

# The 2022 Janssen U.S. Pricing Transparency Brief

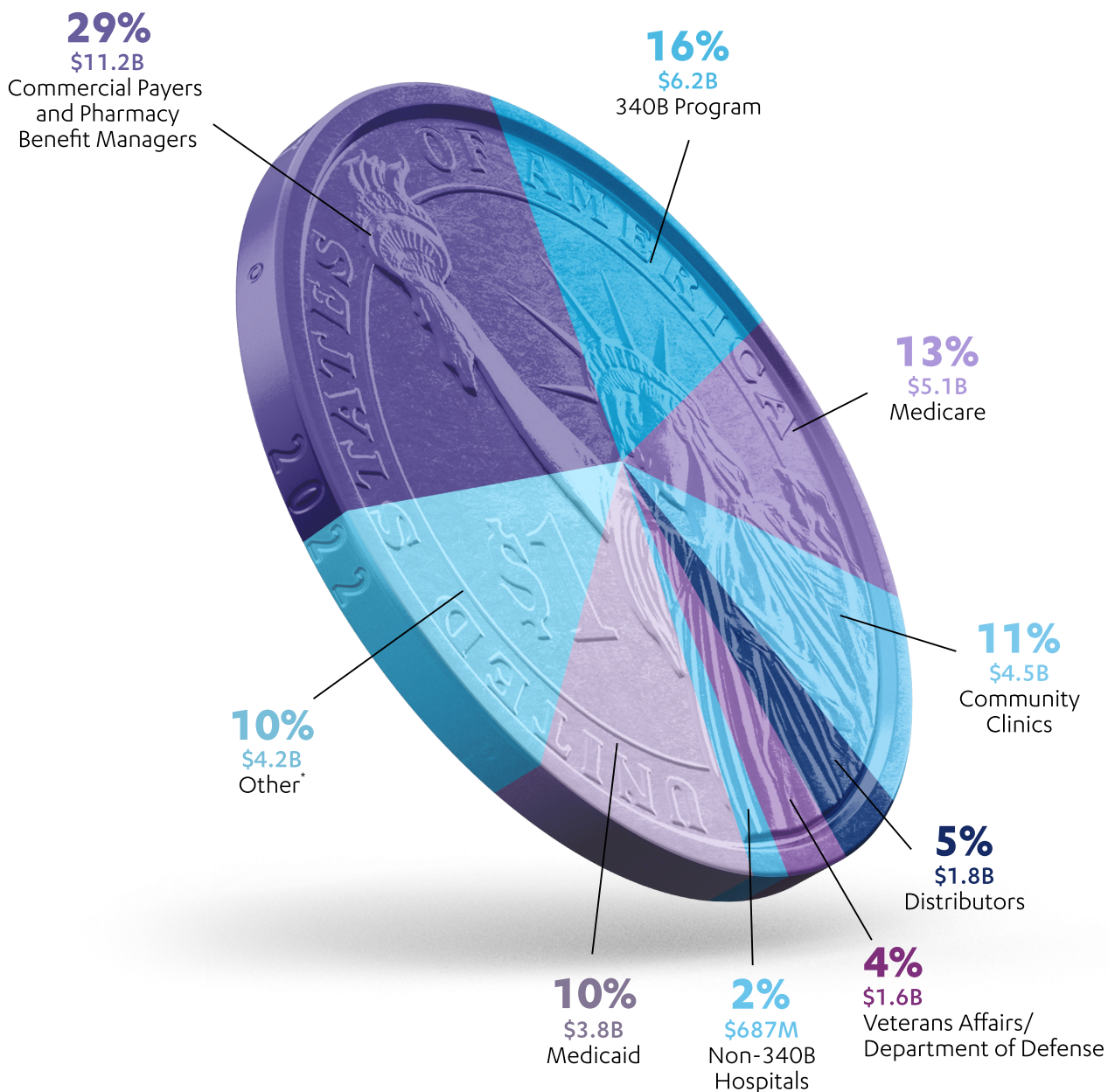
Image Info: Microscopic Biology.

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# \$39 Billion Paid in Rebates, Discounts & Fees: Breaking It Down

In 2022, we provided \$39 billion in rebates, discounts and fees to private payers and government programs, as well as providers, distributors and others.<sup>1</sup> Here is the breakdown:



\* Other: Includes Coupons/Co-Pay, programs such as Long-Term Care, ADAP (a program specific to HIV and AIDS) and other disease-specific sites of care/insurers.



# 2022 at a Glance

**Our net prices declined for the sixth year in a row in 2022.** Unfortunately, the reality for millions of patients is growing affordability and health equity gaps caused by underinsurance and inadequate insurance benefit design driven by middlemen, including pharmacy benefit managers.

## 1 Net Prices for Our Medicines Have Declined for the Sixth Year in a Row

**-3.5%** Average net price decline of Janssen medicines in 2022 (compared to the 9.1% rise in consumer prices over the year ended June 2022)<sup>1,2</sup>

## 2 Rebates and Discounts to Commercial Insurers, PBMs and Government Programs Have Grown

**\$39B** Total amount Janssen paid in **rebates, discounts and fees** to commercial insurers, government programs and others in the healthcare system in 2022<sup>1</sup>

## 3 Insurance Benefit Design Shifts More Costs to Sicker Patients

**32%** Of covered U.S. workers face an **annual deductible above \$2,000**<sup>3</sup>

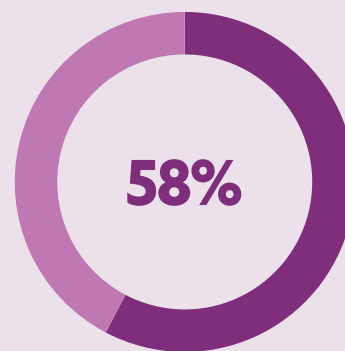
**23%** Of Americans are **considered underinsured**<sup>4</sup>

## 4 Our Investments in R&D Continue to Grow

**\$11.6B** Dedicated in 2022 to the **discovery and development of new treatments and cures**<sup>1</sup>

**110%** Janssen spent **110% more on R&D** than on sales and marketing in 2022<sup>1</sup>

### 3 Facts to Know



Of the **list prices of our medicines** went to commercial insurers and others in the healthcare system<sup>1</sup>

**\$65.7B**

In total R&D spending since 2016<sup>1</sup>

More than

**1.16M**

patients were helped with support to afford their medicines through the **Janssen CarePath Program**<sup>5</sup>



# Introduction

When a prescription medicine becomes reality, it's the result of years of investments, research and the dedication of thousands of individuals across the U.S. healthcare innovation ecosystem that is bolstered by laws and policies supporting this ecosystem. When our ecosystem works as intended, patients and the entire healthcare system benefit from the discovery of next generation medicines that change the way we fight diseases. These discoveries do not happen overnight. They take decades, and the hope patients have today is created by a carefully cultivated innovation ecosystem.

At Janssen, we are proud of the innovative contributions that our dedicated employees have made to enable these medical breakthroughs that create hope for patients.

Since 2016, the first year we published the Transparency Report, Janssen has invested

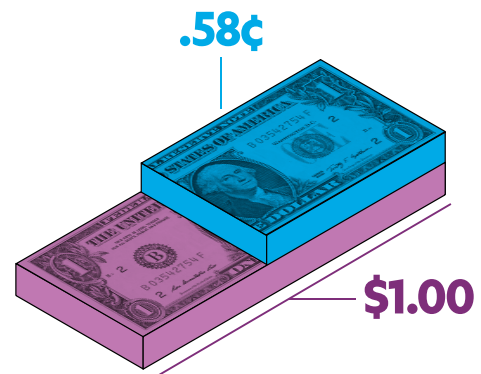
**\$65.7B**

in research and development to push the boundaries to develop innovative therapies and treatments.<sup>1</sup>

These investments have led to significant breakthroughs, including the launch of our first cell therapy to treat multiple myeloma, a blood cancer, in 2022.<sup>6</sup> We are relentlessly pushing the frontier of innovation to bring greater personalization, earlier intervention and smarter, data-driven healthcare.

In addition to developing these transformative medicines that help millions of patients, we also negotiate and provide rebates, discounts and fees to many stakeholders in the healthcare system. These negotiations resulted in **our overall net prices in the U.S. decreasing by 3.5%**, our sixth year in a row of negative net prices.<sup>1</sup> Net prices are the amount we receive after providing rebates, discounts and/or fees to different parts of the healthcare system. In 2022, **we provided \$39 billion in rebates, discounts and fees** to commercial insurers, pharmacy benefit managers (PBMs), hospitals, government payers and others in the healthcare system.<sup>1</sup> This means that nearly **58 cents of every dollar** of our gross sales went back into the healthcare system.<sup>1</sup>

## How Much in Gross Sales Was Returned to the Healthcare System in 2022<sup>1</sup>



Pictured: Crypt Cells.



Notwithstanding our continued R&D investments and negotiations with payers to support patient access, we are deeply concerned about continuing trends and new policies that undermine patient access; further exacerbate gaps in affordability and health equity; and threaten the nation's leadership role in the global pharmaceutical innovation ecosystem. Our specific concerns include:



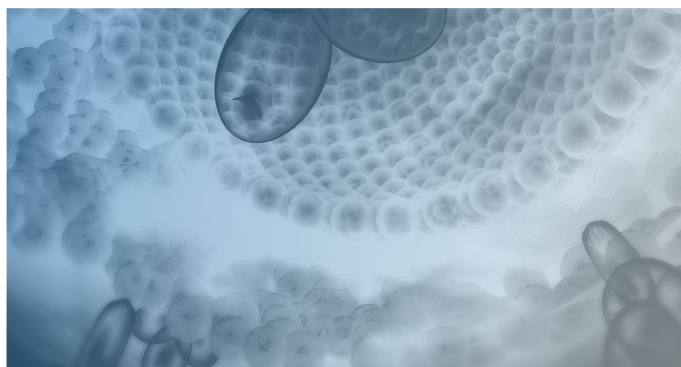
### Patients Are Not Directly Benefiting From Continuously Lower Net Prices and Growing Discounts

While the net prices that payers pay manufacturers for prescription drugs have grown at or below the consumer price index, too many patients continue to pay higher out-of-pocket costs.<sup>7</sup> This difference between the list price and net price has grown significantly, with one analysis putting the total at more than \$200 billion in 2021 for the entire healthcare system.<sup>8</sup>

> **\$200B**

The difference between list price and net price is now more than \$200 billion.<sup>8</sup>

While commercial insurers pay lower net prices, patients do not always directly benefit from these lower prices and continue to pay higher out-of-pocket costs at the pharmacy counter.<sup>7</sup> Patients pay higher out-of-pocket costs because their cost-sharing amount is often based on the initial list price, not the negotiated lower net price the commercial insurer pays.



Pictured: Microscopic Image.



### Underinsurance Is Widening Gaps in Affordability, Health Equity and Access

There are a growing number of Americans who have health insurance but are still at financial risk, or underinsured, due to high deductibles, high out-of-pocket costs and some treatments not even being covered by their insurance plan. These inadequate benefit designs put the greatest burden on the sick, thereby raising concerns about affordability across the entire population and hampering the value of medical innovations.<sup>9</sup> Data show that commercial insurers' cost-shifting is a financial burden for households nationwide, affecting tens of millions of Americans every year who are unable to afford growing out-of-pocket costs.<sup>10, 11</sup>



### Enactment of the Inflation Reduction Act

The Inflation Reduction Act (IRA) threatens to harm the future development of innovative medicines, improvements in existing treatments and patients' access to these treatments. At a time when the nation is on the cusp of transformative innovation to tackle so many unmet healthcare needs, the IRA's drug pricing policies are the exact opposite of what patients need and deserve.

As one of the nation's leading healthcare companies, we have a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability, access and health equity as well as protect our nation's leading role in the innovation ecosystem. Through the 2022 Janssen U.S. Transparency Report, we continue our legacy of contributing insights, data and real-world evidence to help inform and advance policy solutions to create a more sustainable, equitable and innovative healthcare system.

At Janssen, we know that patients are counting on us to develop and bring to market medicines that are safe, effective and accessible. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.



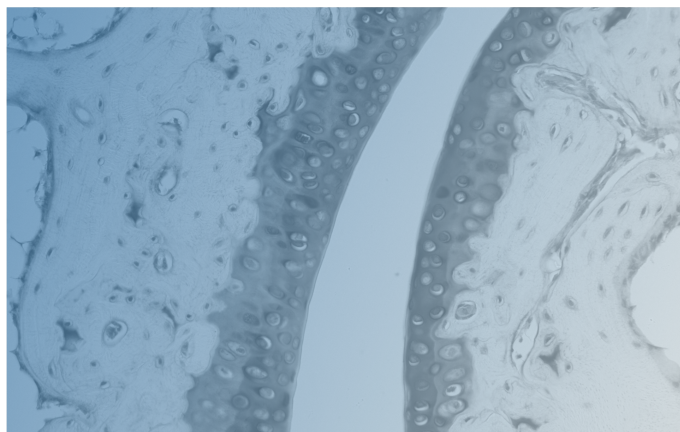
# Prescription Drug Net Prices in the Healthcare System

Intense political focus on healthcare costs, particularly patients' prescription drug costs, continues. Yet, there is a need to better understand three key issues:

- 1 how private market negotiation is driving prescription drug net prices lower;
- 2 why patients' out-of-pocket costs continue to increase; and
- 3 how the Inflation Reduction Act (IRA) will alter the future of patient access to innovative medicines.

## Negotiations Lead to Lower Net Prices

The list price of a medicine is a starting point that is ultimately reduced to a net price, the amount a manufacturer receives after negotiating and providing rebates, discounts and/or fees to different parts of the healthcare system. These include negotiations with private insurance companies, PBMs and entities where medications are dispensed or administered (e.g., hospitals, clinics and private physician practices). In addition, there are mandatory or statutory price reductions provided through government programs. Government programs (e.g., Medicare, Medicaid, etc.) receive prices reduced by both private negotiations and statutory discounts. Vigorous private market negotiations throughout the system result in lower net prices for commercial payers and government programs.

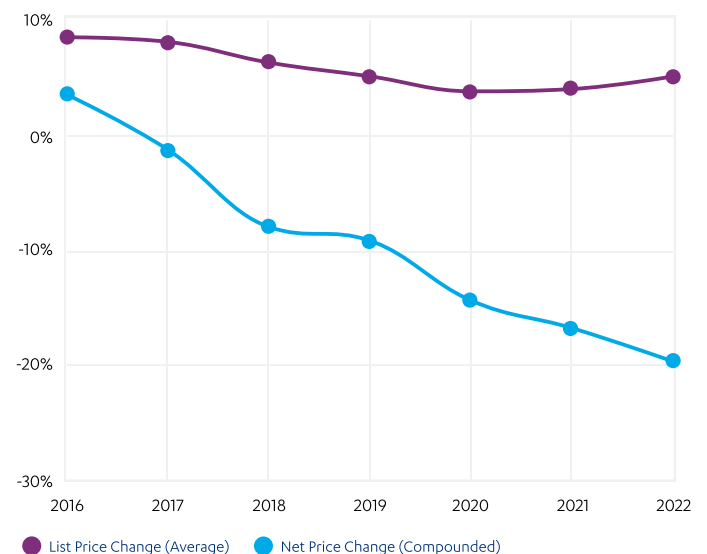


Pictured: Tibia Talus.

## Janssen's Net Prices – Lower for the 6th Year in a Row

In the face of inflationary pressures, American families and businesses experienced the fastest growth in prices in nearly 40 years in 2022.<sup>2</sup> Yet, commercial insurers, pharmacy benefit managers (PBMs) and government payers paid lower net prices for Janssen's medicines for the sixth year in a row.<sup>1</sup> Net prices for our medicines declined by 3.5%, and nearly 20% when compounded over the past six years.<sup>1</sup>

## Change in List Price v. Net Price<sup>1</sup>

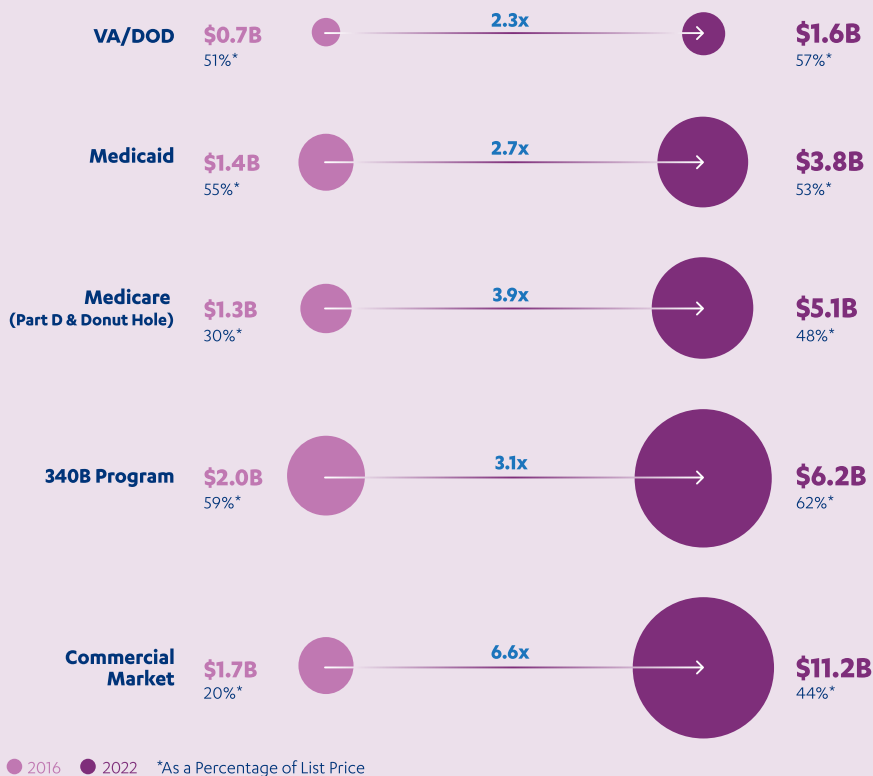


Industrywide, net prices for prescription drugs have grown at or below the consumer price index for the last five years.<sup>7</sup> This difference between the list price and net price has grown significantly over the past five years, with one analysis putting the total at more than \$200 billion for the entire healthcare system.<sup>8</sup> While commercial insurers pay lower net prices, many patients do not directly benefit from these lower prices and continue to pay higher out-of-pocket costs.<sup>7</sup> Patients pay higher out-of-pocket costs because their cost-sharing amount, set by their insurance plan, is often based on the initial list price, not the negotiated lower net price the commercial insurer pays.



### Rebates and Discounts Continue to Grow<sup>1</sup>

Rebates and discounts are one way we help support patients' access to medicines. In 2022, \$39 billion of Janssen's gross sales (nearly 58 cents of every dollar) went back into the healthcare system through rebates, discounts and fees negotiated with or provided to commercial health insurers, PBMs, government healthcare programs and other intermediaries.<sup>1</sup> Since 2016, these rebates, discounts and fees have increased 256 percent, with the 340B Federal Drug Discount Program (340B Program) driving a significant part of this increase in rebates and discounts.<sup>1</sup> The chart to the right outlines where a majority of these rebates, discounts and fees went.

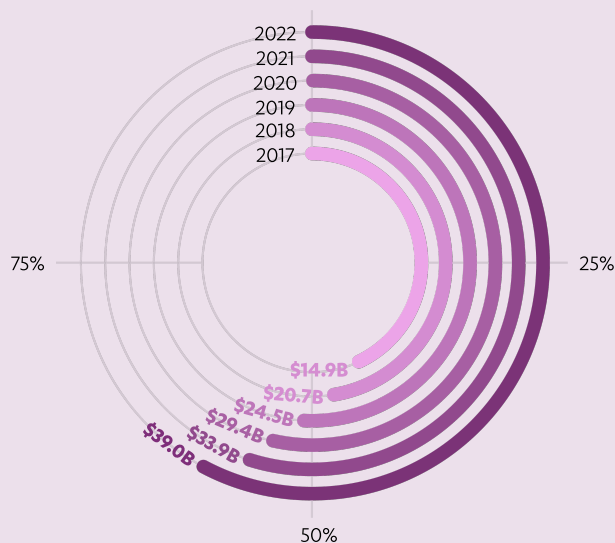


### Percent of Gross Sales Returned to the Healthcare System in 2022<sup>1</sup>



Nearly 58 cents of every dollar in gross sales went back into the healthcare system.<sup>1</sup>

### Rebates, Discounts and Fees (as \$ and as % of Gross Sales)<sup>1</sup>

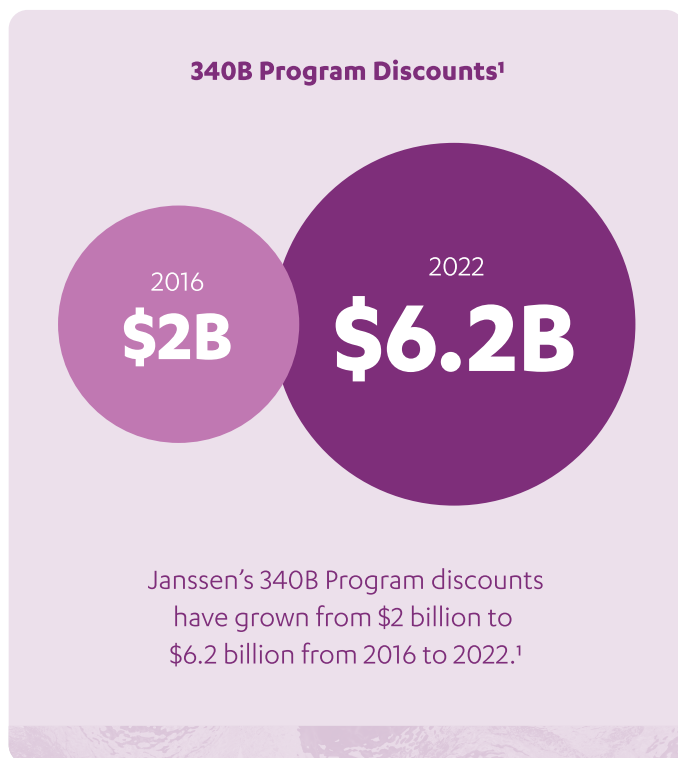


Our rebates, discounts and fees (in \$billions) as a percentage of gross sales have risen consistently, year-over-year.<sup>1</sup>

## Growth in 340B Discounts Puts Pressure on the Program's Sustainability

The 340B Program's original, limited intent was to restore outpatient drug discounts to certain specified safety-net providers that directly purchased and dispensed drugs to their own patients, without having those discounts affect the Medicaid best price calculation.<sup>12</sup> However, the program has grown as large for-profit companies and healthcare systems leverage the program and discounts for maximum financial gain. Since 2016, Janssen's 340B Program discounts have grown from \$2 billion to \$6.2 billion in 2022.<sup>1</sup> The 340B Program now represents nearly one out of every five dollars of the total manufacturer rebates and discounts provided each year across the healthcare system.<sup>13</sup> However, independent research showed that hospitals' 340B participation did not result in an increase of total community benefit spending, and it was not associated with offering low-profit medical care services.<sup>14</sup>

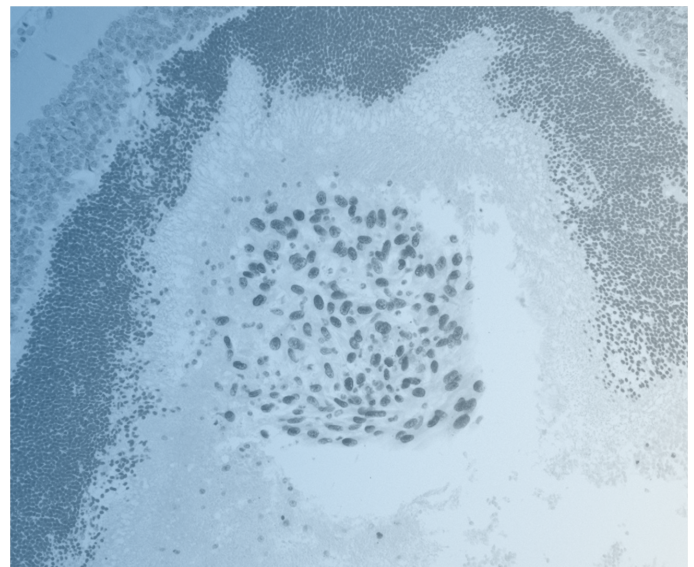
Read more in our [340B Issue Brief](#).



## The Inflation Reduction Act Impact on Prices

On August 16, President Biden signed into law the Inflation Reduction Act of 2022 (IRA).<sup>15</sup> The bill includes Medicare drug pricing policies, among other healthcare related provisions. The major drug pricing provisions include inflation penalties for manufacturers in Medicare Part B & D if prices rise faster than inflation; government price setting in Medicare starting in 2026 for drugs that have been on the market for nine years and biologics that have been on the market for 13; and a Medicare Part D benefit redesign, effective in 2025, to cap patient out-of-pocket costs at \$2,000.<sup>16, 17</sup>

Though the law is in its initial stages of implementation, it is clear that it could disincentivize R&D investments and undermine the generic and biosimilar prescription drug market. While much remains to be settled on the IRA's long-term impact on costs, the concerns are mounting that government-mandated prices could upend the entire healthcare innovation ecosystem. In undermining strong intellectual property incentives, the IRA can eventually result in the loss of choice for doctors and patients of new treatment options. Furthermore, while the law does include some patient out-of-pocket costs protections for seniors, there is growing concern that private health plans providing Medicare benefits (known as Medicare Advantage plans) could further erode the financial protections insurance is meant to provide by implementing greater utilization management programs and creating more hurdles to needed treatments for beneficiaries.



Pictured: Human umbilical cord cells.



# As Net Prices Decline, Who Benefits?

Even as net prices decreased, out-of-pocket costs for patients continued to increase due to:

- 1 underinsurance that puts more financial burden on patients;<sup>4</sup>
- 2 increased prevalence of high-deductible health plans;<sup>18</sup> and
- 3 the growth in patient assistance diversion programs.<sup>19</sup>

In short, while net prices for Janssen's medicines decreased, many patients continued to pay more out-of-pocket for those very same medicines.

## Underinsurance – A Growing Source of Financial Hardship for Millions of Americans

A near record number of Americans had some form of health insurance coverage in 2022.<sup>4</sup> Yet nearly 23% of Americans are considered underinsured.<sup>4</sup> This happens because commercial payers determine patient deductibles, co-insurance, co-pays and other cost sharing.<sup>20</sup> Even though patients have insurance coverage, the benefit design leaves them open to significant financial risk, effectively rendering healthcare unaffordable – the exact opposite of what insurance is supposed to do.<sup>4</sup> This issue is even worse for people with lower incomes and serious health problems, as they have even more financial exposure in times of need.<sup>4</sup>

Exposure to financial risk is even more problematic for people who take medication for one or more chronic illnesses. One out of four people with one or more chronic health problems identify high out-of-pocket costs for prescription drugs as a reason for skipping or not filling a prescription for their specific healthcare need.<sup>4</sup> Additionally, rising deductibles continue to be a major financial challenge for individuals and families – with nearly half of households with employer insurance unable to afford a typical deductible.<sup>21</sup> Similarly, commercially-insured patients with a deductible have seen their out-of-pocket costs for brand medicines increase 50% since 2014.<sup>22</sup> In fact, most patient spending on brand medicines is based on the undiscounted list price of a medicine rather than the net price negotiated by their health plans.<sup>7</sup>

One report projects that commercial insurers will escalate out-of-pocket expenses to a staggering \$800 billion by 2026.<sup>23</sup> To put this in perspective, that burden would equate to an annual tax on every U.S. worker of \$4,774.<sup>24</sup>

What do these higher costs mean for patients starting and staying on their medicines? In 2021, patients starting a new treatment abandoned 81 million prescriptions at pharmacies – and this trend of abandonment grows as out-of-pocket costs rise.<sup>7</sup> For patients with a chronic condition, these higher costs resulted in 5.3 billion lost patient days of therapy, particularly affecting the uninsured.<sup>7</sup>

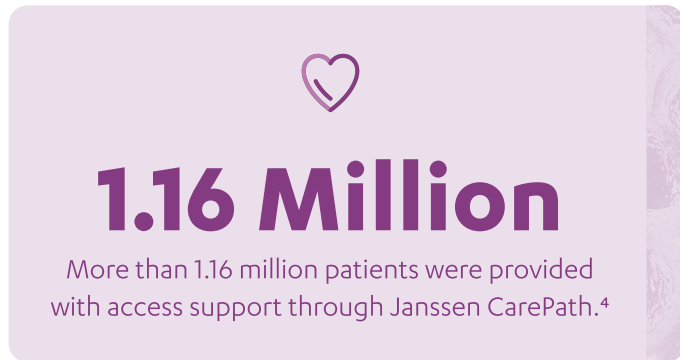
## Beyond Cost-Sharing – Growing Use of Utilization Management Programs Means More Hurdles for Patients and Providers

In the 2021 U.S. Transparency Report, we highlighted how commercial insurers and PBMs implemented more restrictive utilization management programs.<sup>25</sup> Utilization management can be broadly defined as commercial insurers' use of administrative mechanisms (e.g., prior authorization) and financial mechanisms (e.g., patient cost sharing) to control or restrict patient access to healthcare.<sup>25</sup> One such example is the increasing use of exclusion lists, which are designed to block patients from accessing a medicine that their own doctor has prescribed. Since 2014, these exclusion lists have grown more than 961% to include more than 1,156 unique products.<sup>26</sup> Exclusion lists are also being leveraged with specialty drugs, which could disproportionately affect patients with very serious and specialized treatment needs.<sup>26</sup> Utilization programs also include expanded tiered lists with varying cost sharing, prior authorization, non-medical switching and step therapy.

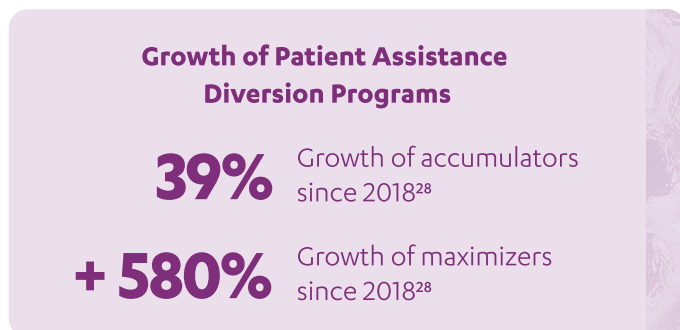
Read more in our [2021 U.S. Transparency Report](#).

### Patient Assistance Should Be for Patients

Patient assistance programs have evolved to become an important source of access support for more patients who face greater financial burdens because of underinsurance.<sup>30</sup> As commercial insurers and PBMs shift more costs onto patients, these programs help patients meet their deductible and out-of-pocket maximums. Through our patient support program Janssen CarePath, Janssen provided more than 1.16 million patients with access support.<sup>5</sup>

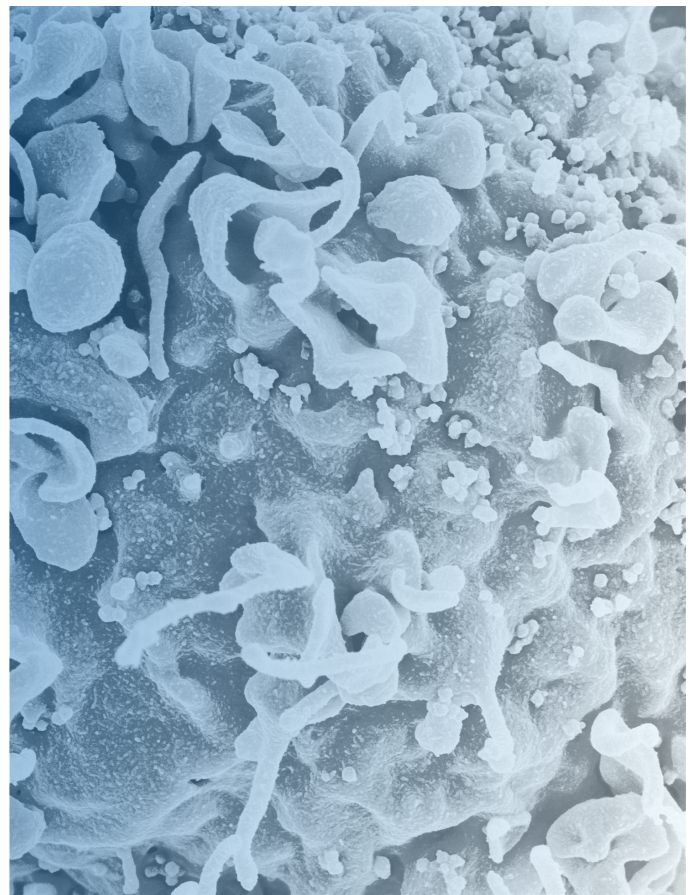
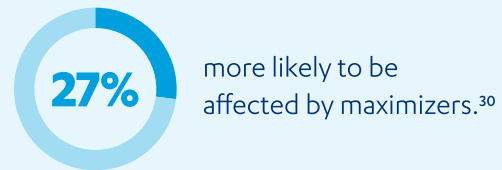


But patients face the growing threat of patient assistance diversion programs, which are implemented by commercial insurers and PBMs to divert patient assistance money away from patients to the financial benefit of non-patient third parties.<sup>27</sup> These programs have numerous, deceptive names (e.g., accumulators, maximizers, optimizers or Alternative Funding Programs), yet they all have the same purpose – to make it harder for patients to access and afford needed healthcare so program operators may financially benefit. The implementation of these programs in commercial insurance has grown significantly since 2018, with accumulators seeing a 39% growth and maximizers seeing a more than 580% growth.<sup>28</sup> As one industry expert and academic recently noted, these types of programs can “cause disruptions in people’s access to their medications.”<sup>29</sup>



### Janssen Policy Position: Health Equity & Patient Assistance Diversion

New data shows that benefit plans imposing accumulators and maximizers place disproportionate burdens on historically marginalized populations and people of color. The research found non-white patients (African American, Asian, Hispanic and other) are



Pictured: HIV Particles.

## What Are Patient Assistance Diversion Programs?

As manufacturer patient assistance programs have grown in conjunction with higher out-of-pocket costs, commercial insurers, PBMs and third-party intermediaries are deploying various programs to divert these funds away from patients.

These patient assistance diversion programs take various forms including:



### Accumulators

Do not allow patient assistance to count toward the patient's deductible and out-of-pocket maximum until the maximum value of any patient assistance is reached. Then the patient's out-of-pocket costs begin counting toward their annual deductible and out-of-pocket maximum.<sup>31</sup>



### Maximizers

Do not allow patient assistance to count toward the patient's deductible and out-of-pocket maximum. Maximizer programs take the maximum value of patient assistance for a year and apply that maximum throughout the plan year, either by distributing the maximum amount evenly or by taking larger amounts early in the year and tapering accordingly, without allowing any of those amounts to count toward a patient's annual deductible or cost-sharing limits under the plan.<sup>31</sup>



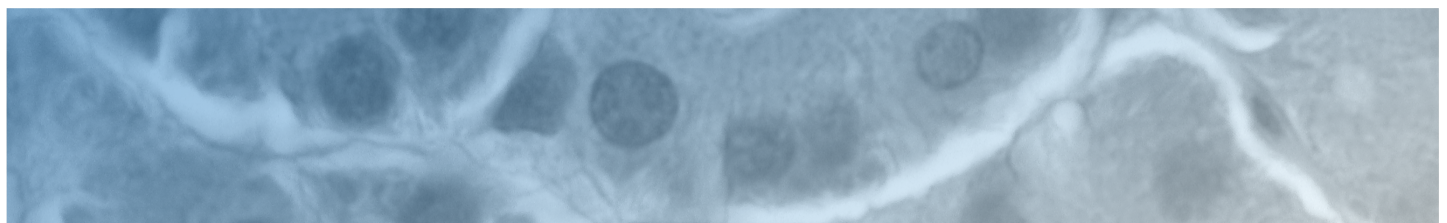
### Non-essential Health Benefit Maximizers

While similar to regular maximizers, this program classifies certain specialty medications as "non-essential," which takes away ACA patient protections related to maximum out-of-pocket limits.<sup>32</sup>



### Alternative Funding Programs

Programs run by third-party vendors that push for the exclusion of specialty drugs from coverage by certain insurance plans. Upon exclusion for a specific medication, the patient becomes "uninsured" or underinsured and is then forced to apply for patient assistance for uninsured individuals through foundation-based patient assistance programs. If the patient is approved, then the third-party vendor claims a fee from the plan sponsor. These programs can cause disruption in coverage for patients.<sup>33</sup>



Pictured: Human pancreas.



# Our Investments Are Helping Make Disease a Thing of the Past

Janssen is proud of our historical investments in helping develop the global healthcare innovation ecosystem aimed at making disease a thing of the past. A healthy innovation ecosystem depends upon many elements working together to support and sustain each other. In the healthcare innovation ecosystem, biopharmaceutical industry R&D spending accounts for 75.5% of all investments in U.S. medical and health research and development.<sup>34</sup> A recent report summarizing an expert symposium on the impact of our R&D ecosystem concludes that “Pharmaceutical innovations have resulted and will continue to result in immense benefits for society, which can be measured directly through increases in life expectancy itself (not to mention improvements in individuals’ quality of life or ancillary societal benefits, such as fewer missed workdays, decreased use of disability insurance and increased economic productivity).”<sup>35</sup>

Such investments across the industry have contributed to our nation’s significant progress in addressing previously untreatable diseases and creating dramatic improvements in patients’ health. This robust approach is also a critical tool in our nation’s efforts to end health inequities across the entire healthcare system.

For example:

- Pharmaceuticals accounted for 76% of the mortality reduction achieved for HIV/AIDS from 1990 to 2015, 60% for cerebrovascular disease, 60% for malignant breast neoplasms, 52% for ischemic heart disease and 27% for colon/rectal/anal cancers.<sup>35</sup>
- Over the past 40 years, the FDA has approved 599 medicines to treat rare diseases, which has brought hope for millions of patients living with a rare disease.<sup>36</sup>
- The biopharmaceutical industry has a robust pipeline of more than 800 new medicines, treatments and cures for diseases that disproportionately impact racial and ethnic communities.<sup>37</sup>

## Janssen’s Continued R&D Investments

In 2022, we spent 110% more on R&D than on sales and marketing.<sup>1</sup> Since 2016, our total investments in R&D have reached \$65.7 billion, nearly double what we spent on marketing and sales in the same timeframe.<sup>1</sup> This growing investment enables our scientists and doctors to rigorously pursue new medicines from early discovery through clinical development with comprehensive efficacy and safety studies. We continue to push the frontier on the next generation of treatments and cures. Since 2016, we produced a total of eight new Janssen medicines approved by the FDA and an additional 52 approvals for expanded indications or new product formulations.<sup>38, 39</sup>

### The Next Generation of Cancer Care for Patients

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.<sup>40</sup> Despite the development of additional treatment options in recent years, most people living with multiple myeloma face poor prognoses after experiencing disease progression following treatment with three major therapy classes, which include an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.<sup>41</sup> Building on Janssen’s legacy and commitment to innovation in multiple myeloma, Janssen received FDA approval in February 2022 for its first CAR-T therapy: CARVYKTI®. This novel cell therapy works by harnessing the patient’s own immune system, or T cells, to fight the disease. This type of personalized cancer therapy is just one example of how Janssen is working to get in front of cancer with a focus ultimately on eliminating the disease.

## Helping Build a More Equitable Healthcare System

We also know a critical part of strengthening this ecosystem is to address inequities in the healthcare system, which is why we are investing in programs, people and research related to achieving health equity. Through *Our Race to Health Equity*, Johnson & Johnson is committed to addressing the systemic health inequities contributing to lower standards of care and outcomes for people in historically marginalized communities.<sup>42</sup> As part of this commitment, Janssen continues to identify innovative programs, community leaders and partners to make health inequity a thing of the past.

In 2022, we continued our investments to build a more equitable healthcare system by:

### 1 Helping to Address Peripheral Artery Disease in Black Communities:

Save Legs. Change Lives.<sup>™</sup> is a multi-year initiative that aims to create urgency and action to address the hidden threat of peripheral artery disease (PAD)-related amputation. The initial focus is on reaching Black Americans, who are more than twice as likely to be impacted by PAD. Janssen has joined forces with leading professional associations, including the American College of Cardiology, as well as healthcare systems and community advocacy organizations to advance equitable care for individuals and communities at an increased risk for cardiovascular disease. There are three pillars to the initiative: driving research, powerful partnerships and empowering individuals.<sup>43</sup>



Pictured: Gene Therapy DNA.

### 2 Empowering the Next Generation of a Diverse Healthcare Workforce:

Building on its partnership with the National Medical Fellowships (NMF), Johnson & Johnson welcomed the newest 20 exceptional and diverse medical students from across the country to participate in the second cohort of the Alliance for Inclusion in Medicine (AIM) scholarship program. The three-year program helps students pursuing medical careers where their work is centered around prioritizing diversity and providing high-quality care to historically marginalized patient populations.<sup>44</sup> In 2023, Johnson & Johnson will expand its partnership and reach with NMF by welcoming its first cohort of diverse pharmacy students from the five accredited Historically Black Colleges and Universities (HBCU) Pharmacy Schools, which will be aligned to the same three-year programming that the diverse medical students experience. This effort will boost Johnson and Johnson's focus and commitment to building a "Diverse Healthcare Workforce." For more information, please visit [www.nmfonline.org](http://www.nmfonline.org).

### 3 Expanding Diversity in Clinical Trials:

Janssen is actively working on ways to improve diversity in clinical trials by changing clinical trial design, ensuring a more inclusive criteria approach for participants and training clinical trial site staff to engage and interact with different communities and people of color. Increasing diversity also involves addressing barriers to enrolling in clinical trials that groups that are historically excluded sometimes face. J&J is actively engaging in work with patient-focused organizations that focus on Black and Brown patients with digestive diseases. The goal of the partnership is to raise awareness about Inflammatory Bowel Diseases (IBD) clinical research, as well as increase education in underserved communities about IBD. Strategic partnership with organizations allows researchers to meet patients where they are in their communities to help them finally feel seen and heard.<sup>45</sup>

**Taken together, these actions are some of the many ways we continue our efforts to build an equitable healthcare system that works for every patient.**

# Supporting Access for Patients

## Janssen CarePath Directly Supports Patients

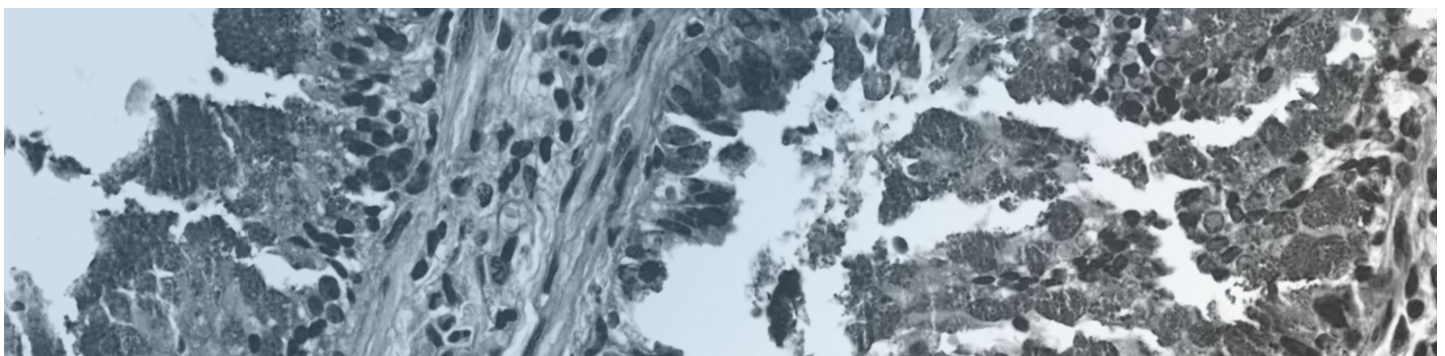
We continue to support patients through Janssen CarePath, a service that provides information about support resources for patients taking Janssen medications. Once a healthcare professional has decided a Janssen medication is right for their patient, the program can help that patient find the tools they may need to get started on a medication and stay on track, including sharing options to help manage out-of-pocket costs. In 2022, more than 1.16 million patients in the U.S. were helped through the Janssen CarePath program.<sup>5</sup>

## Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF)

We also support independent programs and foundations that help patients. In the U.S., Janssen and other Johnson & Johnson companies donate medicines and funding to the JJPAF, an independent, nonprofit organization. JJPAF gives eligible patients prescription medicines donated by Johnson & Johnson companies. In 2022, Janssen donated approximately \$3.8 billion in products and financial support to JJPAF.<sup>1</sup> For more information, please visit [JJPAF.org](https://www.jjfaf.org).

## How Patient Assistance Diversion Programs Are Taking Aid Away from Needy Patients

There are a growing number of companies operating programs called “Alternative Funding Programs” that are diverting patient assistance away from those patients who need aid the most.<sup>46</sup> These programs target patients who have complex or high-risk health needs that require specialty medicines to treat chronic and often fatal diseases, which often incur high cost-sharing because of insurance benefit design.<sup>46</sup> The programs limit or restrict coverage of certain specialty medicines, leaving patients functionally uninsured for a specific healthcare need. Then these program operators direct these “uninsured for the product” patients to seek assistance from charitable foundations (like the Johnson & Johnson Patient Assistance Foundation (JJPAF)) for free product.<sup>47</sup> Once the patients can access this free product, the program operators are financially rewarded for diverting the cost of these specialty medicines away from employers’ health insurance plans. However, the charitable foundations intending to serve patients become overburdened in their ability to help patients in need when commercial insurance does not provide coverage that patients think they have through their existing plans.<sup>46</sup>



Pictured: Exacerbation.

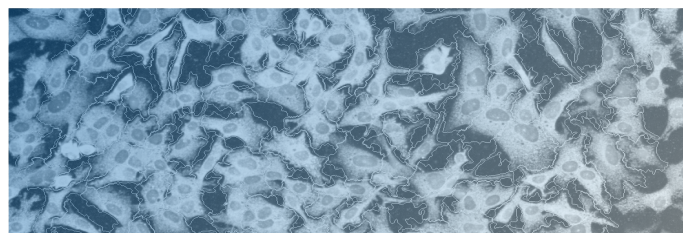


# How We Build a Sustainable, Equitable and Innovative Healthcare System

**We have a responsibility as a leading healthcare company to advance patient-centric policy solutions and ideas that will reduce inequity and foster innovation.** We believe it is important to focus on ways to bring transparency into programs such as the 340B Federal Drug Discount Program and build more awareness of the benefit design changes that affect patients' access to needed treatments and medicines.

## **Inflation Reduction Act – What It Could Mean for Innovation and the Future of Treating Unmet Healthcare Needs**

While the IRA's healthcare provisions include important affordability improvements for seniors by capping out-of-pocket costs, the negative consequences to future innovation could be severe. Some experts have argued that the government negotiating, or "unilaterally setting prices," would lead to likely cuts in "...funding for development of new drugs, with a slowing of innovation."<sup>48</sup> Indeed, several leading biopharmaceutical companies and small biotech companies have already started shifting their R&D investment priorities, portfolios and budgets.<sup>49</sup> Some reports estimate that government-dictated prices like those included in the IRA "...could reduce overall annual cancer R&D spending by about \$18.1 billion, or 31.8%."<sup>50</sup> In fact, this new law may undermine the industry's ability to develop new uses for existing therapies, reach new patient populations with unmet medical needs, including rare diseases, and advance product improvements that significantly increase adherence, tolerability and safety or reduce healthcare costs. The law will severely restrict the time available to research and gain regulatory approval to expand an existing medicine to treat additional patient conditions.



Pictured: Hepatocellular Carcinoma Cells.

The policies included in the IRA will limit future discoveries of new treatments across the entire U.S. healthcare innovation ecosystem, which depends upon the efforts and ingenuity of small biotech companies, universities and academic institutions and large biopharmaceutical companies.

The United States, more than other nations, accounted for a significant share of FDA approvals since 2010, but the IRA could severely curtail the nation's leadership position in the global healthcare innovation ecosystem.<sup>51</sup> At a time when the nation is on the cusp of transformative innovation to tackle so many unmet healthcare needs, the drug pricing policies included in the IRA are the exact opposite of what patients need and deserve.

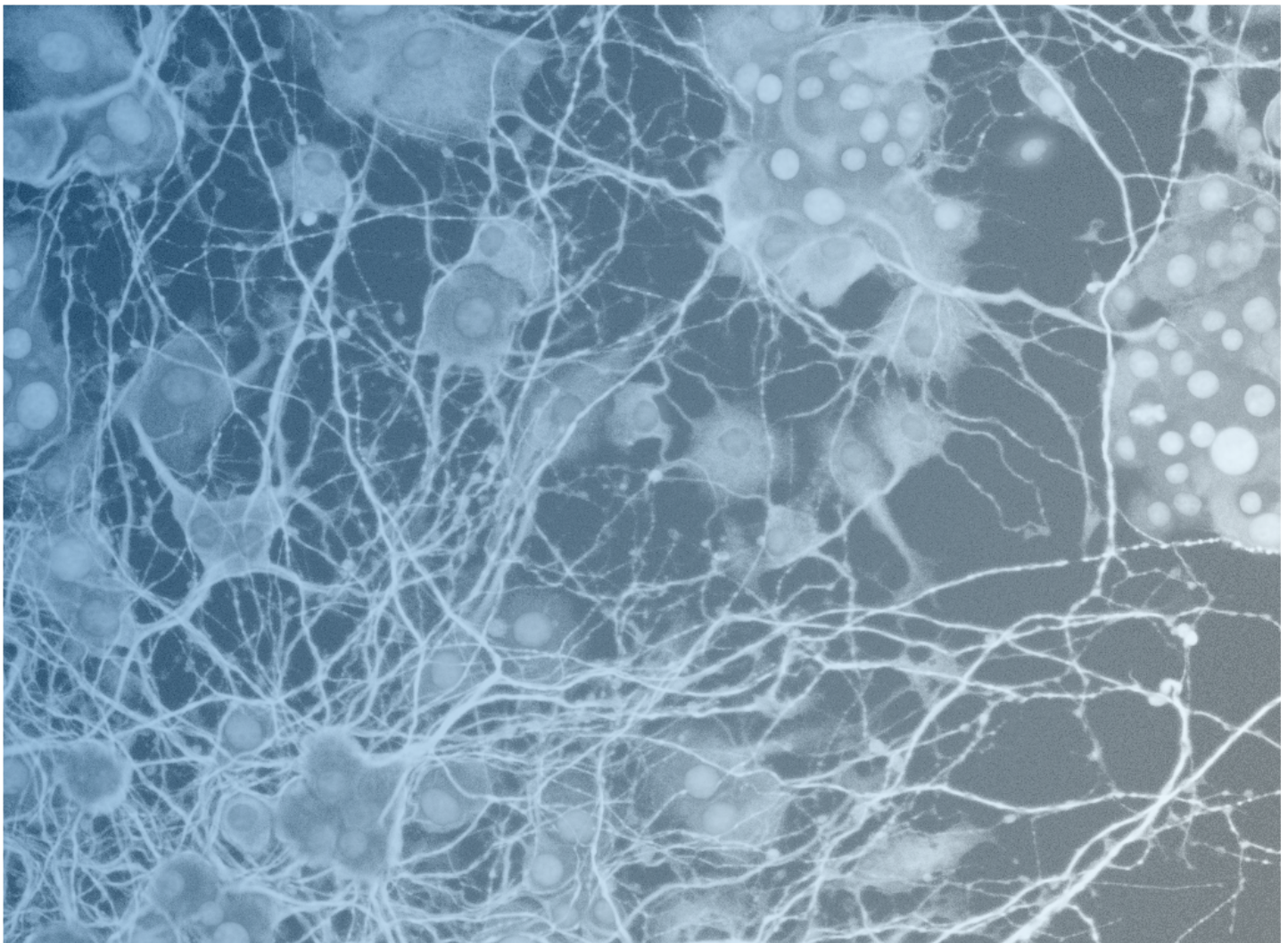
We are committed to working with policymakers, regulators and stakeholders across the healthcare system to identify and advance needed changes to the law that will prevent irreparable and lasting damage from this law to the innovation ecosystem. We have a responsibility to our patients, partners and the healthcare system to ensure we adapt to the mandates of the new law in the most effective manner possible while securing access to treatments for patients. We will highlight to regulators, government officials and policymakers the IRA's real impact – intended or otherwise – while there is still time to address these challenges before the law's full implementation.

**As we continue to provide our insights, analysis and positions on these key policy issues, we are guided by our core principles:**

- 1 Patients should have affordable and timely access to the most appropriate, effective treatment options and sites of care now and in the future.
- 2 Treatment decisions belong in the hands of patients and their healthcare providers, not commercial payers with no accountability for patient outcomes due to misaligned incentives.
- 3 Clinically stable patients should not be switched from their treatments for non-medical reasons (unless deemed interchangeable by the FDA).
- 4 Appropriate clinical rigor and manufacturing quality standards should be applied in all instances to ensure patient safety.

**We believe by keeping these principles at the forefront of policy development, it is possible to create a sustainable healthcare system that:**

- 1 Maintains a fair and competitive marketplace.
- 2 Fosters an environment that supports future investment in transformational innovation.
- 3 Ensures responsible pricing and appropriate transparency system wide.
- 4 Determines value based on evidence that incorporates the benefits and risks for patients, the healthcare system and society.



Pictured: Neuronal Cells.



# Notes & 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 4, 2022 and January 3, 2023, 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 [jn.j.com/about-jnj/annual-reports](http://jn.j.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](http://healthforhumanityreport.jnj.com).

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