PhRMA
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2022 PROFILE

Biopharmaceutical Research Industry

Our core mission is to research and develop treatments and cures which will improve the lives of patients in the United States and around the globe. The COVID-19 pandemic has reaffirmed the value of the scientific advances made by America's innovative biopharmaceutical industry. Our top priorities include:

- *Fostering a policy and regulatory environment to allow our companies to continue to bring new medical advances to the patients who need them*
- *Improving patient access and affordability*
- *Advocating for increased accountability and transparency for insurers, PBMs and other for-profit health care entities in the pharmaceutical supply chain*
- *Ensuring safety net programs like the 340B program serve the vulnerable patients they are intended to serve*

We Stand Behind Innovation

America's biopharmaceutical industry is tireless in the pursuit of new treatments and cures, providing hope for patients around the world. Since 2000, nearly 900 new medicines have been approved by the Food and Drug Administration (FDA). Thanks to the innovative medicines the industry has developed, patients all over the world are living longer, healthier and more productive lives. For example, we can now cure more than 95% of patients with hepatitis C, allowing patients to avoid liver failure and costly transplants.[1] Since peaking in 1991, the cancer death rate has declined by 32%, with experts agreeing that new medicines have contributed greatly to accelerating recent declines in cancer mortality.[2, 3]

Medicines and vaccines continue to play a central role in keeping patients healthy and reducing the need for more costly medical care. In fact, the introduction of COVID-19 vaccines is estimated to have saved 2 million lives and prevented up to 17 million hospitalizations in the United States alone.[4] We remain committed to building on the lessons learned from the pandemic, supporting the ongoing response to the crisis, and building a more resilient health care system moving forward.

Today, more than 8,000 medicines in development around the world offer the potential to provide new treatments and cures for patients.[5] PhRMA members alone have invested hundreds of billions of dollars over the years in research and development (R&D)—including a record $102 billion in 2021 alone.[6] And as researchers explore new frontiers that just a few years ago may have been regarded as science fiction, the biopharmaceutical pipeline has never been more promising. In fact, nearly 70% of medicines across the pipeline have the potential to be first-in-class treatments, representing entirely new approaches to treating disease.[7]

Threats to American Innovation

Unfortunately, recently passed legislation undercuts the industry's R&D efforts and diminishes hope for future treatments and cures. The Inflation Reduction Act (IRA) requires the government to select medicines for price setting in Medicare, after they have been on the market for a certain number of years, creating significant disincentives to biopharmaceutical innovation.[8] What the law fails to recognize is that the development of new medicines is a long, rigorous and costly process, with many setbacks along the way. In fact, only about 12% of products entering clinical trials successfully make it to market. Allowing the government to dictate the price of medicines introduces further uncertainty into the R&D process, severely jeopardizing future innovation. As a result, economists estimate the new law could result in upwards of 100 fewer medicines coming to market over the next two decades.[9]

In particular, the law guts incentives necessary to encourage investment in R&D after medicines are approved by the FDA. Some of the most important research that happens on medicines, particularly for diseases like cancer, happens after initial FDA approval. In fact, nearly 60% of oncology medicines approved a decade ago received additional approvals in later years.[10] This post- approval R&D to address patient unmet need takes significant time and investment. But as a result of the law, companies will be discouraged from investing in this critical research moving forward.

To make matters worse, the law also disincentivizes the development of generic and biosimilar medicines that lower costs for patients and generate savings for the broader health care system. Today's robust U.S. generic and biosimilar markets increase competition and yield substantial savings for patients and the government. But the IRA would allow the government to impose such a low price on an innovator product that biosimilar and generic manufacturers may not see any benefit to bringing these products to market in the first place.

Cover depicts a T cell, a key part of the immune system which cancer medicines are increasingly leveraging to fight cancer.

In the United States, there are legal and regulatory frameworks which recognize the need to maintain incentives for bringing new medicines to market while also encouraging the introduction of generics and biosimilars. This is one of the reasons our competitive market-based system has succeeded in holding down prescription medicine prices and spending. Generics and biosimilars have successfully offset spending on newer brand medicines in the United States, allowing for prescription medicines to account for just 14% of total health care spending over the past decade, even while many new, breakthrough treatments have continued to enter the market to help patients.[11] But the imposition of government-set prices severely disrupts these balanced frameworks, undermining its ability to incentivize competition and control costs.

In addition to the harms imposed by the new law, a broad range of threats to the intellectual property (IP) protections relating to new medicines—including threats to waive international commitments to honor IP related to COVID-19 vaccines and treatments—seriously undermine incentives for innovation moving forward.

Continued Threats to Patient Access and Affordability

While myopically prioritizing price-setting policies that jeopardize future progress for patients, Congress failed to institute key policies that would have had a real and immediate impact on patient affordability. That is because the IRA failed to hold middlemen in the health care system, known as pharmacy benefit managers (PBMs), as well as insurers accountable for practices that force patients to pay high out-of-pocket costs for medicines. In other parts of the health care system, patients pay their coinsurance or deductible based on the negotiated price their insurer receives. Yet nothing in the law prevents PBMs and insurers from continuing to force patients to pay for medicines based on the list price, even when PBMs and insurers receive steep discounts on these medicines. In some cases, patients are forced to pay more for medicines than their health insurer and PBM pay. We cannot address patient affordability without addressing broader dynamics in the health care system that drive up the costs of medicines for patients.

PBMs play a central role in controlling what hundreds of millions of patients pay for their prescription medicines as well as what medicines they have access to—administering drug benefits for more than 266 million publicly and privately insured Americans.[12] In fact, after nearly two decades of consolidation and lack of oversight that has been investigated by Congress, the Federal Trade Commission (FTC), state agencies and others, the combined market share of the three largest PBMs has grown significantly, from 48% in 2010 to 80% in 2021.[13] In recent years, the largest PBMs have also combined with health insurers, pharmacies and provider groups to form vertically integrated organizations with enormous influence over which medicines patients can access, where they can access them, and the affordability of those medications.[14]

As a result, a few insurance companies and PBMs have cornered the market and exploited perverse incentives to collect an ever-growing amount of rebates, fees and discounts on medicines. Total rebates, discounts and other payments from brand manufacturers to PBMs, payers, providers, government and others have tripled since 2012, reaching $236 billion in 2021.[15,16] In fact, these discounts and rebates significantly lower the prices of brand medicines—by an average of 49% last year.[17] As a result, net prices for brand medicines have increased at or below the rate of inflation over the past five years and are projected to remain flat or decline by up to 3% annually through 2025.[18]

While net prices and spending for medicines are growing more slowly than inflation, it doesn't feel that way to patients because a large–and growing–share of the rebates are not being used to lower patient costs at the pharmacy counter. Rather, health plans often use rebate dollars to reduce premiums for all enrollees. This results in a system where patients who need medicines are subsidizing the health insurance coverage of healthy individuals.[19] This is the exact opposite of how health insurance should work.

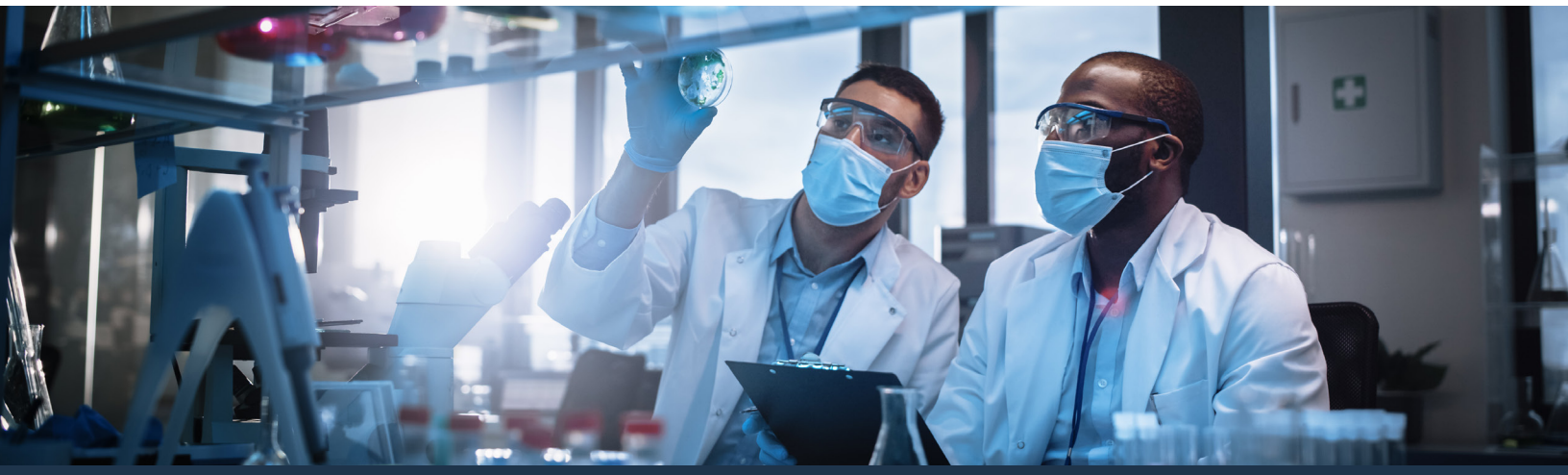
Meanwhile, even as rebates and fees are growing year after year, the number of patients that face high out-of-pocket costs for their prescription medicines has grown significantly as PBMs and health insurance companies have shifted more costs onto patients through the increased use of deductibles and coinsurance for prescription medicines. These benefit designs have increasingly exposed patients to high out-of-pocket costs because they are based on the undiscounted list prices even though the net prices available to PBMs and health plans are often significantly lower. In fact, 60% of commercial and 92% of Part D total patient out-of-pocket spending for brand medicines are based on list price.[20, 21]

To address this continued erosion of health insurance coverage, many drug manufacturers offer help through cost-sharing assistance and patient assistance programs. When insurance falls short, this assistance aims to help patients access and take their medicines as prescribed by their doctors. Research has found that those who use patient assistance were up to 47% more likely to stick with their treatment for a year.[22] Unfortunately, insurers and PBMs are adopting tactics that can deny patients the benefit of this assistance through the use of accumulator adjustment programs, copay maximizers and other schemes designed to get in the way of helping patients afford the medicines prescribed by their doctors.

All of these trends underscore that we cannot address patient affordability challenges without taking a holistic look across the health care system. Today, more than half of every dollar spent on medicines goes to entities in the supply chain–including PBMs, health plans, employers, government, hospitals and other stakeholders–that do not research, develop or manufacture novel medicines.[23] And in recent years, evidence suggests more of the increase in spending on brand medicines has gone to payers, including PBMs and health plans, rather than manufacturers.[24, 25]

Unfortunately, as more health care middlemen benefit from dollars spent on medicines, their efforts to bolster profitability often negatively impact patient access and affordability. For example, hospitals, which represent the largest share of health care spending in the United States, have rapidly consolidated over the past decade as they increasingly buy up physician practices and merge with other hospitals. As a result, they can leverage their size and lack of competition to demand large mark ups on the cost of medicines–on average about 2.5 times what they paid –from commercial payers.[26] These trends are not only impacting patient costs but costs for the broader health system.

A central driver of hospital consolidation and increasing costs is the 340B drug pricing program. The program was designed to help improve access to medicines for vulnerable patients through manufacturer discounts to specific qualifying hospitals and federally funded clinics. But the program strayed from its purpose as it grew, with more and more health care entities using these discounts for themselves.[27] For example, now large hospital systems that obtain steep mark ups on 340B discounted medicines may use these profits to expand care in wealthier areas while underinvesting in hospital locations in lower income areas, which often serve patients of color.[28] Experts also have noted the program creates financial incentives to further consolidate and shift the administration of medicines to more costly hospital outpatient settings–which ultimately increases costs for patients, employers, health plans and the entire health care system.[29, 30] For-profit pharmacies, middlemen and more are also now profiting from the 340B program, with evidence that patients rarely receive the benefit of 340B discounts from 340B drugs filled at these pharmacies.[31] At this point, it seems patients are the only ones not benefiting from the billions of dollars in discounts manufacturers provide each year to fund the 340B program.



Our Health Care System Should Work Better for Patients

Misaligned incentives across our health care system are increasingly benefiting for-profit health care entities while negatively impacting patient access and affordability. Unfortunately, the IRA did nothing to address these challenges. We will continue advocating for solutions that patients and our health care system need. We support policies that take a holistic look at the trends across our health care system and the broader pharmaceutical supply chain that drive these challenges.

We believe healthy competition is the right way to bring costs down and get more treatments in the hands of patients who need them. Robust, competitive markets for generic and biosimilar medicines should play an important role in supporting affordable care. We strongly support policies that strengthen the competitive market while also providing needed incentives for continued biopharmaceutical innovation. We will continue to work to mitigate the IRA's harmful impacts to ensure patients have access to their medicines and researchers can continue to develop new treatments and cures.

While the IRA did include some changes that we have long supported and will make a difference for some seniors covered under Medicare Part D—including capping the annual amount seniors pay out of pocket at the pharmacy and making out-of-pocket costs more predictable month to month—it didn't go nearly far enough to stop insurer and PBM abuses. Most notably, the law actively pushes off implementation of a critical policy that would have provided meaningful relief to millions of seniors by requiring Medicare Part D plans to base seniors' cost sharing on the net price of medicines, rather than undiscounted list prices.

We believe insurance needs to work like insurance; meaning, insurance should pay for care when people are sick. We also believe more medicines should be covered from day one and out-of-pocket costs should be more predictable for patients. Additionally, more of the rebates and other price concessions that payers receive from biopharmaceutical companies should be shared with patients at the pharmacy counter. As we work toward broader health insurance reforms, we also believe it is critical that patients can access patient assistance offered by manufacturers at the pharmacy counter to help make medicines more affordable for those in need.

In failing to hold PBMs and health insurers accountable for their practices, the IRA fundamentally failed to address misaligned incentives in the broader supply chain and health care system that experts have noted can lead to patient affordability challenges today. For example, one Senate investigation found "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs may retain at least a portion of what they negotiate."[32] In fact, PBMs have been shown to exclude lower list price versions of brand medicines from formularies in favor of higher list price versions.[33] To address misaligned incentives that impact patient access and affordability, compensation for PBMs and other entities in the pharmaceutical supply chain should be required to be a flat amount based on the services they provide—not calculated as a percent of a medicine's price. When taking a holistic look at our health care system and areas that are impacting patient spending and costs, it is clear the 340B program has grown so large that it must be updated to address the misaligned incentives it creates, ensuring more 340B discounts are used to help vulnerable patients – not wealthy hospital systems and for-profit pharmacies and middlemen. Greater transparency and accountability are needed to ensure the program works for the patients it is intended to serve and is more sustainable over the long term.

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