



2020 PROFILE

BIOPHARMACEUTICAL
RESEARCH
INDUSTRY

2020 BIOPHARMACEUTICAL INDUSTRY PROFILE

At biopharmaceutical companies across America, people go to work every day with the mission of advancing innovative treatments and potential cures that will make a difference in millions of patients' lives. This goal is more important now than ever as we face the coronavirus pandemic.

We are committed to combatting this public health crisis, to advancing research and development (R&D) to meet the needs of patients, and ensuring patients can access the medicines they need. We stand behind the medicines we develop and the value they provide to patients and the health care system.

DOING OUR PART

America's biopharmaceutical companies are developing solutions to help diagnose, prevent, and treat those with COVID-19. We are leveraging decades of experience researching other viruses and providing critical infrastructure and capabilities to overcome the pandemic and its consequences. In addition to applying scientific expertise to find ways to tackle the virus, the biopharmaceutical industry is providing financial support and in-kind donations to organizations and collaborating with U.S. and global health authorities to combat this public health emergency. We are also expanding manufacturing capabilities and ramping up production capacity, so health authorities are prepared to supply vaccines and treatments to the public when successful candidates are identified.

More than half of PhRMA members are researching and developing potential treatments and vaccines, providing donations of medicines and critical medical supplies or providing financial donations to support patients and first responders in addressing this evolving crisis. And we are not only ramping up output of existing medicines but planning and building manufacturing capacity to ensure that if vaccine or treatment candidates are successful, distribution can occur rapidly.

DRIVING INNOVATION

In times like these, as hospitals are overwhelmed with patients and medical professionals are struggling to fight this virus, the role that medicines play in keeping patients healthy and reducing the need for costly medical care and hospitalizations could not be more apparent. Ensuring continuity in the supply chain so that patients can access needed medicines and continued advances in treatments will be indispensable in addressing society's health and economic challenges in the years ahead.

We are in a new era of medicine where breakthrough science is transforming care and our approach to treating patients. In the last decade alone, biopharmaceutical companies invested half a trillion dollars in R&D, and these investments are yielding results, opening the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time.¹ As a result of this tremendous progress, many diseases previously regarded as deadly are now manageable and potentially curable.

Today, there are more than 8,000 medicines in development around the world.² Across the medicines in the pipeline, 74% have the potential to be first-in-class treatments, representing entirely new approaches to treating a disease.³ The future has never been brighter as researchers explore new frontiers that just a few years ago may have been regarded as science fiction, but now transform patients' lives.

SUPPORTING A STRONG ECONOMY

Investment in biopharmaceutical innovation not only improves lives, but it also drives tremendous contributions to the American economy and solidifies the United States' critical role as a leader in medical innovation. In 2018, biopharmaceutical companies invested about \$108 billion in R&D in the United States—more than any other industry in America.⁴

Cover depicts the novel coronavirus (SARS-CoV-2)

The industry also supports more than 4 million jobs across the country, and more than 800,000 researchers and scientists go to work every day to develop new treatments and cures. This occurs even in the face of continuous setbacks, 10- to 15-year development timelines, extensive R&D costs, a high degree of scientific and regulatory uncertainty, and the challenges and complexities posed by the COVID-19 pandemic.^{5, 6} In times like these where Americans are facing a high degree of uncertainty, the contributions of the biopharmaceutical industry are providing critical support not only to the health of patients but to the health of our economy.

ADDRESSING PATIENT ACCESS AND AFFORDABILITY

This new era of medicine is meaningless if patients can't afford the treatments they need. Unfortunately, out-of-pocket costs for the sickest continue to soar despite a dramatic slowdown in medicine prices and spending. In fact, after factoring in discounts and rebates, prices for brand-name medicines increased in line with or below inflation for the past five years.⁷

One reason our market-based system for purchasing medicines succeeds in containing costs is that health insurers and pharmacy benefit managers (PBMs) leverage their vast purchasing power to negotiate discounts and rebates off the list prices of medicines. Today, the top three PBMs manage more than 74% of all prescriptions filled in the United States.⁸ In 2019 alone, rebates and discounts given to insurance companies, the government, PBMs and other supply chain entities exceeded \$175 billion.⁹ Today, nearly half of U.S. spending on brand medicines goes to the supply chain and other entities, and not to the biopharmaceutical companies that research, develop and manufacture the medicines.¹⁰

Despite the growing size of discounts and rebates retained by entities in the supply chain and a dramatic slowdown in medicine price and spending growth, insurers and PBMs have increasingly shifted more health care costs to patients through high deductibles and coinsurance. Patients with deductibles and coinsurance typically pay cost sharing based on the undiscounted list price of a medicine rather than the negotiated net price.¹¹ More than half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price. Commercially insured patients with a deductible have seen their out-of-pocket costs for brand medicines increase 50% since 2014.¹²

We have a responsibility to not just develop treatments and potential cures, but to also help patients access them. That's why we are making it easier for patients who are struggling to afford their medicines to find the robust patient assistance programs available to them. The industry recently launched the Medicine Assistance Tool ([MAT](#)), to make it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable. And in light of the pandemic, America's biopharmaceutical companies are individually expanding their programs to help more patients during these uncertain times. MAT matches patients with resources and cost-sharing programs that may help lower out-of-pocket costs regardless of insurance status.

WE ARE FOR SOLUTIONS THAT STRENGTHEN THE HEALTH CARE SYSTEM

PhRMA is working to improve the health care system for patients by supporting policies that lower out-of-pocket costs, while avoiding those that reduce patient access and limit much needed medical innovation. Such policies include sharing discounts and rebates with patients at the pharmacy counter, eliminating barriers to innovative payment arrangements and making insurance work like insurance again.

IMPROVING PATIENT AFFORDABILITY

More of the rebates and other price concessions that payers receive from biopharmaceutical companies should be used to directly lower cost sharing for patients at the pharmacy counter. Research shows that high cost sharing is associated with lower medication adherence and increased abandonment rates, putting patients' ability to stay on needed therapies at risk.^{13, 14, 15} Sharing negotiated discounts could save certain commercially insured patients with high deductibles and coinsurance \$125 to \$800 annually while increasing premiums by about 1% or less.¹⁶ In Medicare Part D, policies to ensure that savings from negotiated rebates are passed on to Medicare beneficiaries would also improve affordability for seniors and strengthen competitive incentives in the Part D program. For example, a Part D beneficiary with diabetes taking five medicines could save about \$1,000 a year in out-of-pocket costs.¹⁷

And additional efforts are needed to improve affordability and predictability of costs for seniors in Medicare Part D, where there is currently no limit on out-of-pocket expenses. Adopting an out-of-pocket cap in Medicare Part D would align the benefit with the commercial insurance market and better ensure that beneficiaries who face a catastrophic illness are able to afford their treatments. Additionally, policy changes to help patients spread their cost-sharing obligations more evenly throughout the year would help address the large upfront cost burden faced by those with conditions like cancer, MS, and other debilitating illnesses, often resulting in high out-of-pocket costs and affordability challenges concentrated in a short period of time.¹⁸ As America's biopharmaceutical companies mobilize to bring new treatments and vaccines to address the current crisis, we are also working with governments and insurers to ensure that when these treatments and vaccines are approved they will be available and affordable for patients.

PROMOTING HEALTH EQUITY

The current crisis has served to highlight long-standing health disparities in the United States, as evidenced by the disproportionate impact of COVID-19 on communities of color. Social drivers and determinants of health (e.g., poverty, discrimination, access to resources and services, employment, housing, education, and health) and pre-existing health conditions place communities of color at greater risk for disease. These risk factors, which drive health inequity in these communities, will need to be considered and addressed in any mitigation of the current pandemic as well as any broader efforts to improve quality and access in our health care system. To address these inequities, we stand for meaningful change in our healthcare system through better data collection, research, and broad access to quality care.

SHIFTING TOWARD VALUE

Ensuring the long-term stability of the health care system will require moving toward a system that focuses on results, measures value through the eyes of the patient and enables the private sector to develop new and better ways to pay for medicines through innovative payment arrangements. The move toward a value-driven health care system includes the development of data that provides patients and physicians with easy-to-use information about the costs and benefits of treatments across the health care spectrum, creation of better measures of quality care that take into account patient perspectives and preferences and reforms that allow new ways for insurers to pay for medicines. In order to achieve this we need to remove barriers to innovative contracts (also known as value-based contracts or alternative financing arrangements) that can lower both patient and insurer costs through voluntary, market-based negotiations between innovators and payers. It also means eliminating low-value, inefficient care from our system to create headroom for more innovative treatments. Advancing research and methods related to value assessment that encompass all outcomes that matter to patients and families is an important step toward that goal.

PROTECTING AND SUPPORTING INNOVATION

We are committed to accelerating the development of treatments and vaccines to combat COVID-19 and increasing manufacturing capacity to address patient need. We are also committed to advancing new transformative therapies and antimicrobial medicines to prepare for the next public health emergency and getting medicines approved more efficiently while ensuring patient safety. In order to achieve this we must modernize the drug discovery and development process and equip regulators with new technologies and expertise to keep up with 21st century science. The United States must continue to incentivize medical innovations and competition through strong intellectual property incentives and their enforcement both within and outside the United States through strong trade agreements.

¹PhRMA annual membership survey. Washington, DC: PhRMA; 2007-2020.

²Adis R&D Insight Database. 2020.

³Analysis Group. The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, July 2017.

⁴Research!America, U.S. Investments in Medical and Health Research and Development, 2013-2016, Arlington, VA, Fall 2017. https://www.researchamerica.org/sites/default/files/RA-2017_InvestmentReport.pdf

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

⁶JA DiMasi, HG Grabowski, RW Hansen. Innovation in the Pharmaceutical Industry: New Estimates of R&D costs. J Health Econ. 2016;47:20-33.

⁷IQVIA. "Diabetes Costs and Affordability in the United States." June 2020.

⁸Fein, Adam J., The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, 2020.

¹⁰Berkeley Research Group, "Revisiting the Pharmaceutical Supply Chain: 2013-2018," January 2020. <https://www.thinkbrg.com/newsroom-publications-revisit-pharma-supply-chain.html>

¹¹Devane, K. Patient Affordability Part One, The Implications of Changing Benefit Designs and High Cost-Sharing. May 2018.

¹²Ibid.

¹³MT Eaddy et al. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. Pharmacy & Therapeutics. 2012;37(1):45-55.

¹⁴JA Doshi et al. High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia. American Journal of Managed Care. 2016; 22 (4 Suppl): S78-S86.

¹⁵IMS Institute for Healthcare Informatics. Emergency and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans. September 2015.

¹⁶Bunger, A., et al., Point of Sale Rebate Analysis in the Commercial Market: Sharing rebates may lower patient costs and likely has a minimal impact on premiums.

¹⁷Holcomb K, Klein M. Medicare Part D Diabetic Member Cost-Sharing: Impact on Non-Low Income Members. Milliman. February 2019.

¹⁸Avalere. "Out-of-Pocket Costs Among Medicare Part D Enrollees Reaching the Catastrophic Threshold." October 2019. <https://avalere.com/wp-content/uploads/2019/10/Avalere-OOP-Costs-in-Part-D-Issue-Brief.pdf>