WE ARE IN A NEW ERA OF MEDICINE WHERE BREAKTHROUGH SCIENCE AND PERSONALIZED THERAPIES ARE TRANSFORMING THE WAY WE TREAT PATIENTS.

WE DRIVE INNOVATION

Robust investment in research and development (R&D) by biopharmaceutical companies has resulted in advances and discoveries unlike anything we’ve seen before. In the last decade we have invested half a trillion dollars, and these investments are just beginning to pay off, opening the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time.¹

The progress we’re seeing 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 even curable. And today, there are about 7,000 medicines in clinical development around the world.² Across the medicines in the pipeline, 74 percent in clinical development have the potential to be first-in-class treatments.³ The future has never been brighter as researchers are exploring new frontiers that just a few years ago may have been regarded as science fiction, but are now transforming 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, ultimately saving money for patients and the nation’s health system.

Medicines are our best bet for tackling the country’s biggest health cost driver: chronic disease. Health conditions such as diabetes and heart disease are the leading causes of death and disability in the United States, and patients with these conditions account for 90 percent of health care spending.⁴ Medicines help improve patients’ health and quality of life, improving productivity and allowing patients to make valuable contributions to the economy.

WE SUPPORT A STRONG ECONOMY

Investments in biopharmaceutical innovation are not only improving and saving lives but they are also driving tremendous contributions to the American economy and solidifying America’s role as a leader in medical innovation. In 2016, biopharmaceutical companies invested about $90 billion in R&D in the United States—more than any other industry in America.⁵ The industry supports 4.7 million jobs across the country, and more than 800,000 employees across companies go to work every day to create new treatments and cures for patients, even in the face of continuous setbacks, 10 to 15 year development timelines and extensive R&D costs.⁶,⁷

WE SUPPORT PATIENT ACCESS TO CARE

Changes in insurance design, including the growing use of deductibles and coinsurance for prescription medicines, create affordability challenges for many patients. Patients enrolled in high-deductible health plans may be asked to pay thousands of dollars out of pocket before any of their prescriptions are covered, while patients with coinsurance are responsible for as much as 30 to 40 percent of the total cost of their medicines.⁸,⁹ Since 2012, the share of employer
plans requiring a deductible for the pharmacy benefit has increased 126 percent. In 2017, 55 percent of commercially insured patients’ out-of-pocket spending on brand drugs was for prescriptions filled in the deductible or with coinsurance rather than with a fixed copay. This share has increased 20 percent since 2013 as insurers are increasingly shifting more and more of the costs of medicines to patients. And at the pharmacy, commercially insured patients with a deductible have seen their out-of-pocket costs for brand medicines increase 50 percent since 2014.

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. Patients may also face additional hurdles when filling their prescriptions, such as “fail first” and prior authorization requirements.

Biopharmaceutical companies are committed to ensuring that patients have access to medicines. Manufacturers may offer patient assistance programs to help qualifying underinsured and uninsured low-income patients obtain the medicines they need for free or nearly free. Manufacturer cost-sharing assistance cards can also provide a valuable resource for many commercially insured patients who are struggling to afford out-of-pocket costs associated with insurance coverage for their medicines.

Unfortunately, some pharmacy benefit managers (PBMs) and health insurers have recently started to ignore cost sharing paid with manufacturer cost-sharing assistance cards when calculating whether patients have reached their deductible or out-of-pocket maximum. In some cases, this leads patients to exhaust the full value of their cost-sharing assistance cards, potentially leaving them with unexpected out-of-pocket costs as high as several thousand dollars in order to continue taking their medicine. This threatens access for these patients and could negatively impact adherence and patient health.

WE BELIEVE IN A MARKET-BASED SYSTEM

New medicines are transforming care for patients fighting debilitating diseases like cancer, hepatitis C, high cholesterol and more. Yet, in the midst of all this progress, the share of total health spending devoted to prescription medicines remains constant at 14.1 percent. Over the next decade, many new medicines will further revolutionize care for patients, yet medicines are projected to remain a small and stable share of health care spending.

This is possible because the market-based system in the United States promotes incentives for continued innovation while leveraging competition to control costs. The United States market is highly competitive, with aggressive negotiation by payers and robust competition from brand and generic alternatives. As a result, the prices of medicines fall dramatically as competition occurs among brand name medicines—even further with the introduction of generics. Ninety percent of all prescriptions filled by patients are generics that cost a fraction of the price of the initial brand medicine.

We expect this dynamic to continue in the years ahead, with $105 billion of U.S. brand sales projected to face generic or biosimilar competition between 2018 and 2022.

One reason the current marketplace for medicines has been successful in controlling costs is that health insurers and 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 70 percent of the prescriptions filled in the United States. And evidence suggests that negotiated discounts and rebates have been growing. In fact, between 2012 and 2017, rebates, discounts and other reductions in price provided by biopharmaceutical companies increased by 107 percent, from $74 billion to $153 billion.

While continued growth in rebates and discounts has kept price growth for brand medicines at the slowest rate in years, it doesn’t feel that way for many patients. That is because too often, negotiated savings are not always shared with 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. In fact, more than half of commercially insured patients’ out-of-pocket spending for brand medicines is based on the full list price. As a result, a patient in a high-deductible health plan who pays the list price each month for their medicines may be paying hundreds—or even thousands—more each year than their insurer. This is not how insurance should work.

Moreover, though negotiated rebates have been growing, health plans typically use some portion of 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 whereby payers require patients with high medicine costs 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 with high drug expenditures to subsidize premiums for healthier enrollees is the exact opposite of how health insurance is supposed to work. Patients should benefit from negotiated discounts when their medicines are subject to a deductible or coinsurance. This would be consistent with how cost sharing is typically calculated for other health care services.
WE ARE FOR SOLUTIONS

America’s biopharmaceutical companies are committed to working with policymakers and stakeholders to advance solutions aimed toward driving value in our health care system, supporting innovation, ensuring patient access to needed treatments and combating threats to public health.

Ensuring Affordability for Patients

We need to ensure that health insurance works the way it is intended and offers meaningful protection from out-of-pocket costs for the sickest of patients. To improve patient access and affordability, insurers and PBMs should share more of the discounts and rebates they negotiate with biopharmaceutical companies directly with patients at the point of sale. In addition, insurers and PBMs should have to count all cost sharing patients are asked to pay toward the deductible and out-of-pocket maximum, instead of ignoring amounts paid with the help of cost-sharing assistance provided by biopharmaceutical companies.

Promoting Value-Driven Health Care

In order for biopharmaceutical companies to become partners—rather than simply vendors—we need to modernize regulations developed for a fee-for-service era. Recently the U.S. Food and Drug Administration (FDA) released guidance on biopharmaceutical companies’ ability to share certain information about the potential benefits of a treatment with insurers and health systems. While that guidance was an important first step, to spur more value-based arrangements we also need to reform outdated, unclear regulations that can discourage companies from offering new types of discounts or taking on more risk in new payment arrangements.

Protecting and Supporting Innovation

In order to encourage continued innovation and accelerate the introduction of new medicines for patients, the FDA should continue driving efficiencies aimed at enhancing the prescription drug development process and ensuring timely regulatory review. Additionally, the United States must continue to protect medical innovations through a strong patent system while also ensuring international trading partners value and support biopharmaceutical innovation. Reducing the time and complexity for developing innovative medicines and protecting the intellectual property behind them will further support the new era of medicine benefiting patients’ lives.

Strengthening the Health Care System

The market-based U.S. health care system has worked well over time, but more can be done to help the system work even better for patients. The 340B program needs significant reform as it is widely understood to distort the market and create incentives that raise health care costs. Modernizing the program is essential to ensure it is sustainable and benefits vulnerable or uninsured patients. Likewise, improving affordability and predictability for seniors in Medicare Part D could help strengthen the health care market and improve affordable access to medicines for patients.

Combating Prescription Drug Abuse

The opioid crisis is too broad and complex for any one person or group to solve alone. There are many different factors driving the current public health crisis that must be addressed holistically, including preventing overprescribing, improving patient and prescriber education, expanding access to appropriate treatments and enhancing law enforcement capabilities to crack down on counterfeit fentanyl and other illegal drugs.