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Value-Based Pricing of Prescription Drugs Benefits Patients and Promotes Innovation

By Thomas Waldrop September 2021

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Introduction and summary

In the United States, pharmaceutical companies are able to set the price of a prescription drug at whatever they believe the market will bear. As a result, the prices of prescription drugs are not tied to the value those drugs provide to patients, as they are in many of our peer nations. Countries such as Germany and Australia use value-based pricing, ensuring that the price of a drug is based on the benefit provided to patients in terms of quality of life or efficacy; this pricing approach makes their drugs cheaper and more valuable to the patients taking them.

Because of the pharmaceutical industry's ability to set prices largely unchecked, drug prices in the United States are much higher than they are in peer nations. Multiple recent studies have arrived at this conclusion. A 2021 study by the RAND Corporation compared prices for prescription drugs in the United States with those in 32 other countries, including the United Kingdom, Germany, and Australia; the authors ultimately found that prices in the United States were an average of 156 percent higher than prices in the comparison countries.[1] Even after adjusting for rebates and other discounts in the United States, prices were still nearly twice as high.[2] The U.S. Government Accountability Office found similar results: A 2021 report found that U.S. drug prices were two to four times higher than the prices for those same drugs in Australia, Canada, and France.[3]

In addition to starting at a higher price, prescription prices have risen for several decades at an unsustainable rate, higher than inflation.[4] A 2020 study conducted by researchers at the University of Pittsburgh found that the average list price for brand-name drugs increased by more than 150 percent from 2007 to 2018.[5] A Kaiser Family Foundation analysis of Medicare Part D drugs found a similar result: Half of Part D drugs had list price increases above inflation in 2019, and nearly 15 percent of Part D drugs had list price increases of more than 10 percent.[6] These trends have continued into 2021. According to GoodRx, drug companies increased the prices of 832 drugs by an average of 4.5 percent in January 2021 and 67 drugs by an average of 3.5 percent in July 2021.[7]

These high prices and price increases have a real impact on patients: Nearly 3 in 10 American adults reported not taking medicines as prescribed in 2019 due to cost.[8] American taxpayers also bear the burden of high drug prices, with Medicare and Medicaid spending nearly $290 billion on prescription drugs in 2019.[9] As a result, there has been considerable discussion at both the state and federal level on how to lower both overall prescription spending and high underlying prices.[10]

As policymakers weigh various proposals that would lower drug prices and limit excessive price increases, the pharmaceutical industry has asserted that high prices are necessary to promote innovation and develop new drugs. The reality, however, is that there is not a significant relationship between the prices charged by pharmaceutical companies and either their research and development (R&D) spending or the clinical benefit of their products.

Moreover, the current pricing structure has distorted pharmaceutical innovation; the areas of R&D in which the industry invests do not necessarily reflect the health needs of the U.S. population.[11] This report makes the case that value-based pricing has the potential to better serve the American public by promoting research into products with greater clinical benefit that help meet the country's health care needs.

Why prescription drug prices are so high in the United States

There are a number of policies that contribute to high prescription drug prices and excessive quarterly price increases in the United States. The combination of government-granted exclusivity periods, the industry's success at extending these periods, and the inability of most public payers to meaningfully negotiate prices has created a system in which pharmaceutical companies can largely charge whatever price they want.[12] The resulting system has strained health care payers' budgets, which in turn creates access challenges for patients.

The federal government grants pharmaceutical companies market exclusivity for several years after a drug is submitted for approval by the U.S. Food and Drug Administration (FDA)—essentially a government-backed monopoly for the sale of that drug, intended to help drug companies recoup their investments in developing the product.[13] These exclusivity periods generally range from five to seven years, though some drugs receive shorter or longer periods.[14] The periods are in addition to a product's patent protection, and they are intended to be finite, so that once they have ended, generic drugs can enter the market, driving down prices.[15] Generic drugs significantly lower prices: Even for drugs where there is only a single generic competitor, the generic drug is typically about 40 percent less expensive than the average brand drug.[16]

Drug companies, however, have stifled this intended competition in several ways. For example, under "pay for delay" agreements, pharmaceutical companies agree to pay a generic manufacturer to delay introducing its drug for a period of time.[17] Drug companies also take advantage of patent law by making minor changes to a drug to establish a new patent—called "evergreening"—or by creating a large amount of overlapping intellectual property rights to address before competing with a drug, called a "patent thicket."[18] Without available alternative drugs, manufacturers have much greater ability to charge exorbitant prices.

Pharmaceutical companies' price-setting power extends to public programs such as Medicare. Medicare provides health coverage—including prescription drug coverage—to seniors over the age of 64, certain younger disabled people, and people with end-stage renal disease and amyotrophic lateral sclerosis.[19] The Medicare Modernization Act of

2003, which established the Part D retail prescription drug benefit under Medicare, explicitly prohibits Medicare from negotiating drug prices for patients enrolled in the program.[20] The same law requires Medicare drug plan administrators to cover at least two drugs in most drug classes and every drug in six specific "protected classes" of drugs.[21]

Private payers are also strained by this price-setting power: While private insurers are able to negotiate prices and establish formularies to reduce prescription drug spending, the root issue of high list prices and price increases still sets prices in the United States at unsustainable levels. And even when insurers do not impose access restrictions, patients will still bear the burden of these high prices through out-of-pocket costs and higher premiums.

The current system leaves key health needs unmet

The ability of drug companies to price their products based on their assessment of what the system will bear has led pharmaceutical companies to invest their research and development funds into the health conditions and drugs that they either expect or know to be profitable, rather than the conditions with the most need. A recent report by the Congressional Budget Office put it plainly: "Pharmaceutical companies invest in R&D in anticipation of future profits."[22] This section outlines several examples of these profit-focused investments with low social value.

One example of the pharmaceutical industry prioritizing profit are so-called me-too drugs, which are structurally similar to already existing drugs, with only minor differences.[23] These drugs, despite representing minimal changes from existing drugs, greatly outnumber newly developed drugs.[24] About 60 percent of the World Health Organization's listed essential medicines, for example, are me-too drugs, and estimates of the number of new drugs approved by the FDA have been as high as 75 percent.[25] Importantly, because me-too drugs are not generic drugs, but rather later entries into a therapeutic class, they do not necessarily result in the price reduction that the introduction of a generic drug does.[26] Without the same impact on prices as generic drugs, me-too drugs represent research dedicated to increasing profits rather than improving patient outcomes.

In addition to me-too drugs, what are known as "add-on" drugs represent limited improvement in clinical benefit. An add-on drug is a drug given to make another drug or course of treatment more effective.[27] While these drugs often provide a real, proven benefit to patients, they can also be priced at a level higher than that additional value is worth. For example, long-acting bronchodilators are used as add-on treatments

for asthma patients when an inhaler does not manage symptoms entirely.[28] Several commonly prescribed long-acting bronchodilators, however, have high list prices. For example, fluticasone/salmeterol, mometasone/formoterol, and budesonide/formoterol have average list prices of more than $300 each for a single inhaler.[29] While patients typically pay less than this amount, these add-on drugs still represent inefficient spending by the health system as a result of unchecked pricing practices.

How the pharmaceutical industry spends its profits

The pharmaceutical industry asserts that exorbitant prices in the United States are necessary to fund innovation,[30] but examining where drug companies invest their profits demonstrates that this is not the case. A recent report by the House Oversight and Reform Committee shows this in detail: From 2016 to 2020, 14 of the largest pharmaceutical companies spent $577 billion on stock buybacks and dividends, $56 billion more than they spent on research and development.[31] The committee also found that of $521 billion dedicated to R&D, "a significant portion" of spending was devoted to suppressing generic competition by other drug companies, rather than developing new drugs.[32]

Another method by which drug companies' incentives are skewed is through the guaranteed coverage associated with FDA-approved drugs via Medicare. Multiple studies have found that after the creation of Medicare Part D, Medicare's prescription drug benefit, pharmaceutical companies invested more money into drugs that would be needed among Part D enrollees.[33] A 2014 analysis of these drugs, however, found a marked increase in clinical trials for prescription drugs for health conditions common among Medicare enrollees with several existing treatment options.[34] The same analysis found that these drugs were less likely than other drugs developed during the same time period to receive any of the three FDA designations of innovativeness: orphan drug designation, fast track status, or priority review.[35] Another study found that many of these same drugs were already known as possibly effective drugs but were not viewed as profitable enough to support a clinical trial until the creation of the Part D benefit.[36] Drug companies directed their R&D funding toward the drugs for conditions that are more common among Medicare enrollees, but they prioritized their potential profits over the actual health needs of these patients.

The federal government drives pharmaceutical innovation

A 2017 study of new prescription drugs approved from 2010 to 2016 found that federally funded research was involved in every new drug.[37] Much of this foundational research is funded by two agencies within the U.S. Department of Health and Human Services: the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA).

For example, some of the earliest products that BARDA supported were vaccines for H1N1—also known as swine flu—and antitoxins for anthrax.[38] Likewise, both agencies provided significant funding for the COVID-19 vaccines. The NIH funded the research that led to Moderna's COVID-19 vaccine, including the clinical trials, and BARDA provided about $10.8 billion to multiple pharmaceutical companies to develop the vaccines.[39]

This research is essential because the financial incentives present in the industry disincentivize the foundational research that leads to novel discoveries. Basic pharmaceutical research—discovering new molecules or mechanisms of action[40]—can often be extremely expensive. For example, the NIH spent $60.9 million on grants funding the research that led to Sovaldi, the first drug that cures hepatitis C rather than simply treating the symptoms; this was only $1.5 million less than Pharmasset spent developing the drug. Rather than take on the risk and cost of truly innovative research—such as determining mechanisms of action or discovering molecules that are the core of new drug developments—the industry relies on government funding of such research, after which it applies these findings to specific diseases.[41]

Finally, because the pharmaceutical industry sets the prices for prescription drugs at whatever level it deems appropriate, there are many drugs for which the price is clearly not reflective of the value it provides to patients. An example of this is aducanumab, a recently approved drug to treat Alzheimer's. Despite no clear evidence that the drug improves clinical outcomes, Biogen priced it at $56,000 per year—nearly seven times as expensive as what the Institute for Clinical and Economic Review (ICER), a nonprofit that evaluates the value of prescription drugs, estimated the drug should cost at most.[42] Because the current system limits the ability of most insurers, including public insurers, to meaningfully negotiate prices for prescription drugs, they are left with few options but to pay these inflated prices that do not reflect the value of the drugs.

Value-based pricing would better serve the public

Switching to a value-based pricing system would better serve patients and improve the efficiency of health care spending in the United States. Importantly, making such a switch would promote, rather than hinder, pharmaceutical innovation, especially into the health needs that are currently unmet.

What is value-based pricing?

Value-based pricing refers to paying for drugs in proportion with the benefits they provide to patients over existing drug options.[43] Rather than allow pharmaceutical companies the ability to charge whatever high price they have concluded will maximize their profits, the value-based framework ties the price to whether and to what extent the drug helps patients more than current treatment options. It also works to ensure that patient access to innovative drugs is included when determining the appropriate price for a drug.[44]

Value-based pricing still allows for relatively high drug prices in order to reward significant innovation. One example is Sovaldi, the drug that cures hepatitis C. First approved in 2013, Sovaldi was priced at $84,000 for a course of treatment.[45] When evaluating the clinical value of the drug, ICER's review committee voted in equal numbers that the drug represented either a reasonable or high clinical benefit. But when including the price in its evaluation, the committee overwhelmingly voted that it provided a low benefit to the health system.[46] This lack of value due to price was reflected in coverage of the drug: Public and private insurers both imposed significant access restrictions on the drug after its approval due to the high price.[47] In nations with value-based pricing in place, however, the price was still high: $55,000 for a course of treatment in Canada and $33,000 in France.[48] These are still significant sums of money, but they are consistent with the value that the drug represents to patients, rather than simply the price the drug company expected to charge without backlash; moreover, they ensure that payment concerns do not undercut patient access to these valuable drugs.

International examples of value-based pricing systems

Several of the United States' peer nations use value-based pricing to ensure that prices reflect clinical benefit, do not strain government budgets, and facilitate better health care access.

Germany's Federal Joint Committee

In Germany, the Gemeinsamer Bundesausschuss (Federal Joint Committee) assesses the value of a new prescription drug based on patient outcomes.[49] Importantly, the committee uses direct clinical benefits, rather than proxy outcomes, to determine the benefit to patients. Once these assessments are completed, the nation's health insurers collectively negotiate a single price in exchange for providing coverage with minimal access restrictions.[50]

Germany's approach has been extremely effective at lowering prices without reducing patient access. From 2011, when this approach was first implemented, to early 2019, the committee assessed 230 drugs, with manufacturers withdrawing only 28 from the market.[51] Drugs that are withdrawn are overwhelmingly likely to have received a "no additional benefit" designation by the committee: A 2018 study found that all but one of the drugs withdrawn from 2011 to June 2016 received this designation.[52] The same study found that the final additional drug withdrawn received a "non-quantifiable benefit" designation.[53] Prices in Germany are now far lower than they are in the United States, even though they are still higher than most other European countries.[54]

Australia's Pharmaceutical Benefits Scheme

Australia takes a similar, though more aggressive, approach. Under the nation's single-payer health care system, the federal government has the authority to directly set prices for prescription drugs purchased through the Pharmaceutical Benefits Scheme (PBS).[55] Two independent committees, the Economics Sub-Committee and the Drug Utilisation Sub-Committee, evaluate the cost effectiveness and utilization data for drugs seeking to be covered under the PBS.[56]

The committees evaluate a variety of factors: whether a health condition has few or no other treatment options, the extent to which a new drug is a significant clinical advancement, the total cost to the PBS, and the economic benefit associated with the drug's impact.[57] After these factors are considered, the committees recommend a price, and if the drug manufacturer does not agree to this price, the drug is either not approved or approved with access restrictions.[58] Of the 70 major drug submissions, which require both economic and clinical evaluation, that the PBS reviewed in 2020, more than half were eventually approved; and of the 27 drugs that were not approved, only three were not recommended due to financial concerns.[59]

As with Germany's Federal Joint Committee, Australia's PBS is extremely effective at reducing prescription drug spending. A recent report by the U.S. Government Accountability Office found that prescription drug prices were an average of 4.25 times higher in the United States than in Australia.[60] The same report found that Australia spends significantly less on prescription drugs, spending $651 per capita on prescription drugs in 2018, compared with $1,229 per capita in the United States.[61] Under Australia's system, patients also directly benefit: Copayments are capped at $28 (39.50 Australian dollars) per prescription, and low-income and retirees are eligible for reduced copays.[62]

Lupus is another health condition for which there have recently been high-value drugs approved; the FDA approved belimumab in late 2020 and voclosporin in early 2021. The drugs significantly improve kidney function relative to existing treatments and are priced at $43,000 and $92,000 a year, respectively—roughly in proportion with the value they provide to patients.[63] For both drugs, the prices were roughly in line with the range of prices that ICER estimated was acceptable and representative of the value provided to patients.[64] These new drugs also represent proper valuation of health equity:

90 percent of lupus patients are women, and the disease is three times more common among Black women than white women.[65] While health access inequities persist along gender and racial lines,[66] this kind of drug development is what should be rewarded with higher prices. Importantly, in order to ensure that patients have access to drugs with high value-based prices, there must also be value-based access.[67] For example, utilization management measures such as prior authorization requirements and copay—or coinsurance—should be limited or eliminated.

In the United States, however, there is often a lack of the information needed to perform such assessments. For example, there is not detailed, centralized information on health care utilization, including prescription drug utilization.[68] While the FDA has access to information on drugs' efficacy and safety at treating various health conditions as a necessity of its role in regulating prescription drugs, it does not perform the comparative effectiveness review that is necessary for a value-based pricing approach.[69] Without performing such analyses, drugs are only evaluated based on whether they are better than a placebo rather than other available treatments.[70] Similarly, the FDA does not have the utilization information used by groups such as ICER, the German Joint Committee, or the Australian PBS to determine the expected use of a new prescription drug. These data only exist for patients enrolled in federal programs such as Medicare and Medicaid. Notably, these groups only represent about one-third of the U.S. population,[71] significantly limiting the ability of any value determination for prescription drugs in the United States.

How can value-based pricing realign incentives to improve health?

Value-based pricing has the potential to effect lower health care spending by the health system, alter the health conditions into which the pharmaceutical industry invests research funds, and create better patient outcomes. This section outlines three different ways that value-based pricing can be used to accomplish these goals: 1) limiting spending on drugs without a proven benefit, 2) promoting research into underinvested health conditions, and 3) advancing health equity.

Lower spending on drugs without proven benefit to patients

One of the most significant ways that value-based pricing can realign incentives in the pharmaceutical industry is by limiting the prices that drug companies can charge for drugs without a proven clinical benefit to patients. There are two ways a drug may not have a demonstrated clinical benefit.

The first of these are drugs that provide known but not novel or improved health outcomes. For example, Mylan's EpiPen design changes represented research spending on the part of the company, but it was clear that very few patient outcomes would be altered by the changes. Similarly, me-too drugs, which are late entries to a therapeutic class with several existing drugs, provide a known but minimal benefit over these existing drugs in most cases. Under a value-based system, these sorts of minor modifications to a drug or additional entries into a class would have lower prices, because they do not represent a valuable benefit to patients.

The second way a drug may not have a demonstrated clinical benefit yet is if it was approved through the FDA's expediated pathways, which rely on surrogate endpoints instead of a direct measure of how well a patient feels, functions, or survives.[72] These drugs are approved under the assumption of clinical benefit, rather than evidence of it. For some health conditions, this makes sense: The FDA has approved drugs via the accelerated approval pathway since 1992 as part of its response to the HIV/AIDS crisis, and Congress codified this pathway into law in the 2012 Food and Drug Administration Safety and Innovation Act.[73] However, until a clear clinical benefit is established, drug manufacturers should not be allowed to charge patients and public programs exorbitant prices that may not reflect how well the drug actually works. Addressing the prices of drugs approved through the accelerated approval pathway is even more important as these drug approvals become more common: Only four drugs were approved through this pathway in 2010, while 45 drugs were granted accelerated approval in 2020.[74]

Aducanumab is an example of an accelerated approval drug that would be priced lower under value-based pricing. The drug was approved based on the evidence that it reduces the plaques that form on brain cells, with the assumption that these plaques are the driving force behind the cognitive decline that defines Alzheimer's.[75] Yet the evidence used to approve the drug did not demonstrate a clear clinical benefit, even as it showed the ability to remove these plaques.[76] The prices for such drugs should be limited until such a benefit is established, especially for drugs, such as aducanumab, with potentially dangerous side effects.[77]

Promote research into underinvested health conditions

Another shortcoming of the pharmaceutical industry's approach to research is that it tends to invest in the diseases it anticipates being the most profitable while neglecting others that are common or costly yet less profitable. This underinvesting relative to the health needs of the population means that patients experience poor health outcomes that could be potentially prevented through innovative treatments. Moreover, the underinvestments are often inequitable across gender and racial lines, contributing to existing inequities in health outcomes across both.[78]

Below are three conditions that lack sufficient investment.

Uterine fibroids

Uterine fibroids are noncancerous tumors that grow in the wall of the uterus, a condition that affects an estimated 26 million American women.[79] Another estimated 15 million women in the United States suffer from severe symptoms such as heavy menstrual bleeding, pelvic pressure and pain, and bladder issues.[80] And as with many health conditions, racial disparities exist: Black women are roughly two to three times more likely to develop uterine fibroids, report more intense symptoms, and have higher rates of surgery and hospitalization than are white women.[81] In addition to the health impacts, the direct and indirect costs of even minimal treatment options are significant. The costs of surgeries to remove fibroids, preventive hysterectomies, and treatment for complications from these surgeries are estimated at $4.1 billion to $9.4 billion annually, and the associated lost work-hour costs are estimated between $1.6 billion and $17.2 billion annually.[82]

Despite the widespread burden of the condition, research into uterine fibroids remains significantly underfunded. In 2020, the NIH only allocated $18 million into research for the disease, putting it in the bottom 15 percent of funded diseases.[83] As a comparison, an estimated 18 million people misuse prescription drugs each year in the United States, and NIH funding into prescription drug abuse was $187 million in 2020.[84] The pharmaceutical industry also underinvests in the disease: Only two drugs are currently approved for the condition—elagolix, sold by AbbVie, and relugolix, sold by Myovant and Pfizer[85]—and the majority of treatments are still invasive, surgical interventions.[86]

Endometriosis

Endometriosis is a disorder in which tissue similar to the lining of the uterus grows outside the uterus.[87] The tissue still undergoes its usual processes—thickening, breaking down, and bleeding—but because it has no way to exit the body, it is trapped and can form painful cysts or scars.[88] The condition is common: More than 11 percent of American women between the ages of 15 and 44 are estimated to have some form of endometriosis.[89] A 2019 study of the burden of endometriosis found that patients with endometriosis were 25.9 percentage points more likely to require hospitalization than comparable patients without the disorder, and average health spending on those same patients was more than 136 percent higher.[90]

There is currently only one FDA-approved drug to treat endometriosis: elagolix, which is also approved for use in uterine fibroids.[91] Other drugs used, typically hormonal therapies, have potentially significant side effects. For example, gonadotropin-releasing hormone treatments essentially induce "artificial menopause," leading to potential bone loss as well as interfering with the ability to become pregnant.[92]

Despite a 300 percent increase in the number of pharmaceutical companies conducting trials into endometriosis since 2010, the level of research and development remains only "moderate," according to the consulting company GlobalData.[93]

Sickle cell disease

Sickle cell anemia is an inherited blood disorder in which red blood cells are shaped like sickles or crescent moons, rather than the flexible round shape.[94] These red blood cells can get stuck in blood vessels, slowing or even blocking blood flow and oxygen through the body.[95] This lack of blood flow can cause a variety of problems, including pain episodes, delayed growth, and vision problems, as well as potentially deadly complications such as stroke or organ damage.[96] In the United States, about 100,000 people are estimated to have the disease, and the genetic trait that causes sickle cell anemia is nearly 25 times more common in Black people than in white people.[97]

Despite the clear, significant disparities in the disease, there is only one cure for sickle cell anemia: a bone marrow transplant.[98] This treatment is risky, typically only recommended for children with significant symptoms and complications, and, even with anti-rejection drugs, still carries the risk of rejection and life-threatening complications.[99] The other drug treatments available all focus on minimizing symptoms, especially pain episodes.[100]

The American Society of Hematology has identified dozens of research priorities related to treating sickle cell disease, including insufficient understanding of the predictors of disease severity and the impact of care provided on quality of life.[101]

Improve health equity

In addition to addressing health conditions with limited treatment options, a drug can also be deemed valuable under a value-based pricing approach if it improves health equity.[102] Because prescription drug companies focus on maximizing profit over maximizing benefit to patients, clinical trials are often performed in ways that both reduce cost and their benefit to marginalized populations, even when the drug being tested is for a disease that disproportionately affects these populations.

When a prescription drug is being developed, it goes through clinical trials, research studies designed to test safety and effectiveness.[103] Three trial phases are required for FDA approval: Phase I trials test a drug on a small population to determine its safety and side effects; Phase II trials involve a slightly larger population to determine the efficacy of the drug and continue to monitor its safety; and Phase III trials are the largest, studying

the effects on different populations, at different dosages, and in combination with other drugs.[104] After approval by the FDA, pharmaceutical companies are sometimes required to continue monitoring a drug for long-term side effects that might not have been apparent during the first three phases.[105] These Phase IV trials are also required for drugs approved under the accelerated approval pathway.[106]

Unfortunately, women and pregnant people are often excluded from clinical trials. In a 2019 study published in the *Journal of the American Medical Association*, researchers examined more than 43,000 studies from 1966 to 2018 and 13,000 clinical trial records from 1999 to 2018 to determine the sex balance in medical research.[107] The authors found that women were underrepresented in seven of 11 disease categories and that this level of exclusion did not change over time.[108] Importantly, studies not only underrepresented women relative to their share of the overall population but also compared their share of patients with a given disease.[109]

This underrepresentation is even more stark for people of color. A 2018 ProPublica analysis of FDA clinical trial data found that African American, Asian, and Native American or Alaska Native patients were all significantly underrepresented in clinical trials for the 31 cancer drugs approved since 2015.[110] In fact, nearly two-thirds of the trials examined reported no Native American or Alaska Native participants.[111] All of these groups were underrepresented both relative to their proportion of the population and the relative risk for the cancers these drugs treat.[112] And for people with intersecting identities, such as women of color, data are even more limited.[113]

These trends of underrepresentation carry real risks for patients. When drugs are not tested on populations, critical safety and efficacy information may be missed. For example, the sleep drug Ambien had been on the market for 20 years before follow-up studies by another drug company seeking to sell a competitor drug found that women metabolize it at a slower rate than men, meaning that more of the drug remains in their system the next morning, increasing their risk of driving impaired.[114] This difference in metabolization rates led to more than 700 reports of motor vehicle crashes associated with Ambien before the FDA recommended a lower dose for women than men.[115]

The same poor outcomes can be seen across racial lines among asthma patients: Despite Black and Puerto Rican people, especially children, being significantly more likely to have asthma than white people,[116] 95 percent of studies for albuterol—the most commonly prescribed asthma medication—are performed on white people, leading to the drug being much less effective on the patients with the greatest need.[117]

As a result, mortality rates are even more disparate: Black people are about three times as likely as white people to die from asthma, despite being only twice as likely to have the disease.[118]

These disparities in clinical trial populations are in part due to the financial incentives that drive prescription drug development. Recruiting patients for a trial is "one of the most time-consuming aspects of trials,"[119] meaning that efforts to recruit a more diverse patient population would represent an even greater expense. Without explicit regulatory requirements for greater diversity or a shift in these financial incentives, potentially including increased federal investment into ensuring that clinical trials recruit diverse patient populations, it is likely that patients will continue to be served poorly in trial design.

Conclusion

Prescription drug prices are too high in the United States, and these high prices are driven by the financial incentives present under the current system. The abuse of government-granted monopoly periods and the inability of payers to meaningfully negotiate prescription drug prices has created a system in which drug companies are able to set prices for their product without regard to the value that the drugs provide to patients.

Transitioning to a value-based pricing system in the United States, such as those used in many peer nations, would prevent overinvestment into health conditions solely out of the expectation of easier research leading to high profits. Additionally, it would incentivize research into the actual health needs of the American people.

About the author

Thomas Waldrop is a policy analyst for Health Policy at the Center for American Progress.

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