

THE COMPETITION PRESCRIPTION

A Market-Based Plan *for* Making
Innovative Medicines Affordable

Avik S. A. Roy

The Foundation *for* Research
on Equal Opportunity



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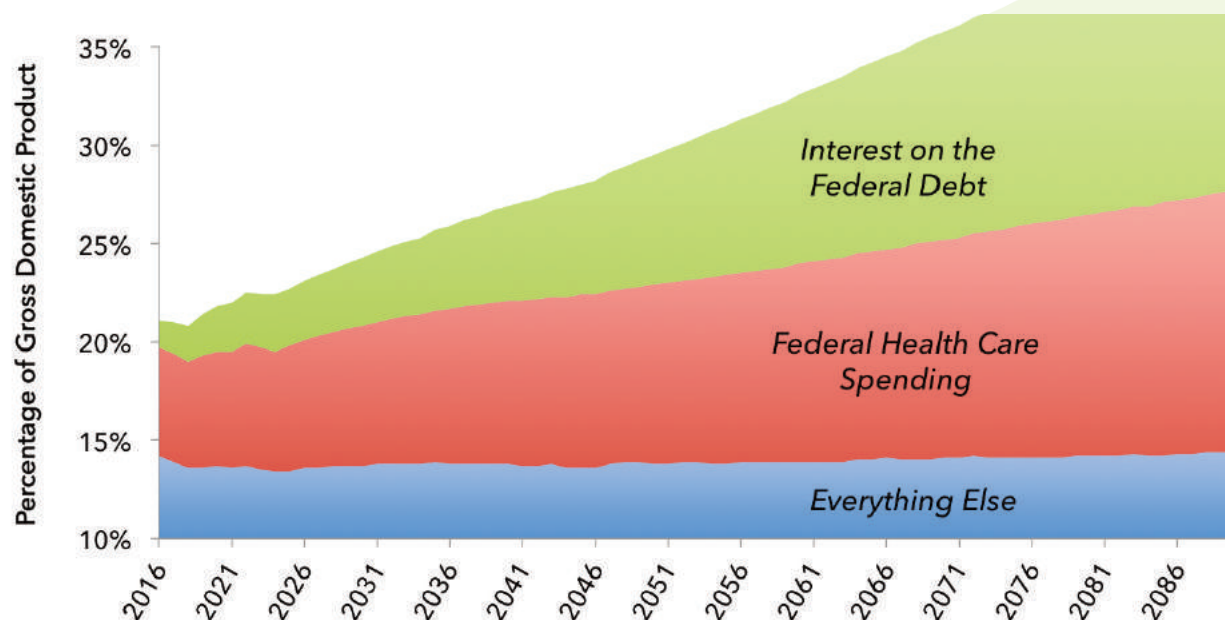
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Figure 1. CBO 2015-2016 Long-Term Federal Spending Projections (Extended Baseline Scenario)

INTRODUCTION

ONE OF THE MOST PRESSING PROBLEMS FACING the United States is the high cost of American health care. Tens of millions of Americans lack health insurance due to the high cost of coverage; far more have seen their disposable income stagnate due to inexorably rising health care costs.

Further still, growth in public health care spending is by far the biggest driver of America's unsustainable budget deficit and federal debt (*Figure 1*), a problem that starves other public programs of needed resources and presents an increasing burden on lower-middle-income taxpayers.¹

Prescription drugs comprise the third-largest component of U.S. national health expenditures, behind only hospital care and physician and clinical services, according to the Centers for Medicare and Medicaid Services.² According to the QuintilesIMS Institute, invoiced sales of prescription drugs amounted to \$450 billion in 2016, representing 13.4 percent of all U.S. health spending.³

As shown in *Figure 2*, prices for prescription drugs in

the U.S., like prices for other health care goods and services, are far higher in the U.S. than they are in other industrialized countries. In 2014, on an invoice price basis, the U.S. spent \$1,327 per capita on prescription drugs; in non-U.S. members of the Organisation for Economic Co-operation and Development, median per capita drug spending was \$489: approximately one-third that of the U.S.⁴

High pharmaceutical prices have received disproportionate attention in the U.S. because the pharmaceutical industry is for-profit, whereas much of the hospital and insurance industries are comprised of non-profit institutions; many on the political left believe that profit-seeking has no place in health care. However, many on the political right who believe in the value of for-profit entities have ignored the high cost of prescription drugs for the opposite reason.

Drug prices continue to grow at rates exceeding inflation and economic growth, due to a policy deadlock between progressives and conservatives about the desirability of further government intervention in the pharmaceutical sector. Both sides have concluded that the only way to reduce prescription drug prices is through price controls; Republican opposition to

Democratic proposals for price regulation has maintained the status quo.

Both sides, however, are mistaken in believing that market forces are responsible for high drug prices. The market for prescription drugs is not “free.” Indeed, as we will discuss in this report, federal laws and regulations that distort the market and create barriers to competition are the primary drivers of high drug prices.

UNDERSTANDING PHARMACEUTICAL PRICES: NET VS. LIST

THE PROBLEM OF HIGH DRUG PRICES IS COMPLEX; indeed, some take advantage of that complexity to argue that high prices are not in fact a concern. Pharmaceutical companies argue that critics of their pricing practices do not take into ac-

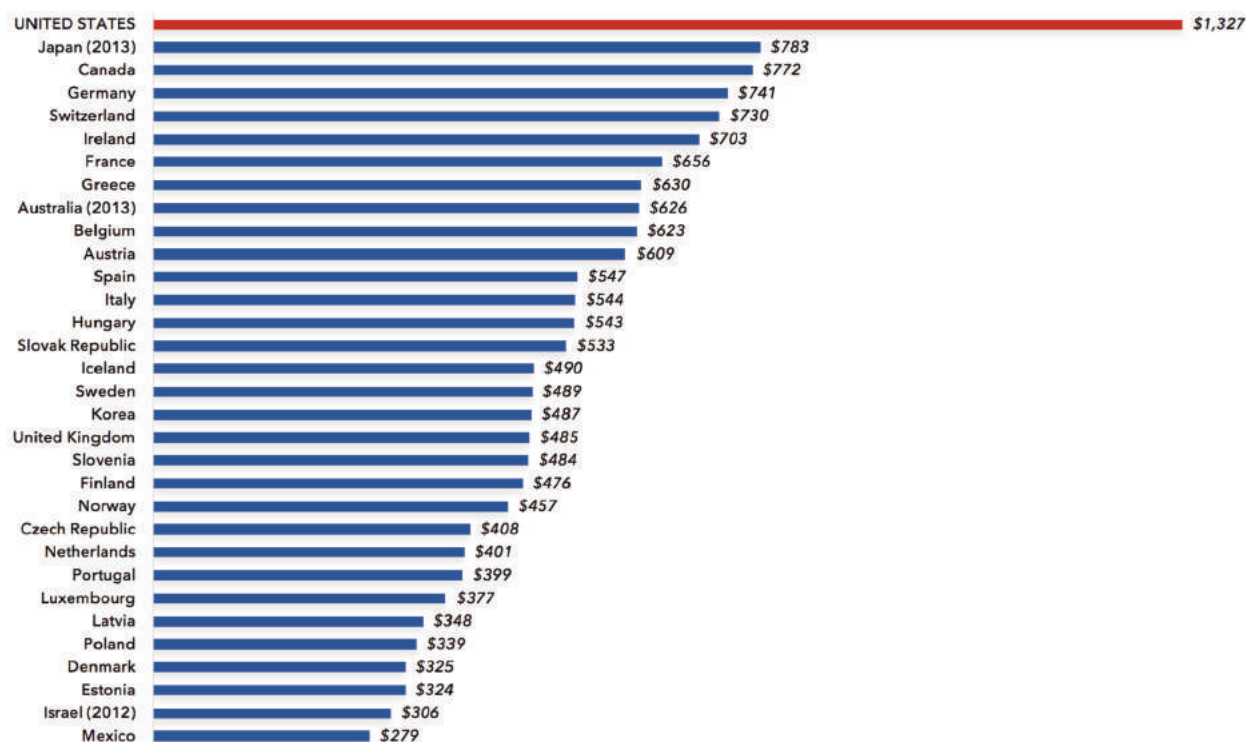
count the difference between list and net pricing, and that on a net basis, pharmaceutical pricing is not a policy problem.

It is true that the prices that manufacturers publicly list do not represent the true cost that consumers pay. Those *list prices* are often referred to as the “wholesale acquisition cost,” or WAC.

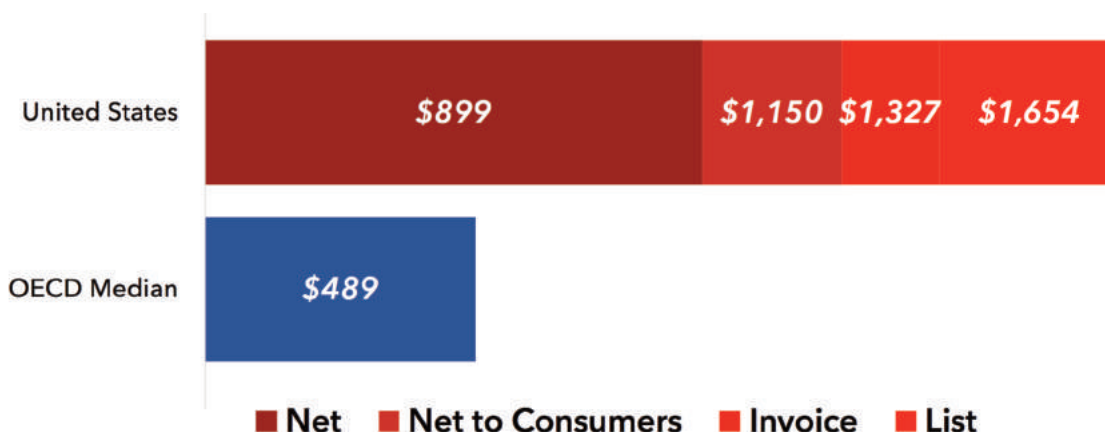
However, large distributors often acquire drugs at a discount, in exchange for prompt payment and/or bulk purchasing. Hence, the average invoice price for a branded drug is 16 percent less than the list price; the average *invoice price* for a generic drug is 45 percent below the list price.⁵

Furthermore, manufacturers frequently offer rebates to insurers in order to persuade insurers to pay for costly drugs, especially when cheaper generic alterna-

Figure 2. Annual Per-Capita Drug Spending, 2014 (US\$ purchasing power parity-adjusted)



U.S. drug spending far exceeds that of other industrialized nations. Data in blue is from the Organisation for Economic Co-Operation and Development, and represents both prescription and over-the-counter drug spending. The U.S. figure, in red, solely includes prescription drug spending, and is based on invoice prices calculated by the QuintilesIMS Institute. (Sources: OECD, QuintilesIMS, FREOPP analysis)

Figure 3. 2014 Net Drug Spending by U.S. Consumers Exceeds OECD Median (US\$ PPP-adjusted)

Net prices to consumers are higher than net prices to pharmaceutical companies. Net prices garnered by pharmaceutical companies are lower than their list prices, because of discounts and rebates paid to wholesalers, pharmacy benefit managers, and consumers. A fraction of the list-to-invoice-to-net savings are retained by participants in the supply chain. Co-pay payments to consumers lead to higher utilization and higher overall consumer costs. (Sources: OECD, QuintilesIMS, FREOPP analysis)

tives are available. Frequently, insurers contract with pharmacy benefit managers (PBMs) to negotiate these rebates. In the commercial insurance market, PBMs retain a portion of these rebates as revenue; insurers retain a portion; and the remainder is passed onto consumers in the form of premiums that are lower, on net, than they would be under list or invoice pricing.

Drug companies often offer to subsidize the co-pays and other out-of-pocket expenses that consumers pay, in order to encourage higher utilization of their products. However, because higher utilization is passed onto consumers in the form of higher premiums, these practices do not necessarily result in lower health care costs for patients in the aggregate.

For branded drugs, according to QuintilesIMS, *net prices* that include these rebates to payors and patients are 33 percent lower on average than invoice prices; for generic drugs, net prices are 30 percent lower on average.⁶

Pharmaceutical companies argue that net pricing is the appropriate figure for policymakers to follow. But because distributors, PBMs, and insurers retain a fraction of the difference between list and net prices, and because co-pay assistance leads to higher premiums, the prices that consumers pay in the form of insurance premiums, out-of-pocket payments, and taxpayer-funded subsidies is higher than the net price.⁷

Still, if we assume that two-thirds of the difference between net and list prices is passed onto consumers, then U.S. spending on drugs in 2014 was \$1,150 per capita: lower than with invoice or list prices, but still far higher than the OECD average (*Figure 3*). And growth in drug spending on a net price basis closely tracks invoice spending growth.⁸

UNDERSTANDING PHARMACEUTICAL PRICES: BRAND VS. GENERIC

THE HIGH PRICES OF BRANDED, PATENTED PRESCRIPTION drugs attracts a justifiable amount of attention in the United States. But it is important to note that the U.S. leads the world in the utilization of inexpensive, off-patent generic drugs (*Figure 4*). In 2014, unbranded generic drugs represented 82 percent of U.S. prescription volume, compared to a European median of 21 percent.⁹

That is because, in 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, an unusually farsighted law most commonly known as the Hatch-Waxman Act. Hatch-Waxman created an abbreviated regulatory process for the approval of generic medicines, and also created greater transparency and certainty around pharmaceutical patent litigation. The U.S. is also unusual in that it is legal for

pharmacies to engage in *generic substitution*, such that when a doctor prescribes a branded medication, pharmacies are free to substitute a cheaper generic equivalent.

The end result has been the formation of a robust generic pharmaceutical industry. Today, it is common for the price of a drug to decline by 80 percent in the first year after generic competition ensues.

However, because of the extraordinarily high price of branded U.S. drugs, growth in the penetration of unbranded generics has not been paired with a moderation in overall drug spending. From 2012 through 2016, unbranded generics' share of U.S. prescription volume has increased from 78 to 85 percent. Spending on unbranded generics actually declined, from \$52 billion in 2012 to \$50 billion in 2016 on an invoice basis (*Figure 5*). But branded drug spending exploded by 47 percent over that same period, from \$228 billion to \$334 billion.¹⁰

Part of that growth can be attributed to the introduction in 2014 of costly but effective new treatments for hepatitis C. However, branded drug spending still grew by 42 percent from 2012 to 2016—from \$225 bil-

lion to \$318 billion—if one excludes the impact of drugs for viral hepatitis.

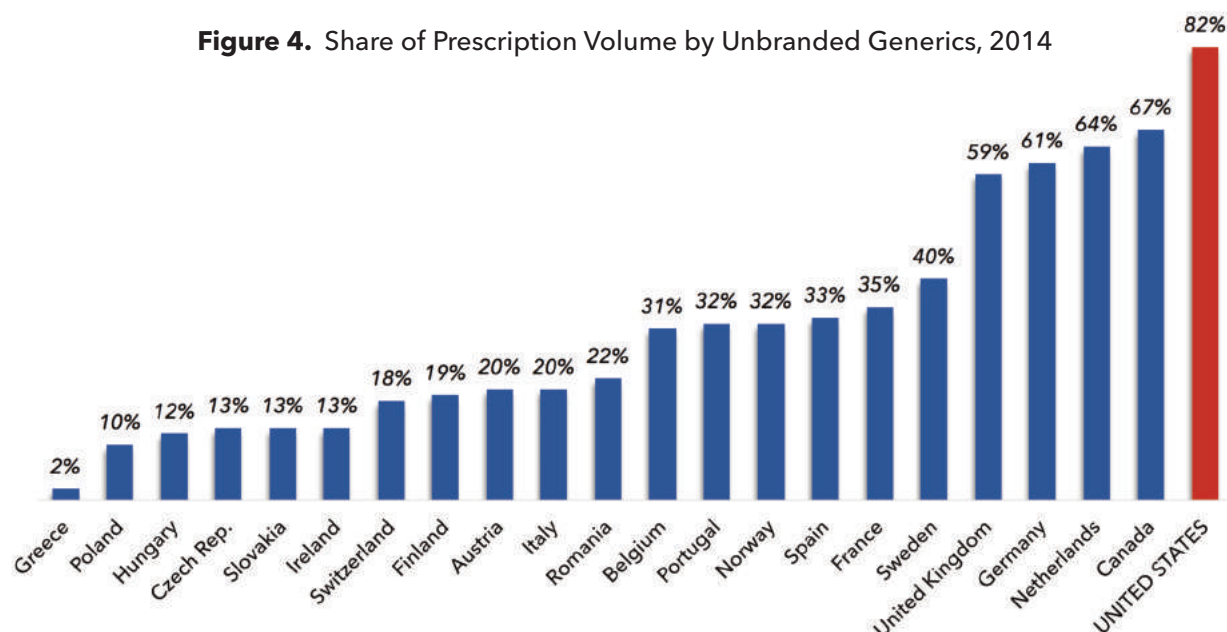
HIGH PRICES DO NOT CORRELATE TO PHARMACEUTICAL INNOVATION

Proponents of high U.S. drug prices argue that high prices are necessary to support pharmaceutical innovation. But, with a modicum of scrutiny, the fatal flaws in this argument become immediately apparent.

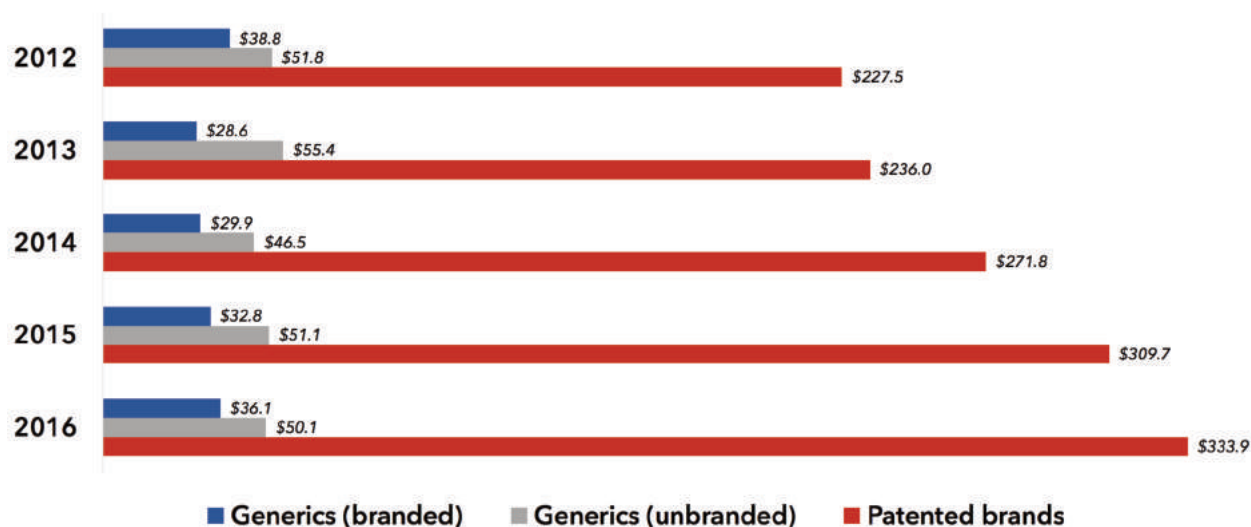
First, there is no correlation between drug prices and the *cost* of innovation.

The costliest drugs to develop are those which require large phase III clinical trials involving tens of thousands of patients, such as drugs for diabetes, high blood pressure, and heart disease.¹¹ Such trials can cost several billion dollars per molecule. But, in fact, new drugs in these areas have little pricing power, because doctors have the ability to prescribe effective and inexpensive generics for these conditions. Indeed, the clinical effectiveness of generics makes them the standard of care for first-line therapy for most common metabolic and cardiovascular diseases.

Figure 4. Share of Prescription Volume by Unbranded Generics, 2014



The U.S. leads the industrialized world in the utilization of unbranded generic medications. While overall drug spending is high in the United States, the ability of U.S. pharmacists to automatically substitute generic drugs for branded drugs, combined with sophisticated formulary management by insurers and pharmacy benefit managers, has led to the highest rate of generic utilization among advanced economies. (Sources: QuintilesIMS, FREOPP analysis)

Figure 5. Prescription Drug Spending on Branded vs. Generic Drugs, 2012–2016 (Invoiced, Billions)

A decline in generic spending has been overwhelmed by the rise in branded spending. Unbranded generics have increased their share of prescription volume from 78 to 85 percent from 2012 to 2016. Remarkably, however, generic spending actually declined during this period. Patent-protected branded drugs accounted for all of the rise in drug spending. (Source: QuintilesIMS)

The cheapest drugs to develop are those which require small clinical trials involving dozens of patients, such as drugs for ultra-rare, or “ultra-orphan” conditions like Fabry disease and paroxysmal nocturnal hemoglobinuria (PNH). Phase III trials for these conditions, which only affect several thousand people in the United States, run in the tens of millions. But manufacturers of such drugs have generated billions in revenues from them. The pioneer in this area, Genzyme, was acquired by Sanofi-Aventis for over \$20 billion in 2011, when it was garnering \$4 billion in annual revenue for drugs including a treatment for Fabry disease. Alexion, the developer of a treatment for PNH, recorded \$3 billion in revenue in 2016. Annual revenues in this range exceed those of many drugs which were at least equally innovative but developed for more common disorders.

It is important to note that the Genzyme and Alexion drugs were in fact innovative, and life-changing for the thousands of patients who receive them. But the cost of developing them was on the low end of the spectrum, whereas their prices and revenues were on the high end.

In addition, there are numerous examples of pharma-

ceutical companies conducting inexpensive clinical trials for previously available but off-patent drugs, and then charging high prices for their “branded” version which now enjoys exclusivity due to FDA approval. The best-known example was Turing Pharmaceuticals’ decision to increase the price of pyrimethamine, branded as Daraprim, by 5,500 percent in 2015. But Turing’s practices are more common within the industry than is widely understood. Other companies, including Valeant, Ovation, Marathon, Horizon, Mylan, and Mallinckrodt have also deployed this strategy.

Furthermore, it is common for manufacturers of branded drugs to increase the prices of their drugs by double-digit percentages once they have already reached the market and their R&D risks concluded. Take, for example, the market for treatments for multiple sclerosis. In 1996, Biogen launched Avonex, a monoclonal antibody, for \$8,723 per patient per year. In 2013, Biogen was charging \$62,394 for exactly the same drug, even though numerous, more effective medicines had been launched in the intervening two decades (*Table 1*).^{12, 13}

In a consumer-driven technology market, such pricing practices would be inconceivable. Samsung, for exam-

ple, would never be able to charge eight times the original price for a 20-year-old cellular phone. Nor would Samsung attempt to justify such price increases by citing “the cost of innovation,” as drug companies do, even though Samsung’s investment in R&D is also significant. Samsung does not believe it has an inherent right to consumers’ money to fund its R&D, regardless of how innovative the company is. In a consumer-driven market, businesses recognize that they must charge prices that consumers will be willing to bear, because otherwise they will fail to sell their products.

Second, there is no correlation between drug prices and the *degree* of innovation.

So-called “biosimilar” drugs that are therapeutically identical to branded biologics are being priced at mild discounts of 10-20 percent of the branded drug, despite the fact that these drugs require little to no innovation. For example, Sandoz’s Zarxio, a biosimilar to Amgen’s Neupogen, was launched in September 2015 at a 15 percent discount to the branded price, though it did not require 85 percent as much innovation as Neupogen to develop.

Two drugs of equivalent therapeutic innovation—for example, monoclonal antibodies that target different cancer-causing gene products—might have entirely

different prices, depending on the competitive landscape of the diseases they treat.

In some cases, drugs that are very similar—such as Genentech’s Avastin for cancer and Lucentis for age-related macular degeneration (a form of blindness in the elderly)—are priced very differently, despite the fact that both drugs were developed by the same company, and that both drugs derive from antibodies to the same molecule, vascular endothelial growth factor (VEGF). Genentech priced its anti-VEGF biologic drug for cancer at \$55 per dose, and its anti-VEGF biologic drug for ophthalmology at \$2,023 per dose: more than 40 times more. Researchers at the University of Michigan calculated that deploying Avastin for age-related macular degeneration instead of Lucentis could save Medicare \$18 billion over a ten-year period.¹⁴

The Avastin-Lucentis case illustrates the very prosaic point: while there is no correlation between high drug prices and innovation, there is a strict correlation between high drug prices and *market power*. Both Avastin and Lucentis were important innovations for the diseases they treat. But the pricing strategies Genentech employed with each drug were not related to their innovativeness or their clinical value, but rather to the competitive situations they faced in each disease.

Put simply, drug companies charge the highest prices

Table 1. Initial and Current Annualized U.S. Prices of Common Multiple Sclerosis Drugs (vs. CPI)

DRUG NAME	LAUNCH DATE	PRICE AT APPROVAL	PRICE IN 2013	AVG. GROWTH/YR	AVG. CPI DRUG GROWTH	AVG. CPI ALL GOODS
Betaseron	7/23/1993	\$11,532	\$61,529	21.0%	4.8%	3.0%
Avonex	5/17/1996	\$8,723	\$62,394	34.6%	4.7%	2.8%
Copaxone	12/20/1996	\$8,292	\$59,158	35.7%	4.7%	2.8%
Rebif	3/7/2002	\$15,262	\$66,394	28.1%	3.6%	2.7%
Tysabri	11/23/2004	\$25,850	\$64,233	16.2%	3.3%	2.4%
Extavia	8/14/2009	\$32,826	\$51,427	13.0%	2.9%	2.0%
Gilenya	9/21/2010	\$50,775	\$63,806	7.9%	2.4%	2.2%
Aubagio	9/12/2012	\$47,651	\$57,553	16.8%	0.0%	1.1%
Tecfidera	3/27/2013	\$57,816	\$63,315	13.8%	1.0%	1.3%

CPI figures are for annualized inflation over the timeframe that the drug has been on the market, up to 2013.

Source: Hartung et al., *Neurology*, 2015 May 26; 84(21):2185-92.

where they have the greatest market power: generally, because they have developed a drug for a disease for which they have no competition. They charge the lowest prices where they have the least market power: generally, because they have developed a drug for a disease in which there is robust competition.

THE U.S. IS NOT A FREE MARKET FOR PRESCRIPTION DRUGS

One of the enduring myths of the pharmaceutical industry is that because drug prices are not regulated by the government, the sector is a “free-market” one. It is not. Indeed, federal policy is entirely responsible for the fact that branded prescription drugs cost so much more in the United States than they do in other advanced economies.

Third party purchase of third party insurance. The fact that the vast majority of Americans with health insurance did not purchase it for themselves, but rather had it purchased on their behalf by third parties such as employers and the government, is the principal driver of drug price inflation, as with other health care services.

Because most individuals are not aware of how much money is withdrawn from their paycheck to pay for health insurance—let alone how much of their premiums are driven by drug spending—they are more likely to complain about their insurer if a needed drug is not covered by their health plan, than if the drug’s price is high, but paid by the insurer (and eventually by the patient, in the form of higher premiums and taxes). The pharmaceutical industry is incentivized to take maximal advantage of the political weakness of insurers.

Legal monopolies. There is Constitutional tradition, and much policy justification, for granting patents—i.e., temporary monopolies—to developers of innovative new medicines.

It is important to reward innovative new medicines with patents, especially given the high risks and costs to drug development. But monopolies are not markets, especially in the dozens of disease areas where therapeutic alternatives are not available.

Most industrialized countries compensate for monopoly pricing under the patent system by enacting some form of price controls. The U.S. has avoided explicit

price controls, but has yet to enact a market-based mechanism that makes branded drug prices affordable.

Federal and state drug coverage mandates. Federal law mandates that Medicare pay for most drugs, if they have been approved by the Food and Drug administration, regardless of price or clinical value. This is especially a problem for drugs covered by Medicare Part A (drugs administered in hospitals) and Part B (drugs administered in physician offices).

Since the passage of the Medicare Modernization Act of 2003, Medicare Part B reimburses physicians for the average sales price of a drug—inclusive of wholesaler discounts and rebates—plus 6 percent, regardless of cost-effectiveness. Indeed, the “ASP plus 6” formula incentivizes physicians to use higher-priced drugs, because receiving a payment of 6 percent of a costlier drug is better for them than receiving a payment of 6 percent of a less-costly drug.

Oncology drugs enjoy particularly high pricing power in the U.S. because cancer is largely a problem of the elderly. Of the \$21 billion Medicare and its enrollees spent on Part B drugs, 55 percent was for anti-cancer drugs.¹⁵ Part B is prohibited from negotiating with drug companies on the basis of price.

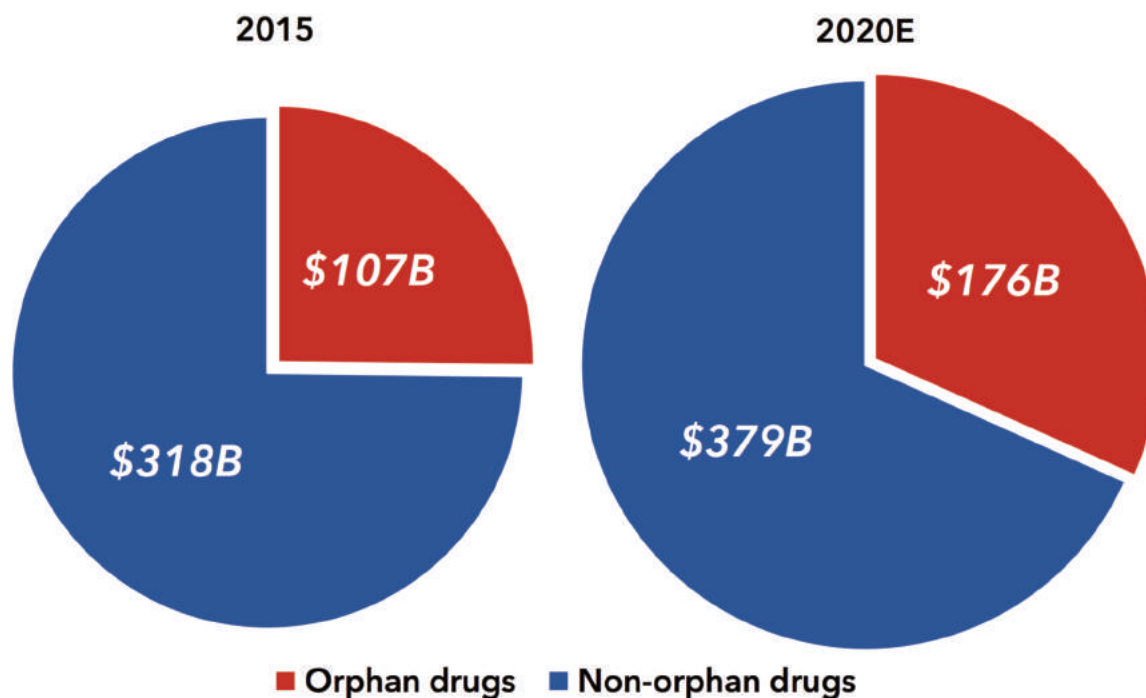
(While Medicare Part D is also prohibited from directly negotiating prices for retail prescription drugs most commonly purchased at pharmacies, pharmacy benefit managers and private insurers do negotiate with manufacturers on behalf of the program.)

Regulations implemented for the Affordable Care Act’s individual market insurance exchanges require that insurers cover “at least the greater of: (i) one drug in every United States Pharmacopeia (USP) therapeutic category and class; or (ii) the same number of prescription drugs in each category and class as the [essential health benefit] benchmark plan” in a given exchange.

The net effect of this rule is to force insurers to cover many brand-name drugs that are not cost-effective, merely because they happen to be in a unique class.

ARTIFICIAL MONOPOLIES FOR OFF-PATENT DRUGS

There are a number of old drugs whose patents have long expired for which prices are unusually high, be-

Figure 6. U.S. Spending on Orphan Drugs, 2015 & 2020E (Billions)

U.S. orphan drug spending is growing faster than non-orphan drug spending. Estimates by Michael Daniel and colleagues at Johns Hopkins University School of Medicine suggest that orphan drug spending will rise from one-quarter to nearly one-third of total U.S. drug spending from 2015 to 2020. (Sources: *American Journal of Clinical Oncology*, *QuintilesIMS*, *FREOPP analysis*)

cause unwise laws FDA regulations effectively guarantee monopolies and prohibit competition.

There are four principal categories of unpatented drugs where federal policies have driven prices upward: old drugs used for rare diseases, old drugs that were first marketed before the existence of the FDA, old drugs delivered via specialized devices, and old drugs with significant safety issues.

Off-patent orphan drugs. The first category, alluded to earlier in this report, is best known for the episode involving Turing Pharmaceuticals and its CEO, Martin Shkreli.

While few of these cases garnered the media attention that Martin Shkreli did for raising the price of Daraprim by 5,500 percent in 2015, the reality is that Shkreli was following pricing practices that are common in the industry. The basic strategy is as follows: a pharmaceutical company acquires rights to an old,

commercially available, off-patent drug that is used to treat a rare disease. If there are fewer than 200,000 patients suffering from that disease in the United States, the off-patent drug can qualify as an orphan drug under the Orphan Drug Act of 1983.

If the manufacturer conducts inexpensive clinical trials that demonstrate the drug's effectiveness—in these cases the effectiveness has usually been well described in the medical literature—the Orphan Drug Act grants the sponsor a seven-year monopoly. Furthermore, as a result of laws passed by Congress in 2007 and 2012, if the drug is used to treat neglected tropical disease or rare pediatric diseases, they can qualify for *priority review vouchers* that can be sold for hundreds of millions of dollars to other companies looking to accelerate FDA review times for their drugs.

A recent example of this strategy comes from Marathon Pharmaceuticals. An old, off-patent steroid called deflazocort had long been available in the U.S.

through European pharmacies to treat some of the symptoms of Duchenne muscular dystrophy, a fatal disease affecting approximately 12,000 boys in the United States, at an annual cost of \$1,200.

Marathon conducted clinical trials to gain FDA approval and orphan drug status for deflazocort in the U.S., thereby obtaining the seven-year monopoly and a priority review voucher. In February 2017, Marathon announced that it would charge \$89,000 per year for its branded version of deflazocort, called Emflaza; Marathon's FDA approval meant that foreign pharmacies were no longer allowed to sell their cheaper versions in the U.S.

After a public outcry, Marathon's chief financial officer Babar Ghias defended the new price as "modestly priced for an orphan drug," pointing to other drugs for rare diseases that cost more than \$300,000 per patient per year.¹⁶ The following month, Marathon sold Emflaza to PTC Therapeutics for \$190 million in cash, stock, and future considerations, along with a royalty exceeding 20 percent on PTC's net sales of the drug.

Yet another problem with orphan drugs is the ability of manufacturers to receive multiple orphan drug designations for the same drug in different diseases, allowing manufacturers to stack these seven-year monopolies on top of each other and protect their exclusivity in the initial disease indication for far longer than the statute originally intended.

Scholars at Johns Hopkins estimate that in 2015, revenue from orphan drugs totaled \$107 billion, representing one-quarter of all U.S. drug revenues (*Figure 6*). They project that share to approach one-third of drug spending in 2020, representing \$176 billion in orphan sales.¹⁷

Off-patent drugs predating the creation of the FDA. A second category of off-patent drugs treat common diseases, but are so old that they were first marketed before the FDA came into existence in 1927, and/or before the passage of amendments in 1962 to the Food, Drug, and Cosmetic Act that gave the FDA broad authority to approve drugs based on their safety and effectiveness. In 2006, the FDA announced an Unapproved Drugs Initiative designed to remove many of these drugs from the market, and require clinical trials for the remainder in exchange for three years of marketing exclusivity.¹⁸

Colchicine, a drug first used to treat gout around 1500

B.C., has now been FDA approved at the agency's insistence, with market exclusivity granted to a small company called URL Pharma. URL initiated a 5,289 percent price increase after gaining exclusivity in 2009 for its branded version of colchicine, called Colcrlys.¹⁹

URL could not gain orphan drug status for colchicine to treat gout, because gout affects as many as 2 million people in the United States. However, URL was able to gain orphan status for the use of colchicine in a rare disease called familial Mediterranean fever, thereby obtaining a seven-year monopoly. In 2012, URL was acquired by Takeda Pharmaceuticals for more than \$800 million.

Off-patent drugs with specialized delivery devices. A third category of off-patent drugs with high prices are generic drugs delivered via specialized, and often patented, devices.

In 2005, the FDA announced it would ban the use of chlorofluorocarbons in asthma inhalers.²⁰ Though the underlying medicines most common to treat asthma have long been off-patent, the requirement for new CFC-free inhalers led to the long extension of market monopolies for companies like GlaxoSmithKline, which created a proprietary inhaler for Advair, its combination of two off-patent drugs: fluticasone and salmeterol. FDA regulations have made it effectively impossible for generic manufacturers to prove bioequivalence to products like Advair without violating the branded company's intellectual property. In 2017 alone, the FDA has rejected attempts by Mylan, Hikma, and Vectura to develop generic versions of Advair.²¹

In 2016, Mylan attracted controversy for raising the price of its EpiPens, which deliver epinephrine in the event of a life-threatening allergic attack called anaphylaxis, from \$100 to \$600 per pen. Epinephrine, also known as adrenaline, was first isolated in 1901, and has long been off-patent. But Mylan's autoinjector has been approved by the FDA specifically for treatment of anaphylaxis, and the agency has made it extremely difficult for would-be competitors to gain approval for similar devices.²²

Off-patent drugs with FDA-mandated risk mitigation strategies. Thalidomide was first marketed in West Germany 1957 to treat nausea and morning sickness in pregnant women. However, it was soon discovered that thalidomide caused birth defects when taken by expectant mothers. The widely publicized controversy around thalidomide was directly respon-

sible for the amendments to the U.S. Food, Drug, and Cosmetic act in 1962 that gave the FDA the authority to approve drugs for both safety and efficacy, and not safety alone.

In 1998, Celgene gained approval for the use of thalidomide for inflammatory complications of leprosy, an orphan disease. The FDA required Celgene, as a condition of approval, to develop what is now known as a risk evaluation and mitigation strategy, or REMS, to ensure that pregnant women never received thalidomide. Celgene was able to obtain patents for its risk management program, patents that do not expire until 2018 and 2020. In effect, the FDA's unusual safety requirements for thalidomide created an artificial monopoly for a drug long off-patent. Would-be generic competitors have been unable to develop their own versions of thalidomide without violating Celgene's risk management patents.

Using the profits they gained from thalidomide, Celgene was able to fund development of additional drugs of clinical value for hematologic cancers. But we may not always be so fortunate. But the FDA has increasingly been deploying risk mitigation strategies for newly approved drugs as a way of bringing more drugs with safety issues to market. A side effect of these REMS programs will be an artificial extension of pharmaceutical monopolies that increases costs and restricts competition.

COMPETITIVE BARRIERS FOR BIOSIMILAR DRUGS

A limitation of Hatch-Waxman is that it only applies to *small molecules*, or medicines formed from relatively simple chemical compounds that can be synthesized in basic laboratories.

Large molecules—such as monoclonal antibodies and other complex proteins—are not governed by the generic provisions in Hatch-Waxman. This has meant that the U.S. success with generic drug penetration has yet to be replicated with biologic medicines. This is a problem, because biologic drugs are an increasingly important part of the branded drug landscape.

Biologic drugs are much larger, with far more structural complexity, than small molecules. For example, a molecule of atorvastatin, a common cholesterol-lowering drug commonly known as Lipitor, weighs 559 Daltons; whereas erythropoietin, the core ingredient in a bio-

logic drug called Epogen, weighs about 32,000 Daltons. The exact structural configuration of large biologic molecules can change significantly in response to the chemical environment.

Regulators have been abundantly cautious in approving generic biologics, or “biosimilars,” because the safety of biosimilars can be compromised if they are not exact replicas of branded drugs.

In Europe, recombinant human erythropoietin was primarily sold by Johnson & Johnson, under the brand name Eprex. Eprex had originally been formulated in association with human serum albumin, but new European regulations forced Johnson & Johnson in 1998 to remove human serum albumin from its Eprex formula and replace it with polysorbate 80 and glycine. Unfortunately, this change caused many patients to generate an immune reaction to Eprex, which then led those patients to lose their ability to natively produce erythropoietin.

Because erythropoietin is necessary for the production of red blood cells, these patients in turn lost their ability to produce red blood cells—a condition called pure red cell aplasia (PRCA)—becoming dependent on blood transfusions for the rest of their lives.

Despite the fact that this episode was the result of unwise regulations issued by the European Medicines Agency—the European equivalent of the U.S. Food and Drug Administration—regulators have responded to the Eprex episode by making it difficult for generic biologics to reach the market. Unlike with small molecules, biosimilar drugs have been historically treated by the FDA like new drugs, requiring large and costly clinical trials for regulatory approval.

Recent legislation has removed some, but not all, of the barriers to the production of biosimilar medicines. The Biologics Price Competition and Innovation Act of 2009 created an abbreviated pathway for biosimilars to reach the market, but not before the original branded drug has been marketed for at least 12 years (for small molecules, the abbreviated pathway kicks in after only 5 years of marketing authorization for the original brand).²³

In order to achieve the equivalent of generic substitution at the pharmacy level, the BPCI Act requires prospective manufacturers of biosimilar drugs to demonstrate that their drug “can be expected to produce the same clinical result as the reference product

in any given patient,” and that “the risk [of alternating] between use of the [biosimilar] and the reference product is not greater than using the reference product” alone. Biosimilar manufacturers are also required to conduct “a clinical study or studies...sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions” for which the original drug is used.

In practice, this means that biosimilar manufacturers must conduct a small phase I clinical trial and a large phase III clinical trial in order to demonstrate therapeutic equivalence to a branded biologic drug.²⁴⁻²⁷ Phase III trials are extremely expensive, costing hundreds of millions of dollars at minimum; by contrast, developers of generic small molecules are only required to conduct small phase I trials that cost several million dollars.²⁸

The high cost of developing biosimilars restricts the number of companies that can participate in this market. It also incentivizes biosimilar manufacturers to charge prices that are comparable to the branded drug. In effect, biosimilar drugs are more like branded generics, for which prices and marketing costs are higher and savings more modest, in comparison to unbranded generics, for which development and marketing costs are very low.

Thus far, biosimilars are coming in at modest dis-

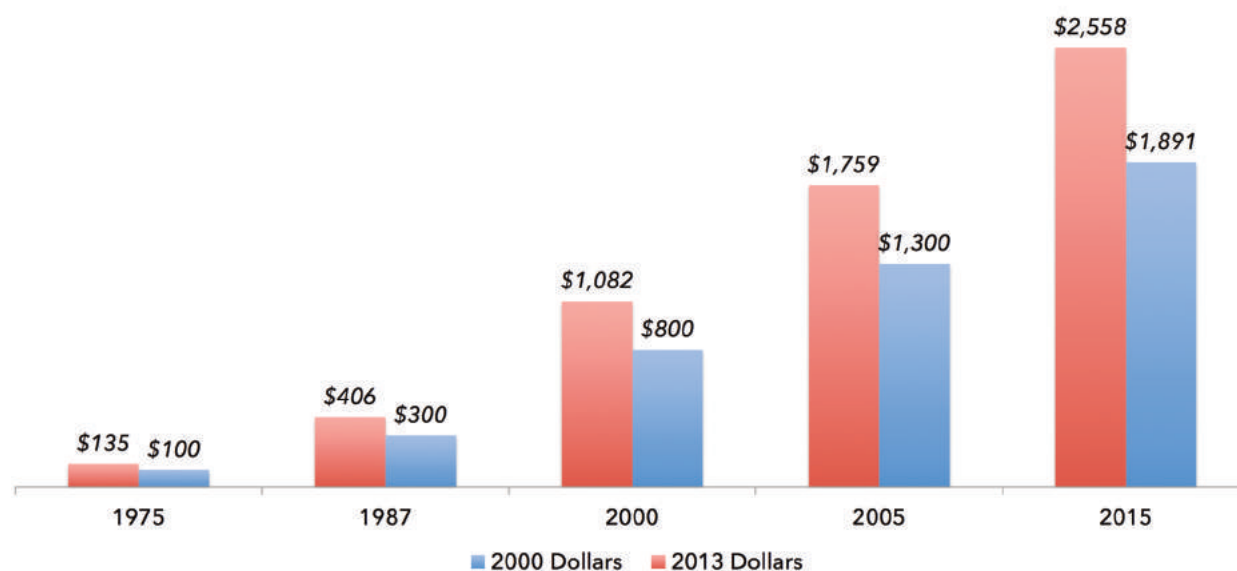
counts of 10 to 20 percent of the brand price, though these discounts may increase as more competitors come on line and give insurers and pharmacy benefit managers more negotiating leverage. A countervailing trend is that 27 states have passed laws restricting pharmacists’ ability to substitute biosimilars for branded drugs even if the FDA has designated them as interchangeable. While these state laws vary in scope and restrictiveness, they cumulatively have the effect of increasing the cost of biosimilar competition.²⁹

THE BIAS AGAINST ‘ME-TOO’ DRUGS

The FDA has long prioritized drugs that address an “unmet medical need”; that is to say, drugs that treat previously untreated diseases, or drugs that are meaningfully superior to the standard of care in an already treated disease. The FDA Modernization Act of 1997 gave the agency the authority to apply a “fast track” designation to drugs it believes to have met this standard. Other aspects of the FDA regulatory process are also geared toward favoring drugs that address unmet medical needs.

It is understandable, from a public health standpoint, that the FDA prioritizes unmet medical needs. But from the perspective of affordable prescription drugs, the FDA undervalues drugs that address met medical

Figure 7. R&D Expenditures per FDA-Approved Drug (\$ Millions)



needs. New drugs that are clinically comparable to existing drugs can provide needed price competition. But in many cases, new drugs that prove to be comparable to the standard of care face a higher level of scrutiny from the FDA than older drugs did. The FDA generally expects new drugs to be superior to the standard of care; any sign of inferiority risks rejection.

So-called “me-too” drugs, which are chemically or mechanistically similar to existing drugs, are often derided because they are less innovative than drugs that create entirely new categories or address an unmet medical need. But such “me-too” drugs can help insurers and pharmacy benefit managers reduce costs for consumers.

We can see this price competition with regards to HMG-CoA reductase inhibitors, commonly known as “statins,” for reducing blood cholesterol; and with angiotensin converting enzyme (ACE) inhibitors for high blood pressure. In each case, several branded drugs once competed with one another. Today, nearly all of them are off-patent, making highly effective medicines affordable for all, and providing a market-based mechanism for discouraging high prices for new drugs.

Insurer antitrust regulations. While the Constitution, federal law, and FDA regulations create pharmaceutical monopolies, insurers are prevented by federal and state antitrust laws from jointly negotiating reimbursement rates for innovative drugs in a given region. In effect, federal policy grants monopolies to the sellers of drugs, while federal and state regulations prohibit insurers from banding together to negotiate with these monopolies.

Rising drug development costs. The FDA places increasing burdens on drug developers each year, increasing the cost of late stage clinical trials. From 1999 to 2005, the number of median procedures per trial protocol—blood work, routine examinations, x-rays, and the like—increased by 65 percent.

The average clinical trial staff work burden increased 67 percent. The average length of a clinical trial increased by 70 percent. And due to more stringent FDA-mandated entry criteria for patients into a clinical trial, enrollment rates for trials declined by 21 percent, and retention declined by 30 percent.³⁰

All of these incremental additional requirements by the FDA have led to rising drug development costs. The Tufts Center for the Study of Drug Development

estimates that it now costs \$2.6 billion to develop an FDA-approved drug in 2013 dollars, inclusive of all of the failed drug candidates one has to study in order to achieve success (*Figure 7*).³¹ That represents an increase from \$1.8 billion in 2005, \$1.1 billion in 2000, \$400 billion in 1987, and \$135 million in 1975.

REMOVING FEDERAL BARRIERS TO PHARMACEUTICAL COMPETITION

In reviewing the pharmaceutical pricing landscape in the United States, one thing becomes abundantly clear: high prices exist where competition is minimal, and low prices exist where competition is robust.

In the rest of the economy, technological innovation drives prices down while increasing quality and expanding access. Google and Facebook are two of the most innovative companies in the world. Their core products—search engines and social networks, respectively—are free to the consumer.

Apple’s products are often more expensive than their competitors’; but even iPhones of comparable quality decline in price over time, as they must, since newer models contain newer features and consumers have alternatives, thanks to price competition. Apple launched the iPhone in 2007. At that time, an iPhone with 8 gigabytes of memory and a 320 x 480-pixel screen cost \$599.

In 2015, Apple launched the iPhone 6s Plus. A 128-gigabyte version of the phone, with a 1080 x 1920-pixel screen, cost \$499. Over eight years, then, the iPhone experienced a 27.4% decrease in inflation-adjusted price, while harboring 16 times more memory and a 13.5-fold increase in screen resolution. Furthermore, the capabilities of the iPhone’s microprocessor and its software have increased substantially.

Pharmaceutical innovation can improve clinical outcomes and lower costs—in a competitive market. There are ways for Congress to expand competition in the pharmaceutical industry while preserving the incentive for innovation.

Minimize FDA barriers to competition for off-patent small molecules. As detailed above, Congress and the FDA have established artificial monopolies for certain categories of off-patent drugs that should be subject to generic competition: (1) off-patent orphan drugs; (2) off-patent drugs that predate major FDA legislation;

(3) off-patent drugs with specialized delivery devices;
(4) off-patent drugs with FDA-mandated risk management strategies.

Legislation from Congress could mitigate these problems. Congress could enact a statute allowing for generic substitution in situations where the risk evaluation and mitigation strategies (REMS) vary. In addition, the FDA could standardize its REMS protocols sufficiently that patents are no longer a barrier to entry.

Similarly, Congress could create a new pathway for generic drugs where specialized delivery—such as through an inhaler, a patch, or an injection—is necessary to achieve the desired clinical effect. This new pathway would allow generic substitution for delivery mechanisms that are not exactly like the original, and develop methods for demonstrating therapeutic equivalence for such products.

Congress should simply eliminate FDA’s Unapproved Drugs Initiative, by explicitly stating that drugs that were marketed before 1962 cannot be removed from the market without new evidence that they are less effective or less safe than previously thought.

Payors and providers have plenty of incentive to ensure that patients avoid unsafe medications. On the

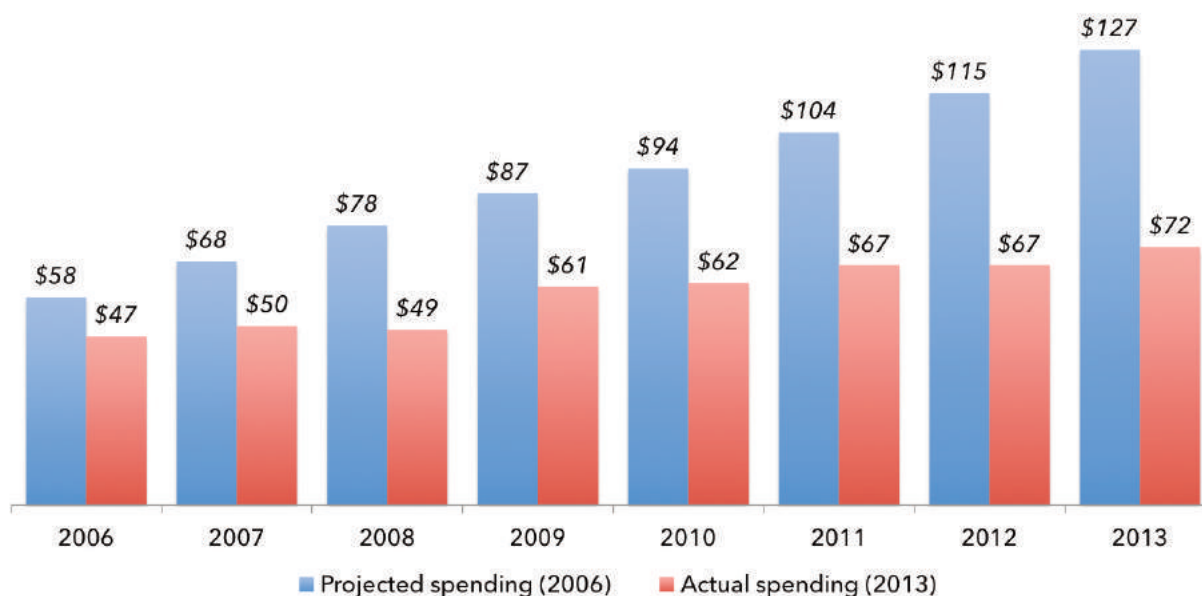
other hand, creating new monopolies for old drugs whose efficacy is well-established benefits profiteers rather than the public.

Exploitative pricing for off-patent orphan drugs is perhaps the best use case for parallel importation of drug product from less-costly foreign jurisdictions. Congress could amend the Orphan Drug Act such that price increases above a certain threshold of the pre-orphan price triggered an automatic review of the feasibility of parallel importation for that medication.

Congress could also amend the Orphan Drug Act to limit the utility of stacking orphan drug designations. While the FDA grants a seven-year monopoly to the first approved orphan indication for an off-patent drug, Congress could require a second approved indication to grant an additional five years of exclusivity, with the third allowing an additional three years, and the fourth one year. A “diminishing returns” policy like this one could retain some incentives to develop drugs for rare diseases, while mitigating the impact of exploitative pricing practices.

Streamline regulations for biosimilars. The Biologics Price Competition and Innovation Act of 2009 takes a cautious and costly stance by requiring biosimilar manufacturers to undertake phase III clinical trials to prove

Figure 8. Medicare Part D Spending, Projected by CMS in 2006 vs. Actual (Billions)



that their drugs are as safe and effective as their branded equivalents. Furthermore, the BPCI act awards biologic drugs 12 years of market exclusivity regardless of their underlying intellectual property, compared to 5 years for small molecules. It is difficult to justify a seven-year difference between mandatory exclusivity periods for biologics vs. small molecules.

While this is not an inappropriate approach given the novelty of biosimilars, Congress should sunset the entire Act after a ten-year period of enactment (i.e., 2020) in order to re-evaluate whether or not such expensive clinical trials are necessary to demonstrate therapeutic equivalence. Given rapidly evolving technology in this area, after 2020 the BPCI Act should require reauthorization every five years to reevaluate its regulatory framework. For example,

Furthermore, Congress should harmonize generic substitution rules for small molecules and biologic drugs, so that FDA-approved biosimilars can be automatically substituted by pharmacists for branded products. Too often, this is not possible today.

Promote ‘me-too’ and clinically comparable drugs. The FDA Modernization Act of 1997 authorized the FDA to designate as “Fast Track” products those which address an unmet medical need and treat a serious or life-threatening condition. Congress could revise this statute such that the “Fast Track” designation was also available to drugs being developed for diseases where only one or two FDA-approved drugs can be considered to represent the standard of care. In this way, the agency can advance the public’s interest in mitigating the adverse impact of monopolies and duopolies.

Minimize federal drug coverage mandates. The effective requirement that Medicare Parts A and B cover all FDA-approved drugs has given them the power to price their products at exceptionally high levels, especially in oncology. One solution may be to migrate all prescription drug coverage to Medicare Part D, where pharmacy benefit managers negotiate drug prices on behalf of the Medicare program. As *Figure 8* illustrates, Medicare Part D has spent far less than originally projected, in large part due to the success of PBMs in encouraging the utilization of generic medications.

Another approach may be to allow Medicare A and B to contract with PBMs to negotiate drug prices on their behalf.

Yet another approach, considered by the Medicare Payment Advisory Commission, would be to require that Medicare B’s drug reimbursement formula of average selling price plus 6 percent to increase at inflation (the Consumer Price Index for All Urban Consumers, or CPI-U) after the first year of launch.³² While such a regime might incentivize manufacturers to inflate their prices at launch, they would not be able to price their products too aggressively at first without encountering resistance from commercial payors. Hence, while manufacturers could still be rewarded for innovation, they would face diminishing returns for extending monopolies instead of developing newer molecules.

The Secretary of Health and Human Services, Tom Price, has expressed a desire to reduce health insurance premiums in the individual market. To this end, he could strike Affordable Care act regulations mandating that individual-market health insurance plans cover at least one branded drug per therapeutic category, regardless of cost-effectiveness.

Accelerate medical innovation. It would be highly beneficial to replace the current “all or nothing” FDA approval system with one that reflects the realities of scientific research and the profiles of chronic long-term conditions.

Such a reform would allow drugs that have been found safe and promising (in Phase I and Phase II clinical trials) to win approval for limited marketing to patients. Doing this would give patients early access to innovative new therapies, while the FDA would retain the ability to collect information confirming the drugs’ safety and effectiveness and to later revoke a drug’s marketing authorization, when appropriate.

While the FDA currently has the legal power to create its own conditional approval process, it has little political latitude to do so. For this reason, Congress must create clear standards for such a pathway. Congressional action, through PDUFA legislation, would allow regulators and companies to develop new tools that are better suited to the economic realities of modern drug development.

A simple, but effective, way to streamline the FDA review process would be for Congress to require that the FDA automatically approve any drug for any indication that has been already approved by the European Medicines Agency (EMA). The pan-European Union approval process is just as rigorous, and in some

cases more so, than the United States', and giving companies the ability to file in one of these developed markets would significantly improve drug development times and financial risk.

Swiss-style safe harbors for insurer drug price negotiation. In Switzerland, private insurers in a given canton (the equivalent of a U.S. state) are encouraged to jointly negotiate with drug manufacturers, as well as with medical device companies, hospitals, and doctors. In this way, they can balance out the monopoly power of branded drugs, while maintaining a health care system that is, on balance, more market-oriented than America's.

Congress could create a safe harbor from antitrust for private insurers who wish to jointly negotiate with drug manufacturers. Indeed, the ability to jointly negotiate with manufacturers would limit the need and desirability of insurers to consolidate, because the primary rationale for consolidation is to level the playing field with providers and drug companies.

Require an up-or-down Congressional vote for major FDA regulations. In January 2017, the U.S. House of Representatives passed the Regulations from the Executive in Need of Scrutiny Act of 2017, also known as the REINS Act. (It has not, at time of publication,

passed the Senate.) The REINS Act designates any regulation with an economic impact of greater than \$100 million as a *major rule*. For any major rule promulgated by the executive branch with an annual economic impact of \$100 million or more, the REINS Act requires that Congress approve such rules within 70 days, or they will not take effect.

FDA regulations routinely cross this \$100 million threshold, particularly in cases where the FDA has required manufacturers to undertake costly additional clinical trials. The REINS Act could help the agency become more sensitive to the regulatory costs it imposes on manufacturers, along with reducing barriers to entry for competitive drugs.

Move toward a consumer-driven health care system. At the end of the day, the most fundamental problem with American health care is that patients do not control the health care dollars that are spent on their behalf. The more we move to a system where consumers control these resources by directly buying their own coverage and care, the more likely we are to have a system in which pharmaceutical companies price their products in patient-friendly ways.



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About the Author

AVIK ROY IS THE PRESIDENT of the Foundation for Research on Equal Opportunity (FREOPP), a non-profit, non-partisan think tank that conducts original research on expanding economic opportunity to those who least have it.

Roy's work has been praised widely on both the right and the left. *National Review* has called him one of the nation's "sharpest policy minds," while the *New York Times*' Paul Krugman described him as man of "personal and moral courage."

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Roy also serves as the Opinion Editor at *Forbes*, where he writes on politics and policy, and manages The Apothecary, the influential *Forbes* blog on health care policy and entitlement reform.

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From 2011 to 2016, Roy served as a Senior Fellow at the Manhattan Institute for Policy Research, where he conducted research on the Affordable Care Act, entitlement reform, universal coverage, international health systems, and FDA policy. Previously, he served as an analyst and portfolio manager at Bain Capital, J.P. Morgan, and other firms.

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