Testimony of Lori M. Reilly, Esq. Chief Operating Officer

Pharmaceutical Research and Manufacturers of America

Before the House Committee on Energy and Commerce

Subcommittee on Health

February 11, 2026

Chairman Griffith, Ranking Member DeGette, and Members of the Subcommittee, thank you for inviting me to participate in today's hearing. As the Subcommittee works to make health care more affordable, examining the role of the pharmaceutical supply chain, and how it affects which medicines patients can access and how much they pay, is essential to the conversation. I appreciate the opportunity to discuss this important issue with you.

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. Over the last decade, PhRMA member companies alone have invested more than $850 billion in the search for new treatments and cures.[1]

This commitment to research and development also makes the biopharmaceutical industry the crown jewel of the American economy.

- Since 2025, the industry has committed more than $582 billion in new U.S.-based infrastructure investments,[2] which will generate an estimated $1.2 trillion in economic output and create 100,000+ new jobs, including 25,000 biopharmaceutical jobs.[3]
- The sector directly employs more than one million workers and supports more than 3.8 million additional jobs for a total employment impact of almost 5 million.[4] All of this has a ripple effect throughout the U.S economy.
- The biopharmaceutical industry generates more than $800 billion in direct output annually and supports another $850 billion in output through its suppliers and other sectors of the economy, for a total of more than $1.65 trillion.[5]

Medicines improve health and help control overall health care costs

More than 900 new medicines have been launched in the U.S. since 2000, giving American patients more treatment options than anywhere else in the world and resulting in significant progress against some of our most costly and challenging diseases.[6]

Not only do medicines save and improve the lives of millions of patients, but they also help control overall health care costs by preventing costly complications and replacing other medical interventions. Medicines enable better disease management and can avert the need for expensive emergency room visits, hospital stays, surgeries, and long-term care.

- In Medicaid, for example, savings realized from avoided complications from hepatitis C fully offset the costs of new curative treatments by 2017, and by 2026, cumulative Medicaid savings are projected to reach $43 billion.[7]
- Similarly, adherence to therapy among Medicare Part D beneficiaries with diabetes reduced total program spending by nearly $4,000 per beneficiary over a two-year period, net of medication costs.[8]

In particular, vaccines are among the most powerful tools we have for protecting our health and have a long track record of safety while providing savings to our health care system.

- Among children born between 1994 and 2023, routine childhood vaccinations provided through the U.S. Vaccines for Children (VFC) program will have prevented approximately 508 million cases of illness, 32 million hospitalizations, and 1,129,000 deaths, resulting in direct savings of $540 billion and societal savings of $2.7 trillion.[9]
- Higher flu vaccination rates among adults aged 18 years and older significantly reduced hospitalization rates among adults aged 50 years and older, and peak vaccination coverage would have reduced total costs by approximately $3 billion and averted more than 8,000 deaths.[10]

Continuing to invest in the research and development of new medicines is good for the economy, for patient health, and for our nation's fiscal future. Innovation that brings the next generation of treatments to patients, as well as better use of existing medicines, offers significant potential to increase productivity, improve outcomes, and drive savings. Consider chronic illness: six in 10 Americans have one or more chronic conditions, and 42 percent have two or more.[11] The cost of chronic illness accounts for 90 percent of the nearly $4 trillion spent on health care in the U.S. each year,[12,13] yet researchers estimate that medical breakthroughs to prevent and treat chronic disease could save 13.5 million lives and reduce health spending by $7 trillion over the next 15 years.[14] Similarly, a future treatment that reduces progression of Alzheimer's disease by 40 percent could yield $186 billion in savings to Medicaid over twenty years.[15]

Biopharmaceutical manufacturers take big risks to deliver cures

The promise of a healthier future does not come without risk – biopharmaceutical manufacturers take big risks to research, develop, and deliver new treatments and cures.

- On average, it takes $2.6 billion and 10 to 15 years to bring a new medicine to patients.[16]
- Only 12 percent of potential medicines that enter clinical trials are successfully approved by the U.S. Food and Drug Administration (FDA). [17]
- Just two in 10 approved medicines produce revenues that exceed average research and development (R&D) costs, including the cost of failures.[18]

Biopharmaceutical companies invest more than $12 million for every patent issued by the U.S. Patient and Trade Office (USPTO) – more than any other sector.[19] Yet when it comes to sales generated per patent, the industry is squarely in the middle of other IP-intensive sectors (defined as

those that use or invest in IP more than the average for their respective manufacturing or service sector).[20]

Policymakers should protect the American innovation ecosystem

By many measures, America's policy framework has allowed the U.S. biopharmaceutical industry to flourish. In particular, biopharmaceutical innovation is made possible through a series of policy choices and market incentives that encourage investment, including:

- An intellectual property (IP) framework that balances innovation with lower costs;
- Effective collaboration between the public and private sectors to support innovation;
- A best-in-class regulatory system; and
- Market-based coverage and payment policies that allow innovation to thrive.

America's intellectual property framework balances innovation with lower costs

The IP system balances innovation with cost savings from generic and biosimilar competition

America's intellectual property (IP) framework uniquely balances the important goals of fostering innovation and promoting competition to control overall health care costs. Thanks to this built-in system of cost containment, retail and physician-administered medicines are projected to remain constant at 14 percent of total U.S. health care spending through 2030, the exact same share as the last decade.[21]

In addition to the IP system ensuring competition and reducing costs, patents provide a period of market exclusivity to encourage biopharmaceutical companies to invest in bringing new and improved medicines to patients. Two key statutory frameworks simultaneously reward innovation while establishing streamlined approval pathways for generic or biosimilar products. Both patent frameworks 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 patent challenge procedure under the Hatch-Waxman Act has proven to be a robust means for generic applicants to come to market prior to expiration of listed patents. On average, brand-name medicines face generic competition after just 13 years on the market, significantly shorter than the basic 20-year patent term.[22]

- Today, more than 90 percent of U.S. prescriptions are filled with generics and biosimilars, offsetting health care spending on innovative brand medicines.[23]
- Due to our extensive use of low-cost generics, the average price of prescriptions filled through Medicare and Medicaid is 18 percent less than in other Organization for Economic Co-operation and Development (OECD) countries.[24]

Similar cost containment mechanisms simply do not exist for other health care services. To give an example, the price of a commonly used medicine to prevent cardiovascular disease dropped by 95

percent between 2007 and 2017 following generic entry,[25] while the average charge for a surgical procedure to treat it increased by 94 percent over the same period.[26]

The IP system encourages brand-to-brand competition

Additionally, long before generic or biosimilar entry occurs, the IP framework fuels competition that drives down costs by encouraging innovators to develop competing brand products different from others already on the market. That is because the certainty provided by this system not only encourages first-in-class medicines, but also next-in-class medicines, as companies compete to improve upon existing medicines and provide additional therapeutic options to meet unmet patient needs. This means most new medicines already have at least one competitor on the market at the time of market entry or will have one shortly thereafter. Two decades ago, it took 16 years on average for a first-in-class medicine to have two competitors – now it takes an average of two years.[27] Payers leverage this competition to negotiate discounts and rebates, which can lower the cost of brand medicines by as much as half.[28]

Collaboration between the public and private sectors drives innovation

In addition to the innovation and competition generated by the U.S. system, 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.[29] 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.

While the public and private sectors play complementary roles in advancing medical treatments, biopharma companies are overwhelmingly responsible for the work required to develop new medicines. A 2016 study of the most transformational medicines 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.[30] And an analysis of 23,230 National Institute of Health (NIH) grants 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.[31]

American patients benefit from our best-in-class regulatory system and "gold standard" regulatory review

The FDA's human drug review program is widely regarded as the global gold standard for regulatory review. Its importance to the biopharmaceutical sector is a result of its role in enforcing rigorous, evidence-based standards for safety and efficacy. The FDA provides the regulatory certainty necessary for companies to invest billions into long-term research and development.

The agency's current success is, in large part, because of the Prescription Drug User Fee Act (PDUFA), which was first enacted by Congress in 1992 as a bipartisan solution to provide resources to speed the FDA's review of drug applications. Before PDUFA, more than 70 percent of medicines were first approved outside of the United States. Currently, most new medicines are approved first in the U.S., including 70 percent in 2025 alone.[32] Together with the U.S. market-based system, gold standard regulatory review has helped ensure that Americans have the best and fastest availability of new medicines anywhere in the world.

- 85 percent of new medicines are reimbursed in the U.S., versus only 24 percent in Australia and 21 percent in Canada.[33]
- U.S. patients have access to 78 percent of new medicines within one year compared to 18 percent in OECD countries.[34]

Market-based pricing supports the next generation of cures

For decades, the competitive dynamics in the market for prescription medicines have worked successfully to balance innovation, patient access, and cost containment. Given the substantial uncertainty in developing new medicines, manufacturers must be able to earn a sufficient return on investment when a product comes to market to account for the many failures. As in other industries, biopharmaceutical companies require revenues sufficient to repay shareholders, secure continued investment, and finance additional R&D that can provide revenue for the future.[35]

Numerous studies have documented the positive relationship between expected returns in the biopharmaceutical industry and investment in R&D.[36]

- Passage of Medicare Part D significantly increased R&D in therapeutic classes with higher Medicare market share.[37]
- $2.5 billion in revenue is needed to invent one new chemical entity.[38]
- A one percent increase in potential market size in a therapeutic area, proxied by population aging, led to a 4 percent to 6 percent increase in new medicines in that area.[39]

Research has also demonstrated the clear impact of price controls on R&D investment. The Inflation Reduction Act's (IRA) price-setting provisions may have substantial impacts on expected investment returns that, in turn, drive R&D decisions.[40] Early evidence shows that the IRA has reduced investment in small-molecule medicines by 68 percent, and by 74 percent for diseases mainly affecting Medicare patients, since the law was introduced.[41]

The U.S. is the only country where half of medicine spending goes to entities that don't make them

Half of every dollar the U.S. spends on medicines goes to entities that play no role in the research, development, or manufacturing of those medicines. In 2023, biopharmaceutical manufacturers retained 49.9 percent of total brand medicine spending, a decrease of 16 percentage points from 2013.[42] As the share of brand spending kept by manufacturers has declined, the share received by other pharmaceutical supply chain entities, including pharmacy benefit managers (PBMs),

hospitals, the government, pharmacies, and insurers, has significantly increased. Of the 50 percent of brand medicine spending that went to entities that did not make the medicine:

- More than 25 percent went to PBMs, insurers, and other supply chain entities;
- 12 percent went to government programs like Medicaid and Medicare Part D through statutory rebates, discounts, and fees;
- 10 percent went to hospitals, providers, and pharmacies participating in the 340B Program;
- Three percent went to manufacturer cost-sharing assistance for commercially insured patients.

Insurers, PBMs and other middlemen account for a quarter of brand medicine spending and the largest share of spending growth

More than 25 percent of brand medicine spending went to PBMs, insurers and other pharmaceutical supply chain entities in 2023, including more than $170 billion in manufacturer rebates, discounts, and other payments.[43] Rebates, discounts, and other payments to middlemen and supply chain entities were the single largest driver of brand medicine spending growth from 2022 to 2023.[44]

PBMs and insurers rarely share rebates and discounts with patients

Manufacturer rebates can reduce the cost of medicines for insurers and PBMs by 50 percent or more, but these savings rarely make their way directly to patients at the pharmacy counter. Instead, PBMs and insurers 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, rather than the discounted net price paid by the PBM.

- The Government Accountability Office (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).[45]
- In the commercial market, two-thirds of patients taking brand medicines fill prescriptions in the deductible or with coinsurance, based on the undiscounted list price. These prescriptions represent a disproportionate share (60 percent) of total patient spending on brand medicines.[46]
- Furthermore, more than 80 million Americans are in high-deductible plans that force them to pay the full list price of the medicine, even when their PBM or insurer is receiving a steep discount.[47,48]

In contrast, health plans typically base patient out-of-pocket spending for care received from doctors and hospitals within the plan's provider network on the discounted rates negotiated by the plan on patients' behalf.

PBMs may have incentives to prefer medicines with higher list prices and large rebates and may discourage manufacturer efforts to reduce list prices

A growing share of PBM compensation is tied to the list price of medicines,[49] which experts note can distort the market by incentivizing PBMs to prefer medicines with higher list prices and large rebates over lower-cost alternatives.[50] Rather than ensuring patients have rapid access to generics, biosimilars, and lower price therapies, PBMs increasingly deny or restrict coverage for these medicines.[51,52] A recent analysis shows how extensively the big three PBMs have excluded low-cost generics and biosimilars from commercial formularies in recent years. The study found a 900 percent increase in generic exclusions since 2014 and a 164 percent increase in biosimilars excluded from at least one of the big three PBMs' formularies since 2022, when several biosimilars medicines entered the market.[53]

Industry analysts note this dynamic is especially acute for biosimilars, prompting some manufacturers to introduce two identical versions of a product – one with a higher list price and large rebates and one with a lower list price – giving payers the option of which to cover.[54] The three large PBMs have consistently favored the versions with large rebates and have in some cases blocked access to lower-list-priced biosimilars by excluding them from their formularies.[55,56,57,58] The net effect on the market potential for biosimilars has contributed to a looming "biosimilar void." Over the next decade (2025 to 2034), 118 biologics are expected to lose patent protection, yet only 12 of those molecules had biosimilars in development as of June 2024. The remaining 106 biologics facing patient expiry leave a $232 billion market opportunity potentially untapped.[59]

The Health and Human Services (HHS) Office of Inspector General (OIG) has observed 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 formulary tier.[60] Other experts have argued that it would be difficult or impossible to lower list prices because "cutting the list price means wholesalers make less money, pharmacies make less money, PBMs make less money, and payers get fewer rebate dollars."[61]

PhRMA has long highlighted problematic PBM business practices and conflicts of interest that distort market competition and drive up costs for patients, employers, and taxpayers. We heartily applaud policymakers' recent actions to begin reining in PBMs' abusive and anticompetitive behaviors, including the bipartisan passage of federal legislation to delink PBM compensation from list prices in Medicare Part D and require PBMs and affiliates to pass through all rebates and discounts to plan sponsors in the private market; a Proposed Rule issued by the Department of Labor that would impose broad transparency requirements on PBMs and increase visibility into their compensation; and the Federal Trade Commission's (FTC) announcement of a proposed consent agreement with Express Scripts that directly targets PBM arrangements that may create perverse incentives and could reduce patient out-of-pocket costs by $7 billion over the next 10 years.

PBMs' business models have shifted beyond rebates, with fees and payments within vertically integrated organizations accounting for a growing share of PBM profits

PBMs have enormous influence over which medicines are covered, when and where patients can access them, and out-of-pocket costs. The PBM market is highly consolidated, with just three large

companies – CVS Caremark, Express Scripts, and OptumRx – controlling nearly 80 percent of prescriptions.[62] In recent years, the three largest PBMs have vertically integrated with health insurers, specialty and mail order pharmacies, provider groups, and other supply chain entities. The three largest PBMs are key drivers of revenues and profits for their respective vertically integrated organizations.[63]

Research confirms that the primary sources of PBM profits have changed significantly over the last decade. The PBM business model has largely shifted away from retention of commercial rebates – perhaps in response to increased public and employer scrutiny – in favor of fees charged to manufacturers, payers, and pharmacies and revenues generated by vertically integrated specialty and mail order pharmacies.[64,65] While the total amount of rebates obtained by PBMs has continued to increase each year, fees and specialty pharmacy are now the fastest-growing components of PBM profits.

Federal and state investigations suggest PBM GPOs may be inappropriately retaining commercial rebates

Each of the big three vertically integrated PBMs has created a separate rebate contracting entity, which they refer to as a group purchasing organization (GPO), that is responsible for negotiating, collecting, and disbursing manufacturer rebates for their commercial book of business. [66] A report authored by Hunterbrook Media, an investigative news outlet and investment firm, found there are fewer than 150 employees across all three PBM GPOs, but they generate more than $50 million in revenue per employee. By comparison, Nvidia generated $3.6 million in revenue per employee.[67] Two of the big three PBMs, Express Scripts and OptumRx, have based their PBM GPO operations overseas, allowing them to take advantage of lower foreign tax rates and more restrictive privacy laws.

The fees PBMs obtain from manufacturers – which are predominantly based on the list price of medicines – have more than doubled in the commercial market over the past five years, including rapid growth in new data and vendor fees charged by PBM GPOs.[68] Because these new fees and the activities of PBM GPOs in general are less transparent to employers and plan sponsors, employers and plan sponsors may not benefit from the additional revenues these entities collect.[69]

PBMs claim that PBM GPOs provide their clients with greater bargaining power to lower costs, but inquiries by members of Congress, industry experts, state Attorneys General, and federal oversight agencies indicate the opposite may be true. Recent investigations suggest PBM GPOs may inappropriately retain rebates in the commercial market and charge fees that are not passed on to plan sponsors or patients.[70]

- For example, federal audits conducted in 2024 found that Express Scripts and its GPO, Ascent, overcharged two Federal Employee Health Benefits Program plans by $63 million over a 6-year period, including $26 million in rebates pocketed by Ascent that should have been passed through to the plan sponsors.[71,72]

- Similarly, a 2024 investigation by the Illinois Office of the Attorney General regarding claims that CVS Caremark and its GPO, Zinc, failed to disclose manufacturer rebates and fees that should have been paid to the state resulted in CVS Caremark paying a $45 million settlement.[73] CaremarkPCS Health and Zinc later sued to stop the Illinois Attorney General from releasing information related to the financial arrangements between the two parties.[74]
- The Ohio Attorney General has also sued PBMs and PBM GPOs, alleging that these entities are engaging in anti-competitive behavior that distorts the market to their advantage and increases the cost of medicines for patients and employers.[75]

PBM GPOs have come under such scrutiny that FTC addressed them in its proposed consent agreement with Express Scripts. The terms would require Express Scripts to relocate its PBM GPO operations to the U.S., a move FTC estimates will reshore more than $750 billion in economic activity over the next 10 years.[76]

Insurers and PBMs may prefer their private-label biosimilars over lower-priced versions

Another recent trend among vertically integrated insurers and PBMs has been the launch of subsidiaries to market private-label biosimilars. These arrangements allow vertically integrated organizations to profit multiple times as the medicine makes its way through the supply chain, including once when the biosimilar is commercialized by their affiliate, again when that product is placed on formulary, and another time when a prescription is filled at a pharmacy they own. This profit potential creates a clear incentive for vertically integrated insurers and PBMs to give preferential coverage to biosimilars in which they have a financial stake, even if those products may not be the lowest-priced options for patients, employers, or taxpayers. For example, several biosimilar versions of a medicine used to treat autoimmune conditions are available with lower list prices than the PBMs' private-label versions, and not one of the big three PBMs covers the version with the lowest list price.[77]

Vertical integration with pharmacies creates sizable and growing revenue streams for PBMs

Vertically integrated pharmacies have grown to account for more than half of PBM profits.[78] PBMs may require patients to use a PBM-owned retail, mail order, or specialty pharmacy or disincentivize the use of independent pharmacies by requiring patients to pay higher cost-sharing. By steering patients towards their affiliated pharmacies, PBMs capture greater margins on each transaction.[79,80] Steering, however, can happen without a patient's knowledge and can deny patients the benefits and convenience of visiting their local pharmacist. It can also result in unnecessary treatment delays, with patients potentially experiencing worse outcomes from not being able to fill prescriptions in a timely manner.[81]

Vertical integration may allow insurers to sidestep "medical loss ratio" requirements

Medical loss ratio (MLR) standards require health insurers to spend a minimum share of premium dollars on patient care and quality improvement activities, limiting the share of premium dollars insurers can allocate to administrative costs and profits. MLR requirements apply to the individual, small group, and large group commercial insurance markets, as well as Medicare Advantage,

Medicare Part D, and Managed Medicaid markets.[82] Insurers that fail to meet the minimum MLR threshold for a given market must refund the difference in the form of a rebate paid to policyholders or the government.

By vertically integrating with PBMs, pharmacies, providers, and other supply chain entities, insurers have discretion over how to characterize certain transactions between affiliated entities and can shift revenues to affiliates whose profits are not subject to regulation. This allows insurers to effectively skirt MLR requirements by capturing more profit at the organizational level than the insurer's MLR limit would otherwise allow.[83] One way that insurers may do this is by paying their vertically integrated pharmacies and providers above-market rates. These inflated payments count towards medical care spending in the insurer's MLR calculation – making it easier to meet the minimum MLR threshold – while the excess reimbursement to the pharmacy or provider generates internal profit for the vertically integrated entity.[84]

A recent Health Affairs study suggests insurers may be flouting MLR requirements by overpaying their affiliated providers. The study found that UnitedHealthcare reimburses its affiliated Optum providers at rates 17 percent higher than the relative price of its competitors, a gap that widens to 61 percent in markets where UnitedHealthcare holds at least a 15 percent market share.[85] Similarly, investigations by the FTC and the Wall Street Journal show that commercial insurers and PBMs pay their vertically integrated pharmacies significantly more than unaffiliated pharmacies for generic medicines used to treat cancer, HIV, multiple sclerosis, and other conditions – sometimes thousands of dollars more per prescription.[86,87] Overall, UnitedHealth Group sends 25 percent of its medical claim revenue to its Optum subsidiaries, while 13 percent of CVS Health's revenues come from its own pharmacies and providers.[88]

Insurer and PBM utilization management and coverage exclusions can delay or prevent patient access to prescribed medicines and medical services

Insurers and PBMs establish formularies that govern which medicines are covered, the associated patient cost sharing, and any restrictions on their prescribing or use. Insurance companies employ a variety of utilization management techniques to direct patients and providers towards their preferred medicines, including prior authorization and step therapy, or exclude certain medicines from the formulary altogether. However, by restricting or excluding coverage, insurers and PBMs can limit patient choice and access to treatment.

Insurers and PBMs increasingly apply prior authorization and step therapy to innovative medicines, including treatments for cancer, rheumatoid arthritis, multiple sclerosis, hepatitis C, and high cholesterol.[89]

- For some medicines in the commercial market, insurers and PBMs require patients to step through up to 10 medicines beyond what is recommended in FDA-approved labeling before accessing the medicine their doctor prescribed.[90]
- Insurers and PBMs also use non-transparent, embedded step therapy to force patients to try and fail on medicines beyond what is recommended by FDA-approved labeling while

misleadingly characterizing these processes as prior authorization. Coverage policies that were more restrictive than what is recommended by FDA-approved labeling increased from 40 percent to 52 percent from 2017 to 2021.[91]

The past decade has also seen a proliferation in the number of medicines PBMs exclude from their formularies.

- In 2025, the three largest PBMs placed a total of 1,453 unique medicines on their formulary exclusion lists, a 1,584 percent increase from 2014 to 2025.[92]
- Additionally, recent research shows that nearly half of Medicare Part D beneficiaries and 70 percent of commercial patients were initially denied coverage when attempting to initiate treatment with a brand medicine in 2025, up from 37 percent and 57 percent in 2021.[93,94]

The Centers for Medicare & Medicaid Services (CMS) has determined that Medicare Part D sponsors sometimes inappropriately reject or deny pharmacy and medicine coverage requests.[95] Among coverage denials that Part D beneficiaries appealed in 2017, plan sponsors fully overturned or partially overturned 73 percent.[96] According to the HHS OIG, denials could have been avoided if plan sponsors had correctly received and processed information at the first request.[97] Similarly, of the 3.2 million prior authorizations denied by Medicare Advantage plans in 2023, nearly 82 percent were partially or fully overturned on appeal, suggesting insurers may have inappropriately denied patients' prescription medicine and medical claims in some cases.[98]

Payers, manufacturers, physicians, and patients incur more than $93 billion in annual costs related to implementing, contesting, and navigating utilization management for medicines and medical services.[99]

- Eight in ten physicians report that prior authorization and step therapy procedures are major or significant barriers to clinical and patient care, and more than half report spending at least six hours per week dealing with utilization management-related paperwork.[100]
- More than 80 percent of physicians report that prior authorization leads to treatment abandonment at least some of the time and more than 90 percent report care delays associated with prior authorization.[101]

Insurers spend more of every premium dollar on profits, marketing, and administrative overhead than on prescription medicines

Over the next 10 years, the federal government will pay health insurance companies and PBMs $16 trillion for health coverage for the American people.[102] Yet, overhead is the second largest category of premium costs, exceeding medicine spending and doctor visits.[103] Roughly 16 cents of every $1 in premiums go to insurer profits and administrative costs. Hospitals account for nearly half of every premium dollar, the largest share of any sector.[104] Brand medicines account for less than 10 cents of every premium dollar.[105]

Government-mandated rebates, discounts, and fees account for a growing share of brand medicine spending

Biopharmaceutical companies paid $79 billion in statutory rebates, discounts, and fees to government programs, including Medicaid and Medicare Part D, accounting for 12 percent of every dollar spent on medicines in 2023.[106] Going forward, price setting and other misguided policies imposed under the IRA will further increase the amount of brand medicine spending that manufacturers pay to government programs, eroding investment in future research and development.

Hospitals and the 340B program drive up costs for patients, employers, and taxpayers

Markups and profit from the 340B Program account for 10 percent of every dollar spent on brand medicines and are a hidden tax that inflates costs for patients, employers, and taxpayers.[107] The largest share of 340B costs is driven by hospital markups – where big tax-exempt hospitals markup medicines by up to ten times or more.[108] 340B hospitals and clinics purchase medicines at prices that are, on average, 57 percent below the list price,[109] but can be as low as a penny.[110] They can then turn around and charge patients, employers, and taxpayers the full price, or more. Hospitals eligible for 340B kept 64 percent of insurer spending on medicines as profit after paying for the medicines, compared to hospitals not eligible for 340B pricing who kept 45 percent, and independent physician practices who kept just 19 percent.[111]

Despite the program's growth, patients are not benefiting due to outdated policies and rules, and in fact may incur higher costs. Covered entities are not required to share any of the discounts they receive on medicines with patients.[112] Nor are they required to dispense 340B-discounted medicines only to poor or underserved patients, as there are no income or health insurance restrictions on which patients are eligible for 340B medicines. Patients can be charged multiple times what the hospital or clinic paid for the medicine. Through higher insurance premiums and higher prices for cash paying patients, consumers and employers are paying for an estimated 27 percent of the profits 340B covered entities generate through the program.[113]

The 340B Program is now the second largest federal prescription medicine program, surpassing Medicare Part B and Medicaid.[114] Covered entities made $81 billion in discounted purchases in 2024, 23 percent higher than the prior year and nine times the program's size in 2014.[115] 340B providers and for-profit companies get 18 times more of the medicine dollar than they did a decade ago, while patients, taxpayers, and employers face inflated costs.[116]

CBO recently issued a report that found the 340B Program has grown much faster than medicine spending overall and that its size and perverse incentives are driving up health care costs for federal and state governments.[117] In fact, the 340B Program costs taxpayers $20 billion a year due to lost Medicaid and Medicare rebates.[118] This is on top of the additional costs driven by the misaligned incentives in the 340B Program, including encouraging the use of more, and more expensive, medicines, and shifting care away from doctor's offices to more expensive hospital settings.[119]

Manufacturer financial assistance helps millions of patients access their medicines

Too many Americans struggle to afford medicines because of a broken health insurance system that burdens patients with coverage denials and unaffordable costs. To fill the gap,

biopharmaceutical manufacturers have stepped in with support programs that provide financial assistance to 10 million patients annually.[120] In 2023 alone, manufacturers provided nearly $23 billion in cost-sharing assistance to commercially insured patients, representing 3 percent of total brand medicine spending in that year.

Insurers and PBMs have implemented practices that prevent patients from receiving the full value of manufacturer cost-sharing assistance. Accumulator adjustment programs (AAPs) prevent the value of this assistance from counting toward deductibles and out-of-pocket maximums for commercially insured patients.[121] Copay maximizers adjust individual patient cost sharing upwards to match and exhaust the full value of the manufacturer-provided assistance.[122] Through these practices, insurers and PBMs siphoned off nearly 22 percent ($5 billion) of the cost-sharing assistance manufacturers provided to commercially insured patients in 2023.[123]

Despite receiving only half of brand medicine spending, manufacturers devote a substantial share to researching and developing new treatments and cures

As discussed above, biopharmaceutical manufacturers retain just half of all brand medicine spending, with the other half going to PBMs, insurers, and supply chain entities; statutory rebates, discounts, and fees paid to the government; the 340B Program; and manufacturer cost-sharing assistance. Yet, manufacturers re-invest a sizable share of their earnings, 33 percent, into R&D activities, compared to the 3.8 percent average for all U.S. health care industries, and the mere 0.1 percent invested by PBMs, insurers, and wholesalers.[124]

Biopharmaceutical R&D is among the most capital-intensive and high-risk undertakings in the U.S. economy. Manufacturers of innovative medicines take on significant risk to develop medicines with a high rate of failure, yet they earn some of the lowest risk-adjusted returns on capital in the health care system. Recent research shows that PBMs, insurers, and wholesalers earn a 41 percent profit rate (i.e., returns relative to investments), four times as much as biopharmaceutical companies.[125] This disparity stems from the fact that PBMs and insurers, whose business models center on administrative functions like claims processing and formulary management, generate high returns with far less capital investment and risk, while biopharmaceutical companies invest billions in research to develop new therapies.

Future competitiveness requires investment in the future

The biopharmaceutical industry is committed to preserving U.S. competitiveness and building a more patient-centered health care system. As we look to the future, we face a choice. We can follow the path of Europe and lose our leadership to China and other economies that have a clear strategy for fostering biopharmaceutical innovation, or we focus on:

- Protecting what works in the U.S. system, including our IP framework; research and development ecosystem; and gold standard approach to regulatory review;
- Fixing the aspects of our system that drive inefficiency and higher costs; and
- Investing in people and systems to ensure the U.S. is built to compete for the next 250 years.

Protect what works in the U.S. system

Avoid unnecessary and harmful changes to the IP framework

The U.S. IP system has facilitated a robust, competitive market for biopharmaceutical innovation as well as generic and biosimilar medicines. While many Arnold Venture-funded critics have claimed manufacturers engage in patent abuse tactics to impede generic and biosimilar competition,[126] a wealth of research from legal scholars[127, 128, 129] points to consistent periods of market exclusivity for brand medicines over the years, even as those products may involve numerous inventions and have been associated with a greater number of patents over the past decade. These observations reinforce the findings of a 2024 USPTO study, which showed no correlation between the number of patents on a product and the length of actual market exclusivity.[130]

Policymakers should not undermine the IP system with harmful legislative proposals that appear to be a solution in search of a problem.[131] Rather than 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.

Protect the FDA's scientific integrity and ensure regulatory predictability

Leadership staffing changes,[132] loss of employees to layoffs and resignations, and changes to regulatory policy announced through informal channels are creating increasing instability at the FDA and undermining confidence that could have far-reaching economic impacts. The FDA regulates products representing nearly 20 percent of U.S. consumer spending[133] and drives investment decisions across the entire life-sciences sector. According to 77 percent of life sciences venture capital (VC) investors, a stable FDA and clearer regulatory guidance would increase investment.[134] Prioritizing stability at the FDA is critical to U.S. competitiveness.

Reject further expansion of price controls

In 2013, medicines accounting for 10 percent of total brand spending were subject to Medicaid rebates, Medicare Part D coverage gap discounts, 340B Program discounts, and other government price controls.[135] By 2031, without further policy action, we estimate that nearly 30 percent of the market will be price set, driven by IRA implementation, expansion of the 340B Program, and increased enrollment in government programs.[136]

Yet, debate continues about expanding the government's role in setting the price of medicines. Price controls, whether through the IRA's flawed "negotiation" program or through "most-favored nation" (MFN) policies, are a bad deal for Americans because they reduce resources available to invest in the economy and cures.

- As an example, MFN reference pricing could eliminate approximately 337,000 biopharma industry jobs and nearly 1.5 million jobs in total across the economy if imposed in Medicare and Medicaid.[137]
- MFN would also result in 500 fewer treatments developed over a 10-year horizon.[138]

Not only are price setting policies bad for American workers and patients, but they also fail to address the real reasons patients pay too much for their medicines.

- The rebates PBMs receive from manufacturers for commonly used medicines can exceed the price of the same medicines abroad by as much as 900 percent.[139]
- Meanwhile, 340B hospitals markups can exceed prices in other wealthy countries by up to 700 percent.[140]

Price setting also does not ensure patients pay less for their medicines.

- In fact, following passage of the IRA, many Medicare beneficiaries are enrolled in plans where their cost sharing will *increase* for many price-set medicines in 2026 compared to before the IRA.[141]
- Recently released MFN policies would not only fail to save the vast majority of beneficiaries money, but they could *cost* seniors $3.6 billion in increased out-of-pocket costs and premiums under the Medicare Part D benefit, by the government's own admission.[142]

Instead of expanding or importing flawed price controls, policymakers should be focused on the aspects of our U.S. system that lead to higher costs for patients, employers, and taxpayers.

Fix the broken aspects of the U.S. system

The U.S. system of denials and barriers to care create challenges for patients trying to afford the medicines necessary for their health. PhRMA's member companies are doing their part by making it easier to buy medicines directly from manufacturers at lower costs, without hidden markups or fees. To do their part, insurers should ensure that spending on medicines purchased directly counts toward deductibles and out-of-pocket maximums.

Meanwhile, rather than expanding price controls, policymakers should put an end to insurer and PBM practices that drive up prices and restrict patient access. The bipartisan passage of PBM reform legislation was an important first step in addressing the opaque system that has allowed PBMs to profit at the expense of patients, employers, and taxpayers, but the PBM industry is already shifting tactics to stay ahead of new rules and regulations and additional action is needed to ensure PBMs cannot game the new safeguards Congress has put in place.

Address the incentives created by vertical integration

As a next step, policymakers must curb the perverse incentives enabled by vertical integration, including the potential for insurers to undermine competition by paying higher reimbursement rates to affiliated pharmacies and providers, the self-dealing that is driving community pharmacies and private physician practices out of business, and the troubling conduct of PBM GPOs, which state and federal investigations suggest are obscuring and retaining rebate savings rightly due to plan sponsors.

Ensure patients get the medicines their doctors prescribe

The rise in payer-imposed restrictions on patient choice and access further underscores the need to hold insurers and PBMs accountable for delivering the care people are paying for. While we applaud President Trump's Great Healthcare Plan for calling on insurers to publish their share of claims denials, transparency alone is not enough. Meaningful reform will require a comprehensive set of measures that impose robust oversight and accountability for insurers and PBMs.

Reform the 340B hospital markup program

Congress should ensure that covered entities participating in the 340B Program are truly helping low-income and uninsured patients afford their medicines, and that the program is better targeted to true safety-net institutions. Strengthening transparency and program integrity requirements is essential to making sure the rules are followed and that misuse of the program does not increase costs for taxpayers and patients. A key step to accomplish this is for the Trump Administration to advance a rebate program. HHS has taken the initial steps toward implementing a new rebate program by seeking Office of Management and Budget (OMB) review, as listed on OMB's website last Friday, February 6. A well-designed rebate pilot would strengthen compliance while avoiding financial hardship or undue administrative burdens for covered entities.

Invest to compete, particularly with China

The leadership position of the U.S. biopharmaceutical industry is at a critical crossroads. While Europe once led the world in the research and development of innovative medicines, extensive use of price controls and reference pricing created launch delays and access restrictions, driving the industry to the U.S.' more favorable policy and regulatory environment.[143,144] However, we cannot take our leadership position for granted. The National Security Commission on Emerging Biotechnology (NSCEB) has assessed that China is beginning to outpace the U.S. in certain domains of biopharmaceutical innovation, threatening our global leadership.[145]

China has spent decades building an innovative biopharmaceutical ecosystem aimed at reducing dependence on foreign supply chains for critical vaccines and treatments. Under its "Made in China 2025" initiative, the Chinese government has increased funding and aggressively pursued leadership in biopharmaceutical development and manufacturing through tax benefits for life sciences companies, streamlined approval processes, and talent recruitment.

- As a result, Chinese companies now account for 30 percent of global clinical trial starts, up from just two percent in 2009, and barely trailing the U.S. level of 35 percent.[146]
- China has also steadily advanced in first-in-class innovative medicine development, with 22 percent annual pipeline growth between 2015 and 2024.[147]
- Its timeline from molecule discovery to human clinical trials is 50 to 70 percent faster than the global average due to parallelized workflows, centralized research hubs, and a culture of executional intensity.[148]

- China now graduates over 100,000 more STEM Master's and PhD students than the U.S., generating scientific talent that underpins the capacity to discover and develop the next wave of the world's medicines.[149]

Without sustained investment and policies that reinforce the U.S. as the world's most attractive environment for biopharmaceutical innovation, America risks ceding leadership to China.

Against this backdrop of rapid global competition, the U.S. must take deliberate steps to protect the unique aspects of America's system that have supported leadership to-date; build upon recent reforms to continue to rationalize system incentives that drive inefficiency and higher costs; and strengthen the U.S. innovation ecosystem to keep pace with other nations.

****

PhRMA appreciates the opportunity to participate in this hearing, and we look forward to continuing to engage with the Subcommittee on these critically important issues.

---

[1] PhRMA. (2025) PhRMA Annual Membership Survey. Available here.
[2] We Work For Health. (January 2026). More Than $582 Billion In New U.S. Investment Since 2025. Available here.
[3] PhRMA. (September 2025). PhRMA Announces Major Actions as Part of Industry's Commitment to American Patients and Workers. Available here.
[4] TEConomy (May 2024). The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. Available here.
[5] *Ibid*.
[6] FDA. (January 2018). Summary of NDA Approvals & Receipts, 1938 to the present, Available here.; FDA. (February 2026). Novel Drug Approvals at FDA, 2021 – 2025. Available here.; FDA. (February 2026). Biological Approvals by Year, 2016 – 2025. Available here.
[7] Roebuck M.C. (December 2022). Impact of Direct-Acting Antiviral Use for Chronic Hepatitis C on Health Care Costs in Medicaid: Economic Model Update. *American Journal of Managed Care*. Available here.
[8] Stuart B.C., Dai M., Xu, J., et al. (June 2015). Does Good Medication Adherence Really Save Payers Money. *Medical Care*. Available here
[9] Zhou F., Jatlaoui T.C., Leidner, A.J., et al. (August 2024). Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023. *CDC*. Available here.
[10] Popovian R., Winegarden W. (December 2025). Influenza's Economic Burden and the Impact of Adult Vaccination. *medRxiv.* Available here.
[11] Buttorff C., Ruder T., Bauman M. (May 2017). Multiple Chronic Conditions in the United States. *RAND.* Available here.
[11] CDC. (June 2022). Health and Economic Costs of Chronic Diseases. Available here.
[12] *Ibid*.
[13] *Ibid*; CMS. (December 2021). Historical National Health Expenditures. Available here.
[14] PFCD. What is the Impact of Chronic Disease in the United States? Available here.
[15] Lam J., Jun H., Cho S.K., et al. (March 2021). Projection of budgetary savings to U.S. state Medicaid programs from reduced nursing home use due to an Alzheimer's disease treatment. Available here.
[16] DiMasi J.A., Grabowski H.G., Hansen R.W. (May 2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*. Available here.
[17] *Ibid*.
[18] Vernon J.A., Golec J.H., DiMasi J.A. (August 2010). Drug development costs when financial risk is measured using the Fama-French three-factor model. *Health Economics*. Available here.
[19] Pham N.D., (April 2025). The Economic Performance of IP-Intensive Manufacturing and Service Industries in the United States, 2012-22. *NDP Analytics*. Available here.
[20] *Ibid*.

[21] Altarum Institute. (July 2022). Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. Available here.
[22] Grabowski H., Long, G., Mortimer, R., et al. (August 2021). Continuing trends in U.S. brand-name and generic drug competition. *Journal of Health Economics*. Available here.
[23] Association for Accessible Medicines. (September 2025). 2025 U.S. Generic & Biosimilar Medicines Savings Report. Available here.
[24] Philipson T.J., Zhang D., Zhao Q. (June 2025) Policy Brief: International Comparison of Prices for Drug Prescriptions. *University of Chicago*. Available here.
[25] IQVIA analysis for PhRMA. (June 2020) Invoice price data for atorvastatin 10mg from IQVIA National Sales Perspective for 2007 (branded Lipitor) and 2017 (generic).
[26] PhRMA analysis of: AHRQ. (July 2020). Healthcare Cost and Utilization Project (HCUP): National (Nationwide) Inpatient Sample (NIS) database, 2007, 2017. Available here.
[27] McKinsey analysis of Evaluate Pharma data. (October 2024). Available here.
[28] MedPAC. (July 2025). Health Care Spending and the Medicare Program: A Data Book. Available here.
[29] Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980).
[30] Chakravarthy R., Cotter K., DiMasi J., et al. (December 2016). Public-and private-sector contributions to the research and development of the most transformational drugs in the past 25 years: from theory to therapy. *Therapeutic innovation & regulatory science*. Available here.
[31] Vital Transformation. (May 2021). Who Develops Medicines? An Analysis of NIH Grants. Available here.
[32] FDA. (January 2026). New Drug Therapy Approvals. Available here.
[33] PhRMA. (2023). Global Access to New Medicines Report. Available here.
[34] *Ibid*.
[35] CBO. (April 2021) Research and Development in the Pharmaceutical Industry. Available here.
[36] Barbosu, S., Axelsen, K., Ezell, S. (December 2024). Evidence to inform biopharmaceutical policy: call for research on the impact of public policies on investment in drug development. *Health Affairs Scholar*. Available here.
[37] Blume-Kohout, M.E., Sood, N. (January 2013). Market size and innovation: Effects of Medicare Part D on pharmaceutical research and development. *Journal of Public Economics*. Available here.
[38] Dubois, P., De Mouzon, O., Scott-Morton, F., et al. (October 2015). Market size and pharmaceutical innovation. *The RAND Journal of Economics*. Available here.
[39] Acemoglu, D., Linn, J. (August 2004). Market size in innovation: theory and evidence from the pharmaceutical industry. *The Quarterly Journal of Economics*. Available here.
[40] Nordyke, R. J., Patterson, J. A., Motyka, J., March, B., Kirson, N. Y., & Long, G. (2025). The Impact of the Inflation Reduction Act's Drug Price Negotiation Program on Incentives for Clinical Development of New Drugs. *Value in Health*. Available here.
[41] Vital Transformation. (April 2025). Inflation Reduction Act – Two Years On. Investor Behavior, R&D Impacts, & Proposed Solutions. Available here.
[42] Blalock, E., Ferritto, M., Taylor, J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research Group*. Available here.
[43] *Ibid*.
[44] *Ibid*.
[45] Government Accountability Office. (September 2023). Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending. Available here.
[46] PhRMA. (November 2022). Deductibles and Coinsurance Drive High Out-Of-Pocket Costs for Commercially Insured Patients Taking Brand Medicines. Available here.
[47] CDC. (June 2025). Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, 2024. Available here.
[48] CDC. (December 2024). Enrollment in High-deductible Health Plans Among People Younger Than Age 65 With Private Health Insurance: United States, 2019–2023. Available here.
[49] Percher E. (September 2023). Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. *Nephron Research*. Available here.
[50] 84 Fed. Reg. 2341 (Feb. 6, 2019)
[51] Association for Accessible Medicines. (September 2023). The U.S. Generic & Biosimilar Medicines Savings Report. September 2023. Available here.
[52] Biosimilars Council. (January 2024). Humira Biosimilar Landscape: Still Waiting. Available here.
[53] Cencora. (July 2025). Persistent growth in PBM formulary exclusions continues to raise concerns about patient access. Available here.

[54] Kansteiner F. (November 2021). Viatris launched 2 version of its interchangeable insulin biosimilar. Why?. *Fierce Pharma*. Available here.
[55] Fein A.J. (July 2023). Four Crucial Questions About the Humira Biosimilar Price War. *Drug Channels Institute*. Available here.
[56] *Ibid*.
[57] Fein A.J. (January 2024). The Big Three PBMs' 2024 Formulary Exclusions: Biosimilar Humira Battles, CVS Health's Weird Strategy, and the Insulin Shakeup. *Drug Channels*. Available here.
[58] Fein A.J. (January 2025). The Big Three PBMs' 2025 Formulary Exclusions: Humira, Stelara, Private Labels, and the Shaky Future for Pharmacy Biosimilars. *Drug Channels*. Available here.
[59] IQVIA (February 2025). Assessing the Biosimilar Void in the U.S.: Achieving Sustainable Levels of Biosimilar Competition. Available here.
[60] 84 Fed. Reg. 2341 (February 2019)
[61] Johnson C. (June 2018). In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet. *The Washington Post*. Available here.
[62] Fein A.J. (March 2025). The Top Pharmacy Benefit Managers of 2024: Market Share and Key Industry Developments. *Drug* Channels. Available here.
[63] Potter W. (February 2023). BIG INSURANCE 2022: Revenues reached $1.25 trillion thanks to sucking billions out of the pharmacy supply chain – and taxpayers' pockets. *Health Care Un-covered*. Available here.
[64] PBM Accountability Project. (December 2021). Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers. Available here.
[65] Percher E. (September 2023). Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. *Nephron Research*. Available here.
[66] Fein A.J. (May 2023). Five (or Maybe Six?) Reasons that the Largest PBMs Operate Group Purchasing Organizations. *Drug Channels*. Available here.
[67] Wadsten L., Horwitz N. (January 2026). "Bullshit" — The New Way Health Giants Hide Billions. *Hunterbrook*. Available here.
[68] Percher E. (September 2023). Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. *Nephron Research*. Available here.
[69] Fein A.J. (May 2023). Five (or Maybe Six?) Reasons that the Largest PBMs Operate Group Purchasing Organizations. *Drug Channels*. Available here.
[70] *Ibid*.
[71] OPM Office of the Inspector General. (March 2024). Audit of the American Postal Workers Union Health Plan's Pharmacy Operations as Administered by Express Scripts, Inc. for Contract Years 2016 through 2021. Available here.
[72] OPM Office of the Inspector General. (November 2024). Audit of Compass Rose Health Plan's Pharmacy Operations as Administered by Express Scripts, Inc. for Contract Years 2017 through 2022. Available here.
[73] Illinois.gov. (May 2025). Illinois Recovers $45 Million Settlement from CVS Caremark. Available here.
[74] Wadsten L., Horwitz N. (January 2026). "Bullshit" — The New Way Health Giants Hide Billions. *Hunterbrook*. Available here.
[75] The Capitol Forum. (April 2023). Healthcare Antitrust Weekly: Ohio AG Sues PBMs for Using "Rebate Aggregators" to Fix Prices; DOJ Decision Not to Litigate CVS/Signify Further Boosts Odds of Section 2 Investigation into U.S. Healthcare Behemoths. Available here.
[76] FTC. (February 2026). FTC Secures Landmark Settlement with Express Scripts to Lower Drug Costs for American Patients. Available here.
[77] Fein A.J. (January 2026). The Big Three PBMs' 2026 Formulary Exclusions: MFP, Private Label Biosimilars, and Direct-to-Patient Threats for PBMs. *Drug Channels*. Available here.
[78]Percher E. (September 2023). Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. *Nephron Research*. Available here.
[79] Mulcahy A.W., Kareddy K. (October 2021). Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships. *ASPE*. Available here.
[80] Duy D., Geldsetzer P. (August 2021). Trends in Mail-Order Prescription Use among U.S. Adults from 1996 to 2018: A Nationally Representative Repeated Cross-Sectional Study. *American Journal of Preventive Med*. Available here.
[81] Community Oncology Alliance. (May 2022). COA Formal Comments to FTC on Harm of Pharmacy Benefit Manager Integration. Available here.
[82] National Association of Insurance Commissioners. (February 2026). Medical Loss Ratio. Available here.
[83] Milliman. (February 2026). Medical Loss Ratio Requirements: Challenges Posed by Vertical Integration. Available here.

[84] Angeles J., Bailit M. (September 2025). How Insurers That Own Providers Can Game The Medical Loss Ratio Rules. *Health Affairs Forefront*. Available here.
[85] Arnold D.R., Fulton, B.D. (November 2025). UnitedHealthcare Pays Optum Providers More Than Non-Optum Providers: Article examines UnitedHealthcare payments to Optum providers compared with other non-Optum providers. *Health Affairs*. Available here.
[86] FTC. (January 2025). Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. Available here.
[87] Walker J. (September 2023). Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. *Wall Street Journal*. Available here.
[88] Warren E. (June 2024). Letter to Federal Trade Commission. Available here.
[89] Avalere. (November 2021). Utilization Management Trends in the Commercial Market, 2014–2020. Available here.
[90]Avalere. (May 2025). Commercial Step Therapy May Include Steps Beyond FDA Label. Available here.
[91] Rucker J.A., Beinfeld M.T., Jenkins N.B., et al (August 2023). Commercial coverage of specialty drugs, 2017–2021. *Health Affairs Scholar*. Available here.
[92] Cencora. (July 2025). Persistent growth in PBM formulary exclusions continues to raise concerns about patient access. Available here.
[93] IQVIA. (Forthcoming, February 2026). Increasing Payer Control for Medicare Patients Initiating Therapy on Branded Medicines.
[94] IQVIA. (Forthcoming, February 2026). Increasing Payer Control for Commercial Patients Initiating Therapy on Branded Medicines.
[95] HHS OIG. (September 2019). Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs. Available here.
[96] *Ibid*.
[97] *Ibid*.
[98] Biniek J.F., Sroczynski N., Freed M., et al. (January 2016). Medicare Advantage Insurers Made Nearly 53 Million Prior Authorization Determinations in 2024. *KFF*. Available here.
[99] Howell S., Yin P. T., Robinson J. C. (August 2021). Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. *Health Affairs*. Available here.
[100] Struthers A., Chapman M.A., Charles D., et al. (November 2024). Utilization Management and Physician Burnout. *The American Journal of Managed Care*. Available here.
[101] American Medical Association. (2025). 2024 AMA prior authorization physician survey. Available here.
[102] PhRMA analysis of: CBO. (June 2024). Medicare Baseline Projections. Available here.; CMS. (June 2025). Projected National Health Expenditures. Available here.; KFF. (February 2025).10 Things to Know About Medicaid Managed Care. Available here.; CBO. (September 2023). Health Insurance and Its Federal Subsidies: CBO and JCT's May 2023 Baseline Projections. September 2023. Available here.; CBO. (June 2024). Health Insurance and Its Federal Subsidies: CBO and JCT's June 2024 Baseline Projections. Available here.
[103] PhRMA. (May 2025). The AHIP premium dollar corrected (again). Available here.
[104] *Ibid*.
[105] *Ibid*.
[106] Blalock E., Ferritto M., Taylor J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research Group*. Available here.
[107] *Ibid*.
[108] Klaisner J., Schweitzer K., Huang P. (December 2025). Variations in outpatient hospital reimbursement for autoimmune drugs. *Milliman*. Available here.
[109] Blalock E. (May 2025). Measuring the Relative Size of the 340B Program: 2022 Update. *Berkeley Research Group*. Available here.
[110] HRSA. 340B Ceiling Price Final Rule, 82 Fed. Reg. 1210 (Jan. 5, 2017); HRSA, Delay of Effective Date of 340B Ceiling Price Final Rule, 83 Fed. Reg. 61563 (November 2018).
[111] Robinson J., Whaley C., Dhruva S. (January 2024). Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance. *N Engl J Med*. Available here.
[112] 340B Industry Roundtable. (January 2024). 340B Program at a Glance. *Berkeley Research Group*. Available here.
[113] Masia N. (May 2021). 340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019. *AIR340B*. Available here.
[114] Blalock E. (May 2025). Measuring the Relative Size of the 340B Program: 2022 Update. *Berkeley Research Group*. Available here.
[115] HRSA. (December 2025). 2024 340B Covered Entity Purchases. Available here.

[116] Blalock E., Ferritto M., Taylor, J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research Group*. Available here.
[117] CBO. (September 2025). Growth in the 340B Drug Pricing Program. Available here.
[118] Blalock E., Launsbach C. (July 2025). The Financial Impact to Medicaid from the 340B Drug Pricing Program. *Berkeley Research Group*. Available here; Blalock E., Taylor J. (October 2025). The Financial Impact to Medicare from the 340B Drug Pricing Program. *Berkeley Research Group*. Available here.
[119] Blalock E., Launsbach C. (January 2026). Site-of-Care Shift for Physician-Administered Drug Therapies: 2026 Update. *Berkeley Research Group*. Available here.
[120] PhRMA. (September 2025). PhRMA Announces Major Actions as Part of Industry's Commitment to American Patients and Workers. Available here.
[121] Mulcahy A.W., Kareddy K. (October 2021). Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships. *ASPE*. Available here.
[122] *Ibid*.
[123] IQVIA. (April 2024) The Use of Medicines in the U.S.: Usage and Spending Trends and Outlook to 2028. Available here.
[124] Pham N.D., Pipes S.C., Winegarden W. (January 2026). Imbalance of Financial Risks and Economic Rewards in the U.S. Healthcare Supply Chain. *PRI Center for Medical Economics and Innovation Issue Brief* here.
[125] *Ibid*.
[126] I-MAK Exposed. (February 2026). Available here.
[127] Lietzan E., Acr K.M. (2022). Solutions Still Searching for a Problem: A Call for Relevant Data to Support" Evergreening" Allegations. *Fordham Intell. Prop. Media & Ent. LJ*, *33*, 788. Available here.
[128] Mossoff A. (2022). Unreliable Data Have Infected the Policy Debates Over Drug Patents. *Hudson Institute*. (January 2022). Available here.
[129] Grabowski H., Long G., Mortimer R., et al. (August 2021). Continuing trends in U.S. brand-name and generic drug competition. *Journal of Health Economics*. Available here.
[130] USPTO. (2024). Drug Patent and Exclusivity Study. Available here.
[131] Royzman I., Sublett D. (July 2025). 'Skinny Label' Legislation Is a Solution in Search of a Problem. *Bloomberg Law*. Available here.
[132] Whyte L.E. (November 2025). RFK Jr. Discussed Curbing FDA Head's Role After Complaints About Management Style. *The Wall Street Journal*. Available here.
[133] FDA at a Glance. (October 2019). Regulated Products and Facilities. Available here.
[134] Incubate Coalition. (2024). Incubate Investment Survey: U.S. Policy Will Decide U.S. - China Race for Biotech Leadership. Available here.
[135] Blalock E., Ferritto M., Taylor J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research Group*. Available here..; All dollar figures were inflation-adjusted to 2020 using CPI data from the Bureau of Labor Statistics.
[136] PhRMA analysis of: Blalock E., Ferritto M., Taylor J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research Group*. Available here. ; CBO. (February 2023). How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. Available here.; Internal baseline and consultant projections of Medicaid rebate and Part D Manufacturer Discount Program discount obligations. All dollar figures were inflation-adjusted to 2020 using CPI data from the Bureau of Labor Statistics and projections of CPI from CBO's January 2025 economic projections.
[137] VitalTransformation. (September 2025). Most Favored Nation (MFN) Reference Pricing in Medicare Impacts on Jobs, Innovation, and State Budgets. Available here.
[138] Philipson T., Zhang D., Zhao Q., et al. (September 2025). Policy Brief: The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs. *University of Chicago*. Available here.
[139] Winegarden W. (June 2025). The 340B Discounts Hospitals Receive Will Often Exceed Total Drug Prices in Europe. *Pacific Research Institute*. Available here.
[140] *Ibid*.
[141] Axelsen K., Jeppson H. (January 2026). Keeping watch on Medicare: 2026 maximum fair prices for ten selected drugs. *DLA Piper.* Available here.
[142] 90 Fed. Reg. at 60338. (Dec. 23, 2025).
[143] Danzon P. M., Wang Y. R., Wang L. (July 2003). The impact of price regulation on the launch delay of new drugs—evidence from twenty-five major markets in the 1990s. *Health economics*. Available here.
[144] Eger S., Mahlich J. C. (October 2014). Pharmaceutical regulation in Europe and its impact on corporate R&D. *Health economics review*. Available here.

[145] National Security Commission on Emerging Biotechnology. (December 2025). New Analysis: Urgent Policy Action Needed to Maintain U.S. Global Leadership over China in Biotech Innovation. Available here.
[146] IQVIA. (March 2025). Global Trends in R&D 2025. Available here.
[147] GlobalData. (October 2025). China's Evolution in Global Drug Development and Clinical Trials: Strategic Intelligence. Available here.
[148] McKinsey and Co. (January 2026). The Emerging epicenter: Asia's Role in Biopharma's future. Available here.
[149] Neufeld J. (March 2022). "STEM immigration is critical to American national security," Institute for Progress. Available here.