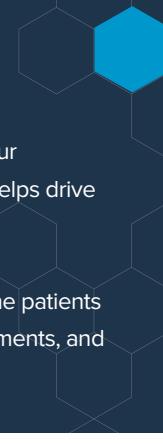




2021 PROFILE

Biopharmaceutical Research Industry

2021 Biopharmaceutical Industry Profile



The global pandemic has reinforced the value of the scientific advances made by America's innovative biopharmaceutical industry. Our breakthroughs in vaccine research and therapeutics to combat COVID-19 are built on a robust policy and regulatory framework that helps drive scientific discovery.

To ensure we are prepared for the next public health crisis, our top priorities include continuing to bring new medical innovations to the patients who need them, helping shape a policy and regulatory environment that supports continued research and development (R&D) investments, and improving patient access and affordability.

Doing Our Part

America's biopharmaceutical companies are working around-the-clock to deliver advances that help diagnose, prevent and treat those with COVID-19. We have leaned on decades of experience in researching other viruses and bringing critical infrastructure and infectious disease expertise to bear to develop solutions. PhRMA members have invested billions of dollars over the years in manufacturing infrastructure and critical technologies which have allowed us to accelerate vaccine development, identify and bring promising treatment options forward and quickly expand manufacturing globally for new vaccines and treatments for patients. This groundbreaking progress has brought us closer to beating COVID-19, but we are not done yet.

Our first order of business is to end the COVID-19 pandemic, but we also must prepare for the challenges ahead. The pandemic demonstrates that we need a health care system that works better for all patients and is more equitable, so that we are better prepared for future public health emergencies. To do so, we need to foster continued innovation and strengthen our health care delivery infrastructure from top to bottom.

Driving Innovation

As hospitals continue to be overwhelmed with COVID-19 patients, the role that medicines and vaccines play in keeping patients healthy and reducing the need for more costly medical care and hospitalizations could not be more apparent. The introduction of COVID-19 vaccines is estimated to have saved 279,000 lives and averted up to 1.25 million hospitalizations in the United States alone.¹

The pandemic has reaffirmed the importance of a robust innovation ecosystem that drives scientific advances for the benefit of patients and society. In the last decade alone, biopharmaceutical companies invested more than a trillion dollars in R&D – including a record-breaking year in 2020 with PhRMA member companies alone investing \$91 billion.² This investment opens the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time, including cancers and many devastating rare and chronic conditions. As a result of this tremendous progress, many diseases previously regarded as deadly are now manageable and even curable.



Today, there are more than 8,000 medicines in development around the world.³ Across the medicines in the pipeline, 74% have the potential to be first-in-class treatments, representing entirely new approaches to treating a disease.⁴ The future has never been brighter as researchers explore new frontiers that just a few years ago may have been regarded as science fiction.

Supporting a Strong Economy

The biopharmaceutical industry also makes tremendous contributions to the American economy and solidifies the United States' critical role as a leader in medical innovation. The industry supports more than 4 million jobs across the country, including 120,000 high-wage manufacturing jobs, and directly employs more than 811,000 Americans.⁵ As a result, the industry contributes \$1.3 trillion to the American economy. Biopharmaceutical researchers and scientists go to work every day to develop new treatments and cures, even in the face of continuous setbacks, 10- to 15-year development timelines, extensive and growing R&D costs, a high degree of scientific and regulatory uncertainty, and the challenges posed by the COVID-19 pandemic.^{6,7} These contributions provide critical support not only to the health of patients, but to the health of our economy.

Addressing Patient Access and Affordability

Advances in medicine are meaningless if patients can't afford the treatments they need. Unfortunately, many patients taking medicines to treat complex and chronic conditions continue to face affordability challenges, despite a dramatic slowdown in medicine prices and spending. In 2020, average net prices for brand medicines actually declined by 2.9%.⁸ Robust brand-to-brand competition, as well as competition from generics and biosimilars and other factors, has resulted in prescription medicines accounting for just 14% of total health care spending over the past decade, even while many new, breakthrough treatments entered the market to help patients—including many who previously had no therapeutic options.⁹

Though the competitive marketplace has worked well in holding down prescription medicine prices and spending, we need to ensure more of the savings negotiated on medicines go to patients and not middlemen in the pharmaceutical supply chain. Pharmacy benefit managers (PBMs) negotiate large rebates from biopharmaceutical companies on behalf of insurers and employers. Today, three large, sophisticated PBMs manage more than 77% of all prescriptions filled in the United States.¹⁰ PBMs leverage their vast purchasing power, further enhanced through consolidation, mergers, and vertical integration, to negotiate discounts, rebates and other price concessions, which have more than doubled in size since 2012.^{11,12} In 2020 alone, rebates and discounts given to insurance companies, the government, PBMs and others exceeded \$187 billion.¹³ As a result of growth in rebates, discounts and other price concessions, nearly half of U.S. spending on brand medicines went to the supply chain and other entities in 2018, and not to the biopharmaceutical companies that research, develop and manufacture the medicines.¹⁴

Despite the decline in medicine prices due to private negotiations, many of the sickest patients are burdened with high out-of-pocket costs. Through an endless web of high deductibles, expanded cost sharing, coverage exclusions and narrow formularies, insurers are increasingly standing between patients and the care they need. In addition, insurers and PBMs have shifted more health care costs onto patients through the use of deductibles and coinsurance—which are typically based on the undiscounted list price of a medicine. In fact, prescriptions filled in the deductible or with coinsurance now account for more than half of total patient out-of-pocket spending.¹⁵ Today patients are paying more for their insurance and getting less. Similarly, in Medicare Part D, more costs are being shifted onto seniors and people with disabilities through the substantial increase in the use of coinsurance and complex, multi-tiered formularies. As a result of this shift, 62% of all medicines covered by Part D plans are now on a coinsurance tier and 92% of total Part D beneficiary out-of-pocket spending is tied to the undiscounted list price.^{16,17}

At the same time, hospitals, which represent the largest share of health care spending in the United States, mark up the cost of medicines nearly 2.5 times, on average, driving up cost sharing and premiums across the country.¹⁸

Biopharmaceutical manufacturers have stepped up to help patients who are struggling to afford their medicines through the Medicine Assistance Tool (MAT). MAT matches patients with resources and cost-sharing programs that may help lower out-of-pocket costs regardless of insurance status. But to truly fix the system and address patient affordability challenges, we need long-term solutions.

Building a Better Health Care System

The health care industry needs to do better for patients, and we are willing do to our part. We have a responsibility to not just develop treatments and potential cures, but to also help patients access them. We stand ready to work with all stakeholders to deliver a stronger, more resilient, affordable and equitable health care system for all.

End the Pandemic and Build a More Resilient Health System

Resilient health care systems have the depth, flexibility and foresight to respond to emerging health challenges and provide equitable health care. This pandemic reinforces the need for infrastructure investments at the federal, state and local levels to ensure a robust response to future public health threats including pandemics, other public health emergencies and natural disasters. Essential for responding to public health threats are globally diverse and resilient supply chains for biopharmaceuticals and other medical equipment, a strong public health and emergency preparedness infrastructure, and public policies that enhance the health care system's ability to respond quickly, whether due to a pandemic, an antibiotic-resistant superbug or other natural and public health disasters. Continued support for the unique innovation ecosystem that has made the United States a global bioscience leader requires avoiding policies that could impede collaboration and progress such as policies that could result in massive cuts in R&D investments or the erosion of critical intellectual property protections.



Make Medicines More Affordable

Insurance needs to work like insurance – it needs to spread costs broadly across all who are insured and pay for care when people are sick. We need to cover more medicines from day one, make out-of-pocket costs more predictable, ensure cost-sharing assistance applies to deductibles and share more of the rebates and other price concessions that payers receive from biopharmaceutical companies with patients at the pharmacy counter. Additional efforts are also needed to modernize how Medicare covers and pays for medicines, including capping out-of-pocket costs in Part D, lowering cost sharing, spreading patient costs over the calendar year and making sure the savings negotiated with health plans are passed directly to patients. Implementing a market-based adjustment in Part B would also allow the government and seniors to benefit from more of the savings already negotiated in the commercial market, which could save some seniors hundreds – if not thousands – of dollars each year.

Middlemen like PBMs often base their compensation and fees on the list price of a medicine. This raises serious questions about whether they are more focused on the size of rebates than on achieving the lowest costs for patients. Compensation for PBMs and other entities in the supply chain should be a fixed amount based on the services they provide – not calculated as a percent of a medicine’s price.

In addition to addressing supply chain incentives, 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 will play an increasingly important role in supporting affordable care. To further enhance competition in the biosimilars marketplace, we agree there is a need to expand education of providers and patients to increase awareness of additional options that allow for lower costs. We also strongly support policies that strengthen the competitive market while also providing needed incentives for continued biopharmaceutical innovation. These include policies to address patent settlements at the federal level and policies to tackle activity referred to as “product hopping,” when such activity is anticompetitive.

We also need to protect the safety net by maintaining coverage of medicines for vulnerable patients served by Medicaid and driving greater oversight and transparency of the 340B program to ensure that hospitals and other entities are using the discounts manufacturers provide to serve needy patients, not siphoning resources away from patients.

Lastly, we need to move toward a system that rewards value to ensure the long-term sustainability of the health care system. This shift must start by measuring and rewarding what matters to patients, and recognizing and valuing differences among patients rather than obscuring them through one-size-fits-all standards. Important reforms to support better value include closing gaps in evidence across the health care system, developing better measures and data on patient-centered outcomes, advancing better tools to guide decision-making such as clinical decision-support and health technology assessment methods, and facilitating more value-based arrangements and innovative payment models. It also involves taking steps to eliminate waste and inefficient care from our system to improve patient affordability and create headroom for new breakthroughs.

Promote Health Equity

America’s biopharmaceutical companies are committed to push for necessary systemic and long-term changes to better meet the needs of underserved communities and create a more equitable health care system for everyone. That means taking a more active role through our own actions as an industry, and as individual companies, as well as supporting public policies that address health disparities. We commit to improving clinical trial diversity and eliminating systemic barriers to clinical trial participation. We also support policies to reduce insurance barriers that disproportionately impact communities of color, address long-standing disadvantages that lead to underdiagnosis and undertreatment in underserved populations, and improve data collection and reporting to better measure and address inequities.

1 A Galvani, et al., [Deaths and Hospitalizations Averted by Rapid U.S. Vaccination Rollout](#), Commonwealth Fund, July 2021.

2 PhRMA annual membership survey. Washington, DC: PhRMA; 2007-2020.

3 Adis R&D Insight Database. 2020.

4 Analysis Group. The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, July 2017.

5 TEconomy Partners; for PhRMA. The Economic Impact of the US Biopharmaceutical Industry 2017: National and State Estimates.

6 Ibid.

7 JA DiMasi, HG Grabowski, RW Hansen. Innovation in the Pharmaceutical Industry: New Estimates of R&D costs. J Health Econ. 2016;47:20-33.

8 IQVIA. Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025, May 2021.

9 Altarum Institute. “Projections of the Non-Retail Prescription Drug Share of National Health Expenditures.” September 2020.

10 Fein AJ. The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2020.

11 The Pew Charitable Trusts. The Prescription Drug Landscape, Explored. March 2019.

12 Fein AJ. The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2020.

13 Ibid.

14 Berkeley Research Group, [Revisiting the Pharmaceutical Supply Chain: 2013-2018](#), January 2020.

15 IQVIA. [Medicine Spending and Affordability in the U.S.](#), August 2020.

16 Avalere Health. 2021 Medicare Part D Formularies: An Initial Analysis. December 2020.

17 PhRMA. [Trends in Out-of-Pocket Spending for Brand Medicines in Medicare Part D](#). May 2021.

18 The Moran Company. [Hospital Charges and Reimbursement for Drugs: Analysis of Markups Relative to Acquisition Cost](#). October 2017.