

**TESTIMONY OF JOCELYN B. ULRICH, VICE PRESIDENT, POLICY AND RESEARCH
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

BEFORE THE SENATE JUDICIARY COMMITTEE

May 21, 2024

Chairman Durbin, Ranking Member Graham, and Members of the Committee, thank you for inviting me to participate in today's hearing. The robust competition that is created by the U.S. intellectual property (IP) framework is critical to both innovation and affordability, and I appreciate the opportunity to explore this topic with you in depth.

I am here today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. The biopharmaceutical sector is one of the most research-intensive industries in the United States: over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly \$101 billion in 2022 alone, more than any other industry.¹ This is also a vastly larger amount than the NIH spends on drug research and development, in FY 2020 the entire NIH budget was \$43.3 billion,² only 8% of which was focused directly on drug development, while the biopharmaceutical industry as a whole invested \$122 billion in research and development (R&D),³ 100% of which was focused on drug development.

PhRMA appreciates the Committee's leadership in exploring opportunities to ensure affordable and accessible medications and examining competition in the prescription drug market. This market relies on a well-functioning, science-based regulatory system, strong and reliable intellectual property (IP) protections, and coverage and payment policies that encourage medical innovation to thrive. My testimony today will focus on two of those pillars, the IP system and coverage and payment policies.

As a starting point, America's IP framework should be credited for its distinct ability to balance the important goals of fostering innovation and promoting competition to control overall health care costs. Patents and other forms of IP protection are critical for the biopharmaceutical industry due to the lengthy, costly, and highly risky nature of biopharmaceutical R&D, which is necessary to bring innovative new medicines to patients. Fewer than 12% of the drug candidates that make it into clinical trials are eventually approved by the Food and Drug Administration (FDA). Estimates of total average capitalized pre-launch R&D costs range from \$161 million to \$4.54 billion (2019 US\$), including one estimate that found it costs \$2.6 billion to develop one medicine, including the costs of the many failures.^{4,5}

By many measures, America's IP framework has been a resounding success, promoting incentives for innovation and patient access to needed medicines while leveraging our market-based system to drive competition and achieve cost containment. Since 2000, biopharmaceutical companies have launched more

than 750 new medicines in the U.S., resulting in significant progress against some of the most costly and challenging diseases.^{6,7,8,9} Even though the period from 2009 and 2018 saw the introduction of many new treatments and cures, a Congressional Budget Office (CBO) examination of nationwide trends in medicine prices found that the average net price per prescription in Medicare Part D and Medicaid declined during that time period.¹⁰

These savings result from a unique system of cost containment: over time, new medicines help to improve patient outcomes and reduce overall health care costs while paving the way for lower-cost generics and biosimilars that bring long-term value to patients and the health care system.¹¹ As a result of the strong legal and regulatory frameworks that undergird this system, today 90% of prescriptions filled at the pharmacy counter are filled with generics and biosimilars, offsetting most of the health care spending on new brand drugs.¹² Going forward, net prices for brand medicines are projected to decline by up to 4 percent annually through 2028, and total prescription spending as a share of National Health Expenditures (NHE) is projected to remain constant at 14% through 2030, exactly the same share as it has been for the last decade.¹³ Similar cost containment mechanisms do not exist for other health care services.¹⁴

Unfortunately, however, critics often rely on a misguided understanding of the vital role of IP to the biopharmaceutical research ecosystem to call for reforms that would put this carefully balanced system at risk over the long term. As such, it is more critical now than ever that we advance thoughtful policies that continue to incentivize urgently needed innovation while supporting a competitive marketplace.

For decades the competitive dynamics in the market for prescription medicines have worked successfully to balance innovation, patient access, and cost containment. But that balance is increasingly threatened by the misaligned financial incentives and conflicts of interest that characterize the pharmacy benefit manager (or PBM) market today. In recent years, the three largest PBMs have vertically integrated with health insurers, specialty and mail order pharmacies, and provider groups to form large health care conglomerates that are significantly impacting whether patients are able to benefit from biopharmaceutical innovation. These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, and when and where they can be dispensed or administered to patients. A growing share of PBM compensation is now tied to the list price of medicines,¹⁵ which experts note can distort the market by incentivizing PBMs to prefer medicines with higher list prices and large rebates over lower cost alternatives.¹⁶ Rather than ensuring patients have rapid access to generics, biosimilars, and lower price therapies, we see PBMs denying or restricting coverage for these medicines.^{17,18} Instead of using the rebates they negotiate with manufacturers to lower patient cost sharing, we see PBMs requiring patients to pay their deductibles and coinsurance based on a medicine's undiscounted list price. We discuss the ramifications of these practices later in the testimony.

PhRMA supports market-based solutions that will spur continued brand-to-brand, generic, and biosimilar competition while incentivizing medical advances to save and improve patient lives. In addition, we believe there are meaningful policy solutions that would solve the true barriers to patient access and affordability and improve competition that would not harm the IP system that underpins America's leadership in biopharmaceutical innovation. My comments provide context on the critical role of the biopharmaceutical industry in the U.S. economy, the existing statutory frameworks that increase access to generic and

biosimilar medicines while preserving incentives for innovation, the importance of the Bayh-Dole Act to the research ecosystem, the role of medicines in reducing spending on health care and improving patient outcomes, the impact of the Inflation Reduction Act (IRA) on competition, the impacts of vertical integration in the health care marketplace, and policy proposals to enhance competition.

Overview of How the Biopharmaceutical Industry Boosts the U.S. Economy

The biopharmaceutical industry is a major driver of innovation and economic growth both within the U.S. and globally. Through its research, production, and overall operations, the U.S. biopharmaceutical industry directly accounts for 1.6 percent of U.S. GDP (*i.e.*, its “value added”). Including the economic activity driven in other sectors of the economy the industry generates and supports more than \$880 billion in value added within the economy, or 3.4 percent of U.S. GDP.¹⁹

The U.S. biopharmaceutical research sector leads the world in the development of new medicines with about 8,000 in development globally.²⁰ The sector generates high-quality jobs and powers economic output and exports for the U.S. economy, serving as “the foundation upon which one of the U.S.’ most dynamic innovation and business ecosystems is built.”²¹ The U.S. biopharmaceutical sector directly employed more than one million workers in 2022, and with its substantial employment multiplier of 4.69, the industry supports more than 3.8 million additional jobs for a total employment impact of more than 4.9 million jobs supported across the U.S. economy.²² The R&D intensive nature of the industry generates a productivity level of more than \$402,000 per employee. In 2022 that was more than twice that of the average U.S. manufacturing worker, and more than three times the average U.S. worker. Furthermore, biopharmaceutical industry jobs are both high-wage and high-quality with average wages and benefits of more than \$157,000 per worker, more than twice the average U.S. worker.²³

Biopharmaceutical companies also support the broader life sciences ecosystem in the United States. The corporate venture capital funds of major biopharmaceutical companies “play an essential role in the sustainability of the biotech ecosystem, advancing the future of pharmaceutical innovation and biotech entrepreneurship.”²⁴ All of this has a ripple effect throughout the U.S. economy, in 2022 the biopharmaceutical industry exceeded \$800 billion in direct output and supported an additional \$850 billion in output through its supplies and other sectors of the economy for a total of more than \$1.65 trillion.²⁵

Overview of the Statutory Frameworks that Increase Competition while Preserving Incentives for Innovation

As noted by the former Director of the U.S. Patent and Trademark Office (PTO) Andrei Iancu, “the progress we have made in the past 200 years is absolutely unparalleled in human history and most of that has been backed by patents.”²⁶ That progress is due to recognition by the Framers of our Constitution of the importance of robust IP protections, empowering Congress in Article 1 Section 8 of the Constitution “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” Under Section 101 of the Patent Act, 35 U.S.C. 101, Congress provided that broad categories of inventions are eligible for patent protection: new and useful processes, machines, manufactures, or compositions of matter, as well as “any new and useful improvement.”

In the biopharmaceutical sector, Congress recognized the need to provide approval pathways that foster competition through the market entry of generic and biosimilar medicines while also maintaining incentives for innovation. Two key statutory frameworks simultaneously reward innovation while establishing streamlined approval pathways for generic or biosimilar products. Both patents and the exclusivities provided under the statutory schemes, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and the Biologics Price Competition and Innovation Act (BPCIA), have been successful in both fostering innovation and creating robust generic and growing biosimilar markets.

The Hatch-Waxman Act was enacted in response to a landscape in which innovator companies were losing substantial effective patent life during clinical development and the FDA review and regulatory approval process. At the same time, generic companies did not have an abbreviated pathway for approval of generic copies of drugs approved after the 1962 amendments to the Federal Food, Drug, and Cosmetic Act after IP protections expired, and could not perform the studies need to support approval during the innovator patent term. The Hatch-Waxman Act created a framework that allowed generic companies to develop products during the period of innovator patent protection without liability for patent infringement,²⁷ overturning a Federal Circuit decision to the contrary,²⁸ and seek FDA approval to market products immediately upon patent expiration, or even prior to patent expiration if they challenge patents through the litigation framework created by the Hatch-Waxman Act. In addition, to protect the valuable clinical data generated by innovators during the drug development process, Congress also provided data protection for the innovator drug. Under the Hatch Waxman Act, with certain limited exceptions, generic companies must wait 5 years before filing abbreviated new drug applications for drugs including a new active moiety.

Given the nature of the framework created, patent litigation is an explicitly contemplated part of the generic pathway, as are settlements of such litigation. The patent challenge procedure under the Hatch-Waxman Act has proven to be a robust means for generic applicants to attempt to market generic versions prior to expiration of listed patents. As a result, the effective patent life for small molecule medicines is about 13.0 years for drugs with sales greater than \$250 million in 2008 dollars the year before generic entry, and 14.1 years overall.²⁹ This means that small molecule brand medicines face generic competition between 13-14 years after brand launch, even though the basic patent term is 20 years. Over the 40 years since enactment of the Hatch-Waxman Act, patent challenges from generic manufacturers (in the form of paragraph IV certifications) have been filed more frequently and earlier in the brand-name drug life cycle, with many as soon as possible under the statute—in the case of a new chemical entity, as early as 4 years after FDA approval.³⁰

The BPCIA was enacted in 2010 and was intended to strike a balance between providing access to biosimilar medicines and preserving incentives for innovation of biological products. Through the BPCIA, Congress created an abbreviated approval pathway for biosimilar and interchangeable biological products. Biosimilar applicants also may develop products during the period of innovator patent protection without liability for patent infringement. At the same time, Congress provided incentives for innovation by providing for a data protection period governing when biosimilar applications could be submitted (as early as four years after approval) and approved (as early as 12 years after approval of the reference or innovator product). Congress also created a different procedure for litigating in court validity and applicability of patents covering the

biosimilar product. Although the dynamics created by the Hatch-Waxman Act and BPCIA litigation procedures differ, they both allow for, and naturally lead to, premarket patent litigation. Since Congress enacted the BPCIA in 2010, a robust biosimilars market has emerged in the U.S, with 38 biosimilars launched and competing on the market against 16 brand biologics, resulting in \$23.6 billion in savings since the first biosimilar entry in 2015.^{31,32}

An important provision of the Hatch-Waxman Act allows the basic term of one of the innovator's drug patents to be extended up to fourteen years from the approval date to ensure that research intensive companies will have the necessary incentives to conduct their R&D activities.¹ This partial patent term restoration is based on the effective patent life lost in FDA review and half of the time lost during clinical development, capped at 5 years, with the extended patent term not to exceed 14 years from FDA approval.³³ During the Congressional debate about the Hatch-Waxman Act it was noted that Congress had carefully considered the 14-year period: “[B]y providing up to fourteen years of market exclusivity, the Committee expects that research intensive companies will have the necessary incentive to increase their [R&D] activities.”³⁴ This period of time to get a return on R&D investment was a pivotal feature of the Hatch-Waxman Act and was described at the time as the “heart of the compromise.”³⁵

IP fosters both innovation and competition, and these dual purposes can be enhanced with carefully crafted statutory schemes. The Hatch-Waxman Act and the BPCIA are two such schemes, resulting in \$2.9 trillion in savings over the past ten years alone.³⁶

Patents Also Support Critical Post-Approval Innovation

R&D doesn't stop the minute a medicine is first approved by FDA. R&D investment in medicines is an ongoing process that continues long past initial FDA approval, resulting in innovations that improve the lives of patients, including new uses, novel delivery mechanisms and new dosing schedules. These advances can involve significant R&D investments and lengthy and resource-intensive clinical trials, with no guarantees of success. Post-approval R&D can lead to new or improved treatment options for patients that may enable better health, quality of life, or reduce treatment burdens improving treatment adherence and health outcomes.

Patents are necessary to incentivize this important work and to ensure the full clinical benefit of medicines are realized. As a result, patents touch nearly every facet of biopharmaceutical production and use, from the active ingredient or component that produces its biological effect, to formulations of it, to new uses of it, to the way it is made; the result of this breadth of innovation is that most medicines are associated with many patents.

The types of patents covering biopharmaceuticals include:

- Active ingredient or component patents. These are the ingredients of the drug that have a physiological or pharmacological action.

¹ Note that patent term restoration also applies to biologic medicines.

- Drug product patents. These refer to the particular form in which the medicine is delivered to a patient. New dosage forms for already FDA-approved medicines can increase patient adherence to therapy, ensure a proper dose is taken, and improve quality of life for patients who must use the medication on a prolonged basis. In turn, these innovations may result in improved health outcomes and a reduction in unnecessary use of health care services, such as hospitalizations. For example, long-acting injectable forms of oral treatments for schizophrenia have allowed for administration every two weeks or even as little as every 6 months. Long-acting forms have led to improved adherence and savings driven primarily by lower hospitalizations and outpatient care.^{37,38}
- Methods of use/treatment patents. Knowledge and understanding of a medicine continue to build over time, through additional study and collection of data. This additional research can culminate in approval of new uses of medicines in different patient populations, conditions, and disease states, expanding treatment options for patients. As an example, medicines initially developed for use in rheumatoid arthritis have been shown to also help treat other autoimmune conditions that share similar molecular pathways, including Crohn's disease and ulcerative colitis. In oncology, for example, research is often under way on multiple additional indications at the time of approval of the initial indication, with post-approval clinical research often demonstrating significant clinical benefit of the therapy in a different disease, stage of disease or population.
- Methods of manufacturing patents, which cover innovations in the process or steps to manufacture increasingly more complex medicines. Advances in manufacturing processes can improve medicines, such as by removing potential impurities that could impact the quality of the medicine. These innovations similarly require R&D incentivized by IP protections. In some cases, innovator firms (and, for that matter, biosimilar firms) may have developed more precise analytical methods, as well as more precise understandings about the effects of different manufacturing method changes. For R&D intensive industries, the manufacturing process is a key factor in developing new products. That's because in these industries, product and process innovation are often intertwined. Manufacturers justifiably may seek to protect these innovations, while also disclosing these processes to the public, through patents. Although biosimilar competitors may need to consider how they will proceed in light of the patents, one approach is inventing around the methods disclosed in the patent. As noted previously, prospective applicants can also choose to challenge the patents or their applicability through the process articulated in the BPCIA.

In contrast to patents that cover the composition of a new compound, new uses, new dosage forms and new methods of manufacturing can be invented at any point in the product lifecycle, and thus patent applications for them can also be filed throughout the product lifecycle. For instance, new methods of manufacture that reduce the potential for immunogenicity are often invented years after a biologic is discovered or has obtained regulatory approval. In addition, manufacturers may invent novel methods for purifying proteins that are more efficient or allow for more precise recovery of specific proteins. Such advances in manufacturing methods should be incentivized to maximize product quality, safety, and effectiveness and ensure efficient delivery of a consistently safe and effective product to patients.

The Importance of the Bayh-Dole Act to the Innovation Ecosystem

Strong and reliable IP protections are critical to fostering public-private partnerships and other forms of collaboration. Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to transform discoveries resulting from government-funded early-stage research into useful products in any sector. By allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and right to use those inventions to private sector partners, the Bayh-Dole Act facilitates the development of commercially available medical treatments. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally-funded inventions – and only 5% of those patents were ever licensed for use in the private sector.³⁹ Collaboration was further incentivized by The Federal Technology Transfer Act of 1986, which authorized Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. These policies have proven critical to maximizing taxpayer benefit for government-funded research. Several studies have demonstrated that increases in NIH-funded basic research results in increased private R&D and innovation.⁴⁰ Analysis of industry R&D spending data found that in the decade following an increase in NIH funding, private R&D spending grew by about 8 times as much as the increase.⁴¹ Another study found that each \$10 million increase in NIH funding resulted in a generation of knowledge that catalyzed private sector investment with a net increase of 2.7 private sector patents per \$10 million.⁴²

While many medical breakthroughs begin in the research laboratories at the NIH or federally funded academic medical centers, technology transfer is what makes these discoveries available to improve public health through licensing and collaboration agreements with the private sector. According to the NIH Office of Technology Transfer, “technology transfer moves medical innovation from the benchtop through additional research and development, testing, regulatory approval, manufacturing, and finally to distribution as a medical product which will improve the health of everyone.”⁴³ Partnership between the government and the private sector is critical because each plays a fundamentally different but complementary role in the biopharmaceutical research and development ecosystem. According to the Congressional Budget Office (CBO), “the complementary relationship between public and private R&D spending arises mainly because NIH funding focuses on basic research that leads to the discovery of new drugs and vaccines, whereas private spending focuses on applications of such research.”⁴⁴ While NIH plays an important role in fostering basic research in genomics, molecular biology and other life sciences that have identified new disease mechanisms, these discoveries are far from fully developed therapies for patients.

The biopharmaceutical industry’s unique role in the research ecosystem is to utilize its scientific and industrial expertise to take the necessary risks to build upon and further advance basic science research into safe and effective treatments that can be made available to patients. The federal government cannot research, develop and manufacture new treatments and vaccines without the resources, scientific expertise, R&D, manufacturing and technological platforms from private sector biopharmaceutical companies. A rich body of research describes the nature of the complementary roles of the public and private sectors in advancing medical treatments. In 2001, the NIH concluded in a study for Congress that the biopharmaceutical industry was responsible for the discovery and development of 91 percent (43 out of 47) of all the top-selling marketed drugs in 1999.⁴⁵ A 2010 analysis of 252 drugs approved between 1998 and 2007 found that 76 percent originated in industry vs. 24 percent in academia.⁴⁶ A 2014 study of the most transformational drugs

of the 25 prior years, as identified by over 200 physicians, found that the private sector was responsible for the vast majority of the work required to develop a therapy.⁴⁷ An analysis of the contribution of NIH funding to new drug approvals 2010 – 2016 found that although NIH funding contributed to published research associated with every one of the 210 new drugs approved by the FDA in those years, 90% of the NIH funding supported basic research related to the biological targets for drug action rather than the drugs themselves.⁴⁸ And an analysis of 23,230 NIH grants awarded in the year 2000 that were ultimately linked through the reported patent filings to 18 FDA-approved therapies showed that NIH funding totaled \$0.670 billion, whereas private sector funding totaled \$44.3 billion.⁴⁹ The research reflects that the disparate funding between the public and private sectors is a feature of allowing each sector to perform the role it does best in the ecosystem with federal funding: the public sector performs basic research to identify nascent concepts, and the private sector contributes the technical expertise and takes the significant, and necessary, financial risks to bring the initial research to fruition in the marketplace.

The NIH has certain rights and procedures when it seeks to license a patented invention for further development by the private sector. Companies that want to obtain a license to develop an NIH invention must complete an application, and if the applicant has requested an exclusive or partially exclusive license the NIH will publish a notice in the Federal Register, as required by law, and after review and evaluation of public comments will make a final determination regarding the license.⁵⁰ Private companies often prefer exclusive licenses that allow them to be the sole user of a patented invention for a specified period of time in order to provide a measure of certainty and predictability during the highly risky, lengthy, and costly drug development process which can cost an average of several billion dollars and take 10-15 years and with limited probabilities of success.⁵¹ Manufacturers seek the certainty and predictability provided by IP protections to make the decades-long investments in new technologies, and in building and expanding upon state-of-the-art manufacturing facilities.

Though the Bayh-Dole Act allows the federal government to “march-in” under a narrow set of circumstances, “march-in” was never intended to serve as a mechanism for regulating the pricing of any products, including prescription medicines. The law’s provisions provide the right for the government to “march in” under a narrow set of circumstances and force patent holders to grant a license to a “responsible applicant” able to utilize the technology to address an unmet need. In the nearly four decades that the Bayh-Dole Act has been in place, NIH, after careful review, has rejected each of the 7 march-in petitions based on pricing that have been submitted to the agency. In each case, NIH consistently concluded that the products subject to a march-in petition had reached practical application and health or safety needs were reasonably satisfied. Even in an instance where march-in was requested to respond to a manufacturing supply challenge, NIH concluded that the manufacturer was “working diligently to resolve its manufacturing difficulties”⁵² and “no remedy that is available under the march-in provision would address the problems identified by the requestors.”⁵³

Policy proposals to place pricing restrictions on the private sector as a condition of partnering with the government have been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed “reasonable pricing” conditions in all CRADAs between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers after which the agency concluded that these pricing conditions

significantly chilled collaboration between the public and private sectors.⁵⁴ In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D. said, “An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public,” Dr. Varmus further said, “Eliminating the clause will promote research that can enhance the health of the American people.”⁵⁵ After the removal of the clause, there was a subsequent rebound in CRADAs.⁵⁶

In an Op-Ed to the Washington Post, the bill’s authors Senators Birch Bayh and Bob Dole stated, “The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.”⁵⁷ Similar provisions cover the licensing of NIH inventions, which empower the NIH to terminate the license in whole or in part if the agency determines that the licensee is not executing its commitment to achieve practical application of the invention, the licensee is in breach of an agreement, termination is necessary to meet requirements for public use, or the licensee has been found by a court to have violated Federal antitrust laws in connection with its performance under the license agreement. Changing policy on these provisions to allow price to be considered as a factor for action on the part of NIH would chill the private sector’s willingness to enter into contractual agreements and licenses with the agency.

Prescription Medicines Play a Key Role in Reducing Spending on Health Care and Improving Patient Outcomes

Prescription medicines are transforming the treatment of many diseases, resulting in decreased mortality rates, improved health outcomes and better quality of life for patients. For example, game-changing new medicines have played a key role in declining mortality across many forms of cancer. Due in part to many treatment advances, since peaking in the early 1990s, cancer death rates have declined by 33%.⁵⁸ Similarly, since the introduction of highly effective antiretroviral therapy in the mid-1990s and the many treatment advances that followed, the HIV/AIDS death rate has declined by 91% and patients with HIV today can hope to live close to normal life spans.⁵⁹ Across many diseases, biopharmaceutical innovation is ushering in the next generation of treatment advances for patients while also driving greater efficiency in health care. For example, personalized medicines are increasingly enabling the targeted delivery of the right medicine to the right patient at the right time—achieving better outcomes and avoiding unnecessary health care utilization.

Innovative medicines are a crucial part of the solution to our most pressing health care challenges, as they can dramatically reduce existing disease burden while helping to avoid other costly medical care by keeping patients healthy and out of the hospital. Importantly, unlike other parts of the health care system, new medicines also provide long-term value to society as they pave the way for low-cost generics and biosimilars, which improve health in perpetuity while keeping spending on prescription medicines a small and steady share of overall health care spending.⁶⁰ Meanwhile, the costs of hospitalizations, emergency room visits, and other medical procedures and services comprise a growing share of the nation’s overall health care burden and threaten the future sustainability of our health care system.

Better disease management achieved through use of prescription medicines has long been credited with avoiding health complications and avoiding spending on other costly health care services such as emergency room visits, hospital stays, surgeries and long-term care. But new medicines can also dramatically reduce spending on existing disease burden and associated health care costs. These features make prescription medicines a central component of any strategy to improve health while reducing costs.

Improved adherence to prescribed treatment regimens is one of the primary mechanisms by which prescription medicines have demonstrated these cost-saving or “offsetting” benefits. A large body of evidence demonstrates that better use of medicines can reduce other sources of health care spending across a broad range of chronic conditions. For example, one study by CMS and CVS researchers found that every \$1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes, or high cholesterol generated \$3 to \$10 in savings on emergency room visits and inpatient hospitalizations.^{61,62} In the Medicare program, savings associated with improved adherence to treatment regimens to address chronic conditions is also well documented:

- Medicare saved \$2.3 billion due to improved adherence to congestive heart failure medications as a result of seniors and people with disabilities gaining Medicare Part D prescription drug coverage. Further improvements in adherence could potentially save Medicare another \$1.9 billion annually, generating upwards of \$22.4 billion in federal savings over 10 years.⁶³
- Among Part D beneficiaries with diabetes, adherence to therapy reduced total Medicare spending by \$4,000 and fully offset the cost of medications for select therapeutic areas over 2 years.⁶⁴
- Another study found that if Medicare beneficiaries who were nonadherent to high blood pressure medications became adherent, Medicare could save \$13.7 billion annually, with over 100,000 emergency department visits and over 7 million inpatient hospital days averted.⁶⁵

Evidence of medication adherence driving medical cost savings is similarly apparent in the Medicaid program. Among Medicaid patients with congestive heart failure, hypertension, high cholesterol, diabetes, asthma/chronic obstructive pulmonary disease, depression and schizophrenia/bipolar disorder, improvements in adherence could produce \$8 billion in savings annually.⁶⁶ Similarly, Medicaid patients with schizophrenia who were adherent to their antipsychotic treatments had, on average, \$20,787 lower health care costs than non-adherent patients over the course of a year.⁶⁷ And if 80% of the children enrolled in Medicaid achieved high adherence to asthma treatment in just 14 states, Medicaid could achieve \$57.5 million in savings in one year.⁶⁸

Beyond common chronic illnesses, a growing body of evidence demonstrates savings from use of medicines to treat complex chronic health conditions. For example, research shows that better adherence to medicines to treat Parkinson’s disease, Crohn’s disease, cystic fibrosis, multiple sclerosis and advanced melanoma leads to lower health care spending.^{69,70,71,72,73}

Notably, the cost-saving benefits of prescription medicines are specifically supported by research showing that use of medicines curbs overall Medicare spending growth. One study found that roughly half of the marked slowdown in Medicare spending growth over the past decade or more is attributable to fewer acute

events among patients with cardiovascular disease. Moreover, about half of the reduction in cardiovascular deaths is due to greater use of cardiovascular medications capable of reducing hospitalizations for heart disease and stroke. The authors underscore the role that improved use of therapies can play in reducing acute events and medical spending over time.⁷⁴

Given the immense disease burden across a range of health conditions in the United States, the opportunity to improve health and drive savings through better medication adherence in the years ahead is substantial. Consider chronic illness: 6 in 10 Americans have one or more chronic conditions, and 42% have 2 or more.⁷⁵ The cost of treating chronically ill patients accounts for 90% of the nearly \$4 trillion spent on health care in the United States each year.^{76,77} The number of individuals with 3 or more chronic conditions is projected to nearly double by 2030, greatly increasing the economic burden of chronic disease.⁷⁸ But it is estimated that just half of medications for chronic diseases are taken as prescribed.⁷⁹

Moreover, in communities of color, evidence suggests that lower medication adherence is a key driver of health inequities across insurance coverage types and patients with a wide range of diseases, such as high blood pressure, hepatitis C and many more.^{80,81,82} The downstream consequences of medication nonadherence include increased health care costs,⁸³ poor health outcomes,^{84,85} and increased risk of mortality.⁸⁶ Therefore, the longstanding disparate outcomes faced by patients of color and other underserved communities represent enormous potential to reduce health care costs through improved adherence, while also driving towards a more equitable health care system.

The IRA Threatens the Future Innovation That Will Make Our Health Care System More Sustainable

Unfortunately, as a result of the price-setting policies imposed by the Inflation Reduction Act (IRA), the biopharmaceutical innovation most likely to drive down other health care costs will unfortunately be discouraged. In fact, these policies are expected to reduce the number of medicines developed in the future, some of which could reduce or eliminate the need for hospitalizations, surgeries, or other costly medical care. Accounting for this negative impact on patient health, one study from economists at the University of Chicago estimating the impact of certain price setting policies on biopharmaceutical innovation, found they would increase overall health care spending by \$50.8 billion over a 20-year period.⁸⁷

Specifically, the IRA allows the government to set prices for eligible medicines in Medicare. Small molecules—those that typically come in pill or capsule form—may be selected just 7 years after FDA approval, and biologics can be selected at 11 years—with the government-set price going into effect for both types of medicines 2 years later. As a result, these medicines would face price setting earlier than they would otherwise face generic or biosimilar competition. Shortening the timeframe by which manufacturers can earn potential revenues on medicines is expected to impact the future development of treatments.⁸⁸

The timelines for price setting in the IRA also fails to recognize that after initial FDA approval, additional clinical studies—often those involving clinical trials—are conducted to understand the benefits of medicines in other diseases, treatment populations or in combination with other therapies. As a result, biopharmaceutical companies are now forced to make difficult decisions about whether it is feasible to invest in post-approval R&D that could lead to important new uses for already approved medicines. In disease areas

that rely heavily on this form of R&D to drive treatment advances for patients, the impact of these disincentives may be devastating.⁸⁹

Additionally, CMS' inappropriate approach to defining qualifying drugs by active ingredient or moiety rather than by marketing application treatment under the new price setting framework further discourages the development of new dosage forms and formulations. To illustrate this point, while CMS was permitted to select 10 drugs for the first price-setting year, CMS' definition of drugs that qualify for price-setting enabled it to sweep in a broad range of dosage forms and formulations—including those that were submitted under entirely different drug applications. These actions send a clear signal discouraging drug manufacturers from developing new or improved dosage forms and formulations which offer to ease treatment burdens or improve outcomes for patients.

Moreover, by affording small molecule medicines a shorter timeframe on the market relative to other medicines before price-setting may occur, the “pill penalty” especially jeopardizes the development of these critical treatments and the post-approval R&D that is necessary to realize their full therapeutic potential. In disease areas such as cancer, where the majority of medicines approved are small molecules and post-approval R&D has been indispensable in driving progress for patients, the impact of price setting is expected to be substantial.⁹⁰ In fact, research shows more than 60% of small molecule cancer medicines approved a decade ago received additional indications in later years, and nearly half of those occurred 7 or more years after initial approval.⁹¹

One of the reasons small molecules play such an important role in the treatment of cancer is their unique ability to reach therapeutic targets inside cells. Similarly, the ability for small molecule medicines to cross the blood-brain-barrier also make them critical in the treatment of diseases with therapeutic targets inside the brain—including illnesses impacting the central nervous system, mental health conditions, neurodegenerative diseases, and many more.⁹²

Beyond the reliance of small molecules in the treatment of many illnesses, they also provide great flexibility and convenience to patients, reducing barriers to treatment adherence—particularly as they are often available in oral dosage forms, which may be easily stored at home and self-administered. These features in turn reduce the burden of transportation challenges, caregiver costs, lost wages and other hurdles that have played a role in driving treatment non-adherence and longstanding health inequities.⁹³ Unfortunately, the IRA risks leaving many patients who rely on these valuable treatments behind.

In addition to the impacts on innovation, the IRA disrupts both the Hatch-Waxman and the BPCIA frameworks by substituting government price setting for future competition from generics and biosimilars. That is because, as the law has no floor price, it allows the government to impose such low prices on an innovator product that biosimilar and generic manufacturers may not be able to compete in the market, discouraging them from bringing products to market in the first place. This risk is heightened by the fact that generic and biosimilar manufacturers will not be able to predict with any certainty whether the branded reference product they are seeking to compete against will be selected for price setting under the IRA at the time when they need to make their investment and development decisions.

Specifically, with regard to small molecule drugs, the IRA undermines existing incentives for generic competition established in the Hatch-Waxman Act of 1984 by implementing price-setting far earlier than current timelines for generic competition. Currently the average effective patent life for small molecule drugs before generics enter the market is 13 to 14 years.⁹⁴ But under the IRA, the government may impose a set price for small molecule medicines 9 years after FDA approval, far earlier than current timelines. This timeline may be further exacerbated by CMS's inappropriate approach to defining qualifying drugs by active ingredient or moiety rather than by marketing application. That means potential generics must now weigh the economic viability of entering the market to compete against a brand product with a low government-set price. But generics rely on the ability to offer sharply lower prices to attract market share from brand competitors. In fact, generics often enter the market immediately upon patent expiration and are often adopted rapidly as a result of this successful dynamic. Today, 90% of prescriptions filled at the pharmacy are filled with generic or biosimilar medicines and many capture as much as 90% of the market within 3 months of entry.⁹⁵ But with limited ability to offer a sharply lowered price to attract market share from the price-set brand, the IRA imposes restraints on generic competition and upends incentives that currently drive market entry.

With regard to biologic medicines, the IRA will also strongly discourage biosimilar development as the new framework imposed by the IRA is at odds with the timelines created under BPCIA. The IRA allows for biologics to be selected for price-setting at year 11, with the government-set price going into effect 2 years later, unless the biologic has a biosimilar available. But under the BPCIA, a biosimilar cannot be approved until 12 years after the first licensure of a reference biologic. Seemingly to mitigate against this tension, a special rule was established in the law, which allows for potential biosimilar manufacturers to request a "pause" in the price setting process if there's a "high likelihood" for biosimilar entry within the requisite timeframe. However, the biosimilar pause leaves too much uncertainty as to whether or not drugs with legitimate biosimilar competition will be able to be exempted from price setting. This reality makes the decision to invest in biosimilar development extremely risky and potentially financially infeasible moving forward. Biosimilar manufacturers face long development timelines and significant costs due to the complexities of biologics manufacturing. In fact, biosimilar development can take 7-8 years and \$100-\$250 million in investment.⁹⁶ As a result, the prospect of entering a market to compete against a low government price-set product is likely to serve as a significant disincentive for biosimilar manufacturers.

The negative impact on the future of generic and biosimilar competition is already apparent with selection of CMS' initial list of drugs for 2026.⁹⁷ In fact, the majority of medicines on CMS' initial drug selection list for price setting already face pending generic and biosimilar competition.⁹⁸ However, due to the provisions in the IRA and CMS' flawed interpretation, if the pending generic and biosimilar products are unable to reach the market by August 1, 2024, they will be forced to compete against price-controlled products, reducing the chances of success in the marketplace. The disruption to longstanding legal and regulatory frameworks comes with considerable risk, potentially jeopardizing future competition and savings driven by generics and biosimilars in the years ahead. These savings totaled \$408 billion last year alone, including \$130 billion to Medicare.⁹⁹

Impacts of Vertical Integration on Competition in the Health Care Marketplace

The PBM industry is dominated by three large companies with opaque business practices

PBMs act as intermediaries on behalf of payers to control coverage and reimbursement arrangements for prescription medicines. Situated between the biopharmaceutical companies that research, develop and manufacture innovative medicines and the patients likely to benefit from those treatments, PBMs play a central role in determining which medicines patients will have access to and at what cost for hundreds of millions of Americans.

After nearly two decades of horizontal consolidation, the PBM industry is now dominated by three large companies: CVS Caremark, Express Scripts, and OptumRx.¹⁰⁰ The combined share of these three largest PBMs has grown significantly, from 48 percent of prescription drug claims in 2010 to 80 percent in 2023.^{101,102} Today, just six companies control 94 percent of prescription drug claims¹⁰³ and patients residing in more than three quarters of states are subject to highly concentrated “PBM markets” as defined by Department of Justice (DOJ) and Federal Trade Commission (FTC) Horizontal Merger Guidelines.¹⁰⁴ In many instances, smaller PBMs contract or partner with larger PBMs to leverage their infrastructure, with the larger entities acting as rebate aggregators in the commercial market for the smaller entities.^{105,106} Such arrangements further contribute to the overall concentration of negotiating power.¹⁰⁷

In recent years, the three largest PBMs have vertically integrated with health insurers, specialty and mail order pharmacies, and provider groups to form large health care conglomerates. These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, and when and where they can be dispensed or administered to patients. The three largest PBMs have become key drivers of revenues and profits for their respective vertically integrated organizations.¹⁰⁸ Express Scripts generated more than 70 percent of its parent company’s total revenues, and OptumRx and CVS Caremark were responsible for approximately one third of their affiliated insurance companies’ total revenue in 2023.¹⁰⁹

Extensive consolidation and vertical integration throughout the health care delivery system, including PBMs, insurers, hospitals, providers, and their affiliates, can have wide reaching effects on (1) patients’ out-of-pocket costs, (2) patients’ access, choice, and quality of care, (3) broader health system costs, and (4) market dynamics.

Consolidation and Vertical Integration in the Health Care System Impact Patient Access and Costs

Government agencies, economists, and other experts have noted that PBMs’ fee models based on list prices can incentivize PBMs to favor medicines with higher list prices to maximize their revenues.^{110,111} These dynamics demonstrate that having a generic or biosimilar version of a branded medicine available on the market is no longer sufficient for driving the expected cost savings to patients or the health care system. According to a Senate Finance Committee report, “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.”¹¹² Industry analysts have noted that these market dynamics have prompted some manufacturers to introduce two identical versions of a product – one with a higher list price and large rebates and a version with a lower list price, giving payers the option of which to cover.¹¹³ This dynamic is especially acute when biosimilar and generic manufacturers are seeking to introduce lower list price versions of branded medicines. The three large PBMs appear to favor the versions with large rebates and have in some cases blocked access to the lower list priced options by

excluding them from their formularies.^{114,115} The Health and Human Services (HHS) Office of Inspector General (OIG) has indicated that PBMs may have incentives to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred cost sharing tier, both of which may result in higher costs for patients.¹¹⁶ In a recent survey, more than two thirds of biopharmaceutical company respondents indicated that they perceived list-price based fees charged by PBMs as a barrier to lowering list prices.¹¹⁷

Covering higher list price products with large rebates may financially benefit the PBM and health plan but can leave patients paying significantly more out of pocket due to benefit designs and pharmacy network arrangements established by PBMs and their vertically integrated affiliates. PBMs and health plans typically require patients with deductibles and coinsurance – who pay a percentage of the cost of their medicine rather than a fixed copayment – to pay based on the undiscounted list price. Benefit designs that incorporate high deductibles and coinsurance expose patients to high out-of-pocket costs, even though PBMs and health plans are often receiving a significant discount. This can result in patients paying more for their medicines than their health plan. For example, among drugs with high rebates, Part D beneficiary cost sharing can exceed plans' net costs.¹¹⁸ The Government Accountability Organization (GAO) found that for 79 of the top 100 highly rebated medicines in Medicare Part D, the total costs to beneficiaries exceeded the total net costs to plan sponsors by nearly 400 percent (\$21 billion vs. \$5.3 billion).¹¹⁹

In addition, slow uptake of lower cost generic and biosimilar alternatives is directly related to the ability of PBMs and their affiliated specialty pharmacies to prefer medicines with higher list prices, which can increase costs for patients.¹²⁰ For example, newly available biosimilars for a leading biologic to treat autoimmune conditions initially struggled to gain market share due to significant access restrictions imposed by the big three PBMs. Despite estimates that substituting the biosimilar would lower employer costs by 58 percent and patient costs by 68 percent, early uptake was largely concentrated among patients covered by smaller PBMs and health plans.¹²¹ According to a recent report from IQVIA, PBMs and PBM-owned specialty pharmacies have strong financial incentives to encourage uptake of the versions that are most profitable for them. IQVIA estimates that compared to utilization of the brand name biologic, a full transition to biosimilars for this autoimmune product would reduce PBM and affiliated specialty pharmacy profits by 84 percent and 78 percent, respectively.¹²²

Likely in an effort to mitigate this potential loss of profit, two of the three largest PBMs, CVS Health and Express Scripts, launched their own version of this autoimmune biosimilar in April 2024.^{123, 124} CVS Health will co-market a biosimilar through Ireland-based Cordavis,¹²⁵ a wholly owned subsidiary, and Express Scripts' biosimilar will be co-branded by Cayman Islands-based private-label distributor, Quallent Pharmaceuticals.^{126,127} These arrangements allow CVS and ESI to profit off of their referral stream. It does not appear that CVS provides any meaningful manufacturing services related to their co-branded product other than a captive referral stream. These arrangements will allow CVS and Express Scripts to profit three separate times as the medicine makes its way through the supply chain: once when the biosimilar is commercialized by their affiliate, again when the product is placed on formulary, and a third time when the prescription is filled at a pharmacy they own. This profit potential creates a clear incentive for PBMs to favor coverage of the biosimilar they have a financial stake in and to pad their own bottom lines by steering

patients to fill those prescriptions at PBM-owned pharmacies. This co-ownership structure also allows the PBMs to keep remuneration from the drug, and to keep those remuneration flows related to the drugs secret.

Having access to lower list-priced medicines could reduce out-of-pocket costs for some patients by hundreds or thousands of dollars per prescription,¹²⁸ yet PBMs often exclude generics, biosimilars, and lower list priced versions of products from their formularies.¹²⁹ One study found the availability of lower list price versions of medicines to treat high cholesterol and hepatitis C was associated with a 14 percent to 60 percent reduction in out-of-pocket costs for commercially insured patients, with the largest savings observed for patients with coinsurance.¹³⁰ PBM decisions to deny or restrict coverage for generic drugs can also undermine market forces meant to drive investment in generic manufacturing, which can create or exacerbate generic drug shortages.^{131,132}

PBMs often bill their health plan clients more than what they pay to the pharmacy for medicines and keep the difference, a practice known as spread pricing. An investigation by the *Wall Street Journal* (WSJ) revealed another way that vertically integrated PBMs profit from spread pricing: by marking up the cost of low-cost generic drugs and reimbursing their vertically integrated pharmacies significantly more than their pharmacies' acquisition cost. The WSJ investigation revealed that generic drugs dispensed by PBM-affiliated pharmacies can cost thousands of dollars more than the very same generic drugs dispensed at independent pharmacies because of this practice. Across a selection of generic drugs analyzed by the WSJ, the prices that CVS Health and Cigna/ Express Scripts charged to plan sponsors were 24 and 27 times higher, respectively, than the prices charged by the generic manufacturers themselves. For one generic cancer drug, CVS Health and Cigna/ Express Scripts reimbursed their own specialty pharmacies between \$6,600 and \$7,000 per prescription, while the same generic drug cost just \$54 at a non-affiliated pharmacy.¹³³ The potential to earn high profits on otherwise low-cost generic drugs further incentivizes vertically integrated PBMs to steer patients to their own specialty and mail order pharmacies.

Generic drugs are a central part of the cost-containment mechanism built into the prescription medicine lifecycle. Once a brand medicine's patent protection ends and generics launch, it is not unusual for the cost of treatment to decline by upwards of 90 percent.¹³⁴ Marking up the prices of generic drugs eliminates this important source of cost savings in the health care system. It can also result in significantly higher out-of-pocket costs for patients, particularly those with coinsurance or deductibles. In the case of the aforementioned generic cancer drug, a CVS Health patient with 25 percent coinsurance would be responsible for paying \$1,750 out of pocket if they filled their prescription at CVS Health's vertically integrated specialty pharmacy vs. \$13.50 at an independent pharmacy. According to one health policy expert, "Someone in the middle of that transaction is making a lot of money, and they're doing it at the detriment of the consumers."¹³⁵

Researchers estimate that misaligned PBM incentives result in U.S. consumers overpaying for generic drugs by as much as 20 percent.¹³⁶ Consequently, in 2021, 70 percent of Medicare Part D spending on 45 high-utilization generic drugs went to intermediaries' gross profit, rather than to the generic manufacturers who produced the drug.¹³⁷ These dynamics, whereby intermediaries leverage their vertically integrated relationships to absorb would-be generic manufacturer margins, have contributed to the instability in the

generics market leading to drug shortages, further throwing off the balance established under Hatch-Waxman.^{138, 139}

Hospitals and the 340B program increasingly impact patient access and affordability

Unfortunately, health plans, PBMs, large hospital systems, and others in the supply chain continue to find ways to benefit from spending on medicines to bolster their own profitability, which often negatively impacts patient access and affordability. For example, hospitals have rapidly consolidated over the past decade, buying up physician practices and merging with other hospitals. Today, nearly 90% of U.S. metropolitan areas have “highly concentrated” hospital markets.¹⁴⁰ As a result, these hospital systems can leverage their size and lack of market competition to mark up the cost of medicines by an average of 500% from what they paid to acquire the medicine.¹⁴¹ According to a study in JAMA, leading hospitals for cancer treatment mark up the cost of common cancer medicines for commercially insured patients by as much as 634%.¹⁴² Another study found that hospital outpatient departments markup physician-administered drugs by 76% compared to physician offices.¹⁴³ These trends are not only impacting patient costs, and access to treatments, but also costs for the broader health system.

Given trends towards hospital consolidation, it is not surprising that hospital spending, which represents the largest share of health spending in the U.S., continues to grow. Hospitals account for nearly a third of every dollar spent on health care,¹⁴⁴ while retail and non-retail prescription medicine spending represent just 14%.¹⁴⁵ Additionally, hospital spending increased 4.5 times more than retail prescription drug spending between 2016 and 2021.¹⁴⁶ According to CMS, hospital spending is on track to expand by around 6% per year, through at least 2031.¹⁴⁷

A central driver of hospital consolidation and increasing costs is the 340B drug pricing program. Congress created the 340B program in 1992 to provide access to discounts on outpatient medicines for certain health care safety-net providers treating large numbers of uninsured or otherwise vulnerable patients.¹⁴⁸ To achieve that goal, hospitals and clinics that meet certain eligibility criteria receive steep discounts on outpatient medicines from manufacturers. The average discount on 340B medicines is nearly 60%,¹⁴⁹ and in some cases, the discounts bring the price of a medicine down to just a penny.

The 340B program of today is unrecognizable in both character and size when compared to the targeted program Congress originally created, with more hospital conglomerates and for-profit companies using these discounts for themselves, leaving vulnerable patients behind.¹⁵⁰ For example, large hospital systems that generate significant profits 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.¹⁵¹ To make matters worse, experts note the program creates financial incentives to further consolidate and shift the administration of medicines to more costly hospital outpatient settings—which again increases costs for patients, employers, health plans and the entire health care system.^{152,153}

Purchasing dynamics associated with the 340B program also create misaligned incentives to prescribe more expensive medicines, further driving up costs for patients and payers. While eligible hospitals receive large discounts on 340B medicines, they may still be reimbursed by payers at the same rates as non-340B

providers, creating financial incentives for 340B hospitals to prescribe more and/or more expensive medicines to capture a greater “spread.”^{154,155} According to Harvard researchers, “the most insidious effect of 340B...is the incentive it gives clinics to prescribe high-cost medications, even when effective and far cheaper options exist.”¹⁵⁶ To this point, there is also evidence demonstrating the 340B program incentivizes use of more expensive medicines in the Medicare program when a lower-cost biosimilar may be available.¹⁵⁷

As a result of these trends, several reports and studies have found higher drug spending at 340B facilities for Medicare and commercially insured patients compared to non-340B sites of care.^{158,159} Additionally, MedPAC has noted that, although 340B hospitals are able to purchase outpatient medicines at a steep discount, beneficiary cost sharing in Medicare Part B is based off the default payment rate (typically, average sales price plus 6%), which leaves seniors paying higher out-of-pocket costs than they would face if Medicare paid less for 340B-discounted medicines.¹⁶⁰

For-profit pharmacies, often affiliated with large PBMs, also profit from the 340B program. However, evidence shows the 340B discounts received by these pharmacies are rarely shared with patients.¹⁶¹ 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.

Policy Proposals to Enhance Competition

PhRMA strongly supports policies that foster a robust, competitive market for generic and biosimilar medicines while providing needed incentives for continued biopharmaceutical innovation. Robust, competitive markets for generic drugs and biosimilars are critical for supporting affordable care. Prior to the passage of the IRA, the natural evolution of medicines was that, after an innovator undertook the time-consuming, uncertain, and expensive development process and obtained FDA approval, it would enjoy an appropriate period of IP protections, including both data protection and patent protections, following which generic or biosimilar versions, as appropriate, could be approved. Indeed, this is the very cycle that Hatch-Waxman and BPCIA were intended to encourage. The IRA is already significantly disrupting this cycle, reducing the incentives for the introduction of innovative therapies and disrupting the competition that results when there are multiple alternatives in a given therapeutic class. Furthermore, the increasing impact of vertical integration is hindering the ability of patients to access lower cost alternatives to brand medicines once they are available.

There are several areas where competition could be enhanced without reducing incentives for innovation, which are described below:

Address Certain Types of Patent Settlements

Congress enacted as part of the Hatch-Waxman Act a complex framework governing the timing of generic applications that respects IP and specifically contemplates patent litigation. Under the process, innovator companies are required to submit information on patents claiming the drug substance, drug product, and methods of using the drug to FDA (known as “listing”) for publication in FDA’s Orange Book. A generic applicant needs to certify with respect to listed patents whether it seeks to market its proposed generic product prior to expiration of the patent or after expiration. If it seeks to market its product prior to patent

expiration, it generally must file a “Paragraph IV certification” with FDA in which it certifies its belief that the patent is invalid or would not be infringed by the generic product, and it must notify the innovator company of that certification. The innovator company can then bring a lawsuit under a special cause of action for patent infringement that allows for litigation prior to the generic marketing its product. If the suit is brought within 45 days of the innovator receiving notice of the Paragraph IV certification, FDA cannot approve the generic application for 30 months (or sooner if the generic is successful in the litigation) so that the court can address the patent issues prior to marketing of the generic product. Hatch-Waxman also provided an incentive to generics to challenge patents under the Hatch-Waxman process in the form of 180-day generic exclusivity for the first generic to file a paragraph IV certification against later filed generic applicants.

In general, if the generic applicant wins in litigation, FDA can approve the generic product; but if the innovator wins, FDA cannot approve the generic product for marketing until patent expiration. There can be many generic challengers for individual products, so Hatch-Waxman can lead to a substantial amount of litigation. Like other patent infringement litigation, the parties may choose to settle the case, with such settlements generally leading to generic companies entering the market prior to patent expiration, and potentially prior to when they could have entered if the litigation had continued. Settling such litigation is not surprising given the burden of litigation and the uncertainty for both innovators and generics.

The FTC and some other stakeholders have asserted that there are anticompetitive settlements in which innovator companies have provided cash payments and generic companies have delayed marketing their products. Under the 2013 Supreme Court decision in *FTC v. Actavis*, the FTC can seek to enforce the existing law against patent settlements with cash payments under the “rule of reason” standard, which is a legal standard involving a fact-based inquiry. The FTC has asserted a broader view, and there is legislation pending that would create a presumption that certain agreements are anticompetitive. There have also been bills introduced in several states, and California has passed restrictive legislation.

PhRMA supports addressing patent settlements with federal legislation to ensure generic, biosimilar and innovator companies can resolve patent litigation and allow generic and biosimilar medicines to enter the market prior to expiration of innovators’ patents, without applying new policies retroactively to previous agreements or restricting companies’ ability to enter into pro-competitive agreements in the future. We are committed to working with the Committee to address concerns in this area and promote competition.

Advance a Balanced Approach to Addressing Product Hopping

There have been situations in which companies have been held liable after taking steps in conjunction with the introduction of new versions of products that were found to be anticompetitive. Legislation is pending that would create a presumption of anticompetitive effect in situations defined as “hard switches” or “soft switches.” A “soft switch” as defined in the legislation, for instance, can include situations in which a company develops a new product and takes actions that may “unfairly disadvantage” the earlier version of the product, even though that earlier version is still marketed. The legislation, however, gives little guidance on what activities could constitute “unfairly disadvantaging” the earlier product. This could put a cloud over many types of innovations after an original FDA approval that render a medicine safer or more effective or improve patient care or quality of life. If Congress acts, it should do so in a balanced way that supports

continued improvement to medicines that bring new benefits for patients, while addressing potential anticompetitive behavior.

Ensure the Patent System Continues to Provide Certainty to Investors and Innovators

As noted above, the IP system is a fundamental incentive to innovate. When making long-term decisions about investments in R&D, companies look for certainty, including with respect to the availability of IP protections that would protect the investments. PhRMA is pleased to see the Committee engaging on ways to ensure that the U.S. patent system continues to incentivize innovation and provide certainty to investors and innovators across sectors including with respect to providing clarity for patent owners on patent subject matter eligibility and Patent Trial and Appeal Board proceedings.

Ensure That Agencies Treat Information Shared Amongst Them with Proper Confidentiality Considerations

There have been discussions and legislation proposed about requiring enhanced collaboration between the USPTO and FDA. Data have not been presented suggesting there is a systemic issue warranting such legislation. There are also fundamental differences in how the agencies treat information provided to them, as the USPTO generally publishes information it receives after a period of time and FDA protects the highly sensitive trade secret information it requires about products. Any requirement to share such information with the USPTO would need to address fully confidentiality considerations.

Break the Link Between PBM Compensation and the Price of Medicines

To the extent that PBMs provide services to stakeholders in the pharmaceutical supply chain, they should be entitled to compensation based on the value of those services. However, PBM compensation should not be tied to the price of a medicine. PhRMA supports efforts in the both the House and the Senate to “delink” PBM compensation from the price of a medicine in both the commercial and Part D markets and instead limit PBM compensation to bona fide service fees based on the fair market value of services appropriately rendered for a manufacturer.¹⁶² Multiple bills that would accomplish this goal are currently under consideration by Congress, including the Modernizing and Ensuring PBM Accountability Act (S.2973) and the Delinking Revenue from Unfair Gouging Act (DRUG) Act (H.R. 6283).^{163,164,165,166} The Congressional Budget Office (CBO) has projected that delinking in both the Part D and commercial market would reduce federal spending.^{167,168}

Rebate Pass Through at the Point-of-Sale

Requiring PBMs and health plans to share the savings they receive on medicines directly with patients at the pharmacy counter in the commercial market and Medicare Part D would lower patient out-of-pocket costs and help realign payer incentives. Patients who take brand medicines with large rebates could see sizable reductions in out-of-pocket costs if the rebates were passed on to them at the pharmacy counter.¹⁶⁹ Actuaries estimate that sharing negotiated rebates directly with patients at the point-of-sale would have a negligible impact on premiums.¹⁷⁰ The substantial savings for patients at the pharmacy counter would outweigh those premium increases and provide patients with increased access and affordability for often lifesaving medicines.

PBM Transparency

Lack of transparency and the complexity of PBM arrangements can make it difficult for plan sponsors to assess PBM performance on their behalf. Requiring PBMs (and their affiliates) to report aggregate information on prescription drug utilization, costs, rebates, and fees, as well as conflicts of interest would provide information necessary for employers and plan sponsors to properly evaluate whether PBMs are effectively managing the pharmaceutical benefit and would help ensure accountability to PBM customers.¹⁷¹ According to CBO, proposed federal legislation that would require PBMs to disclose detailed aggregate information on prescription medicine spending and utilization to plan sponsors could enable employers and plan sponsors to better evaluate PBM contract provisions and obtain more favorable contracting terms, as well as increase competition among PBMs.^{172,173,174} Improved transparency into PBMs' business model, including existing conflicts of interest, would provide valuable information to federal and state policymakers, employers, and patients.

Protect Patient Assistance

Policymakers should ensure that patient assistance benefits patients by closing policy loopholes that allow PBMs, their affiliates, and other vendors to utilize accumulator adjustment programs (AAPs), copay maximizers, and alternative funding programs to capture money intended for patients. The bipartisan Help Ensure Lower Patient (HELP) Copays Act would require commercial health plans to count patient assistance towards deductibles, coinsurance, copayments and out-of-pocket limits. This patient-centered reform would protect patients' choices about how they pay their cost-sharing obligations, effectively prohibiting the use of AAPs in all non-grandfathered commercial health plans and mitigating copay maximizers. The bill builds on action taken by 19 states, DC, and Puerto Rico that have already passed AAP bans in their state-regulated markets.¹⁷⁵

Address the "Pill Penalty"

Rectify the disparate treatment of small molecule medicines under the IRA by aligning the price setting timeline for small molecule medicines with those applicable to other drugs under the IRA's Medicare Drug Price Negotiation Program.

Fix the "Special Rule" for Biosimilars in the IRA

Ensure that biosimilar products that are seeking to come to market have adequate certainty and predictability under the "Special Rule" process to allow the necessary time to launch. Improvements should include making the pause automatic in certain circumstances, making the pause two years long, and providing a more appropriate timeframe for product launch.

As the Committee considers policy solutions, we urge the Committee to avoid broad policies that would chill innovation, destabilize important incentives for research and development of new medicines, and negatively impact patient access to innovative therapies and cures. Instead of focusing on proposals that undermine the

competitive marketplace for medicines and incentives for innovation, we encourage a focus on addressing market distortions and pragmatic solutions. PhRMA appreciates the opportunity to testify and looks forward to continuing to engage with the Committee on these critically important issues.

¹ PhRMA, 2023 PhRMA Annual Membership Survey, 2023, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.

² PhRMA analysis of NIH grant data.

³ Research!America, U.S. Investments in Medical and Health Research and Development 2016 – 2020. January 2022.

⁴ Schlander, M., Hernandez-Villafuerte, K., Cheng, CY. et al. How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment. *Pharmacoeconomics* 39, 1243–1269, 2021. <https://doi.org/10.1007/s40273-021-01065-y>

⁵ JA DiMasi, Grabowski, RW Hansen. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* 2016;47:20-33. <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub>.

⁶ US Food and Drug Administration. Summary of NDA Approvals & Receipts, 1938 to the Present. <https://www.fda.gov/about-fda/histories-fda-regulated-products/summary-nda-approvals-receipts-1938-present>.

⁷ US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2012 – 2014. <http://wayback.archive-it.org/7993/20161022052126/http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm>.

⁸ US Food and Drug Administration: Novel Drug Approvals for 2022. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022>.

⁹ US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2015 – 2021. <https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products>.

¹⁰ Congressional Budget Office. Prescription Drugs: Spending, Use, and Prices. January 2022. <https://www.cbo.gov/publication/57772>.

¹¹ IQVIA. The Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028. April 2024. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2024/the-use-of-medicines-in-the-us-2024-usage-and-spending-trends-and-outlook-to-2028.pdf>.

¹² Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.

¹³ Altarum Institute. Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. July 2022. <https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf>.

¹⁴ For example, the price of a medicine commonly used to prevent cardiovascular disease dropped 95% between 2007 and 2017, while the average charge for a surgical procedure to treat it increased 94% over the same period. PhRMA analysis of Healthcare Cost and Utilization Project (HCUP). National (Nationwide) Inpatient Sample (NIS) database. 2007, 2017. Accessed July 2020. <https://www.ahrq.gov/research/data/hcup/index.html>.

¹⁵ Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023.

¹⁶ 84 Fed. Reg. at 2341.

¹⁷ Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. September 2023. <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>.

¹⁸ Biosimilars Council, Humira Biosimilar Landscape: Still Waiting, January 2024. <https://biosimilarscouncil.org/resource/humira-biosimilar-landscape-still-waiting>.

¹⁹ TEconomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. May 2024. Report prepared for PhRMA. <https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf>

²⁰ Adis R&D Insight Database.

²¹ Battelle Technology Partnership Practice, The Economic Impact of the Biopharmaceutical Industry, July 2013.

²² TEconomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. May 2024. Report prepared for PhRMA. <https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf>

²³ *Ibid.*

²⁴ von Krogh, G, et al., “The Changing Face of Corporate Venturing in Biotechnology,” *Nature Biotechnology* 30, no. 10 (2012): 911-15.

-
- ²⁵ TEconomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. May 2024. Report prepared for PhRMA. <https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf>
- ²⁶ Patent and Trademark Office Director Andrei Iancu, 2018, Public Remarks, “The State of Care: Innovation and Access,” July 2018.
- ²⁷ See 35 U.S.C. 271(e)(1).
- ²⁸ Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984)
- ²⁹ Grabowski H et al. Continuing trends in U.S. brand-name and generic drug competition. *J Med Economics* 2021;24(1):908-917.
- ³⁰ *Ibid.*
- ³¹ Cencora. US Biosimilars Landscape, Updated as of March 2024. <https://www.amerisourcebergen.com/-/media/assets/cencora-biosimilars-usmarketlandscape-11mar24.pdf>.
- ³² Association for Accessible Medicines. 2023 U.S. Generic and Biosimilar Medicines Savings Report, September 2023. <https://accessiblemeds.org/resources/reports/2023-savings-report>
- ³³ 35 U.S.C. § 156(c)(3). See H.R. Rep. No. 98-857, at 17 (1984); 130 Cong. Rec. 23,058 (1984) (statement of Rep. Synar) (“The average effective patent life of a pioneer drug is reduced by 7 years because of FDA review”); *id.* at 23,059 (statement of Rep. Kastenmeier) (noting that “the effective market life of [innovators’] patented inventions was being eroded by excessively long periods of regulatory review”).
- ³⁴ H.R. Rep. No. 98-857, at 41 (1984).
- ³⁵ 130 Cong. Rec. 23,060 (statement of Rep. Kastenmeier).
- ³⁶ Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.
- ³⁷ Zachary S. Predmore, et al., Improving Antipsychotic Adherence Among Patients With Schizophrenia: Savings for States, 66 *Psychiatric Services in Advance* 343 (2015).
- ³⁸ Rimal Bera, et al., Hospitalization Resource Utilization and Costs Among Medicaid Insured Patients With Schizophrenia With Different Treatment Durations of Long-Acting Injectable Antipsychotic Therapy, 34 *Journal of Clinical Psychopharmacology*, 30, 2014.
- ³⁹ Government Accountability Office (GAO). Information on the Government’s Right to Assert Ownership Control Over Federally Funded Inventions, 2009. Available at: www.gao.gov/products/GAO-09-742.
- ⁴⁰ Wendy H. Schacht, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*, Report RL32324 (Congressional Research Service), November 30, 2012.
- ⁴¹ PhRMA. 2023 PhRMA Annual Membership Survey, July 2023. <https://phrma.org/resource-center/Topics/Research-and-Development/2023-PhRMA-Annual-Membership-Survey>.
- ⁴² See Pierre Azoulay and others, “Public R&D Investments and Private-Sector Patenting: Evidence From NIH Funding Rules,” *Review of Economic Studies*, vol. 86, no. 1 (January 2019), pp. 117–15. Available at: <https://academic.oup.com/restud/article/86/1/117/5038510?login=true>.
- ⁴³ The National Institutes of Health (NIH), The NIH and Its Role in Technology Transfer, <https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer>. NIH, The NIH and Its Role in Technology Transfer, <https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer>.
- ⁴⁴ The Congressional Budget Office, Research and Development in the Pharmaceutical Industry, April 2021. <https://www.cbo.gov/publication/57126>.
- ⁴⁵ Department of Health and Human Services (DHHS), NIH. (2001). Report to the United States Congress, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers’ Interests are Protected. July 2001.
- ⁴⁶ Kneller, R., The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs. *Nature Reviews/Drug Discovery*, 9, 867-82, 2010.
- ⁴⁷ Chakravarthy R, Cotter K, DiMasi J, et al. Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years: from theory to therapy. *Ther Innov Regul Sci*. 2016;50(6):759-768.
- ⁴⁸ Galkina Cleary, E., Beierlein, J. M., Khanuja, N. S., McNamee, L. M., & Ledley, F. D. (2018). Contribution of NIH funding to new drug approvals 2010-2016. *Proceedings of the National Academy of Sciences of the United States of America*, 115(10), 2329–2334. <https://doi.org/10.1073/pnas.1715368115>.
- ⁴⁹ D. Schulthess et al, The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals, September 2023, <https://vitaltransformation.com/2022/09/the-relative-contributions-of-nih-and-private-sector-funding-to-the-approval-of-new-biopharmaceuticals/>.
- ⁵⁰ NIH, Licensing Overview, <https://www.techtransfer.nih.gov/licensing>.
- ⁵¹ JA DiMasi, Grabowski, RW Hansen. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ*. 2016;47:20-33.
- ⁵² Thomas, J. March-In Rights Under the Bayh-Dole Act. CRS, 2016. Available at: <https://fas.org/sgp/crs/misc/R44597.pdf>.

-
- ⁵³ NIH. NIH Office of the Director: Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation, 2010. Available at: <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf>.
- ⁵⁴ NIH. Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development, December 1994. Available from: [https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH %20CRADA Report on Reasonable-Pricing Clause 1994.pdf](https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH%20CRADA%20Report%20on%20Reasonable-Pricing%20Clause%201994.pdf)
- ⁵⁵ Press Release, NIH News, April 11, 1995. Available from: <https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf>.
- ⁵⁶ <https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf>
- ⁵⁷ Bayh, B. and Dole, R. Our Law Helps Patients Get New Drugs Sooner. *Washington Post* op-ed, 2011. Available at: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=sr_1.
- ⁵⁸ Siegel, RL, Miller, KD, Wagle, NS, Jemal, A. Cancer statistics, 2023. *CA Cancer J Clin.* 2023; 73(1): 17-48. doi:[10.3322/caac.21763](https://doi.org/10.3322/caac.21763).
- ⁵⁹ CDC, NCHS, Deaths: Final Data for 2007. Vol. 58, #19, May 2010. https://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf; CDC, NCHS, Deaths: final data for 2019. *Natl Vital Stat Rep.* 2021;70(8):1-87. Accessed July 2022. <https://www.cdc.gov/nchs/data/nvsr/nvsr70/nvsr70-08-508.pdf>.
- ⁶⁰ Altarum Institute. Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. July 2022. <https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf>.
- ⁶¹ MC Roebuck et al. Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending. *Health Aff* 30 no. 1 (2011): 91-9.
- ⁶² Urick, B. Y., et al. (2023). Estimating Medical Cost Offsets from Continuous Adherence Improvement Using Commercially Insured Members' Real-World Data. In AMCP Conference. https://www.primetherapeutics.com/wp-content/uploads/2023/02/4085-C-AMCP_SP23_AdherenceImprovement_POSTER.pdf.
- ⁶³ TM Dall et al. The Economic Impact of Medicare Part D Coverage on Congestive Heart Failure. *AJMC*, 2013;19:S97-S100
- ⁶⁴ Stuart, B. C., Dai, M., Xu, J., E Loh, F. H., & S Dougherty, J. (2015). Does good medication adherence really save payers money?. *Medical care*, 53(6), 517-523.
- ⁶⁵ Lloyd, JT., et al. How much does medication nonadherence cost the medicare fee-for-service program? *Medical care* 57.3 (2019): 218-224.
- ⁶⁶ MC Roebuck, et al. Impact of Medication Adherence on Health Services Utilization in Medicaid. *Medical care* 56.3 (2018): 266-273
- ⁶⁷ Pilon, D. P., C.; Lafeuille, M.; Zhdanava, M.; Lin, D.; Cote-Sergent, A.; Rossi, C.; Lefebvre, P.; Joshi, K (2021). Economic burden in Medicaid beneficiaries with recently relapsed schizophrenia or with uncontrolled symptoms of schizophrenia not adherent to antipsychotics. In *Journal of Managed Care and Specialty Pharmacy* (Vol. 27, pp. 904-914).
- ⁶⁸ G Rust, et al. Potential Savings from Increasing Adherence to Inhaled Corticosteroid Therapy in Medicaid-Enrolled Children. *AJMC* 2015 March 21(3):173-180
- ⁶⁹ YJ Wei, et al. Antiparkinson Drug Adherence and Its Association with Health Care Utilization and Economic Outcomes in a Medicare Part D Population. *Value in Health* 2014 17(2), 196-204.
- ⁷⁰ BG Feagan, et al. Healthcare Costs for Crohn's Disease Patients Treated with Infliximab: A propensity Weighted Comparison of the Effects of Treatment Adherence. *J Med Econ.* 2014;17(12):872-80.
- ⁷¹ AL Quittner et al., Pulmonary Medication Adherence and Health-Care Use in Cystic Fibrosis. *CHEST Journal* 2014, 146(1), 142-151.
- ⁷² Zhou, J. W., E.; Hira, N. (2022). Adherence to Cystic Fibrosis Transmembrane Regulator Modulator Therapies, Hospitalizations, and Medical Costs in Patients with Cystic Fibrosis Using MarketScan Commercial Claims and Encounters Database. In ISPOR Conference.
- ⁷³ K Gupte-Singh, et al. Adherence to Cancer Therapies and the Impact on Healthcare Costs among Patients with Advanced melanoma in the USA. *Proceedings of the 22nd Annual International Meeting International Society of Pharmacoeconomics and Outcomes Research*; 2017 May.
- ⁷⁴ DM Cutler, K Ghosh, KL Messer, TE, Raghunathan, ST Stewart, and AB Rosen, [Explaining the Slowdown in Medical Spending Growth Among the Elderly](#), Health Affairs, February 2019.
- ⁷⁵ Buttorff C, Ruder T, Bauman M. [Multiple Chronic Conditions in the United States](#). Rand Corporation, 2017.
- ⁷⁶ Centers for Disease Control and Prevention. Health and economic costs of chronic diseases. Published June 6, 2022. Accessed July 6, 2022. <https://www.cdc.gov/chronicdisease/about/costs/index.htm>
- ⁷⁷ Buttorff C, Ruder T, Bauman M. [Multiple Chronic Conditions in the United States](#). Rand Corporation, 2017; [National Health Expenditure Data: Historical](#). Center for Medicare & Medicaid Services. December 15, 2021.
- ⁷⁸ Partnership to Fight Chronic Disease (PFCDD). [What is the Impact of Chronic Disease on America?](#)

- ⁷⁹ M Viswanathan et al. [Interventions to Improve Adherence to Self-Administered Medications for Chronic Diseases in the United States: A Systemic Review](#). *Ann of Internal Med*, Dec 2012.
- ⁸⁰ Mehta KM, Yin M, Resendez C, Yaffe K. Ethnic differences in acetylcholinesterase inhibitor use for Alzheimer disease. *Neurology*. 2005 Jul 12;65(1):159-62. doi: 10.1212/01.wnl.0000167545.38161.48. PMID: 16009909; PMCID: PMC2830864.
- ⁸¹ Lauffenburger JC, Robinson JG, Oramasionwu C, Fang G. Racial/ethnic and gender gaps in the use of and adherence to evidence-based preventive therapies among elderly Medicare part D beneficiaries after acute myocardial infarction. *Circulation*. 2014; 129:754–763.
- ⁸² Schmittiel JA, Steiner JF, Adams AS, et al. Diabetes care and outcomes for American Indians and Alaska natives in commercial integrated delivery systems: a Surveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM) Study. *BMJ Open Diabetes Res Care*. 2014;2(1):e000043. Published 2014 Nov 17. doi:10.1136/bmjdr-2014-000043
- ⁸³ Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care*. 2005 Jun;43(6):521-30. doi: 10.1097/01.mlr.0000163641.86870.af. PMID: 15908846.
- ⁸⁴ Bansilal S, Castellano JM, Garrido E, Wei HG, Freeman A, Spettell C, Garcia-Alonso F, Lizano I, Arnold RJ, Rajda J, Steinberg G, Fuster V. Assessing the Impact of Medication Adherence on Long-Term Cardiovascular Outcomes. *J Am Coll Cardiol*. 2016 Aug 23;68(8):789-801. doi: 10.1016/j.jacc.2016.06.005. PMID: 27539170.
- ⁸⁵ Choudhry NK, Glynn RJ, Avorn J, Lee JL, Brennan TA, Reisman L, Toscano M, Levin R, Matlin OS, Antman EM, Shrank WH. Untangling the relationship between medication adherence and post-myocardial infarction outcomes: medication adherence and clinical outcomes. *Am Heart J*. 2014 Jan;167(1):51-58.e5. doi: 10.1016/j.ahj.2013.09.014. Epub 2013 Oct 17. PMID: 24332142.
- ⁸⁶ Khunti K, Seidu S, Kunutsor S, Davies M. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. *Diabetes Care*. 2017 Nov;40(11):1588-1596. doi: 10.2337/dc16-1925. Epub 2017 Aug 11. PMID: 28801474.
- ⁸⁷ TJ Philipson, G Di Cera, Issue Brief: The Impact of Biopharmaceutical Innovation on Health Care Spending. <https://ecchc.economics.uchicago.edu/2022/08/03/the-impact-of-biopharmaceutical-innovation-on-health-care-spending>.
- ⁸⁸ TJ Philipson, Y Ling, R Chang, The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act, October 2023, <https://ecchc.economics.uchicago.edu/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf>.
- ⁸⁹ TJ Philipson, Y Ling, R Chang, The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act, October 2023, <https://ecchc.economics.uchicago.edu/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf>.
- ⁹⁰ PhRMA, Emerging Value in Oncology, How Ongoing Research Expands the Benefits of Oncology Medicines, July 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_Emerging-Value-Report/PhRMA_Emerging-Value-Report_FIN-web_July2023_v2.pdf.
- ⁹¹ Partnership for Health Analytic Research, Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines, June 2023. <https://www.pharllc.com/publication/implications-of-the-ira-price-setting-provisions-on-post-approval-indications-for-small-molecule-medicines>.
- ⁹² PhRMA, Small Molecule Medicines: Why They're Vital for Patients, 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/S-U/Pharma_Small-Molecule_White_Paper_factsheet_042623_v5.pdf.
- ⁹³ PhRMA, Small Molecule Medicines: Why They're Vital for Patients, 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/S-U/Pharma_Small-Molecule_White_Paper_factsheet_042623_v5.pdf.
- ⁹⁴ Grabowski H, Long G, Mortimer R, Bilginsoy M. Continuing trends in U.S. brand-name and generic drug competition. *J Med Econ*. 2021 Jan-Dec;24(1):908-917.
- ⁹⁵ AAM, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023. <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>
- ⁹⁶ Blackstone EA, Joseph PF. The economics of biosimilars. *Am Health Drug Benefits*. 2013 Sep;6(8):469-78.
- ⁹⁷ HHS, HHS Selects the First Drugs for Medicare Drug Price Negotiation, September 2023. <https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html>.
- ⁹⁸ Analysis based on publicly available information at FDA Orange Book and Purple Book and press sources. Additional generic applications may be pending with FDA beyond the 3 noted.
- ⁹⁹ AAM, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023. <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>.
- ¹⁰⁰ Herman B. FTC may probe pharmacy benefit managers. *Axios*, February 2022. <https://www.axios.com/ftc-study-pharmacy-benefit-managers-drug-prices-3078116f-382a-4b05-ac62-da5bc1d1b892.html>.
- ¹⁰¹ Top 50 PBM Companies and Market Share by Annual Prescription Volume (Second Quarter 2010). *Drug Benefit News*, April 2010.
- ¹⁰² Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute*, March 2024.

-
- ¹⁰³ *Ibid.*
- ¹⁰⁴ Guardado J. Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update. American Medical Association, 2023. <https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf>.
- ¹⁰⁵ Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute*, March 2024.
- ¹⁰⁶ Levitt JE, Lee DY. Cautionary tale: Plan sponsors losing manufacturer rebate dollars to PBMs through rebate aggregators. *BenefitsPRO*. April 2021. <https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators>.
- ¹⁰⁷ PBM Accountability Project. Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers, December 2021. https://www.pbmaccountability.org/files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true.
- ¹⁰⁸ Potter W. Big Insurance Earnings Report Analysis 2023, April 2024. <https://wendellpotter.substack.com/p/big-insurance-2023-revenues-reached>.
- ¹⁰⁹ *Ibid.*
- ¹¹⁰ 84 Fed. Reg. at 2341.; Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. Chapter 13: The Medicare Prescription Drug Program (Part D): Status Report, March 2021. <https://www.medpac.gov/document/chapter-13-the-medicare-prescription-drug-program-part-d-status-report-march-2021-report>.
- ¹¹¹ Sood N, Ribero R, Van Nuys K. The Association Between Drug Rebates and List Prices. USC Schaeffer White Paper, February 2020. <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices>.
- ¹¹² Senate Finance Committee. Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug. 2021. <https://www.finance.senate.gov/imo/media/doc/Insulin%20Exhibit%20List.pdf>.
- ¹¹³ Kansteiner F. Viartis launched 2 version of its interchangeable insulin biosimilar. Why? Fierce Pharma, November 2021. <https://www.fiercepharma.com/pharma/viartis-launches-two-versions-its-interchangeable-biosimilar-semglee-bid-to-tackle-pricing>.
- ¹¹⁴ Fein AJ. Four Crucial Questions About the Humira Biosimilar Price War. *Drug Channels Institute*, July 2023. <https://www.drugchannels.net/2023/07/four-crucial-questions-about-humira.html>.
- ¹¹⁵ Fein AJ. The Big Three PBMs' 2023 Formulary Exclusions: Observations on Insulin, Humira, and Biosimilars. *Drug Channels Institute*, January 2023. <https://www.drugchannels.net/2023/01/the-big-three-pbms-2023-formulary.html>.
- ¹¹⁶ Health and Human Services Office of Inspector General. Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. 84 Fed. Reg. 2340 (November 20, 2020). <https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.
- ¹¹⁷ Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. *Nephron Research*. September 2023. <https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities>.
- ¹¹⁸ Hayes T, Schmidt R, Suzuki S. Assessing Postsale Rebates for Prescription Drugs in Medicare Part D. *MedPAC*, 2023. <https://www.medpac.gov/wp-content/uploads/2022/07/Tab-F-DIR-data-April-2023-SEC.pdf>.
- ¹¹⁹ Government Accountability Office. Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, September 2023. <https://www.gao.gov/products/gao-23-105270>.
- ¹²⁰ IQVIA. Adalimumab Biosimilar Tracking. *Biosimilar Council*, April 2024. https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf.
- ¹²¹ *Ibid.*
- ¹²² *Ibid.*
- ¹²³ David Wainer. "Coming to a CVS Near You: A Store Brand Monoclonal Antibody," *Wall Street Journal*. April 29, 2024. <https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182>.
- ¹²⁴ Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." *Drug Channels*. September 6, 2023. <https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html>.
- ¹²⁵ Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." *Drug Channels*. September 6, 2023. <https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html>.
- ¹²⁶ David Wainer. "Coming to a CVS Near You: A Store Brand Monoclonal Antibody," *Wall Street Journal*. April 29, 2024. <https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182>.
- ¹²⁷ Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." *Drug Channels*. September 6, 2023. <https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html>.
- ¹²⁸ Xcenda. Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access. September 2020. <https://www.xcenda.com/insights/skyrocketing-growth-in-pbm-formulary-exclusions-raises-concerns-about-patient-access>.
- ¹²⁹ *Ibid.*

- ¹³⁰ Wong WB, Seetasith A, Hung A, Zullig LL. Impact of list price changes on out-of-pocket costs and adherence in four high-rebate specialty drugs. *PLoS One*. 2023 Jan 19;18(1):e0280570. doi: 10.1371/journal.pone.0280570.
- ¹³¹ GAO. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, February 2014. <https://www.gao.gov/assets/d14194.pdf>.
- ¹³² FDA. Drug Shortages: Root Causes and Potential Solutions, February 2020. <https://www.fda.gov/media/131130/download>.
- ¹³³ Walker J. Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. *Wall Street Journal*, September 2023. <https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-e13d055>.
- ¹³⁴ Conrad R, Lutter R. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. US Food and Drug Administration, December 2019. <https://www.fda.gov/media/133509/download>.
- ¹³⁵ Walker J. Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. *Wall Street Journal*, September 2023. <https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-e13d055>.
- ¹³⁶ Trish E, Van Nuys K, Popovian R. U.S. Consumers Overpay for Generic Drugs. *USC Schaeffer*, May 2022. <https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/>.
- ¹³⁷ Mattingly TJ 2nd, Ben-Umeh KC, Bai G, Anderson GF. Pharmacy Benefit Manager Pricing and Spread Pricing for High-Utilization Generic Drugs. *JAMA Health Forum*. 2023 Oct 6;4(10):e233660. doi: 10.1001/jamahealthforum.2023.3660.
- ¹³⁸ GAO. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, February 2014. <https://www.gao.gov/assets/d14194.pdf>.
- ¹³⁹ FDA. Drug Shortages: Root Causes and Potential Solutions, February 2020. <https://www.fda.gov/media/131130/download>.
- ¹⁴⁰ Highly concentrated as defined by the Department of Justice and Federal Trade Commission Horizontal Merger Guidelines. <https://www.justice.gov/atr/horizontal-merger-guidelines-08192010>;
https://www.finance.senate.gov/imo/media/doc/20230605_sfc_testimony.pdf.
- ¹⁴¹ Moran, Hospital Charges and Reimbursement for Medicines: 2023 Update Analysis of Markups Relative to Acquisition Costs. August 2023. <https://themoracompany.com/wp-content/uploads/2023/08/PhRMA-Hospital-Charges-Report-August-2023.pdf>.
- ¹⁴² Xiao R, Ross JS, Gross CP, et al. Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance. *JAMA Intern Med*. 2022;182(6):603–611. doi:10.1001/jamainternmed.2022.1022. <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2791386>.
- ¹⁴³ EBRI, Cost Differences for Physician-Administered Outpatient Drugs by Site of Treatment: State and Metropolitan Statistical Areas Variation, May 25, 2023. [https://www.ebri.org/docs/default-source/fast-facts-\(public\)/ff-469-costdifferences-25may23.pdf?sfvrsn=3ff8392f_2](https://www.ebri.org/docs/default-source/fast-facts-(public)/ff-469-costdifferences-25may23.pdf?sfvrsn=3ff8392f_2).
- ¹⁴⁴ CMS. National Health Expenditure Historical Data. Released Dec 2022.
- ¹⁴⁵ Altarum. “Projections of the Non-retail Prescription Drug Share of National Health Expenditures.” July 2022
- ¹⁴⁶ CMS. National Health Expenditure Historical Data. Released Dec 2022.
- ¹⁴⁷ CMS. National Health Expenditures Projections 2022 – 2031. Released Jun 2023. <https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf>.
- ¹⁴⁸ See 42 U.S.C. § 256b (the “340B statute”).
- ¹⁴⁹ Brownlee A, Watson J. “The Pharmaceutical Supply Chain, 2013-2020.” Berkeley Research Group, January 2022. <https://ecomunications.thinkbrg.com/44/2328/uploads/brg-pharmaceutical-supply-chain-2022.pdf?intlaContactId=IXKabwLWBtOm%2fz%2fpgW%2btPQ%3d%3d&intExternalSystemId=1>.
- ¹⁵⁰ A Fein, [The 340B Program Climbed to \\$44 Billion in 2021—With Hospitals Grabbing Most of the Money](#), August 2022
- ¹⁵¹ K Thomas, J Silver-Greenberg, [How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits](#), New York Times, September 2022.
- ¹⁵² S. Desai and J.M. McWilliams, “[Consequences of the 340B Drug Pricing Program](#),” *N Engl J Med* 2018.
- ¹⁵³ Gaynor, M “[Antitrust Applied: Hospital Consolidation Concerns and Solutions Statement before the Committee on the Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights U.S. Senate](#)” May 2021.
- ¹⁵⁴ Conti, Rena M., and Peter B. Bach., Cost Consequences of the 340B Drug Discount Program, *Journal of the American Medical Association*, May 15, 2013, <https://jamanetwork.com/journals/jama/article-abstract/1680369>.
- ¹⁵⁵ Desai, Sunita, and J. Michael McWilliams, [Consequences of the 340B Drug Pricing Program](#), *New England Journal of Medicine*, Feb. 8, 2018,
- ¹⁵⁶ Marcus JL, et al., Perverse Incentives — HIV Prevention and the 340B Drug Pricing Program, *New England Journal of Medicine*, Jun 2, 2022, <https://www.nejm.org/doi/full/10.1056/NEJMp2200601>.
- ¹⁵⁷ Bond, Amelia M., Emma B. Dean, and Sunita M. Desai, The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program, *Health Affairs* May 1, 2023, <https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00812>.

-
- ¹⁵⁸ GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, Jun. 2015, <https://www.gao.gov/products/gao-15-442>.
- ¹⁵⁹ Hunter MT, et al., Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals, Milliman, Sept. 2022, https://www.milliman.com/-/media/milliman/pdfs/2022-articles/9-13-22_phrma-340b-commercial-analysis.ashx.
- ¹⁶⁰ MedPAC, Report to Congress: Medicare and the Health Care Delivery System, Jun. 2015, <https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-chapter-3-part-b-drug-payment-policy-issues-june-2015-report-pdf>.
- ¹⁶¹ IQVIA White Paper. Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies? October 2022
- ¹⁶² United States, Congress, Senate Finance. Business meeting to consider an original bill entitled, "Modernizing and Ensuring PBM Accountability (MEPA) Act". Congress.gov, <https://www.congress.gov/event/118th-congress/senate-event/334680?s=1&r=29>. 118th Congress, Senate Committee Meeting, 26 Jul. 2023.
- ¹⁶³ United States, Congress, House. Protecting Patients Against PBM Abuses Act. Congress.gov, <https://www.congress.gov/bill/118th-congress/house-bill/2880>. 118th Congress, House Resolution 2880, Introduced 26 April 2023.
- ¹⁶⁴ United States, Congress, Senate. Modernizing and Ensuring PBM Accountability Act. Congress.gov, <https://www.congress.gov/bill/118th-congress/senate-bill/2973>. 118th Congress, Senate Bill 2973, Introduced 28 Sep. 2023.
- ¹⁶⁵ United States, Congress, Senate. DRUG Act. Congress.gov, <https://www.congress.gov/bill/118th-congress/senate-bill/1542>. 118th Congress, Senate Bill 1542, Introduced 10 May 2023.
- ¹⁶⁶ United States, Congress, House. DRUG Act. Congress.gov, <https://www.congress.gov/bill/118th-congress/house-bill/6283>. 118th Congress, House Resolution 6283, Introduced 08 Nov. 2023.
- ¹⁶⁷ Congressional Budget Office. Health Care Legislation As ordered reported by the House Committee on Energy and Commerce on December 6, 2023. March 2024. <https://www.cbo.gov/system/files/2024-03/hr4881.pdf>.
- ¹⁶⁸ Wanneh G. Senate Finance Passes Extra Policies To Build On MEPA PBM Bill. Inside Health Policy, November 2023. <https://insidehealthpolicy.com/daily-news/senate-finance-passes-extra-policies-build-mepa-pbm-bill>.
- ¹⁶⁹ Department of Health and Human Services Office of Inspector General. Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Final Rule. November 30, 2020. <https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.
- ¹⁷⁰ Milliman. Measuring the Impact of Point of Sale Rebates on the Commercial Health Insurance Market, July 2021. <https://www.milliman.com/en/insight/measuring-the-impact-of-point-of-sale-rebates-on-the-commercial-health-insurance-market>.
- ¹⁷¹ Advisory Council on Employee Welfare and Pension Plan Benefits. Report to the Honorable Thomas E. Perez, United States Secretary of Labor: PBM Compensation And Fee Disclosure. 2014. <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf>.
- ¹⁷² Congressional Budget Office. Cost Estimate: Estimated Direct Spending and Revenue Effects of H.R. 5378, the Lower Costs, More Transparency Act. December 8, 2023. https://www.cbo.gov/system/files/2023-12/hr5378-DS-and-Revs_12-2023.pdf.
- ¹⁷³ Congressional Budget Office. Cost Estimate: S.1895, Lower Health Care Costs Act. July 16, 2019. https://www.cbo.gov/system/files/2019-07/s1895_0.pdf.
- ¹⁷⁴ CBO has continued to recognize savings from PBM transparency proposals. For example, see: <https://www.cbo.gov/system/files/2022-06/hr7666.pdf>.
- ¹⁷⁵ Avalere. Cort Ruling Will Limit Accumulators. October 2023. <https://avalere.com/insights/court-ruling-will-limit-accumulators>.