP plus 6 payment amount, Medicare makes an additional payment for administration of the drug to the outpatient department of the hospital or the physician office, and the program also pays an additional dispensing fee to pharmacies that dispense other Part B drugs.

Medicare also offers beneficiaries coverage of prescription drugs that are not covered under traditional Medicare through private health plans approved by Medicare under Medicare Part D. Beneficiaries covered by traditional Medicare can enroll in a stand-alone prescription drug plan, or beneficiaries may obtain drug coverage when they enroll in Medicare Advantage Plans.

Medicare's payments to these private plans are based on bids submitted by each plan sponsor, and Medicare sets certain standards and requirements for each plan. But within these broad parameters, each plan sponsor has the flexibility to design the prescription drug benefit—such as different formularies and cost-sharing amounts—within the broad requirements of the Medicare program. Medicare is prevented by federal law from negotiating drug prices for Part D; rather, each plan sponsor separately negotiates pharmacy networks and specific price discounts—usually using a PBM—just as they do in the private market. In addition to paying a premium for coverage, beneficiaries pay different deductibles, copayments, and coinsurance amounts depending on the plan's design. Low-income beneficiaries qualify for financial assistance to help with these out-of-pocket costs.

Medicaid

State Medicaid programs have the flexibility to set prescription drug payment policies as long as they comply with federal requirements, some of which are complex and highly technical. In some ways, Medicaid payment rules are similar to those of Medicare. States pay for prescription drugs based on their ingredient costs, which is intended to reimburse pharmacies for the prices they pay to purchase drugs.⁹⁴ States calculate this amount using various approaches, but in many cases, states will take a set percentage reduction to various list prices for a drug.⁹⁵ Pharmacies also receive a separate dispensing fee. In states where Medicaid-managed care plans cover drugs, the state pays for drug expenses as part of the payments it makes to the plan, and then the plan separately negotiates payments to pharmacies.

The greatest difference between Medicaid drug payment policies and those of other parts of the health care system is the Medicaid Drug Rebate Program, which is designed to guarantee that the Medicaid program receives the lowest prices available to private payers, accounting for discounts and other price concessions. The rebate program requires manufacturers to pay a minimum rebate to states and the federal government as a condition for Medicaid covering their drugs. Manufacturers must pay a rebate on all Medicaid-covered drugs, including drugs paid for by Medicaid-managed care plans. In 2012, Medicaid drug rebates totaled \$16.7 billion.⁹⁶ In addition to the federal rebate requirements, 45 states and the District of Columbia also have supplemental rebate agreements.⁹⁷

Key terms

Cost sharing: The share of costs that individuals pay out of their own pockets through coinsurance, copayments, and deductibles. Out-of-pocket costs are costs that individuals pay directly for health care services that are not reimbursed by insurance, such as to doctors, for items such as prescription drugs or for noncovered services. Out-of-pocket costs do not include premiums.

Copayment: A fixed amount that an individual pays for a covered health care item or service after they meet their deductibles, usually at the time of service.

Coinsurance: A type of cost sharing in which individuals must pay a percentage share of the costs of a covered item or service after they meet their deductibles.

Deductible: The amount that patients owe for covered health services before the health insurance plan begins to pay any costs.

Formulary: A list of prescription drugs that a health insurance plan covers. Drug formularies are often organized by tier, with different tiers having different cost-sharing levels based on safety, effectiveness, and cost. A common tiered formulary includes the following four tiers: generic drugs, preferred brand-name drugs, non-preferred brand-name drugs, and specialty drugs.

Payers: Entities other than consumers that pay for health care. Private payers include insurers and organizations that sponsor health care plans, such as employers or unions. Public payers include the Medicare and Medicaid programs.

Consumers

These high drug prices are increasing costs for all consumers. First, rising drug prices contribute to the growth of premiums. Second, patients are paying a larger share of the costs of their prescription drugs because of increasing deductibles and greater out-of-pocket costs.

The ACA capped out-of-pocket costs for individuals and families enrolled in health plans through the new marketplaces, as well as most employer-sponsored health plans. The annual limits in 2015 are \$6,600 for an individual and \$13,200 for a family plan.⁹⁸ While these limits are an important new consumer protection, individuals with chronic conditions who need expensive prescription drugs must still pay thousands of dollars per year and will quickly reach this out-of-pocket limit, in some cases paying thousands of dollars per month during the start of the plan year.

Cost sharing has been increasing for all health care services, but as drug prices have grown at an even faster rate than prices for most other health care services, insurers increasingly have targeted this area of spending. Insurers generally design plan benefits to keep premiums as low as possible, especially in the new market-

places. When faced with increasing drug prices, insurers therefore respond by increasing deductibles and cost-sharing amounts, which shift a greater share of costs to individuals with greater health needs. How much a consumer actually will pay out of pocket for prescription drugs varies based on the structure of their health insurance plan, but overall, patients are paying a greater share of these costs.

Patients who need prescription drugs must first reach their deductible. High-deductible plans with lower premiums and high deductibles—\$1,000 for single coverage and \$2,000 for family coverage—are increasingly common in employer-sponsored plans.⁹⁹ Consumers enrolled in marketplace plans typically face even higher deductibles. The average deductible for a silver plan is more than twice the average deductible for an employer plan. Bronze plans can have deductibles that exceed \$5,000 for an individual and \$10,000 for a family.¹⁰⁰

Once a consumer reaches the plan's deductible, the out-of-pocket share that patients pay for their medications can still be extraordinarily high. Health plans—including marketplace plans—commonly place the most costly products on a specialty drug formulary tier and impose very high coinsurance for these drugs. Cost sharing on marketplace plans, including the most common silver plans, is even higher; many plans charge 40 percent coinsurance for high-cost specialty drugs, with some plans requiring 50 percent coinsurance.

An analysis of marketplace plans in 36 states by Avalere Health found that the number of plans using specialty tiers increased sharply from 2014 to 2015. In 2015, for instance, about 30 percent of all plans placed all brand-name HIV/AIDS drugs on the specialty tier.¹⁰¹ A growing number of plans also placed all drugs used to treat serious, life-threatening diseases such as HIV, cancer, and multiple sclerosis on the highest cost-sharing specialty tier.¹⁰² As a result, patients who need these and other lifesaving medications face thousands of dollars in out-of-pocket costs per month before they reach their out-of-pocket limit.

Other consumers are not exempt from this trend: Average coinsurance for specialty drugs is 29 percent in employer plans.¹⁰³ And more than half of Medicare Part D enrollees are in plans that charge 33 percent coinsurance for specialty drugs.¹⁰⁴ And as the underlying prices for drugs increase, these coinsurance amounts become even less affordable. Rising drug prices and increased cost sharing create a financial burden for patients whose medications are becoming

increasingly unaffordable. Not surprisingly, high deductibles and rising cost sharing increase the risk of nonadherence to medication use. As researchers noted in a study in *The New England Journal of Medicine*,

*Different changes in formulary administration may have dramatically different effects on utilization and spending and may in some instances lead enrollees to discontinue therapy. The associated changes in copayments can substantially alter out-of-pocket spending by enrollees, the continuation of the use of medications, and possibly the quality of care.*¹⁰⁵

Another study that focused on patients with multiple sclerosis who were enrolled in a plan with coinsurance found that a 10 percent increase in cost sharing caused a 9 percent decline in treatment adherence.¹⁰⁶

Policy recommendations

The fragmented, siloed nature of the U.S. health care system—together with the complexity of prescription drug payment policies—creates a number of challenges for policymakers who wish to improve this part of it. But certain reforms can help across the entire health care system, such as those that encourage a greater investment in research and development and require comparative effectiveness research, or CER, so that payers, doctors, and patients have a better understanding of how new treatments compare with prior options. Because prices paid by private insurance are linked to prices paid by public programs, reforms that address the former will also address the latter.

These reforms must also recognize that high prices can be appropriate for certain truly innovative, lifesaving drugs. In those cases, the challenge for policymakers is to find a way to pay for these products without passing along too much of the burden to patients. Successful long-term reforms must also lower overall costs instead of simply shifting them. For example, limiting cost-sharing amounts without also adopting reforms to lower overall costs for prescription drugs just masks the larger issue by shifting costs from patients with high-cost prescriptions to payers, who will in turn restructure benefits or raise premiums to account for these added costs.

Encourage true innovation

The pharmaceutical industry commonly responds to questions about drug costs by redirecting attention to its R&D efforts and noting the innovative nature of its products. But as detailed above, the industry-generated numbers about its R&D spending pale in comparison to its marketing budgets and profit margins. Furthermore, not all new drugs are innovative, even though payers and patients continue to pay increasingly high costs for newly approved drugs.

Reforms that encourage both additional R&D and comparative effectiveness research can help remedy these related challenges. Greater R&D investments ultimately will lead to additional treatment options, and CER will help determine if a drug is truly innovative or if it is just new.

Provide transparency on R&D costs

Most pharmaceutical companies spend significantly more on marketing than on R&D.¹⁰⁷ This is worrying both because it suggests that pharmaceutical companies may be underinvesting in R&D and because analyses suggest that the most heavily marketed drugs are generally those that offer little to no improvement over existing therapies.¹⁰⁸

The following table compares revenue with the amount of R&D funding and spending on marketing for the top-grossing brand-name pharmaceutical companies.

TABLE 1
2013 revenue, R&D, and marketing budgets for major pharmaceutical companies, in billions

	Total revenue	R&D spending	Ratio of R&D to revenue	Marketing spending	Ratio of marketing to revenue
Novartis	\$58.8	\$9.9	16.8%	\$14.6	24.8%
Pfizer	\$51.6	\$6.6	12.8%	\$11.4	22.1%
Hoffmann-La Roche	\$50.3	\$9.3	18.5%	\$9.0	17.9%
Sanofi	\$44.4	\$6.3	14.2%	\$9.1	20.5%
Merck & Co.	\$44.0	\$7.5	17.0%	\$9.5	21.6%
GlaxoSmithKline	\$41.4	\$5.3	12.8%	\$9.9	23.9%
AstraZeneca	\$25.7	\$4.3	16.7%	\$7.3	28.4%
Eli Lilly and Company	\$23.1	\$5.5	23.8%	\$5.7	24.7%
AbbVie	\$18.8	\$2.9	15.4%	\$4.3	22.9%

Note: Johnson & Johnson is excluded since its numbers include nonpharmaceutical revenue and spending.

Source: Adapted from Richard Anderson, "Pharmaceutical industry gets high on fat profits," BBC News, November 6, 2014, available at <http://www.bbc.com/news/business-28212223>.

Other than this aggregate information, very little is known about the R&D costs of individual products or how those numbers compare with marketing and sales budgets despite the significant and ongoing public investment in this industry.¹⁰⁹ Yet federal and state health care programs and individual patients pay billions of dollars each year for these products at prices that contribute to industry-leading profits and multimillion dollar executive salaries. Over the next 10 years, manufacturers of brand-name prescription drugs will receive more than \$1.1 trillion in revenues from the sale of outpatient drugs to federal health care programs, including Medicare and Medicaid.¹¹⁰ Drug companies also receive billions of additional dollars in federal funding through the R&D tax credit.¹¹¹

Federal taxpayers also support drug companies indirectly when the government funds basic research at universities and at other institutions and organizations. A federal law—the Bayh-Dole Act—gives private-sector entities intellectual property rights to certain discoveries and innovations that result from federally funded research.¹¹² Before the Bayh-Dole Act, the federal government owned the intellectual property developed from federally supported R&D and generally issued licenses for use of the intellectual property on a nonexclusive basis, which made these discoveries far less attractive for drug companies to develop because their competitors also would have use of the research.¹¹³ After this change to federal law, universities and other federally funded institutions not only receive grants from the National Institutes of Health but also are allowed to sell or license their inventions to third parties, including pharmaceutical companies. In this way, taxpayers underwrite an even greater share of pharmaceutical R&D.

For these reasons, policymakers in several states are pressing for greater transparency from pharmaceutical companies. Legislators in Massachusetts, North Carolina, Pennsylvania, and New York have introduced legislation that would require drugmakers to publicly disclose certain information for expensive drugs.¹¹⁴ The drug cost transparency bills differ in their precise requirements, but they all would require pharmaceutical companies to disclose most or all of the following: the total costs of production for the drug; R&D costs for specific drugs, including details on R&D paid for with public funds; marketing spending for the drug; different prices charged for the drug, including international rates; and total profit made from the drug.

Transparency about the total costs of R&D, production, and sales and marketing budgets is critical. In addition, policymakers should require drug companies to report the amount of their R&D budgets that is spent on basic research, as well as R&D efforts that have not resulted in any approved drugs.

By improving transparency, laws such as these would require pharmaceutical companies to justify high prices and provide much-needed context to policymakers and the public. Both policymakers and taxpayers could then gain a clearer picture of how drug companies are using more than \$1 trillion in taxpayer money to advance innovation. Increasing transparency in the prescription drug market is also consistent with the trend of overall transparency in the health care system. As health care costs continue to squeeze federal, state, employer, and individual budgets, payers and consumers are seeking more information about the costs of their care and seeking lower-cost, higher-value treatments.

Categorize new drugs by their comparative effectiveness

Today, a variety of organizations conduct CER, including insurers; pharmacy benefit managers; and various nonprofits, including the Patient-Centered Outcomes Research Institute, or PCORI, and the wholly private Institute for Clinical and Economic Review, or ICER. Pharmaceutical companies also conduct their own CER, including CER that foreign regulators require as part of their drug approval processes.

Additional CER is needed to properly inform payment policy, but an important starting point is aggregating these data and requiring pharmaceutical companies to submit any CER data they may have from their own studies as part of this effort. The secretary of Health and Human Services should certify a research-based, independent entity with adequate stakeholder participation—including insurers, providers, and patient representatives—as a clearinghouse for this information to assess independently industry-sponsored CER and to conduct additional, independent CER to supplement existing studies. This could be PCORI, ICER, or another organization that meets these strict criteria.

For each newly approved drug, the organization would consider CER conducted by the drug's manufacturer, as well as its own independent analysis of the product. The organization would then evaluate whether each new drug provides no added benefit, minor added benefit, or significant added benefit compared with the existing drug. Added benefits should include measures such as improved health status, shortened disease duration, extended life expectancy, reduced side effects, and improved quality of life.

Provide star ratings on comparative effectiveness in labeling and marketing

After a drug is assessed to provide zero added benefit, minor added benefit, or significant added benefit, drug companies should include this information in their labeling and marketing—including in direct-to-consumer advertisements. The information would be conveyed to physicians and patients through easy-to-understand star ratings, allowing them to compare their treatment options.

A public awareness campaign should help inform the public of the star ratings and their meaning. As patients and doctors start to look for these star ratings, the incentive for drug companies to develop products that qualify for this designation will increase. Other ratings have successfully encouraged private-sector innovation in this way. The National Highway Traffic Safety Administration's 5-Star Safety Ratings system, for example, has encouraged safety innovations, and consumers know to look at these ratings to make more informed purchasing decisions. The ratings also evolve as the safety of vehicles improves; the agency continues to look at ways to encourage further safety advances.¹¹⁵

This shift may not occur quickly, but even incremental changes to how pharmaceutical and biomedical innovation is defined will start to counter the industry message that every new drug is innovative and worthy of a large price tag.

Incentivize drug companies to invest more in R&D

As detailed above, taxpayers not only directly and indirectly subsidize pharmaceutical R&D, but drug companies also will collectively receive about \$1.1 trillion from the sale of brand-name outpatient prescription drugs to federal health program beneficiaries in the next decade.¹¹⁶ The pharmaceutical industry benefits from sizable taxpayer assistance when developing its drugs, then charges the federal government and taxpayers exorbitant prices. Simply put, the drug industry profits from multiple levels of public support.

The Affordable Care Act guarantees that premium payments to insurers benefit consumers; the law's medical loss ratio, or MLR, policy requires insurers to spend most of their revenue from premiums on medical expenses for consumers.¹¹⁷ This policy guarantees that consumers see a return on their premium dollars. Similarly, policymakers should ensure that public support for pharmaceutical R&D is a sound investment of taxpayer dollars that leverages additional research spending by drug companies.

Drug companies should invest a minimum percentage of their revenue in R&D. If a company does not meet this minimum over a five-year period, the company should be required to refund a portion of the revenue derived from public programs, up to the shortfall amount. The refund would be dedicated to a new Research Incentive Fund to support NIH. This incentive would ensure that a larger portion of the public's payments to the pharmaceutical industry would be reinvested in research to transform care.

Ensure that the system pays for value

Reforms that increase the transparency of pharmaceutical R&D and inform patients and providers about CER data are important. But the critical next step is to ensure that payers use this information. The following proposals would both lower overall drug costs and pay for drugs based on their benefits to patients.

Develop voluntary payment recommendations to inform private-sector negotiations

The independent, expert organization that evaluates the comparative effectiveness of new drugs also should recommend voluntary ranges of price increases for drugs that provide zero, minor, or significant benefit compared with existing drugs. When a drug is used for different purposes, the organization should recommend different ranges if the various uses provide different levels of added benefit. Payment for drugs with zero added benefit would have a recommended price equal to the price of existing drugs that treat the same disease or condition. Drugs with minor added benefit would have a recommended price increase that is up to a certain percentage higher than the price of existing drugs that treat the same disease or condition. And drugs with significant added benefit for treating a specific disease or condition would have a recommended price increase range higher than the range for drugs that provide minor added benefit.

Existing efforts by various researchers to evaluate the value and effectiveness of prescription drugs can help inform this work. For instance, Dr. Peter Bach of Memorial Sloan Kettering Cancer Center has developed an online research tool called DrugAbacus, which allows users to consider the value of cancer drugs based on different factors, including patient benefit, side effects, and the cost of discovering and developing the treatment.¹¹⁸ Based on the value assigned to each

factor by the user, DrugAbacus will then compare the price of the drug based on those results with the actual price of the drug.¹¹⁹ ICER also has started a new drug assessment program to analyze certain new drugs, selected based on their potential to change patient care or affect health system budgets.¹²⁰ ICER will publish reports detailing its findings, which will include a value-based price benchmark for each drug based on the benefit that the drug provides to patients.¹²¹

Using these recommended ranges, insurers and PBMs will be armed with information to strengthen their negotiating position and negotiate the best possible prices with drug companies. The independent analysis of a drug's comparative effectiveness also should help shield payers from claims that they are rationing care or trying to skim on expensive new products.

Incentivize drug companies to charge reasonable prices

After consideration of the recommended range of prices discussed above, if a negotiation between a drug company and a payer were to result in a price that fell outside the recommended range, additional transparency would be triggered. The drug company would need to submit the final price, as well as a detailed justification for the increase, to the private, independent organization, which would then post that information on its website in a consumer-friendly format.

In addition, if the final price exceeds the recommended range by more than 20 percent, it would be deemed unreasonable. If the drug's patent resulted from federally funded research, the federal government could then license the patent to competitors for the development of cheaper generic versions.

This incentive is authorized under existing statutory law. Under the Bayh-Dole Act, in certain circumstances, the federal government may exercise its “march-in rights” to license patents that resulted from federally funded research but that are now owned by drug companies.¹²² These rights apply when a drug company has not achieved “practical application” of the research—meaning that its benefits are not “available to the public on reasonable terms.”¹²³ They also apply when “action is necessary to alleviate health or safety needs.”¹²⁴ Thus, if a drug company is not charging a reasonable price for a drug, or if its pricing harms public health by substantially restricting access to the drug, the federal government is well within its rights to ensure the availability of cheaper generic versions.¹²⁵ A price that exceeds

the range recommended by a private, independent organization by more than 20 percent would be presumed to be unreasonable and to harm public health by substantially restricting access to the drug.

This incentive for drug companies to charge reasonable prices is more than fair given that taxpayers paid for the development of these drugs. More than 9 percent of all new drugs—and nearly one-quarter of priority-review drugs that were considered to be especially important—were patented using federally funded research and would therefore be subject to this incentive.¹²⁶ However, because drug companies may not disclose that their patents resulted from federally funded research, it is likely that more drugs would be affected.¹²⁷ Furthermore, many of the drugs that would be subject to this incentive are cancer drugs, which tend to have exceptionally high prices.¹²⁸

Level the playing field to improve private-sector negotiations

Drug manufacturers enter contract negotiations with insurers, other payers, and PBMs with significantly greater market power. For brand-name drugs, patent protection and market exclusivity give manufacturers a monopoly on their products. Manufacturers set the initial price, and negotiations are guided by that asking price, with final payment amounts set as a discount off that price. In many cases, the numerous payers in the health care system lack the market power to push back in a meaningful way against drug manufacturers' price demands.

To create a more competitive market—in which prices are based on value rather than the extreme market power of one player—the purchasing power of payers and PBMs should be aggregated to negotiate prices for specialty drugs. Any health plan or PBM that offers a Medicare plan or plan through the marketplaces would participate. These parties would receive a limited antitrust waiver to allow them to negotiate with drug manufacturers on behalf of both Medicare drug plans and their commercial business. The final, negotiated prices would be published, along with a transcript of the negotiations, to promote transparency throughout the entire process. In exchange for this antitrust exemption, PBMs would have to disclose their contractual relationships with drug manufacturers and pharmacies, including any rebate payments that flowed from drug manufacturers, so that insurers and other payers could better understand these arrangements and decide how to structure their future contracts with PBMs. For example, this information helps insurers negotiate for lower fees, which in turn lowers costs for consumers.

Reform Medicare payment for physician-administered drugs

Medicare payment for physician-administered drugs should be changed to eliminate any financial incentive for doctors to prescribe more costly treatments. As discussed above, Medicare's ASP plus 6 payment formula pays providers based on a drug's average sales price and adds an additional 6 percent to the price to cover overhead.¹²⁹ As a result of this payment being structured as a percentage rather than as a flat fee, physicians earn more for choosing expensive drugs over less expensive alternatives.

From the perspective of overall Medicare spending, the added 6 percent is not huge, but it is significant: According to a recent Medicare Part B payment database, it amounts to about \$690 million annually, or almost \$7 billion over 10 years.¹³⁰ Yet for the most expensive physician-administered drugs covered by Part B, this payment structure creates distorted incentives for doctors that could drive up costs and influence treatment decisions. The 10 drugs with the highest overall level of Medicare expenditures accounted for \$368 million of the \$690 million in 2013.¹³¹

There are several alternative approaches that could remove or curtail the current incentive to choose more expensive drugs. The Medicare Payment Advisory Commission has analyzed two different deficit-neutral approaches, with the first being a \$24 flat fee per drug per day and the second being a blended payment that incorporates a 2.5 percent payment along with a \$14 flat fee.¹³² The Obama administration's fiscal year 2016 budget would reduce the 6 percent payment to 3 percent of the ASP, while also permitting the Department of Health and Human Services to experiment with substituting a budget-neutral flat fee in place of the percentage-based payment.¹³³ The Congressional Budget Office estimates that this would save \$7 billion over 10 years.¹³⁴

Another option would be to establish two payment alternatives, such as a 3 percent add-on and a flat fee that is sufficient to cover overhead costs, with Medicare paying whichever of the two options is the lowest for any particular drug. This last option recognizes that for extremely low-priced drugs, a flat fee might actually increase costs.

The Centers for Medicare & Medicaid Services, or CMS, should test these different approaches and expand the most successful one. The ACA established the Center for Medicare & Medicaid Innovation, or CMMI, to test payment and delivery system reforms and expand them if they reduce costs while maintaining

the quality of care or improve the quality of care without increasing costs. To test these reforms, CMMI may waive existing statutory requirements. CMMI should design a model to not only compare savings between the different approaches, but also to assess how well the different models adequately cover provider overhead and if the reforms alter prescribing patterns.

Regardless of the specific approach taken to reform the ASP plus 6, Medicare reimbursement for physician-administered drugs also should maximize savings from generics and biosimilars—generic versions of biologic drugs. Today, when a chemical drug covered under Medicare Part B has a generic version, Medicare payment is based on the ASP plus 6 of all the equivalent drugs. Medicare operationalizes this policy by assigning the same reimbursement code to each of these drugs.¹³⁵ As biosimilars start to enter the market, Medicare should encourage greater use of them by assigning approved biosimilars to the same code as the brand-name biologic. Medicare should then pay for all drugs based on the ASP of the generics or biosimilars, rather than an inflated ASP that includes the brand-name price.

Allow payers to pay for success

Some new drugs are high cost, but their benefits relative to existing drugs may be uncertain. In such cases, Medicare should pay the high cost only if the new drugs turn out to be successful, providing significant benefits relative to existing drugs. Initially, Medicare payment for the new drug would be based on the lower cost of existing drugs. But if the new drug improves average outcomes in real-world populations, Medicare would then supplement the initial payments, ultimately paying a higher total price for the new drug. CMMI should design a pay-for-success model to test this reform.

A *Health Affairs* evaluation of similar private-sector programs found that these types of pay-for-success models work best when a drug has an objective, clearly defined outcome such as blood glucose levels or specific reductions in the number of patient fractures.¹³⁶ The evaluation also found that this payment model is not appropriate for drugs that treat diseases with long and uneven progressions.¹³⁷ CMMI should use these criteria in selecting drugs for this payment model.

Many drugs are used to treat several different conditions. For example, physicians prescribe drugs for off-label uses that are different from the uses approved by the FDA. In particular, cancer drugs are commonly used to treat different types of cancers.¹³⁸ While drugs may work very well for one condition, they may not work as well for another condition—yet payers pay for them at the same price regardless of which condition they are being used to treat.¹³⁹ For example, the drug Tarceva works better against lung cancer than pancreatic cancer.¹⁴⁰ Similarly, Abraxane works much better against breast cancer than lung cancer.¹⁴¹

It is exceedingly difficult for payers to pay different amounts for different uses of a drug based on its effectiveness for each use. The biggest obstacle to this value-based payment is that the FDA assigns drugs National Drug Codes, or NDCs, that do not specify their use. Payers use these codes for payment and claims.¹⁴² To remedy this problem, the FDA should issue NDCs that differentiate each approved use of a drug as well as off-label uses. These more specific codes will also facilitate more data collection on real-world outcomes.

Vary Medicaid rebates based on comparative effectiveness

Instead of setting a single default rebate amount, rebates should vary based on CER classification. To increase the likelihood of adoption, this proposal would be budget neutral. That is, the overall rebate amount would remain constant, but within that amount states could vary the rebates, with higher-value drugs paying a smaller amount than the minimum 23.1 percent under current law. To offset this amount, states could then impose greater rebates on lower-value, more costly products.

Lower out-of-pocket costs for individuals

Lowering overall spending for prescription drugs will do little to improve the health or financial well-being of patients if individuals continue to face high cost-sharing amounts. A key piece of any prescription drug payment reform must be adopting reforms to ensure that required cost sharing is not excessive, especially for the most expensive specialty drugs.

A number of states have passed legislation to limit out-of-pocket spending on prescription drugs. The ACA's out-of-pocket annual limits still apply in these plans, but consumers' spending on prescription drugs is further capped within those total amounts.

For example, New York prohibits specialty tiers, and the state marketplace's standardized silver-level plan design has no deductible for prescription drugs.¹⁴³ The standard benefit design for silver-level plans offered in Covered California—that state's marketplace—includes a separate \$250 deductible for pharmacy benefits.¹⁴⁴ After meeting the deductible, consumer cost sharing for drugs is generally limited to \$250 per month.¹⁴⁵ Legislation would expand this limit to health plans sold outside the marketplace.¹⁴⁶

Other states also have passed legislation to protect patients. Maine and Vermont limit yearly out-of-pocket expenses for prescription drugs to \$3,500 and \$1,250 per year, respectively.¹⁴⁷ And Louisiana, Delaware, and Maryland all limit copayments to \$150 per month after the consumer has met a plan's deductible. Alaska has required that insurers give consumers 90-day notice before implementing specialty tiers.¹⁴⁸

One analysis recently found that these limits would not affect premiums materially.¹⁴⁹ However, if drug prices continue to rise at their current pace, limits on cost sharing alone, without additional changes to lower the overall costs of drugs, will result in high premiums or higher cost sharing for other health care services.

Limit cost sharing in marketplace plans

The secretary of Health and Human Services should adopt similar requirements for silver-level plans in all exchanges. A standardized benefit plan should, at a minimum, include monthly out-of-pocket limits for prescription drugs and a separate, smaller deductible. Together, these two changes will give patients with chronic conditions greater predictability about their out-of-pocket expenses. The California limits would cap cost sharing for drugs at \$3,250 per year.¹⁵⁰ For low-income enrollees, this amount may still be prohibitively expensive, causing patients to skip doses or to entirely forego critical medications. Consumers should not spend more than 5 percent of their income on prescription drugs.

In exchange for these cost-sharing limits, insurers should have greater flexibility in designing their formularies. Today, plans must cover a specific number of drugs in various categories, based in part on what the original benchmark plan covered. If insurers have flexibility when designing their formularies, plans will have greater leverage in negotiating costs with insurers, which will help limit premium growth.¹⁵¹ For example, if a benchmark plan covered 10 drugs in a particular category, insurers would be able to design a formulary with five drugs. Patients would still have access to an appeals process and coverage for the drug if medically necessary. In addition, patients currently taking a drug would have continued access to the drug until the completion of the appeals process.

Limit cost sharing in employer-sponsored plans

The recent trend of employers shifting health care costs to employees through higher cost sharing, and especially by the use of high-deductible plans, has placed much of the financial burden for higher drug prices on employees.¹⁵² For this reason, policymakers should cap prescription drug cost sharing for the millions of Americans enrolled in employer-sponsored plans. New limits will guarantee that employees share in the savings that result from reforms to lower drug prices.

Policymakers should extend a yearly limit of \$3,250 for prescription drug spending to individuals with employer-sponsored insurance, as well as the monthly \$250 limits. This yearly amount is higher than the current mean out-of-pocket maximum for prescription drugs for individuals enrolled in employer-based plans, but it will offer important new financial protections for employees with significant prescription drug costs whose yearly expenses far exceed those of the average employee.¹⁵³

Provide cost-sharing information for specific drugs to consumers and physicians

In addition to new financial protections, consumers need additional information about their prescription drug coverage and costs when choosing their marketplace plans, especially if insurers have additional flexibility when designing formularies.

There are several models for increasing transparency for consumers. For instance, Covered California has taken important steps to increase transparency about drug costs for enrollees.¹⁵⁴ Plans must give consumers an estimate of their out-of-

pocket costs for specific drugs and explain to enrollees how to obtain drugs not listed on the plan's formulary.¹⁵⁵ Plans must also report formulary details, such as “coverage, tiering, and utilization management information,” on a standardized template, including for drugs covered under the plan's medical benefit.¹⁵⁶ This information must be updated monthly on the plan's website. Covered California also links directly from its own website to the plans' formulary pages.

For the 2016 plan year, insurers offering plans on the federal marketplace must post plan-specific formularies on their websites so that consumers can compare them while shopping.¹⁵⁷ This is an important update, but unlike the California requirements, CMS does not require plans to post this information in a standardized template, which would make comparisons easier. Instead, the formulary must be machine readable so that third parties can develop tools to help shoppers compare.¹⁵⁸ Moreover, there is still no federal marketplace requirement that insurers post specific cost-sharing information on the formulary; instead, insurers must post information regarding cost-sharing tiers, which consumers can use to estimate costs.¹⁵⁹

Neither CMS' nor California's approach offers consumers the same level of detail about potential out-of-pocket costs as Medicare Part D's Plan Finder. Most important for consumers is the feature on the Part D Plan Finder that allows people to compare plans' cost sharing and coverage for specific drugs through an online tool. For the 2017 plan year, CMS should implement similar requirements for the federal marketplace in order to improve comparison shopping.

Also, doctors should have access to their patient's cost-sharing information as part of their e-prescribing systems so that they can consider specific formulary and out-of-pocket costs when making prescribing decisions. This information will allow doctors to choose—from clinically appropriate treatment options—the drug that minimizes a patient's out-of-pocket costs.

Conclusion

Drug companies currently benefit from a system that favors their interests over those of patients, taxpayers, providers, payers, and the larger health care system. Without significant reforms, prices for prescription drugs—which are already extraordinarily high—will continue to rise at a rate that is unsustainable for families, businesses, and state and federal budgets.

Some policymakers may dismiss action to address drug prices as politically untenable. This view represents the fallacy that what has happened before will continue to happen. Further, three things have changed. First, and most importantly, the American public is now demanding action at unprecedented levels. Second, it is a truism that what cannot continue will not: Drug prices have become so high that they are simply unsustainable and must come down. Third, important parts of this report's proposed framework can be achieved without the need for congressional legislation. The evaluation of drugs and pricing guidelines can be implemented independently of government—and a critical incentive for drug companies to charge reasonable prices is authorized under existing statutory law.

All that is needed is the will to challenge the status quo and the powerful interests that seek to protect their monopoly prices and economic rents. The American public has said loudly and clearly that enough is enough. The time has come for taxpayers to get a better deal that lowers their costs, improves public health, and jumpstarts true innovation.

About the authors

Topher Spiro is the Vice President for Health Policy at the Center for American Progress, where he leads the Health Policy team that includes former Obama administration official Zeke Emanuel, former Medicare administrator Don Berwick, and Sen. Tom Daschle (D-SD). Spiro's work has been published in *The New York Times*, *The New England Journal of Medicine*, *The Christian Science Monitor*, *The Atlantic*, Politico, The Hill, and the *Annals of Internal Medicine*. He has also testified before Congress and appeared on National Public Radio.

Maura Calsyn is the Director of Health Policy at the Center. Prior to joining the Center, Maura was an attorney with the Department of Health and Human Services' Office of the General Counsel. During her time there, she served as the department's lead attorney for several Medicare programs and advised the department on implementation of the Affordable Care Act. Before joining the Office of the General Counsel, Calsyn worked as a health care attorney at two international law firms.

Thomas Huelskoetter is the Research Assistant for Health Policy at the Center. Prior to joining the Center, he was a legislative affairs intern with the Center on Budget and Policy Priorities and a policy and research intern with President Barack Obama's re-election campaign in Virginia, and he also spent eight months teaching high school English in France. Huelskoetter graduated from Kenyon College in 2012 with a bachelor's degree in political science.

Acknowledgments

The Center for American Progress thanks the Peter G. Peterson Foundation for its support of our health policy programs and of this report. The views and opinions expressed in this report are those of The Center for American Progress and the authors and do not necessarily reflect the position of the Peter G. Peterson Foundation. The Center for American Progress produces independent research and policy ideas driven by solutions that we believe will create a more equitable and just world.

The authors would like to thank former Health Policy team intern Justin Morgan for his research assistance on this report.

Endnotes

- 1 National Center for Health Statistics, *Health, United States, 2014: With Special Feature on Adults Aged 55–64* (U.S. Department of Health and Human Services, 2015), available at <http://www.cdc.gov/nchs/data/abus/abus14.pdf>.
- 2 Ana Swanson, “How new drugs helping millions of Americans live longer are also making them go broke,” *Wonkblog*, June 30, 2015, available at <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/06/30/how-new-drugs-helping-millions-of-americans-live-longer-are-also-making-them-go-broke/>.
- 3 Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey* (U.S. Department of Health and Human Services, 2012), tables 2, 5, and 7.
- 4 Bianca DiJulio, Jamie Firth, and Mollyann Brodie, “Kaiser Health Tracking Poll: June 2015” (Menlo Park, CA: Kaiser Family Foundation, 2015), available at <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-june-2015/>.
- 5 Optum, “The Growth of Me-Too Drugs,” March 9, 2015, available at <https://www.optum.com/thought-leadership/metoodrugs.html>.
- 6 Sean P. Keehan and others, “National Health Expenditure Projections, 2014–24: Spending Growth Faster Than Recent Trends,” *Health Affairs* 34 (8) (2015): 1407–1417.
- 7 Altarum Institute, “Hospitals and Prescription Drugs Leading Health Spending Acceleration,” Press release, April 10, 2015, available at <http://altarum.org/about/news-and-events/hospitals-and-prescription-drugs-leading-health-spending-acceleration#sthash.ncALRWzD.dpuf>.
- 8 Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, “2015 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds” (2015), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf>.
- 9 Christopher S. Girod, Scott A. Weltz, and Susan K. Hart, “2015 Milliman Medical Index” (Seattle: Milliman, 2015), available at <http://us.milliman.com/uploadedFiles/insight/Periodicals/mmi/2015-MMI.pdf>.
- 10 Sam Ro, “Here Are The Profit Margins For Every Sector In The S&P 500,” *Business Insider*, August 16, 2012, available at <http://www.businessinsider.com/sector-profit-margins-sp-500-2012-8>.
- 11 The Center for American Progress Health Policy Team, “The Senior Protection Plan” (Washington: Center for American Progress, 2012), available at <https://www.americanprogress.org/issues/healthcare/report/2012/11/13/44590/the-senior-protection-plan/>.
- 12 Aaron S. Kesselheim, “Rising Health Care Costs and Life-Cycle Management in the Pharmaceutical Market,” *PLoS Medicine* 10 (6) (2013): e1001461, available at <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001461>.
- 13 Leigh Purvis, “Consumer Perspectives on Biosimilars” (Washington: AARP Public Policy Institute, 2014), available at https://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/purvis.pdf.
- 14 Market exclusivity is separate from patent protection. See Food and Drug Administration, “Frequently Asked Questions on Patents and Exclusivity,” available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm> (last accessed August 2015).
- 15 Yahoo Finance Industry Browser, “Sectors: Health-care: Industry List,” available at <https://biz.yahoo.com/p/5qpmu.html> (last accessed July 2015).
- 16 Food and Drug Administration, “Investigational New Drug (IND) Application,” available at <http://www.fda.gov/drugs/developmentapprovalprocess/howdrug-saredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm> (last accessed July 2015).
- 17 The Tufts Center is largely funded by the pharmaceutical industry. See Tufts Center for the Study of Drug Development, “Financial Disclosure,” available at http://csdd.tufts.edu/about/financial_disclosure (last accessed August 2015).
- 18 Tufts Center for the Study of Drug Development, “Briefing: Cost of Developing a New Drug” (2014), available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014.pdf.
- 19 For example, the priority review program shortens the time of FDA review. The standard review goal for the FDA is 10 months. While the agency generally meets this goal, the clock begins after a 60-day filing period, so the total time is about 12 months from application. See Food and Drug Administration, “The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective,” available at <http://www.fda.gov/Drugs/Resources-ForYou/Consumers/ucm143534.htm> (last accessed September 2015). When a drug is submitted for priority review, the goal is six months, though it generally takes eight months when the filing period is included. Other programs expedite the entire clinical trial and approval process. See Food and Drug Administration, “Fast Track,” available at <http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm> (last accessed July 2015). Between 2000 and 2013, 32 percent of new molecular products, including biologics, were approved under two pathways—the fast track and accelerated approval pathways—intended for serious and life-threatening conditions. See Aaron S. Kesselheim and others, “Existing FDA Pathways Have Potential to Ensure Early Access to, and Appropriate Use of, Specialty Drugs,” *Health Affairs* 33 (10) (2014): 1770–1778. Lastly, “breakthrough therapy” designation is designed for drugs that show early signs of clinical promise. In 2013, the FDA received about 100 applications for this designation. See Food and Drug Administration, “Breakthrough Therapy,” available at <http://www.fda.gov/ForPatients/Approvals/Fast/ucm405397.htm> (last accessed July 2015); Kesselheim and others, “Existing FDA Pathways Have Potential to Ensure Early Access to, and Appropriate Use of, Specialty Drugs.”
- 20 Ibid.
- 21 Kesselheim and others, “Existing FDA Pathways Have Potential to Ensure Early Access to, and Appropriate Use of, Specialty Drugs.”
- 22 Ibid.

- 23 Tufts Center for the Study of Drug Development, "Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion," Press release, November 18, 2014, available at http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.
- 24 Aaron Carroll, "\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions," *The Upshot*, November 18, 2014, available at <http://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html?rref=upshot&abt=0002&abg=1&r=0>.
- 25 Jerry Avorn, "The \$2.6 Billion Pill — Methodologic and Policy Considerations," *The New England Journal of Medicine* 372 (2015): 1877–1879.
- 26 Carroll, "\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions."
- 27 Food and Drug Administration Center for Drug Evaluation and Research, *Novel New Drugs 2013 Summary* (U.S. Department of Health and Human Services, 2014), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugInnovation/UCM381803.pdf>; Food and Drug Administration Center for Drug Evaluation and Research, *Novel New Drugs 2014 Summary* (U.S. Department of Health and Human Services, 2015), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugInnovation/UCM430299.pdf>; Food and Drug Administration, "Drug Approval Reports," available at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu> (last accessed July 2015).
- 28 Carroll, "\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions."
- 29 Pharmaceutical Research and Manufacturers of America, "2015 Biopharmaceutical Research Industry Profile" (2015), available at http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.
- 30 Pharmaceutical Research and Manufacturers of America, "New Medicine Approvals in 2013" (2014), available at <http://www.phrma.org/sites/default/files/NDA%202013.pdf>.
- 31 BDO, "2013 BDO Biotech Briefing" (2013).
- 32 National Science Foundation, "Business R&D and Innovation: 2011, Detailed Statistical Tables," available at <http://www.nsf.gov/statistics/2015/nsf15307/> (last accessed July 2015).
- 33 Donald W. Light and Joel R. Lexchin, "Pharmaceutical research and development: what do we get for all that money?," *BMJ* 345 (2012): e4348.
- 34 Aaron S. Kesselheim, Yongtian Tina Tan, and Jerry Avorn, "The Roles Of Academia, Rare Diseases, And Repurposing In The Development Of The Most Transformative Drugs," *Health Affairs* 34 (2) (2014): 286–293.
- 35 Richard Anderson, "Pharmaceutical industry gets high on fat profits," *BBC News*, November 6, 2014, available at <http://www.bbc.com/news/business-28212223>.
- 36 Ro, "Here Are The Profit Margins For Every Sector In The S&P 500."
- 37 Anderson, "Pharmaceutical industry gets high on fat profits."
- 38 Charles Ornstein and Ryann Grochowski Jones, "The Drugs That Companies Promote to Doctors Are Rarely Breakthroughs," *The Upshot*, January 7, 2015, available at <http://www.nytimes.com/2015/01/08/upshot/the-drugs-that-companies-promote-to-doctors-are-rarely-breakthroughs.html?rref=upshot&abt=0002&abg=0>.
- 39 Ibid.
- 40 Aidan Hollis, "Me-too drugs: is there a problem?" (Geneva, Switzerland: World Health Organization, 2004), available at http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf.
- 41 Ibid.
- 42 Peter Bach, "Cancer: Unpronounceable Drugs, Incomprehensible Prices," *Forbes*, August 13, 2014, available at <http://www.forbes.com/sites/matthewherper/2014/08/13/cancer-unpronounceable-drugs-incomprehensible-prices/>.
- 43 Sarah Kliff, "Want to cut health care costs? Start here," *The Washington Post*, April 21, 2012, available at http://www.washingtonpost.com/blogs/ezra-klein/post/want-to-cut-health-care-costs-start-here/2012/04/20/gIQA2P0NWT_blog.html.
- 44 Nicholas Downing and others, "Avoidance of Generic Competition by Abbott Laboratories' Fenofibrate Franchise," *Archives of Internal Medicine* 172 (9) (2012): 724–730.
- 45 Ibid.
- 46 Girod, Weltz, and Hart, "2015 Milliman Medical Index."
- 47 Ibid.
- 48 Bach, "Cancer: Unpronounceable Drugs, Incomprehensible Prices."
- 49 Stephen Schondelmeyer and Leigh Purvis, "Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans 2006 to 2013" (Washington: AARP Public Policy Institute, 2014), available at <http://www.aarp.org/content/dam/aarp/ppi/2014-11/rx-price-watch-report-AARP-ppi-health.pdf>.
- 50 Pharmaceutical Research and Manufacturers of America, "Medicines: Cost in Context," available at <http://www.phrma.org/cost> (last accessed July 2015).
- 51 Centers for Medicare & Medicaid Services, "National Health Expenditure Data," available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last accessed July 2015).
- 52 MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System" (2015).
- 53 Peter Bach, "Why Drugs Cost So Much," *The New York Times*, January 14, 2015, available at <http://www.nytimes.com/2015/01/15/opinion/why-drugs-cost-so-much.html>.
- 54 Ibid.
- 55 Gilead Sciences, "U.S. Food and Drug Administration Approves Gilead's Sovaldi™ (Sofosbuvir) for the Treatment of Chronic Hepatitis C," Press release, December 6, 2013, available at <http://www.gilead.com/news/press-releases/2013/12/us-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-the-treatment-of-chronic-hepatitis-c>.
- 56 The Campaign for Sustainable Rx Pricing, "Specialty Drug Hyperinflation: The Risk to Patients and the Health Care System" (2015).

- 57 Ibid.
- 58 The Express Scripts Lab, "The 2014 Drug Trend Report" (2015), available at <http://lab.express-scripts.com/drug-trend-report/>.
- 59 Ibid.
- 60 The Campaign for Sustainable Rx Pricing, "Specialty Drug Hyperinflation."
- 61 Ibid.
- 62 UnitedHealth Center for Health Reform & Modernization, "The Growth of Specialty Pharmacy: Current trends and future opportunities" (2014), available at <http://www.unitedhealthgroup.com/~/-/media/uhg/pdf/2014/unh-the-growth-of-specialty-pharmacy.ashx>.
- 63 Milliman, "Milliman Specialty Medical Drug 2010 Commercial Benchmark Study" (2012), available at <http://us.milliman.com/uploadedFiles/insight/Research/health-rr/pdfs/specialty-medical-drug-benchmark-study.pdf>.
- 64 Andrew Pollack, "New Drug Sharply Lowers Cholesterol, but It's Costly," *The New York Times*, July 24, 2015, available at http://www.nytimes.com/2015/07/25/business/us-approves-drug-that-can-sharply-lower-cholesterol-levels.html?_r=0; Toni Clarke, "FDA approves Amgen's cholesterol-lowering drug Repatha," Reuters, August 27, 2015, available at <http://www.reuters.com/article/2015/08/27/amgen-repatha-fda-idUSL1N1122KX20150827>.
- 65 Ibid.
- 66 Ransdell Pierson, "CVS urges cost controls for new cholesterol, specialty drugs," Reuters, February 17, 2015, available at <http://www.reuters.com/article/2015/02/17/us-cvs-health-cholesterol-idUSKBN0LL1CQ20150217>; Marc O'Connor, "Is the new class of cholesterol drugs the next battleground for payers and prescribers?," MedCity News, June 22, 2015, available at <http://medcitynews.com/2015/06/healthcare-and-pharma-next-battleground-pcsk9-drugs/>.
- 67 William Shrank and others, "In The Debate About Cost And Efficacy, PCSK9 Inhibitors May Be The Biggest Challenge Yet," Health Affairs Blog, February 17, 2015, available at <http://healthaffairs.org/blog/2015/02/17/in-the-debate-about-cost-and-efficacy-pcsk9-inhibitors-may-be-the-biggest-challenge-yet/>.
- 68 Schondelmeyer and Purvis, "Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans 2006 to 2013."
- 69 Robert Langreth, "Big Pharma's Favorite Prescription: Higher Prices," Bloomberg Business, May 8, 2014, available at <http://www.bloomberg.com/bw/articles/2014-05-08/why-prescription-drug-prices-keep-rising-higher>.
- 70 Ibid.
- 71 The Express Scripts Lab, "The 2014 Drug Trend Report"
- 72 The Express Scripts Lab, "The 2013 Drug Trend Report" (2014).
- 73 Experts in Chronic Myeloid Leukemia, "The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts," *Blood* 121 (22) (2013): 4439–4442.
- 74 Jonathan D. Rockoff and Ed Silverman, "Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Prices," *The Wall Street Journal*, April 26, 2015, available at <http://www.wsj.com/articles/pharmaceutical-companies-buy-rivals-drugs-then-jack-up-the-prices-1430096431>.
- 75 Ibid.
- 76 Ibid.
- 77 UnitedHealth Center for Health Reform & Modernization, "The Growth of Specialty Pharmacy."
- 78 Ibid.
- 79 Ibid.
- 80 Ibid.
- 81 Pharmaceutical Care Management Association, "About PCMA," available at <http://www.pcmnet.org/about-pcma/about-pcma> (last accessed August 2015).
- 82 Girod, Weltz, and Hart, "2015 Milliman Medical Index."
- 83 Ibid.
- 84 Thomas Gryta, "What is a 'Pharmacy Benefit Manager?'" *The Wall Street Journal*, July 21, 2011, available at <http://www.wsj.com/articles/SB10001424053111903554904576460322664055328>.
- 85 Barbara Martinez, "Pharmacy-Benefits Managers Are Sued Over 'Secret Dealings,'" *The Wall Street Journal*, March 19, 2003, available at <http://www.wsj.com/articles/SB104802976818451100>.
- 86 Pete Abilla, "4 Things You Didn't Know About the Pharmaceutical Supply Chain," Shumula.com, available at <http://www.shumula.com/pharmaceutical-supply-chain-things-you-didnt-know/8503/> (last accessed July 2015).
- 87 Pharmaceutical Care Management Association, "About PCMA."
- 88 Susan Thaul, "Pharmaceutical Supply Chain Security" (Washington: Congressional Research Service, 2013), available at <http://www.ncsl.org/documents/statedfed/health/CRS-PharmSupChSec2013.pdf>.
- 89 Kaiser Family Foundation, "Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain" (2005), available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>.
- 90 Ibid.
- 91 MedPAC, "Report to the Congress."
- 92 Ibid.
- 93 Ibid.
- 94 Brian Bruen and Katherine Young, "Paying for Prescribed Drugs in Medicaid: Current Policy and Upcoming Changes" (Menlo Park, CA: Kaiser Family Foundation, 2015), available at <http://kff.org/report-section/paying-for-prescribed-drugs-in-medicaid-current-policy-and-upcoming-changes-policy-implications-8593/>.
- 95 Ibid.
- 96 Office of Inspector General, *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin* (U.S. Department of Health and Human Services, 2015), available at <http://oig.hhs.gov/oei/reports/oei-03-13-00650.asp>.
- 97 Ibid.

- 98 HealthCare.gov, "Out-of-pocket maximum/limit," available at <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/> (last accessed July 2015).
- 99 Michelle Andrews, "Large Companies Are Increasingly Offering Workers Only High Deductible Health Plans," Kaiser Health News, March 26, 2013, available at <http://khn.org/news/032613-michelle-andrews-on-high-deductible-plans-and-large-employers/>.
- 100 Robert Pear, "On Health Exchanges, Premiums May Be Low, but Other Costs Can Be High," *The New York Times*, December 9, 2013, available at <http://www.nytimes.com/2013/12/09/us/on-health-exchanges-premiums-may-be-low-but-other-costs-can-be-high.html>.
- 101 Avalere Health, "Avalere Analysis: Exchange Benefit Designs Increasingly Place All Medications for Some Conditions on Specialty Drug Tier," Press release, February 11, 2015, available at <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-exchange-benefit-designs-increasingly-place-all-medication>.
- 102 Ibid.
- 103 Kaiser Family Foundation and Health Research & Educational Trust, "Employer Health Benefits 2014" (2014), available at <http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report>.
- 104 Jack Hoadley and others, "Medicare Part D in its Ninth Year: The 2014 Marketplace and Key Trends, 2006-2014" (Menlo Park, CA: Kaiser Family Foundation, 2014), available at <http://files.kff.org/attachment/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014-report>.
- 105 Haiden A. Huskamp and others, "The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending," *The New England Journal of Medicine* 349 (2003): 2224–2232.
- 106 UnitedHealth Center for Health Reform & Modernization, "The Growth of Specialty Pharmacy."
- 107 Anderson, "Pharmaceutical industry gets high on fat profits."
- 108 Ornstein and Jones, "The Drugs That Companies Promote to Doctors Are Rarely Breakthroughs."
- 109 Ed Silverman, "California Lawmaker Wants Pharma to Reveal Costs for Pricey Drugs," WSJ Pharmalot, February 21, 2015, available at <http://blogs.wsj.com/pharmalot/2015/02/24/california-lawmaker-wants-pharma-to-reveal-costs-for-pricey-drugs/>.
- 110 Avalere Health, "Federal Spending on Brand Pharmaceuticals" (2015), available at <http://avalere.com/expertise/life-sciences/insights/access-avaleres-latest-research-on-brand-name-prescription-drug-spending>.
- 111 National Science Foundation, "Appendix table 4-36: Federal research and experimentation tax credit claims, by NAICS industry: 1998–2008" (2012), available at <http://www.nsf.gov/statistics/seind12/appendix.htm>.
- 112 *Amendments to the Patent and Trademark Act*, Public Law 517, 96th Cong., 2d sess. (December 12, 1980). Commonly referred to as the Bayh-Dole Act.
- 113 Wendy H. Schacht, "The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology" (Washington: Congressional Research Service, 2012), available at <https://fas.org/sgp/crs/misc/RL32076.pdf>. The Bayh-Dole Act is not limited to the pharmaceutical industry, but the discussion in this source is limited to this particular sector.
- 114 S. 1048, 189th General Court, Reg. sess. (Mass. 2015);
- H.B. 839, 2015 General Assembly, Reg. sess. (N.C. 2015); H.B. 1048, 199th General Assembly, Reg. sess. (Pa. 2015); S. 5338, 201st State Legislature, Reg. sess. (N.Y. 2015).
- 115 National Highway Traffic Safety Administration, "5-Star Safety Ratings Frequently Asked Questions," available at <http://www.safercar.gov/Vehicle+Shoppers/5-Star+FAQ#five> (last accessed July 2015).
- 116 Avalere Health, "Federal Spending on Brand Pharmaceuticals."
- 117 Public Health Service Act § 2718 (added by section 1001 of the Affordable Care Act).
- 118 Memorial Sloan Kettering Cancer Center, "Welcome to DrugAbacus," available at <http://www.drugabacus.org/> (last accessed August 2015).
- 119 Ibid.
- 120 Institute for Clinical and Economic Review, "ICER Launches New Drug Assessment Program with \$5.2 Million Award from the Laura and John Arnold Foundation," Press release, July 21, 2015, available at <http://www.icer-review.org/icer-ljaf-drug-assessment-announcement/>.
- 121 Ibid.
- 122 35 U.S.C. section 203.
- 123 35 U.S.C. sections 201(f) and 203(a)(1).
- 124 35 U.S.C. section 203(a)(2).
- 125 For a legal review of this authority, see Michael Henry Davis and Peter S. Arno, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally-Funded Research," *Tulane Law Review* 631 (75) (2001): 631–693.
- 126 Bhaven N. Sampat and Frank R. Lichtenberg, "What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?," *Health Affairs* 30 (2) (2011): 332–339; Ashley J. Stevens and others, "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *The New England Journal of Medicine* 364 (2011): 535–541.
- 127 Sampat and Lichtenberg, "What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?"
- 128 Stevens and others, "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines."
- 129 Centers for Medicare & Medicaid Services, "2015 ASP Drug Pricing Files," available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McPartBDrugAvgSalesPrice/2015ASPFiles.html> (last accessed July 2015).
- 130 CAP analysis of Centers for Medicare & Medicaid Services, "Medicare Provider Utilization and Payment Data: Physician and Other Supplier," available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html> (last accessed June 2015).
- 131 Ibid.
- 132 MedPAC, "Report to the Congress."
- 133 U.S. Department of Health and Human Services, *Fiscal*

- Year 2016 Budget in Brief: Strengthening Health and Opportunity for All Americans* (2015), available at <http://www.hhs.gov/sites/default/files/budget/fy2016/fy-2016-budget-in-brief.pdf>.
- 134 Congressional Budget Office, "Proposals for Health Care Programs-CBO's Estimate of the President's Fiscal Year 2016 Budget" (2015), available at <https://www.cbo.gov/sites/default/files/cbofiles/attachments/50013-HealthPolicy.pdf>.
- 135 Office of Inspector General, *Medicare Payments for Newly Available Generic Drugs* (U.S. Department of Health and Human Services, 2011), available at <http://oig.hhs.gov/oei/reports/oei-03-09-00510.pdf>.
- 136 Peter J. Neumann and others, "Risk-Sharing Arrangements That Link Payment For Drugs To Health Outcomes Are Proving Hard To Implement," *Health Affairs* 30 (12) (2011): 2329–2337.
- 137 Ibid.
- 138 Peter Bach, "Indication-Specific Pricing for Cancer Drugs," *The Journal of the American Medical Association* 312 (16) (2014): 1629–1630.
- 139 Ibid.
- 140 Peter Loftus, "New Push Ties Cost of Drugs to How Well They Work," *The Wall Street Journal*, May 26, 2015, available at <http://www.wsj.com/articles/new-push-ties-cost-of-drugs-to-how-well-they-work-1432684755>.
- 141 Ibid.
- 142 Food and Drug Administration, "National Drug Code Database Background Information," available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829> (last accessed August 2015).
- 143 Pharmaceutical Research and Manufacturers of America, "New York's 2015 Exchange Plans" (2015); S. 5000-B, State Legislature, 2009 reg. sess. (N.Y. 2010), available at <http://open.nysenate.gov/legislation/bill/s5000B>.
- 144 Covered California, "2016 Standard Benefit Plan Designs" (2015).
- 145 Ibid.
- 146 Virgil Dickson, "Calif. Senate considers cap on out-of-pocket drug costs," *Modern Healthcare*, July 4, 2015, available at <http://www.modernhealthcare.com/article/20150704/MAGAZINE/307049947>.
- 147 Milliman, "Pharmacy Cost Sharing Limits for Individual Exchange Benefit Plans: Actuarial Considerations" (2015); Cap the Copay, "State Laws Limiting Patient Out-of-Pocket for Specialty Tier Drugs," March 2014, available at http://www.capthecopay.org/wp-content/uploads/2014/03/Existing_State_OOP_Laws_Specialty_Tiers_10-2014_ML1.pdf.
- 148 Milliman, "Pharmacy Cost Sharing Limits for Individual Exchange Benefit Plans"; H.B. 218, State Legislature, 2012 reg. sess. (A.K. 2012), available at <http://www.legis.state.ak.us/PDF/27/Bills/HB0218Z.PDF>.
- 149 Ibid.
- 150 Covered California, "2016 Standard Benefit Plan Designs."
- 151 Mari Edlin, "Exchange formularies need flexibility beyond PPACA," *Managed Healthcare Executive*, October 1, 2013, available at <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/content/tags/exchanges/exchange-formularies-need-flexibility-beyond-ppa?page=full>.
- 152 Topher Spiro, Maura Calsyn, and Meghan O'Toole, "The Great Cost Shift: Why Middle-Class Workers Do Not Feel the Health Care Spending Slowdown" (Washington: Center for American Progress, 2015), available at <https://www.americanprogress.org/issues/healthcare/report/2015/03/03/105777/the-great-cost-shift/>.
- 153 For mean out-of-pocket maximums for preferred provider organization plans, see Christine Buttorff and others, "Comparing Employer-Sponsored And Federal Exchange Plans: Wide Variations In Cost Sharing For Prescription Drugs," *Health Affairs* 34 (3) (2015): 467–476.
- 154 Covered California, "Covered California Board Protects Consumers Against Skyrocketing Specialty Drug Costs To Ensure Access To Vital Medications," Press release, May 21, 2015, available at <http://news.coveredca.com/2015/05/covered-california-board-protects.html>.
- 155 Ibid.
- 156 Caroline F. Pearson, Jenna M. Stento, and Milena Sullivan, "Disease Matters: Comparing Prescription Drug Benefits in Covered California Plans" (Sacramento, CA: California HealthCare Foundation, 2015), available at <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/D/PDF%20DiseaseMattersDrugBenefitsCoveredCA.pdf>.
- 157 Centers for Medicare & Medicaid Services, "HHS Notice of Benefit and Payment Parameters for 2016," *Federal Register* 80 (39) (2015): 10819–10820, available at <http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf>.
- 158 Ibid.
- 159 Ibid.

Our Mission

The Center for American Progress is an independent, nonpartisan policy institute that is dedicated to improving the lives of all Americans, through bold, progressive ideas, as well as strong leadership and concerted action. Our aim is not just to change the conversation, but to change the country.

Our Values

As progressives, we believe America should be a land of boundless opportunity, where people can climb the ladder of economic mobility. We believe we owe it to future generations to protect the planet and promote peace and shared global prosperity.

And we believe an effective government can earn the trust of the American people, champion the common good over narrow self-interest, and harness the strength of our diversity.

Our Approach

We develop new policy ideas, challenge the media to cover the issues that truly matter, and shape the national debate. With policy teams in major issue areas, American Progress can think creatively at the cross-section of traditional boundaries to develop ideas for policymakers that lead to real change. By employing an extensive communications and outreach effort that we adapt to a rapidly changing media landscape, we move our ideas aggressively in the national policy debate.

