# 2019 PROFILE

BIOPHARMACEUTICAL RESEARCH INDUSTRY

GOBOLDLY™

# 2019 BIOPHARMACEUTICAL INDUSTRY PROFILE

At biopharmaceutical companies across America, people go to work every day with the mission of advancing innovative treatments and cures that will make a difference in millions of patients' lives.

We are committed to ensuring patient access to medicines, preserving a strong economy, and supporting vibrant research and valuable jobs. We also stand behind the medicines we create and the value they provide not only to patients, but across the health care system.

**WE ARE COMMITTED TO ENSURING PATIENT ACCESS TO MEDICINES, PRESERVING A STRONG ECONOMY, AND SUPPORTING VIBRANT RESEARCH AND VALUABLE JOBS.**

## WE DRIVE INNOVATION

We are in a new era of medicine where breakthrough science is transforming care and our approach to treating patients. Robust investment in research and development (R&D) by biopharmaceutical companies is resulting in advances and discoveries unlike anything we've seen before. The application of genomics to develop personalized medicines is enabling physicians to tailor treatments to the unique needs of the patient, and immunotherapies are harnessing patients' own immune systems to fight off various conditions, including cancer and rare diseases. In the last decade alone, biopharmaceutical companies invested half a trillion dollars in R&D, and these investments are just beginning to yield results, opening the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time.[i]

The progress we see today is revolutionizing how we treat disease, saving patients' lives and improving quality of life and public health across a broad range of chronic and rare conditions. In this new era of medicine, many diseases previously regarded as deadly are now manageable and potentially curable. Today, there are about 8,000 medicines in clinical development around the world.[ii] Across the medicines in the pipeline, 74% in clinical development have the potential to be first-in-class treatments, representing entirely new approaches to treating a disease.[iii] 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.

This new era of medicine isn't just good news for our health—it's good news for our health care system and society. New, innovative medicines keep patients healthy and out of the hospital, reducing the need for costly emergency room visits, hospital stays, surgeries and long-term care. This saves money for patients and the nation's health system.

Looking forward, medicines are our best bet for confronting the country's biggest health cost driver: chronic disease. Health conditions such as cancer, diabetes and heart disease are the leading causes of death and disability in the United States, and patients with these conditions account for 90% of health care spending.[iv] Continued advances in treatment will be indispensable in addressing society's health and economic challenges in the years ahead.

## WE SUPPORT A STRONG ECONOMY

Investment in biopharmaceutical innovation not only improve and save lives, but also drive tremendous contributions to the American economy and to America's role as a leader in medical innovation. In 2017, biopharmaceutical companies invested about $97 billion in R&D in the United States—more than any other industry in America.[v] The industry supports more than 4 million jobs across the country, and more than 800,000 employees across companies go to work every day to research and develop new treatments and cures for patients. This occurs even in the face of continuous setbacks, 10- to 15-year development timelines, extensive R&D costs, and high rates of scientific and regulatory uncertainty.[vi, vii]

**Cover depicts abnormal red blood cells characteristic of sickle cell disease.**

## WE BELIEVE IN A MARKET-BASED SYSTEM

New medicines transform care for patients fighting debilitating diseases like cancer, hepatitis C, heart disease and many rare conditions. Yet, in the midst of all this progress, spending on retail and physician-administered medicines continues to represent only 14% of overall health care spending.[viii] Over the next decade, many new medicines will further revolutionize care for patients, yet spending on medicines is projected to continue to remain a small and stable share of health care spending. This occurs because the market-based system in the United States promotes incentives for continued innovation and increased patient access to needed medicines while leveraging competition to control costs.

The U.S. market is highly competitive, with robust competition from brand, generic and—increasingly—biosimilar alternatives. As a result, medicine prices fall dramatically as competition occurs among brand name medicines. And prices fall even further when generics are introduced in the market. In fact, 90% of all prescriptions filled by patients in the United States are generics that typically cost a fraction of the price of the initial brand medicine.[ix] We expect this dynamic to continue in the years ahead, since $105 billion of U.S. brand sales are projected to face generic or biosimilar competition between 2019 and 2023.[x]

Another reason the current marketplace for medicines successfully controls costs is that health insurers and pharmacy benefit managers (PBMs) are powerful, sophisticated purchasers who use their leverage to negotiate discounts and rebates off the "list prices" of medicines. Today, the top three PBMs manage more than 75% of the prescriptions filled in the United States.[xi] On average, more than 40% of the list price of medicines is given as rebates or discounts to insurance companies, the government, PBMs and other entities in the supply chain who often require large rebates for a medicine to be covered.[xii] In fact, evidence suggests that negotiated discounts, rebates and other price concessions have more than doubled since 2012, totaling over $166 billion in 2018.[xiii]

## WE SUPPORT PATIENT ACCESS TO CARE

While continued growth in rebates and discounts keeps prescription medicine price growth at the slowest rate in years, it doesn't feel that way for many patients. That is because too often, negotiated savings do not make their way to patients who are increasingly being asked to pay more out of pocket for innovative medicines.

Unlike care received at an in-network hospital or physician's office, patients with high deductibles or coinsurance pay cost sharing based on the list price of a medicine, even though their insurer may receive a steep discount. More than half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price.[xiv] That means a patient in a high deductible health plan who pays the list price each month for their medicines may pay hundreds—or even thousands—more each year than their insurer pays for their medicines.

**CHANGES ARE NEEDED TO ENSURE MORE OF THE $166 BILLION IN NEGOTIATED REBATES, DISCOUNTS AND OTHER PRICE CONCESSIONS ARE USED TO LOWER COSTS FOR PATIENTS AT THE PHARMACY COUNTER.**

As insurers increasingly expose patients to the list price of medicines, patients have seen their out-of-pocket costs continue to grow. At the pharmacy, commercially insured patients with a deductible have seen their out-of-pocket costs for brand medicines increase 50% since 2014.[xv]

Though rebates and discounts have grown substantially, health plans typically use some portion of these negotiated rebates to reduce premiums for all enrollees rather than to directly lower costs for patients facing high cost-sharing due to deductibles and coinsurance. This creates a system where payers require patients to pay more out of pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums. Asking sicker patients to subsidize premiums for healthier enrollees is the exact opposite of how health insurance is supposed to work.

Changes are needed to ensure more of the $166 billion in negotiated rebates, discounts and other price concessions are used to lower costs for patients at the pharmacy counter.[xvi] 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[xvii, xviii, xix] Sharing negotiated discounts could save certain commercially insured patients with high deductibles and coinsurance $145 to more than $800 annually while increasing premiums by about 1% or less.[xx] In Medicare Part D, policies to ensure that savings from negotiated discounts are passed on to Medicare beneficiaries would also improve affordability for seniors and strengthen competitive incentives in the Part D program. For example, a typical Medicare beneficiary with diabetes taking five medicines could save about $1,000 a year in out-of-pocket costs.[xxi]

## WE ARE FOR SOLUTIONS

America's biopharmaceutical companies are committed to working with policymakers and stakeholders to advance market-based solutions aimed toward ensuring patient access to needed treatments, supporting continued innovation, driving value in our health care system and addressing misaligned supply chain incentives.

## ENSURING AFFORDABILITY FOR PATIENTS

The status quo is not working for patients, and misaligned incentives in our health care system need to change. Rebates and other price concessions that payers receive from biopharmaceutical companies should be used to lower cost sharing for patients at the pharmacy counter. And we need to do more 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 ensure that beneficiaries who face a catastrophic illness are able to afford their treatments. To provide patients with more transparency about medicine costs, PhRMA members voluntarily direct patients to links to cost information in their direct-to-consumer (DTC) television advertising. PhRMA also launched the Medicine Assistance Tool, or MAT, to provide these links referenced in DTC television advertising and help patients connect to financial assistance programs.

## PROMOTING VALUE-DRIVEN HEALTH CARE

We can make medicines more affordable by moving toward a health care 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. 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 how different medicines work, creation of better measures of quality care that take into account how patients feel and reforms that allow new ways for insurers to pay for medicines. Advancing research and methods related to value assessment that encompass all the outcomes that matter to patients and families is an important step toward that goal.

## PROTECTING AND SUPPORTING INNOVATION

We are committed to advancing market-based reforms that promote competition and modernize the drug discovery and development process. To get medicines approved more efficiently while ensuring safety, we need to modernize the drug discovery and development process and equip regulators with new technologies and expertise to keep up with 21st century science. We also need to ensure timely review and approval of generic and biosimilar medicines so that patients benefit as less expensive generic and biosimilar medicines replace treatments following the expiration of patents and data protection. Additionally, 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.

## STRENGTHENING THE HEALTH CARE SYSTEM

The market-based U.S. health care system works well to control costs, but more can be done to help it work even better for patients. Our current system can create misaligned incentives where PBMs and others in the supply chain favor medicines with high list prices and rebates which can impact patient affordability. Reforms are needed to prevent PBMs and others in the supply chain from being paid off the list price of a medicine and instead a fee based on the value their services provide. The wrong way to address misaligned incentives is through greater government intervention in marketplace negotiations or through adopting harmful practices from countries that restrict patient access to needed medicines. Strengthening our health care system must also address misaligned profit incentives which fuel hospital markups on medicines and provider consolidation. Addressing these misaligned incentives presents an opportunity to reduce the largest and fastest contributor to health care costs—hospital spending.


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