2023 Johnson & Johnson
Innovative Medicine

U.S. pricing transparency report

Creating the next era of healthcare advancements for patients

Johnson&Johnson

cp-468421

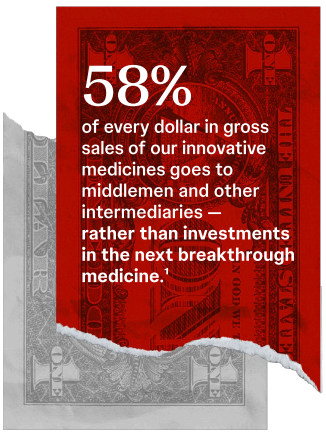
2023 at a glance

J&J Innovative Medicine is advancing the next era of medical innovation through our continuous R&D investments. Our net prices have continued to decline since 2016, but despite that, patients' cost exposure and access challenges are increasing because of distorted insurance benefit design.[1]

Rebates and discounts to middlemen and private insurers continue to grow

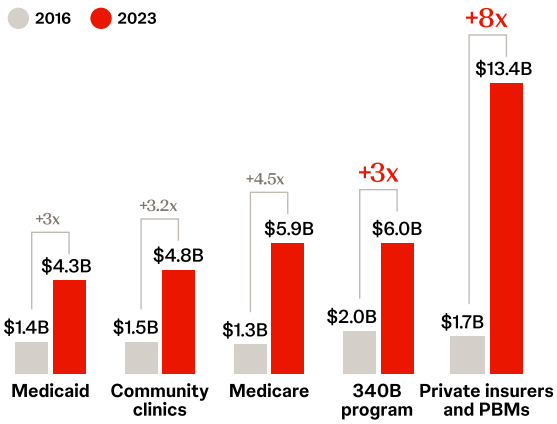
Our rebates, discounts and fees reached **$42.8 billion in 2023.**[1]

The result:



Since 2016, the first year of the Transparency Report, our rebates, discounts and fees have grown each year.

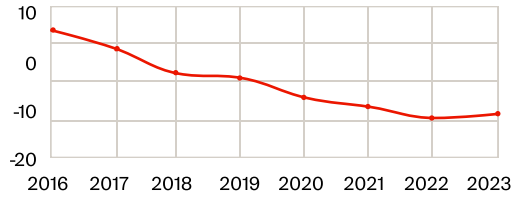
Growth in rebates, discounts and fees, 2016–2023[1]



Our net prices have declined by 18.6% since 2016[1]

The gap between U.S. list prices, which is what we charge insurance companies, and net prices for brand-name medicines, which is after rebates and discounts provided to private insurers and other intermediaries, **grew by 45% from 2017 to 2022.**[2]

J&J Innovative Medicine net price change (compounded %)[1]



Higher premiums and increasing cost exposure are a growing burden for families

The continuous growth in health insurance premiums is associated with limiting growth in wages for families, while patient cost exposure increases faster than the net cost of medicines that insurers and middlemen pay.[3,4]

By one estimate total out-of-pocket costs to patients may escalate to $800 billion by 2026...

... equivalent to placing a **$4,500** tax on every U.S. worker[5]

Our R&D: Developing the next generation of medicines

$12B

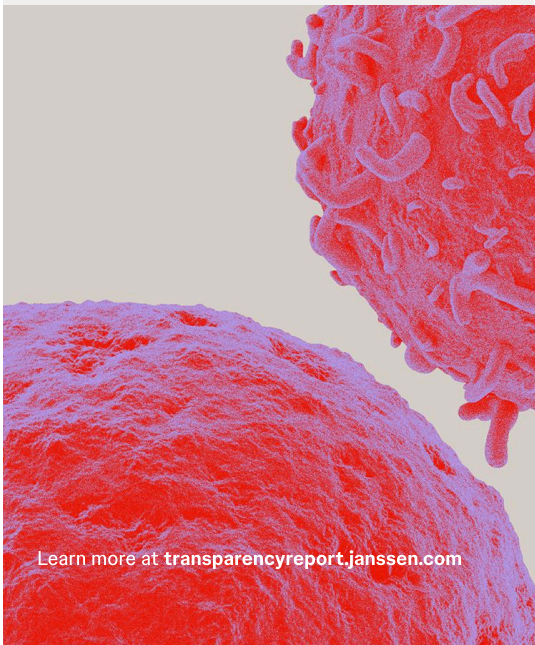
J&J Innovative Medicine total investments in 2023 to research and develop treatments and cures[1]

>124%

Amount spent on R&D in 2023 compared to sales and marketing[1]

94

Current number of new products and indications listed for pharmaceutical development[6]



Learn more at **transparencyreport.janssen.com**

Introduction

The inspiration and possibility of discovering the next breakthrough treatment for patients energizes our scientists, researchers and medical professionals to relentlessly pursue cutting-edge science every day. This complex, interconnected and often misunderstood system is supported through private sector investment and scientific expertise, public sector infrastructure and targeted public policy.

What has this healthcare innovation ecosystem delivered for patients?

Across the healthcare innovation ecosystem, more than 600 critical treatments have been discovered that are meeting the unmet healthcare needs of millions of patients living with rare diseases:[7]

- The development of a first-of-its-kind, FDA-approved CAR-T therapy harnessing a patient's own immune system, or T cells, to fight cancer.[8, 9]
- The discovery of a potential breakthrough therapy to treat pregnant individuals at high risk of severe hemolytic disease of the fetus and newborn (HDFN) — a serious and rare condition that occurs when a mother's immune system attacks her unborn child's blood cells.[10, 11]

However, these advancements in healthcare do not guarantee benefits for patients. More needs to be done to protect our nation's innovation ecosystem, especially when the following is considered:

- One out of every five Americans lives with some form of mental illness, including more than one of every 20 adults who live with severe mental illness.[12]
- Millions more will suffer from debilitating diseases like psoriasis that, left untreated, can severely undermine a patient's quality of life.[13]
- By 2030, 22.1 million individuals in the U.S. will be newly diagnosed with cancer.[14]

By putting patients' healthcare needs first, it is possible to propel America's leadership role in delivering the next era of healthcare advancements benefiting patients, the healthcare system and society.

So how does the nation protect and spur the next wave of healthcare advancements for patients?

It starts with continual investments into research and development. Every year, the private sector commits upwards of a quarter trillion dollars to research and develop innovative medicines.[15] Since 2016, J&J Innovative Medicine alone has invested **$77.7 billion** in research and development to deliver the next era of treatments and cures.[1] Our investments to discover the next generation of breakthrough treatments focus on a wide spectrum of diseases including cancer, neurological diseases, mental illnesses and tough-to-treat autoimmune diseases. J&J Innovative Medicine expects to achieve eight approvals by the FDA in 2024.[16] By 2030, J&J Innovative Medicine expects to launch or file more than 70 novel therapies and expanded treatment options for patients.[17]

Second, **patients need access to critical treatments and cures.** J&J Innovative Medicine supports access through negotiations that lower the prices (our net prices) of medicines paid by middlemen as well as other intermediaries.

Since 2016, J&J Innovative Medicine has invested **$77.7 billion** in research and development to deliver the next era of treatments and cures.[1]

$77.7B

$42.8B

In 2023 alone, we provided **$42.8 billion** in rebates, discounts and fees to insurers, pharmacy benefit managers (PBMs), hospitals, government programs and other healthcare entities.[1]

In 2023 alone, we provided $42.8 billion in rebates, discounts and fees to insurers, PBMs, hospitals, government programs and other healthcare entities.[1] Since 2016, these negotiations have lowered our U.S. net prices by **18.6%**.[1]

We also support patient access through free product provided both directly to patients as well as donated through the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF), which totaled **$3.8 billion in 2023.**[1] Our patient access support programs helped more than **1.1 million patients** get their medicines in 2023.[18]

Third, **targeted policies are needed to bolster medical innovation and make it easier for patients to get their medicines.** Due to increasing payer restrictions and cost exposure policies, only 46% of the prescriptions patients received from their doctors for novel medicines were filled at the pharmacy counter in 2023.[19] Benefit design needs to change so that patients aren't just nominally insured but are also covered. Policies should work to close the "affordability gap"—the difference between the actual prices insurers and intermediaries pay for medicines and what these middlemen charge patients. Policies are also needed to prevent misguided government price setting and regulations from undermining the nation's R&D innovation ecosystem.

Our eighth U.S. Pricing Transparency Report provides key data, analysis and insights that will help advance solutions to create a more sustainable, equitable and innovative healthcare system.

We issue this report annually to help shape future policy that supports patients and fosters innovation. By bolstering the current patient-centric innovation ecosystem, together our nation will advance human health more in the next decade than we have in the last century.

J&J's R&D investments:

Making the hope of innovation a reality for patients in the next decade ... and beyond

Johnson & Johnson aims to drive scientific breakthroughs that improve health for everyone. We know a great idea can come from anywhere, and we are proud of our strong record of cultivating data-driven innovation and targeting our scientific know-how to meet patient needs.

Since 2016, J&J Innovative Medicine has invested more than $77.7 billion in R&D, nearly double what we spent on marketing and sales in the same timeframe.[1] This growing investment enables our scientists to rigorously pursue new medicines from early discovery through clinical development, informed by comprehensive safety and efficacy studies.

Our investments to discover the next generation of breakthrough treatments focus on a wide spectrum of diseases, including cancer, neurological diseases, mental illnesses and tough-to-treat autoimmune diseases. J&J Innovative Medicine expects to achieve eight approvals by the FDA in 2024.[16]

As we look to the future of medicine, J&J Innovative Medicine is focused on continuing to lead where medicine is going. **Today, we have 94 new products and indications listed for pharmaceutical development.[6] Through 2030, we expect to launch or file more than 70 novel therapies and expanded treatment options for patients.[17]**

94 New products and indications we have listed for pharmaceutical development.[6]

Number of novel therapies and expanded treatment options for patients we expect to launch or file by 2030.[17] **70+**

Protecting the health of mothers and babies

Hemolytic disease of the fetus and newborn (HDFN) is a serious and rare disease that was once responsible for thousands of infant deaths each year.[20] HDFN also puts the health of mothers at risk.[11] While medical advancements have been made to treat HDFN (including blood transfusion), these treatments also carry risks.[21]

J&J has been leading research to discover treatments for HDFN. FDA granted Breakthrough Therapy Designation (BTD) for a J&J Innovative Medicine treatment that is a novel approach for patients at risk of severe HDFN who need safe, non-surgical solutions to help address the serious health consequences of this condition.[10, 11]

How important is the U.S. as a leading global hub for R&D?[15]

Based on a comprehensive measure, industry R&D funding is even larger than conventionally reported: Every year, the private sector commits upwards of a quarter trillion dollars to research to develop innovative medicines. The U.S. is the undisputed global hub for biopharmaceutical R&D: In 2021, approximately 48% of all global companies engaged in biopharma R&D were headquartered in the U.S., accounting for 55% of worldwide R&D investments and 65% of all development-stage funding. The R&D intensity, or the share of revenues pharmaceutical companies reinvest back into research, is highest for U.S.-based companies. R&D intensity is 30% for publicly listed firms in the U.S., ranking above any other country's biopharmaceutical innovation sector.

A success story for patients: Private-sector R&D investments coupled with effective government policy helps meet unmet patient needs

An orphan drug is one intended for use in a rare disease, which is defined as a disease that affects fewer than 200,000 people in the United States.[7] More than 7,000 rare diseases have been identified, and an estimated one in 10 Americans lives with a rare disease; half of them are children.[7] Still, about 95% of rare diseases don't have a treatment approved by the U.S. Food and Drug Administration (FDA), according to the Rare Disease Company Coalition.[22] To encourage manufacturers to address this unmet patient need, in 1983 the federal government passed the Orphan Drug Act (ODA). Under the ODA, a company may qualify for research grants, tax credits for qualified clinical trials and potential seven-year market exclusivity after a drug's approval, among other benefits.[23]

The result: Before the ODA was passed, the FDA had approved just 38 orphan drugs to treat rare diseases. Today, more than 650 orphan drugs have been approved by the FDA — with more in development.[22]

Orphan drugs approved to treat rare diseases **before the ODA passed[22]**

Orphan drugs approved to treat rare diseases **after the ODA passed[22]**

Tackling the hardest unmet patient needs

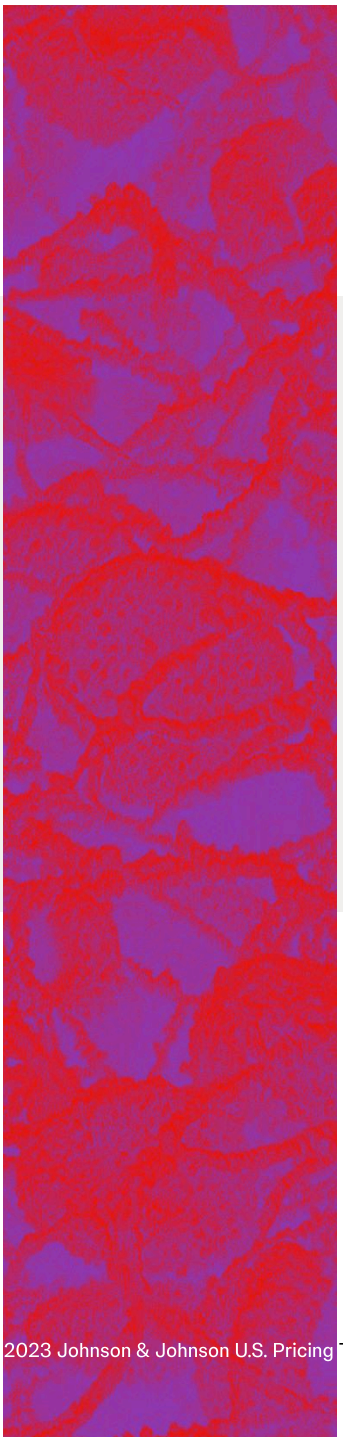
J&J Innovative Medicine uses its unique experience, scientific know-how and technology to help patients with unmet needs. Our scientists are relentlessly searching for the next breakthrough in areas of medicine that can make the biggest difference, including discovering treatments for rare diseases like pulmonary arterial hypertension, rare inherited retinal diseases, rare maternal/fetal diseases, blood cancers (including multiple myeloma and non-Hodgkin's lymphoma), AL amyloidosis and myasthenia gravis.[23]

Harnessing the next generation of personalized treatments with precision medicine

Teams of J&J scientists, researchers and medical experts are focused on innovative treatments in the emerging field of precision medicine. Precision medicine relies on identifying individual patient characteristics, such as a patient's genetic profile, to be included in clinical trials of therapies and treatments.[24, 25] If these treatments or therapies are then approved, they can be quickly and properly adopted in healthcare systems around the world. The goal is to treat patients with greater precision — and greater success. J&J Innovative Medicine has been at the forefront of precision medicine with the delivery of a first-of-its-kind targeted treatment for an aggressive form of bladder cancer (which received FDA Breakthrough Therapy Designation in 2019)[26]; the first targeted therapy approved by the FDA for advanced non-small cell lung cancer in patients with a specific genetic mutation (2021)[25]; and first-line targeted treatment for prostate cancer patients who carry a certain mutation and for whom chemotherapy is not clinically indicated (2023).[25]

J&J Innovative Medicine is at the forefront of precision medicine, using genetic profiles to discover treatments, like gene therapies, for previously untreatable diseases. We are leading where medicine is going. The challenge ahead is supporting greater patient access and advancing policies that bolster, not undermine, the next era of medical breakthroughs.

Patients need affordable access to medicines



Affordable access to medicines is a major concern for patients and their families. At J&J Innovative Medicine, we understand our dual responsibilities: (1) to develop the next generation of medicines across a vast continuum of diseases for the patients of tomorrow and (2) to help support affordable access to our medicines.

To meet these responsibilities we have to patients, the healthcare system and society, we consider three factors when pricing our medicines:

01 We price our medicines based on the value they bring to patients, the healthcare system and society.

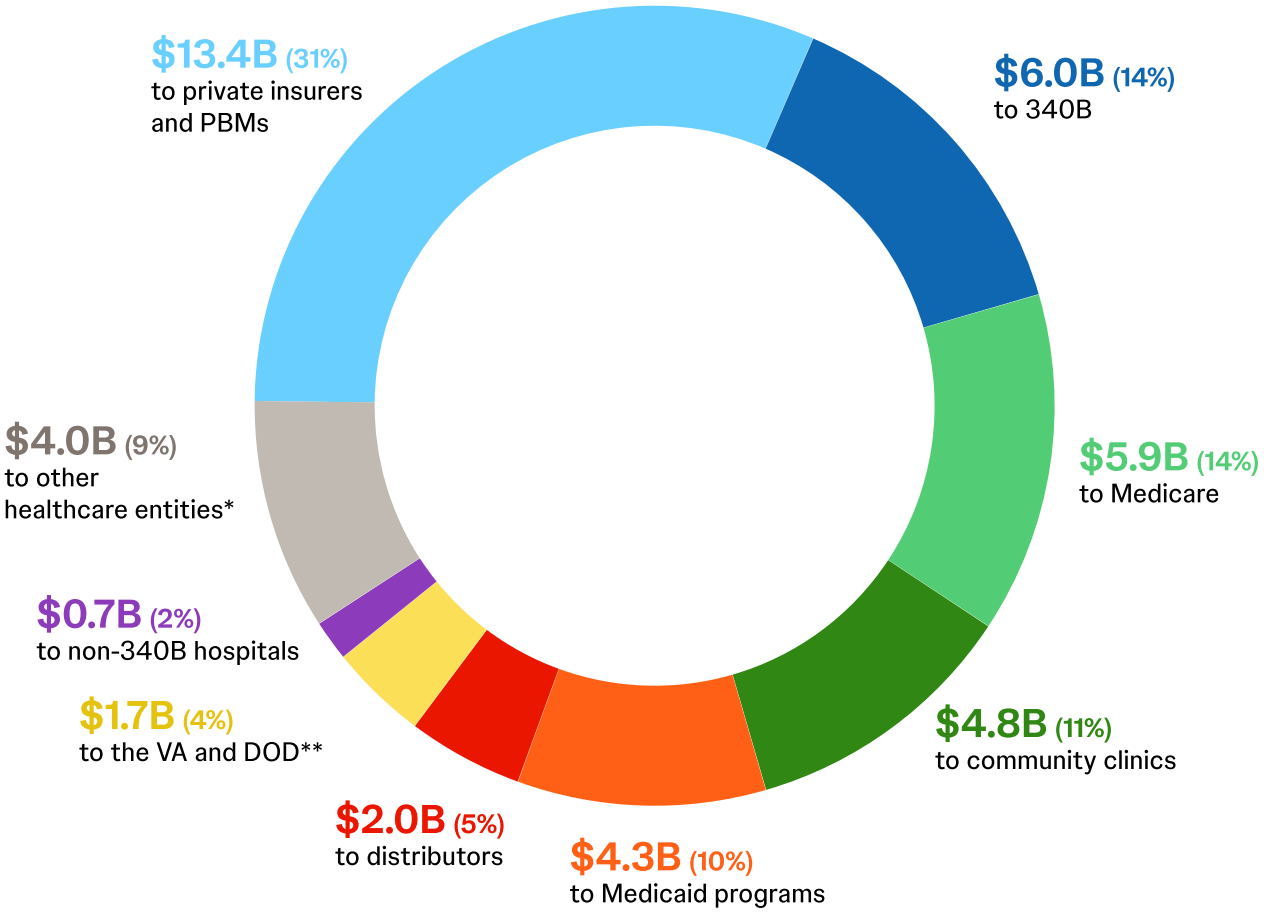
02 We price our medicines to further support patient access.

03 We price our treatments so we can continue innovating and developing new medicines for the patients of today and tomorrow.

Our negotiations with private payers and PBMs lead to lower net drug prices. Our net prices have declined by nearly 20% over the past seven years.[1] Despite lower net prices paid by insurers for our medicines, millions of patients are still facing higher costs and barriers to access. Some payers are even taking patient assistance from patients. The choice moving forward is to keep the current system or move toward a system that ensures (1) rebates are passed on to patients to lower their cost exposure and (2) patient assistance is not diverted away from the patients it is meant to help.

$42.8 billion paid in rebates, discounts and fees

In 2023, we provided **$42.8 billion in rebates, discounts and fees** to insurers, pharmacy benefit managers (PBMs), hospitals, government programs and other healthcare entities.[1]



*"Other healthcare entities" refers to other sites of care, less known payer organizations and other healthcare intermediaries.
All figures according to Johnson & Johnson internal financial accounting. Figures have been rounded.
**Department of Veterans Affairs and Department of Defense

The summary

01

42% of all discounts, rebates and fees go to government programs[1]

02

Nearly 1/3 of discounts, rebates and fees go to health insurers and PBMs[1*]

03

Patients are not directly benefiting from these growing savings

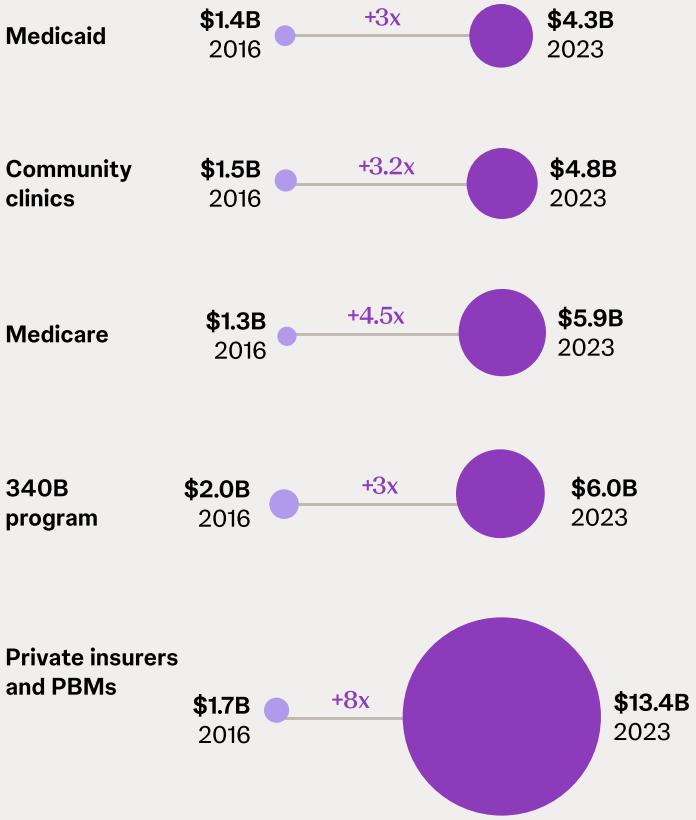
Drug list prices are simply a starting point. Manufacturers like J&J Innovative Medicine support patients' access to their medicines through vigorous private-market negotiations with health insurance companies, PBMs and other intermediaries that dispense medications (e.g. hospitals and clinics). J&J Innovative Medicine negotiates lower net prices to expand access and to make drugs more affordable for patients, not to benefit middlemen and other intermediaries.

Despite a more than $250 billion growth in industry-wide rebates and discounts in 2022 — which has lowered net prices — middlemen are making it harder for patients to get the medicines they need.[2, 28, 37] These middlemen, who control access to medicines through insurance design, have made changes including programs that divert financial assistance away from patients, changes to the types of medicines covered and changes to the extent of coverage.

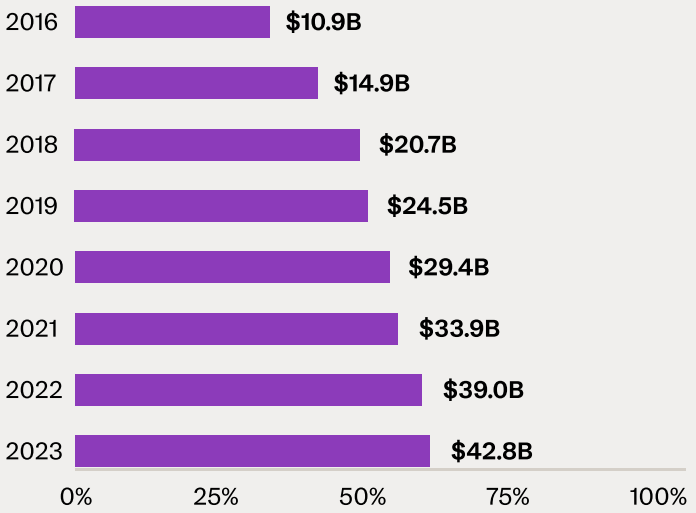
J&J Innovative Medicine's net prices have declined by nearly 20% since 2016[1]

Soaring inflation has impacted every sector of the U.S. economy. Prices on American goods were more than 20% higher in January 2024 than they were seven years earlier.[29] Since 2016, our net prices have declined by 18.6%.[1]

Rebates, discounts and fees from 2016 to 2023[1*]



Rebates, discounts and fees as a % of gross sales[1*]



*Figures have been rounded.

How J&J Innovative Medicine directly supports patients

In 2023, our CarePath program helped more than 1.1 million U.S. patients access their prescribed treatments.[18] We delivered more than $3.8 billion of free product provided both directly to patients as well as donated through the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF), an independent, nonprofit organization.[1]

Underinsurance leaves patients financially exposed

The share of Americans without *any* health insurance hit an all-time low in 2023, but 23% of working-age adults with insurance coverage are now classified as being *under*insured.[31, 32] That means their insurance benefit design leaves them open to significant financial risks that effectively make healthcare unaffordable.[31] Vulnerable patients are disproportionately impacted by this financial hardship.[31]

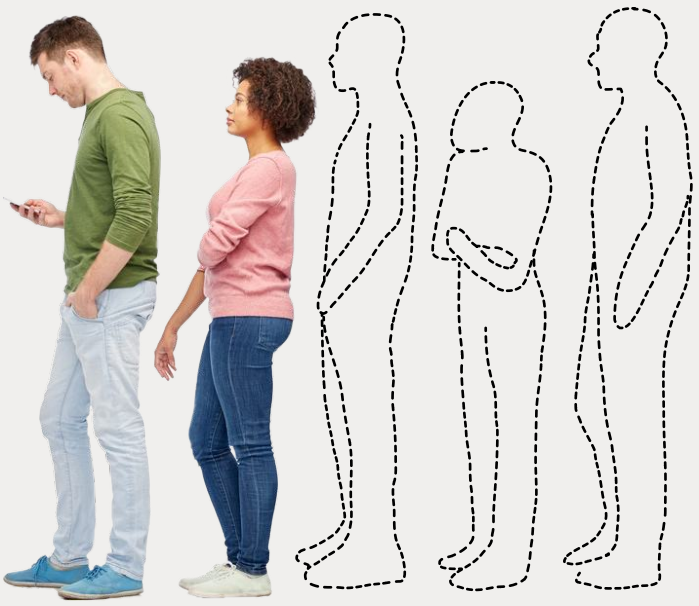
Pharmacy benefit managers create barriers to access

In theory, PBMs manage prescription drug benefits for insurers. In practice, PBMs have become medical middlemen, often impeding provider and patient healthcare decision-making. To restrict the types of medicines covered, PBMs use programs like prior authorization, step therapy and formulary exclusions, which can even eliminate access to certain medicines.[7] PBMs' growing use of restrictions and opaque operating models are creating significant hurdles for providers and patients to make the right healthcare decisions based on clinical evidence.

Distortions in health insurance benefit design are changing what it means to be insured

When health insurance works as intended, insured patients can affordably access their treatments when they need to. But for millions of Americans, health insurance does not fulfill this basic purpose.[30]

When patient costs exceed $250, **more than half** of patients abandon their newly prescribed treatment.[33]



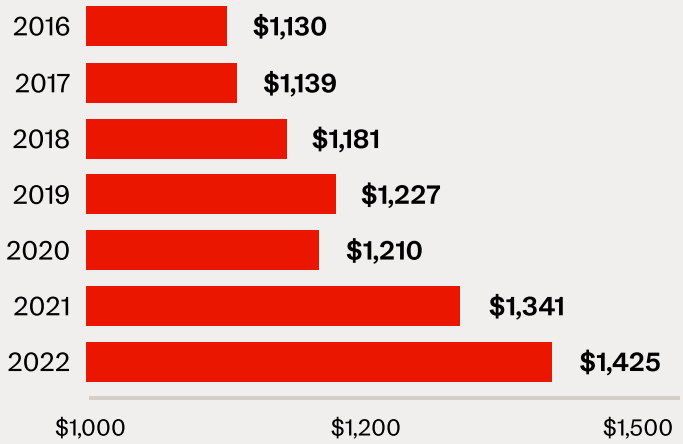
When patients' cost exposure rose to $10 and above, the total number of abandoned prescriptions rose by 24% to 52 million in 2022.[33]

Out-of-pocket costs cut access to critical treatments

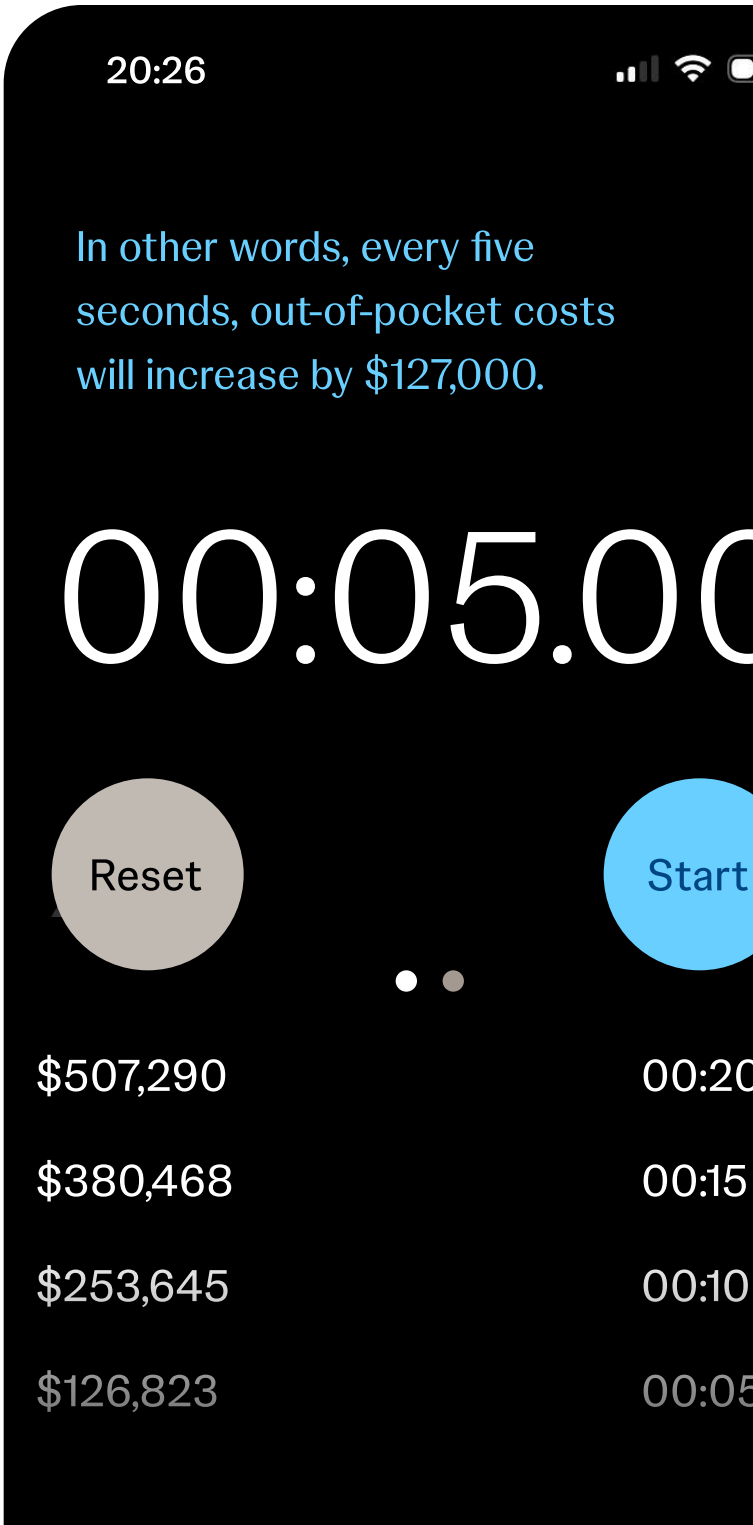
Even when insurance covers needed treatments, high deductibles and cost-sharing requirements can still make care inaccessible. Half of all adults, and 68% of low-income adults, said they could not pay an unexpected $1,000 medical bill.[34] Another report found 37% of Americans lack enough savings to cover an unexpected $400 expense.[34] Meanwhile, patient cost exposure continues to climb, causing per capita out-of-pocket patient costs to increase 26% from 2016 to 2022, totaling $1,425 in annual costs.[35] The continuous growth in health insurance premiums is associated with limiting growth in wages for families, while patient cost exposure increases faster than the net cost of medicines that insurers and middlemen pay.[3, 4] By one estimate, total out-of-pocket costs to patients may escalate to $800 billion by 2026—equivalent to placing a $4,500 annual tax on every U.S. worker.[5] As health insurance premiums continue to increase for Americans, many are falling into an affordability gap between what insurance will cover and an individual's ability to pay. For example, in Affordable Care Act (ACA) marketplace plans, families are exposed up to $18,900 before the 2024 cap on out-of-pocket costs kicks in.[36] This does not include premium payments or out-of-network care.

Between 2016 and 2022, out-of-pocket costs rose 26%.[35]

Per capita OOP expenditures, 2016-2022[29]



According to an independent study, total OOP costs are expected to grow at an annual rate of 9.9% which would result in almost $800 billion in consumer OOP healthcare spending in 2026.[5]



Patients are not directly benefiting from lower net prices

While private insurers pay lower net prices, patients still pay higher and higher costs. Why? Because the patient cost-sharing amounts set by insurance plans are often based on the initial list price, not the negotiated lower net price the private insurer pays. This is different than the costs patients typically pay for other negotiated healthcare services like hospital stays and doctor visits.[37, 38] **The gap between U.S. list prices, which is what we charge insurance companies, and net prices for brand name medicines, which is after rebates and discounts provided to private insurers and other intermediaries, grew by 45% from 2017 to 2022.[2]**

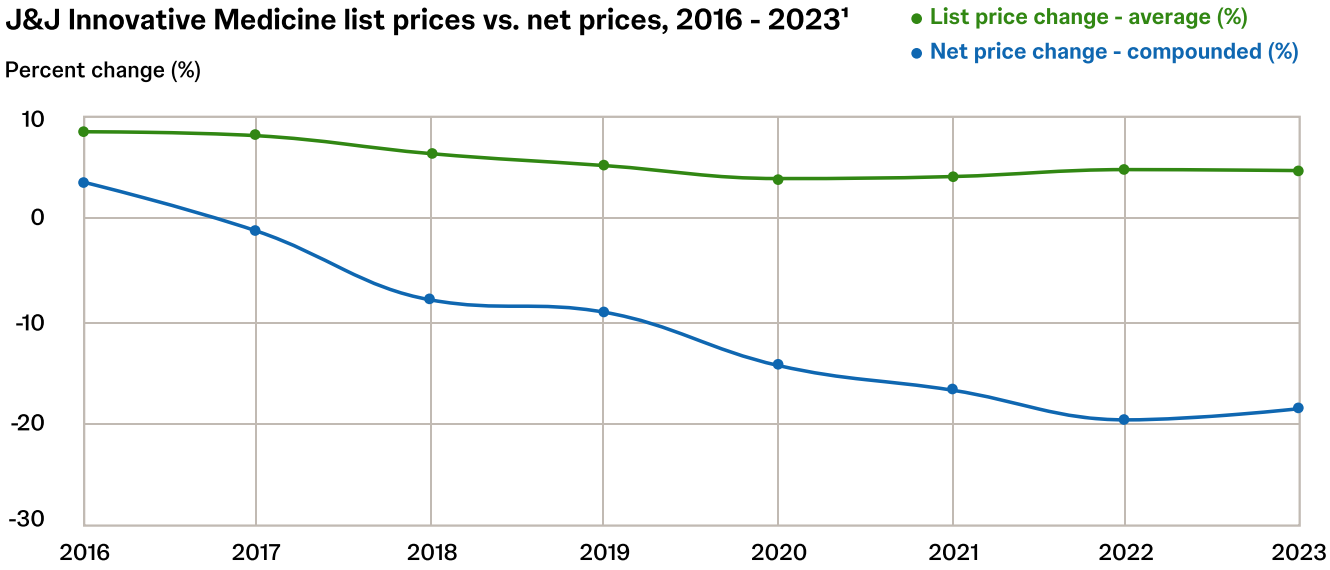
> “The choice moving forward is to keep the current system or move toward a system that lowers patients’ cost exposure, improves patient access and makes sure patient assistance is for patients only.

Patient assistance diversion programs undermine patient care

As patients face higher out-of-pocket costs due to insurance design, manufacturers have expanded patient assistance programs.

However, insurers, PBMs and other entities are deploying programs to divert these funds away from patients. These diversion programs take manufacturer assistance meant for patients by manipulating their benefit design around this assistance, effectively raising out-of-pocket costs for patients. These diversion programs make it more likely patients will abandon their treatments.[39] And critically, non-white patients are roughly 30% more likely to be exposed to these diversion programs.[40] Some third party intermediaries are also using alternative funding programs (AFPs), which can cause patients to be denied or receive delayed coverage of a needed treatment or medicine.[41] Ultimately, patient assistance should be for patients only, not third party intermediaries or middlemen.

J&J Innovative Medicine list prices vs. net prices, 2016 - 2023[1]



Understanding the policy challenges to the healthcare innovation ecosystem

Johnson & Johnson is committed to bringing life-saving medicines to patients, but the innovation ecosystem also needs policies and regulations that bolster scientific advancement. Discovering and developing life-saving medicines requires significant resources and cooperation between researchers and regulators. On average, it takes more than 12 years and $4 billion, including cost of capital for the total lifecycle, to bring a new medicine to market.[42, 43] There is inherent risk in this process, as approximately 93% of the drugs that enter clinical trials (and 97% of drugs addressing the nervous system) fail before they can make it to market.[44] Incentivizing risk-taking is a critical part of advancing medicine for patients, but many policies (either enacted or under consideration) could severely undermine the innovation ecosystem that has delivered healthcare benefits for patients.

Federal government price setting

The Inflation Reduction Act's Drug Price "Negotiation" Program enables the federal government to set prices on Medicare Part D and B drugs. Concerns are mounting that government-mandated prices could upend the ecosystem that makes discovery and development of these medicines possible, as well as the ability to expand existing treatment options to new patient populations.[45] In fact, one analysis shows the IRA could mean that 130 drugs are not discovered or developed over the next 10 years.[46] Industry analysis indicates that federal price controls have already shifted research and development away from small molecule medicines (tablets and pills), despite the numerous benefits these types of drugs have for patients.[47]

Prescription drug affordability boards (PDABs)

State policymakers are turning to prescription drug affordability boards (PDABs) and upper payment limits (UPLs) on branded medications to attempt to lower state drug expenditures and improve affordability for patients.[48] However, UPLs on branded medications remain new and untested, with minimal understanding of their short- and long-term impacts on the drug pricing ecosystem and patient access. UPLs' long-term impacts across benefit design, patient access and pricing and contracting may further impede drug pricing reform across state-regulated commercial markets. Moreover, policy changes that focus exclusively on drug pricing at the manufacturer level do not always account for responses from other stakeholders and hence may not deliver the intended shifts in patient access and affordability.

As more states take this approach and select a greater number of drugs each year for UPLs, these issues may be compounded even further.

There is no guarantee that PDABs will save patients any money at the pharmacy counter. Many state PDAB laws do not explicitly require cost savings to be passed on to the patients taking the medications subject to price controls.[48]

PDABs may also fail to consider the value and benefit to the patient.[48] PDABs could target the most innovative medicines, which would disproportionately impact patients who require specialized medicines.[48] PDABs have begun to evaluate drugs intended for vulnerable patients with chronic, life-threatening conditions, including those living with HIV, Crohn's disease or cystic fibrosis, who cannot afford to lose access to their medications.[49]

International Reference Pricing

Some policymakers have also proposed benchmarking U.S. drug price negotiations to prices in foreign countries, ignoring differences in healthcare system structure, reimbursement systems, economic circumstances, standard of care and local priorities across countries.[50]

The U.S. has benefited historically from investing in earlier access and more innovative treatments for its population. A recent analysis demonstrated that the U.S. makes available to its population through public plans 85% of new medicines, versus the 40-60% provided by established European markets.[51] As price reflects local value, setting prices based on prices in other countries also imports that country's local value system. For instance, 56% of Medicare beneficiaries who received physician-administered medicines for breast cancer would not have had access if England's National Institute for Health Care Excellence (NICE) criteria had been used.[52] Patients' timely access to prescription medicines is critical in driving better health outcomes.

The United States is globally admired for its leadership in biopharmaceutical innovation. This success stems from several key factors, including a strong domestic market and a policy environment that has historically supported basic science research and robust intellectual property protections for the private sector and which has avoided government price-setting of innovation. These policy choices have fostered significant private investment in R&D. This investment has activated the world's most advanced biomedical research infrastructure, comprehensive biomedical education and talent development, a thriving biotech startup scene and strong collaboration among academia, government and industry. This robust system delivers unmatched results — 65% of all drugs launched by G20 countries in 2021 were first launched in the United States.[51] By linking the U.S. health system to countries with completely different health economies and value systems, policymakers risk:

- Removing patient treatment options without reducing patients' costs.
- Straining providers' reimbursements, potentially forcing some to cut vital patient services.[53]
- Undercutting the innovation ecosystem that develops lifesaving treatments.
- Diminishing a critical part of the nation's economic engine and national security strength.

Intellectual property rights

The U.S. patent system sets standards that enable innovative companies to bring new products to market in every industry. In healthcare, companies strive to solve the nation's greatest medical challenges, even if it takes years of costly research to find and realize those solutions. Our patent system achieves this by requiring inventors to disclose their product details in return for time-limited rights to those inventions. The U.S. medical innovation ecosystem was built on this framework, and it now supports a robust pipeline of more than 800 treatments being developed across the biopharmaceutical industry.[54]

Limiting the ability to protect inventions or enforce patent rights associated with pharmaceutical innovation would upend the R&D innovation ecosystem that advances treatments for patients today, as well as pharmaceutical innovations for years to come.

"Marching in"

The 1980 Bayh-Dole Act was passed to promote the use of critical inventions and spur collaboration between government-funded entities and innovative companies with the expertise and capabilities necessary to develop and commercialize innovative products.[55] Since its passage, it has directly contributed to $1.3 trillion in economic growth, 4.2 million more jobs and 11,000 new startup companies.[56] As an additional measure to ensure inventions were utilized, the Act gave the federal government limited rights to "march in" if licensed innovative companies were not taking reasonable steps to advance those inventions towards commercialization. Due to the overwhelming success of the Bayh-Dole Act in fostering public-private sector collaboration, no federal agency has ever utilized this policy. The Bayh-Dole Act was never intended to be used as a price-setting mechanism, nor as a tool to seize intellectual property rights based on a government-dictated "reasonable" price. If the government "marches in" and licenses patent rights to widely available treatments, public-private sector collaboration and the innovation ecosystem will suffer.[57]

65% 65% of all drugs launched by G20 countries in 2021 were first launched in the United States.[51]

340B Program: How diversion and duplicate discounts are hurting vulnerable patients

The 340B program was designed by Congress to be a very limited, targeted program enabling manufacturers to restore deep discounts that manufacturers historically had provided voluntarily to safety net providers. However, the program has grown out of control as for-profit pharmacy chains and larger health systems have used it to boost profits without directly benefiting patients either in the hospital or at the pharmacy counter. The 340B program now accounts for nearly one out of every five dollars of manufacturer discounts.[60] In July 2023, more than 33,000 pharmacy locations—more than half the entire U.S. pharmacy industry—were contracted to dispense 340B drugs.[59] This represents a 2,400% increase since 2010.[59, 60]

As the 340B program has grown, two problematic trends have become clear: diversion and duplicate discounts. In critical program integrity provisions in the 340B statute, Congress prohibited both diversion and duplicate discounting. Diversion happens when a 340B provider dispenses 340B discounted drugs to non-eligible patients. The risk of diversion increases as the 340B program grows. Federal government audits have made more than 500 diversion-related findings among covered entity audits over an eight-year period.[61]

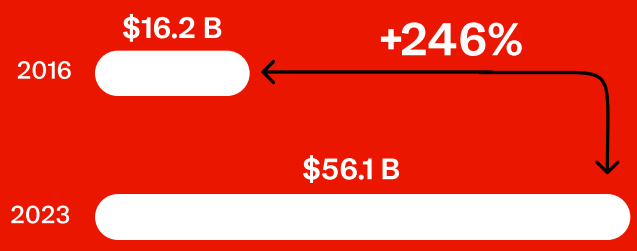
Duplicate discounts happen when a manufacturer sells a drug to a 340B provider at the 340B discount price and then pays a Medicaid rebate on that same drug. This risk, too, grows as the 340B program grows. The Government Accountability Office (GAO) found more than 400 instances of noncompliance related to duplicate discounts among audited covered entities.[61] GAO further noted that "HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts," and that "drug manufacturers [are] at risk of providing duplicate discounts."[63]

Indeed, because the Medicaid rebate program has expanded to include drugs provided through Managed Medicaid, the risk of duplicate discounting is even greater.

The evidence is unclear on whether vulnerable patients are actually benefiting from the 340B program's immense growth. Research shows the most profitable 340B hospitals are spending very little on charity care.[64] Certain 340B-covered entities purchase drugs at discounted rates and contract with external pharmacies to dispense those drugs at much higher prices. One 340B hospital made headlines in 2022 for charging seven times the amount it paid for a particular cancer drug.[65] 340B hospitals in North Carolina made headlines in 2024 for marking up cancer infusion drugs 5.4 times the 340B acquisition cost — nearly twice the mark-up rate of non-340B hospitals.[66] A recent academic study reaffirmed criticism that "the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics."[67]

According to new research in the New England Journal of Medicine, 340B hospitals now capture 64% of the insurance spending on pharmaceuticals they administer.[68] 340B discounts are not free. There is a very real cost to the larger healthcare ecosystem of increasing 340B discounts beyond the limited scope Congress intended. As the 340B program grows each year, unfettered 340B discounts reduce the resources available for future investments into tomorrow's treatments and cures. Without common-sense reform, our nation's innovation ecosystem will be undermined. **Read more in our 340B Issue Brief.**

Purchases by covered entities at discounted 340B prices have also risen.[58, 62]



340B fast facts

84.8% Higher price markup by 340B hospitals versus non-340B hospitals in North Carolina for state employees from 2020-2022[66]

12x Increase in the amount of 340B brand spending received by providers and their contract pharmacies, since 2013[69]

$10B Estimated 340B profits captured by for-profit contract pharmacies in 2023, not directly benefiting underserved populations in need[70]

Valuing pharmaceuticals in the U.S.

When the U.S. innovation ecosystem works as intended, supported by policies that promote innovation, it leads to more effective and personalized treatments that are available faster, earlier intervention and smarter, less invasive healthcare for patients today and in the future.

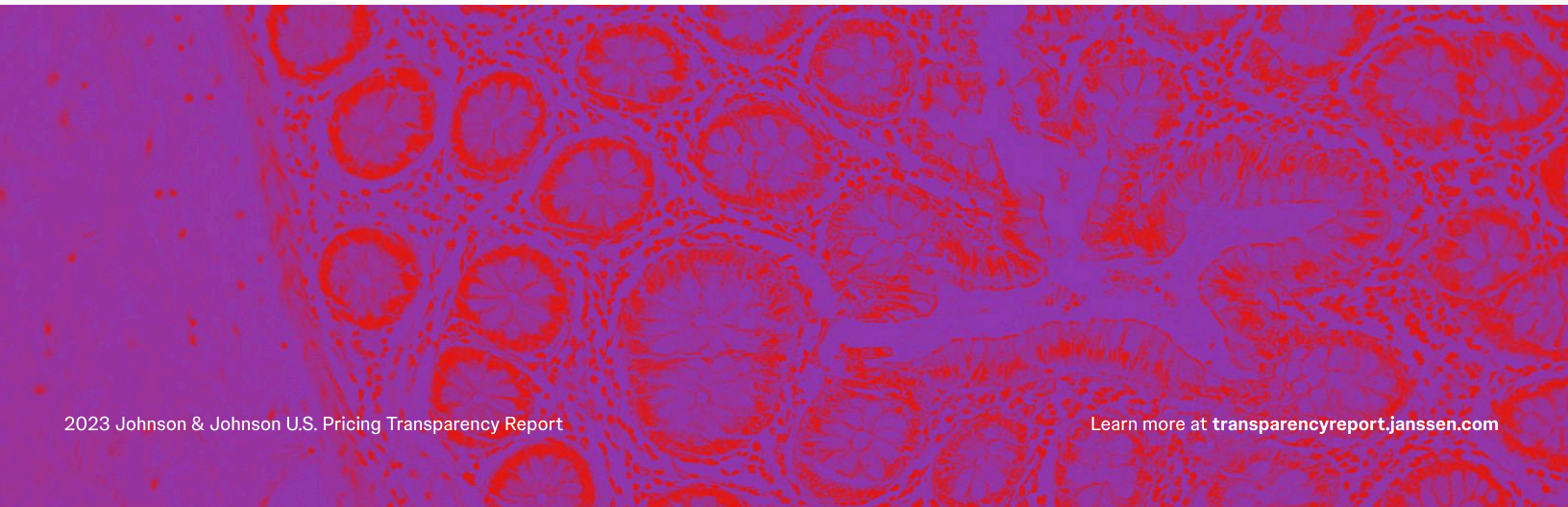
Misunderstanding the value of medicines

Each patient has unique needs, and the healthcare ecosystem should support all patients in getting timely, affordable access to the treatments that are best for them. Unfortunately, insurance companies routinely exclude certain medications from formularies and put in place financial barriers to limit use, often based on what works best for the average patient. This "one size fits all" approach to coverage can lead to patients being denied the treatment that is most valuable to them just because they are different from the average.[71]

Rather than fixing the problems with insurance that prohibit patients from getting the best care, some argue that the U.S. should implement a top-down population-level "value assessment" process like those used in some countries where the government dictates prices and decides on access. While these assessments begin with comparing important evidence about a treatment's efficacy, safety and quality (among other factors) versus other treatment options, they ultimately prioritize the payer perspective.[72] Even though they are based on incomplete information, the results are used as proxies for the value of medicines in the real world.

Evidence from top-down population-level value assessment systems, like those found in Europe, indicates that access challenges could be exacerbated if the U.S. adopted similar value assessment frameworks. Undervaluing medicines will not fix access problems for today's patients, and it distorts the innovation ecosystem by disincentivizing investment in the science needed to develop the treatments of tomorrow.

When the U.S. innovation ecosystem works as intended, supported by policies that promote innovation, it leads to **more effective and personalized treatments that are available faster, earlier intervention and smarter, less invasive healthcare.**



U.S. patients benefit from the earliest access to the broadest, most innovative set of therapies in the world, helping patients more easily find the treatments that work for them the best.

U.S. patients have medicines sooner

Of the 37 drugs the U.S. Food and Drug Administration (FDA) approved in 2022, 68% were first approved in the U.S.[73]

In Canada, publicly insured patients waited an average of 2.5 years longer than Americans with Medicare to have access to newly approved drugs.[74]

U.S. patients have more options

78% of drugs launched by G20 nations between 2012 and 2021 were available in the U.S. within one year of their launch, compared to just 38% in the United Kingdom and 21% in Canada.[51]

If existing U.S. top-down value assessments for treatments for multiple myeloma, multiple sclerosis and non-small cell lung cancer were applied in Medicare Part B, most patients could be forced to switch their current treatment (multiple sclerosis: 99%, non-small cell lung cancer: 85% and multiple myeloma: 83%).[75]

U.S. patients battling cancer benefit from better access

Of the 124 new cancer medicines approved globally from 2012 to 2021, American patients have access to 94% of these treatments, compared to the average of 46% in other G20 countries.[51]

Patients' needs should determine value

At Johnson & Johnson we are guided by Our Credo. Our first responsibility is to "the patients, doctors and nurses, to mothers and fathers and all others who use our products and services."[76] We need a system that supports clinically nuanced, patient-centric access to medicines so that each individual person can easily obtain the therapy that they and their doctor determine is best. This is why we believe that respect for individual patient values must be center stage in any solution and any value assessment.

We support valuations of medicines that adhere to the following principles:

Patient-centered:

A patient-centered approach is fundamental to achieve the most efficient use of medicines, not waste resources and ensure that access to treatments is nondiscriminatory. This approach respects patient autonomy by placing every patient's outcome at the forefront of decision-making.

Decentralized and locally relevant:

Valuations must consider the specific needs of local health systems. Treatment needs in rural areas or underserved communities, for instance, may differ significantly from treatment needs in metropolitan areas or communities that are adequately resourced.

Deliberative and flexible:

Valuations should be done in a deliberative way and not use strict decision rules or oversimplified metrics, like the discriminatory quality-adjusted life year (QALY), expected value of life years gained (evLYG) or healthy years in total (HYT). Instead, the full diversity of healthcare values must be considered, prioritizing those of patients.

Holistic:

Valuations must not rely on information from a small set of simple summary statistics, such as average life expectancy and average cost, but instead consider the full range of impacts to the patient, healthcare system and society. Valuations that are incomplete will distort the marketplace, resulting in both today's and tomorrow's patients receiving suboptimal care.

Clinically driven:

Clinically driven valuations best preserve the opportunity to maximize the health of every patient and should prioritize their health and safety. Financing of medicines should be considered separately and addressed through insurance solutions.

Building an equitable health system for every patient

Johnson & Johnson strives to eliminate the threats that racial and social inequities pose to public health. Every day across our organization, researchers and advocates work to identify community partners, programs and funding opportunities to help make health inequity a thing of the past. For instance, we launched Our Race to Health Equity in 2020, a $100 million program that aims to help close the racial gap in U.S. healthcare.[77]

Already, this program has committed more than $52 million to advance efforts across four key areas:[77]

01

Building community health capacity

By the end of 2022, 307,000 U.S. HCPs and researchers were provided support to develop management and community care skills.[77]

02

Making clinical trials more representative

Every patient is unique. To develop cures and treatments that serve *all* patients, clinical trial participants should reflect the diverse populations we serve. We have launched several initiatives to diversify clinical trials, such as Research Includes Me, a community-focused campaign to engage Black and Brown communities and elevate discussions around clinical trials. For more information, please visit www.researchincludesme.com.[77]

03

Engaging and educating communities

My Health Can't Wait is a community wellness initiative that connects people of color in the U.S. with vital health information and resources. To date, the initiative has reached over 100,000 people, delivered 16,000 health screenings and distributed 35,000 packets of educational materials to communities of color.[78] J&J's My Health Can't Wait initiative will also sponsor several patient-focused initiatives that are helping create greater urgency around specific health inequities that disproportionately impact communities of color. This includes the "Save Legs. Change Lives." initiative, which is addressing peripheral arterial disease-related amputations that disproportionally affects Black and Hispanic Americans.

04

Delivering culturally competent care

To tackle the role of unconscious bias in our health system, we recently co-launched a cross-sector initiative called Unconscious Bias and Disparities in Healthcare: A Call to Action, a program that helps health providers in communities of color alter their daily practices to improve patient experiences. Additionally, we continue to sponsor the Alliance for Inclusion in Medicine Scholarship Program, a scholarship fund designed to produce more doctors from historically underrepresented groups. In recent years, J&J has donated more than $2 million in scholarships.[77]

Our values

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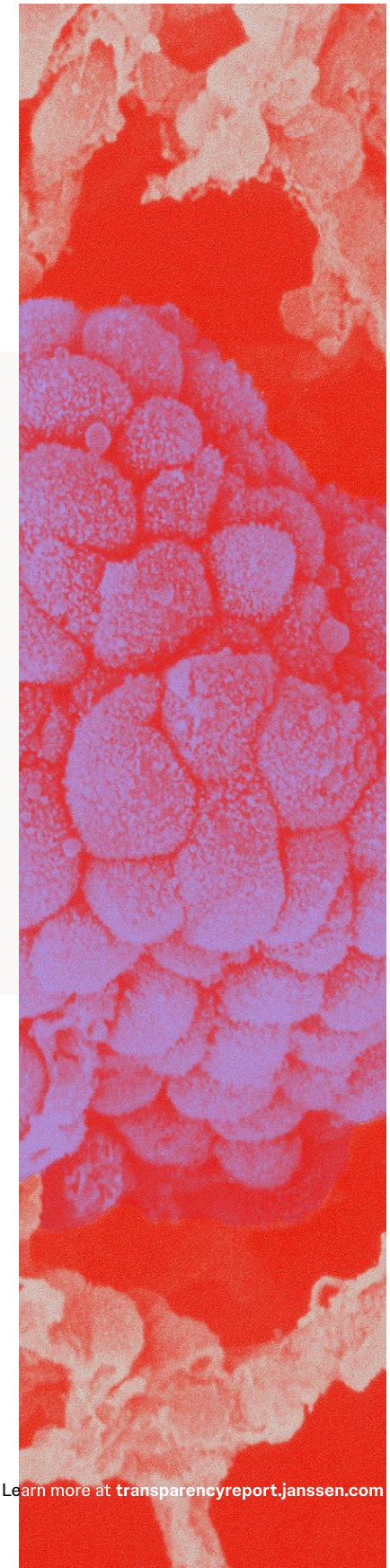

We pursue health solutions that keep patients at the center:

- Preserve the unmatched U.S. innovation ecosystem that delivers transformative treatments to the patients who need them
- Protect the patient-physician relationship and eliminate the undue influence of commercial middlemen on patient health decisions
- Reduce the racial and socioeconomic disparities that undermine public health outcomes
- Ensure patients have affordable access to effective treatments, both now and in the future

Our values inform our policy ideas so that we advance solutions that create a more sustainable, equitable and innovative healthcare system.

We also consider the experiences of our patients, who use our medicines every day, the perspectives of our scientists and researchers discovering the next medical breakthrough and our concerns about the misaligned incentives in the marketplace.

Specifically, we think the following reforms are needed:

Reform PBMs to prevent patient access hurdles, lower patient costs and promote patient-provider decision-making:

Patients would benefit from greater PBM transparency and having their costs based on net price, not list price. Patients should not face restrictive utilization management programs that interfere with patient access, affordability and treatment choice. Medical decision-making should remain between a provider and the patient. Reforms should also ensure that patients more directly benefit from the savings provided by rebates and discounts. Federal and state legislatures should pursue policies that increase PBM transparency, accountability and delink PBM fees from list prices.

Reform the 340B Program to benefit patients:

We support the original intent of the 340B program and believe increased transparency and accountability in the program will improve access to care in vulnerable communities. Federal legislation, the *340B Affording Care for Communities and Ensuring a Strong Safety-Net Act (340B ACCESS Act)*, includes critical reforms to 340B and is supported by J&J.[79] Federal reforms, like those included in the 340B Access Act, are needed to eliminate duplicate discounts and diversion, provide a robust patient definition and require 340B discounts to be shared directly with needy patients at the pharmacy counter.

Stop patient assistance diversion programs:

Patients should be protected from these types of harmful programs operated by middlemen. First, CMS should enforce the rule that health plans must count patient assistance toward out-of-pocket limits unless there is a generic option. Second, Congress should pass the HELP Copays Act, which would prohibit copay accumulator programs unless an appropriate generic equivalent is available.[80] At the state level, lawmakers can pass legislation (at least 19 states have done so already) that ensures cost-sharing assistance is counted toward patient out-of-pocket contributions, prohibits third parties from altering or conditioning the terms of health plan coverage or benefit design on the availability of financial or product assistance for a prescription drug and requires disclosures about these programs to patients.[43, 81]

Prevent the spread of alternative funding programs (AFPs): More transparency and oversight can mitigate the harms AFPs cause for patients and the larger healthcare system. The Federal Trade Commission and state regulators should review AFP industry practices. Consumers are at the most risk with the deceptive business practices of AFPs. The federal government should take steps to increase oversight of AFP practices in employer-sponsored plans. Congress and states should pursue legislation that prohibits the use of AFPs by group health plans, health insurance issuers and other entities.

Johnson & Johnson seeks to collaborate with stakeholders across the U.S. healthcare system to advance the important work of pursuing novel healthcare solutions that benefit patients. We believe together, we can find solutions to address the mental health crisis, modernize regulatory pathways, provide critical access to affordable medicines and enhance diversity in clinical trials.

At Johnson & Johnson, we are leading where medicine is going.

Citations

Notes on this report. All information in this report refers to the U.S. operations of the Janssen Pharmaceutical Companies of Johnson & Johnson, unless noted otherwise. Financial and nonfinancial information covers the period between January 3, 2023, and January 2, 2024, except where noted. The methodologies used for analyses in this report may be different from those used by other organizations. This report is not audited and is not intended to address all our required disclosures.

Additional resources. In this report, we refer to locations where you can find more information about specific Janssen U.S. and Johnson & Johnson programs, disclosures, and patient resources. Financial performance information for our parent company and its subsidiaries, as well as its "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors," can be found in Johnson & Johnson Annual Reports at jnj.com/about-jnj/annual-reports. Information on corporate sustainability measures can be found at the Johnson & Johnson Health for Humanity Report at healthforhumanityreport.jnj.com.

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