



BUILDING A HEALTHIER  
FUTURE FOR ALL:

# THE 2020 JANSSEN U.S. TRANSPARENCY REPORT

janssen  | PHARMACEUTICAL COMPANIES OF  
Johnson & Johnson

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# LETTER FROM OUR LEADERS

We launched our first annual Janssen U.S. Transparency Report four years ago because we wanted to provide policymakers and patients with useful information about what drives the cost of healthcare, including the cost of prescription medicines. We wanted to shed light on the aspects of our health system that stood in the way of patients getting needed care and ultimately, advance the dialogue about how to deliver greater access to medicines at a more manageable cost.

We currently face many challenges in our health system. Long-standing affordability challenges have only been exacerbated by the economic fallout of COVID-19, while the pandemic revealed that susceptibility to illness is unevenly distributed, with communities of color especially vulnerable. But we also have significant opportunities. The speed with which scientists developed COVID-19 vaccines reflects the vigor of our country's R&D ecosystem. In January 2020, Janssen scientists immediately mobilized to begin researching and developing a COVID-19 vaccine for use globally that earned Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) and several other health authorities in the early spring of 2021. Today, millions of doses have been administered and we are on track to deliver one billion doses in 2021 at a not-for-profit price for emergency pandemic use as an example of our commitment to help bring this pandemic to an end.

That's why with our 2020 Janssen U.S. Transparency Report, we outline our vision of better health for all and continue the journey we began with the first report:

- Since the beginning of 2016 (the first year covered by a Janssen U.S. Transparency Report), the **compound net price decline of Janssen medicines was -14.4%.**<sup>1</sup>
- For 2020, the **average net price decline** of our medicines was -5.7%.<sup>2</sup>
- In 2020, we provided **\$29.4 billion in rebates, discounts and fees** to government and private payers,<sup>3</sup> as well as hospitals and others in the supply chain—more than half the list price (53%) of our medicines.<sup>4</sup>
- Globally, we **invested \$9.6 billion** in 2020 in discovering and developing new medicines and vaccines<sup>5</sup>—106% more than we spent on marketing and sales.<sup>6</sup>
- Since 2016, we've spent **\$42.2 billion on R&D**<sup>7</sup>—resulting in a total of four new medicines approved by the FDA<sup>8</sup> and an additional 42 approvals for expanded indications or new product formulations over the same five-year period.<sup>9</sup>
- We provide specific actions we are taking to **address systemic racism and create a more equitable healthcare system.**
- We offer policy solutions to help make healthcare **more accessible and affordable** for patients.

This year, we offer a more detailed look at the price reductions we offer payers and others in the healthcare system to support access to our medicines. We want disclosures like these to shape the conversation about how to sustain the innovation that's the hallmark of the U.S. health system. That's the legacy we've established with the Janssen U.S. Transparency Report and the legacy we are humbled to carry forward.



**SCOTT WHITE**

Company Group Chairman  
North America Pharmaceuticals  
Johnson & Johnson



**ANASTASIA G. DAIFOTIS, M.D.**

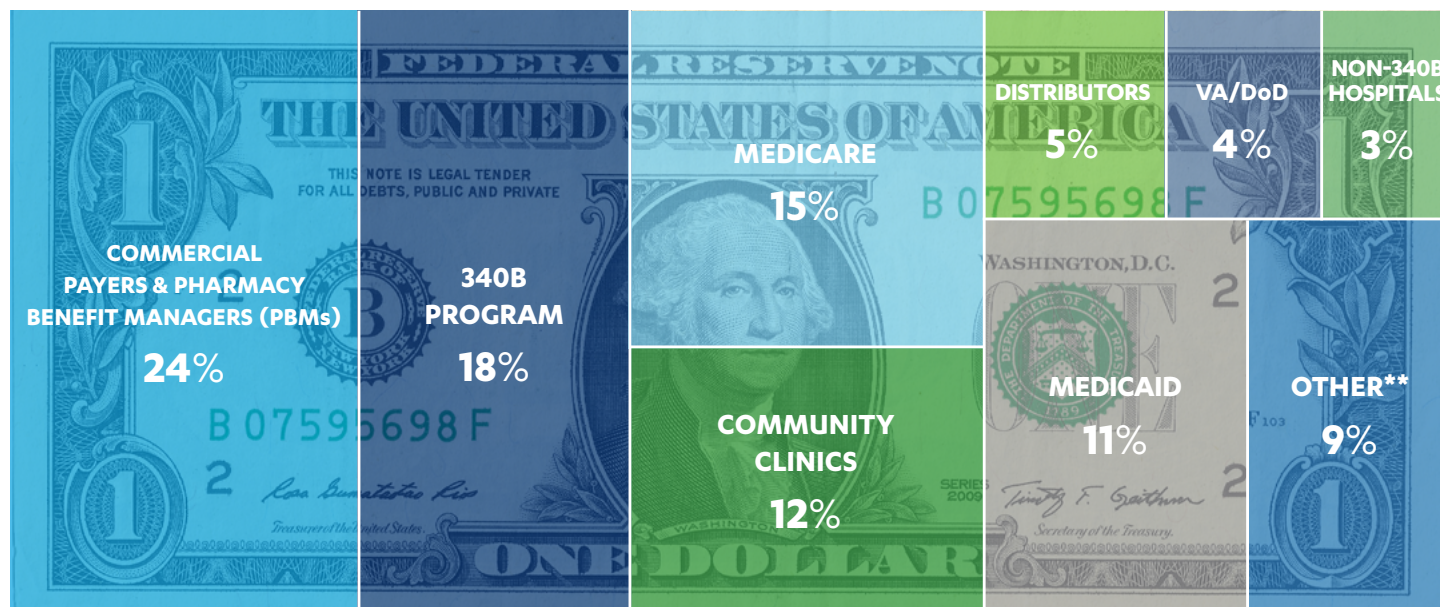
Chief Scientific Officer  
Janssen North America  
Pharmaceuticals



# \$29.4 BILLION: BREAKING IT DOWN<sup>10</sup>

## \$29.4 BILLION: BREAKING IT DOWN

In 2020, **we provided \$29.4 billion in rebates, discounts and fees<sup>11</sup>** to private payers and government programs as well as providers, distributors and others. Here is the breakdown\*:



Government programs benefit from vigorous commercial competition as well as legally required price concessions. Medicaid discounts also reflect the extra, “supplemental,” rebates states negotiate with manufacturers.

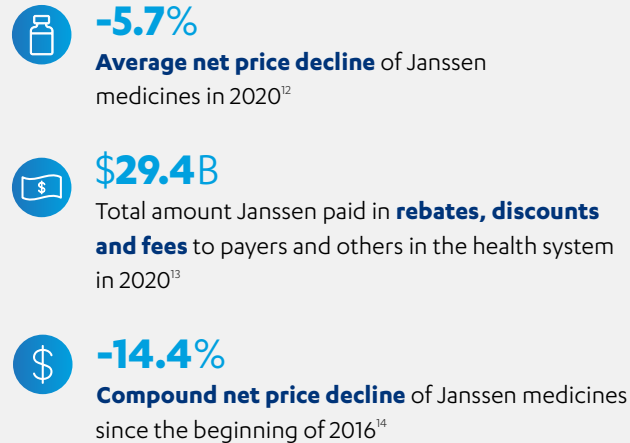
\*Note: Due to rounding numbers add up to over 100.

\*\*Other: Programs such as long-term care, ADAP (a program specific to HIV and AIDS) and other disease-specific sites of care/insurers.

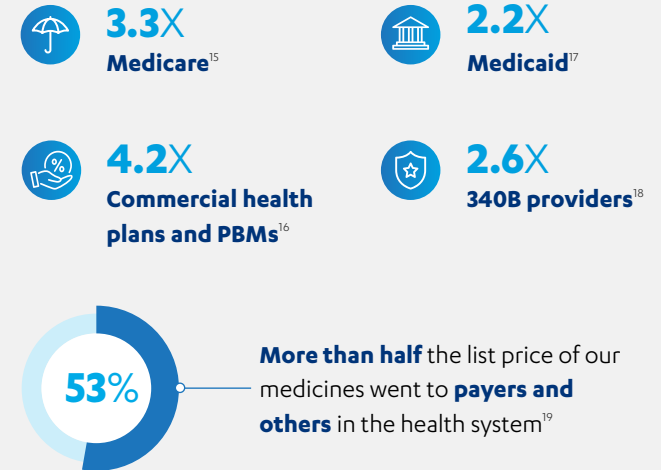
# 2020 AT A GLANCE

## 2020 AT A GLANCE

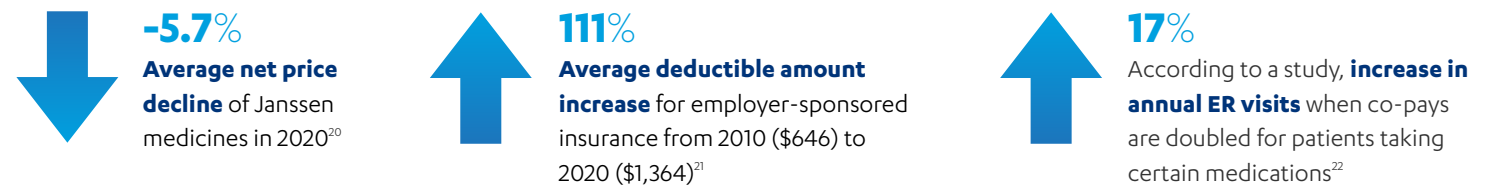
### NET PRICES FOR OUR MEDICINES HAVE DECLINED...



### BECAUSE OUR DISCOUNTS HAVE GROWN FROM 2016-2020\*



### DESPITE PRICE REDUCTIONS, BENEFIT DESIGNS PUT MORE FINANCIAL BURDEN ON PATIENTS



### WE'RE SUPPORTING PATIENTS TODAY AND TOMORROW

Nearly **1.2 million** patients helped with **access, affordability and treatment support** through the Janssen CarePath Savings Program<sup>23</sup>

**646,000** commercially insured patients **reduced their out-of-pocket costs** through the Janssen CarePath Savings Program<sup>24</sup>

**8.1%** increase in average R&D investment from 2016-2020<sup>25</sup>

**\$9.6B** dedicated in 2020 to the discovery and development of new medicines and vaccines<sup>26</sup>

# OUR PRIORITY: AFFORDABLE ACCESS FOR PATIENTS

People should have affordable access to the medicines they need, yet many in the U.S. do not.

Well before the COVID-19 pandemic, one in four adults in the U.S. reported difficulty affording their medication.<sup>27</sup> Even for families with insurance, many could not afford needed medical care or medicines.<sup>28</sup> This is happening despite declining net prices to payers, pharmacy benefit managers (PBMs) and government programs.

## SECTION HIGHLIGHTS:



Our **net prices decreased for the fourth year in a row** because of the significant rebates and discounts we provide.<sup>29</sup>



**Payers typically do not share rebates and discounts directly with patients** and are shifting more costs to them.



Janssen CarePath provided access and affordability **support to nearly 1.2 million people**,<sup>30</sup> including **financial assistance to help 646,000 patients** access their Janssen medications.<sup>31</sup>

## OUR RESPONSIBLE APPROACH TO PRICING

We recognize our responsibility to patients today and to patients tomorrow. Today's patients need affordable access to medicines. Tomorrow's patients count on us to deliver preventions, treatments, and cures for challenging illnesses and emerging diseases, like COVID-19.

### In setting a list price for a medicine, we balance:



#### **Its value to patients, the healthcare system and society.**

We assess how our medicines and vaccines improve individual health and allow a person to live their life to the fullest as well as the potential to lower healthcare costs and advance existing standards of care.



#### **The importance of supporting affordable access to our medicines and vaccines.**

We negotiate with insurers, PBMs and governments, as well as hospitals, physicians, and other providers of care, so patients who are prescribed our medicines or need our vaccines can get access to them.



#### **The importance of preserving our ability to develop future groundbreaking vaccines, treatments and cures.**

Sales from our existing innovations provide us the necessary resources to meet the growing costs of R&D to address unmet medical needs, better help underserved populations and remain prepared for emerging health threats.

## HOW A LIST PRICE BECOMES A NET PRICE

In 2020, we provided \$29.4 billion in rebates, discounts and fees to payers and others in the health system<sup>32</sup>—more than half the list price of our medicines (53%).<sup>33</sup>

### We provide rebates and discounts\* in exchange for payer coverage of our medicines.

The **list price** of a medicine is a starting point that is ultimately reduced to a **“net price,”** the amount a manufacturer receives after providing rebates, discounts and/or fees to different parts of the healthcare system. These include private insurance companies, PBMs and/or employers, as well as government programs (e.g., Medicare, Medicaid, the Department of Veterans Affairs, etc.), the 340B Drug Discount Program, and entities where patients receive care (e.g., hospitals, clinics and private physician practices).

Some price reductions are the result of commercial negotiations with private payers. Other reductions are required by law. The U.S. government requires that pharmaceutical companies provide discounts to ensure that seniors, as well as the nation’s most vulnerable populations and low-income individuals and families, can access medicines at a very low cost. As we explain in more detail below, government programs receive prices reduced by both private negotiations and statutory discounts.

### JANSSEN U.S. PRICING OVERVIEW<sup>34</sup>

YEAR	LIST PRICE CHANGE	NET PRICE CHANGE
2020	3.8%	-5.7%
2019	5.1%	-1.2%
2018	6.3%	-6.8%
2017	8.1%	-4.6%
2016	8.5%	3.5%

### A PRIMER ON PAYERS:



**Commercial Payers:** Private health insurers, self-insured employers and the PBMs who manage pharmacy benefits on their behalf.



**Government:** Federal and state governments provide different insurance coverage for seniors, veterans and vulnerable populations through Medicare, Medicaid, the Department of Veterans Affairs, Department of Defense and Indian Health Service, among others.

\*Note: Throughout the report, we use rebates and discounts interchangeably.

## A CLOSER LOOK: ACCESS AND AFFORDABILITY

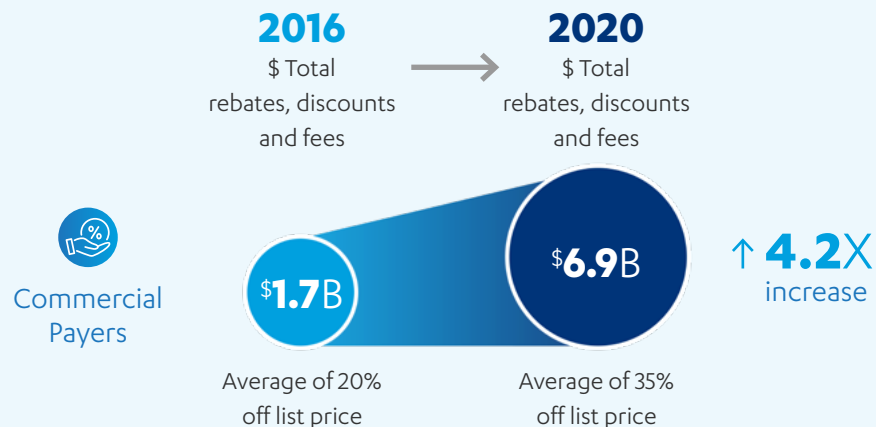
### How Payers Determine What Patients Will Pay

Each year, health insurers create tiered lists of covered medicines called formularies. These tiers reflect how much a patient is expected to pay out-of-pocket for a medicine he or she is prescribed. Pharmaceutical manufacturers offer payers discounts and rebates to have their medicines placed on “preferred” formulary tiers with lower patient out-of-pocket costs and fewer access hurdles. Access hurdles often include “utilization management” tools including:

- Requiring a patient to fail treatment on the payer’s preferred medicine before trying another: also known as “step therapy;”
- Limiting access for some medicines to patients whose diseases have progressed to a certain stage;
- Imposing administrative requirements such as a healthcare professional needing to submit documentation before a prescribed medicine can be covered; and
- Changing the medicines covered on a formulary in the middle of a plan year, forcing patients to switch medicines for economic rather than medical reasons, also known as “non-medical switching.”

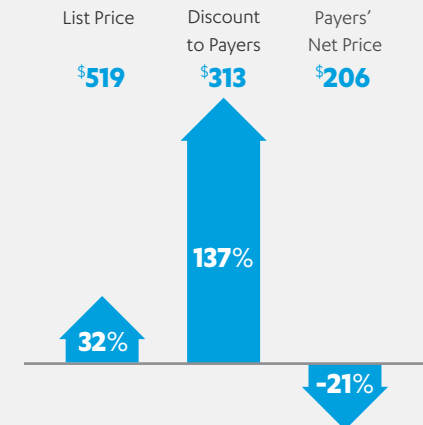
Since 2016, the first year covered by a Janssen U.S. Transparency Report, the rebates and discounts we provide have nearly tripled, reflecting payers’ growing negotiating power. Three PBMs currently cover 256 million Americans—more than 2/3 of the U.S. population—and handle 74% of all prescriptions processed in the U.S.<sup>35</sup> Further, the number of unique medicines not covered (that is, placed on “exclusion lists”) nearly quadrupled, growing from 209 in 2016 to 846 in 2020.<sup>36</sup>

### POLICIES SHOULD ENSURE REBATE SAVINGS ARE SHARED DIRECTLY WITH PATIENTS<sup>37</sup>



## A LOOK AT INVOKANA® FROM 2016-2020

### Payers are paying less as net prices decrease<sup>38</sup>



Payers often base patients’ cost-sharing on list price. Therefore, when net prices decline patients may not directly share in the savings that payers receive.

### WHAT PATIENTS MAY PAY FOR INVOKANA DEPENDS ON TYPE AND PHASE OF BENEFIT DESIGN

#### Hypothetical Example:

Patient with HDHP still in 100% deductible phase	Patient with Co-insurance of 25%	Patient with a flat copay amount
\$519	\$129.75	\$40

Higher out-of-pocket costs result in abandonment<sup>39</sup> and could potentially lead to worse outcomes.

## OUR PRIORITY: AFFORDABLE ACCESS FOR PATIENTS

We provide U.S. government programs with substantial discounts. Growth in these discounts reflects vigorous commercial competition as well as increases in the amounts of legally required, or statutory, price concessions. For an explanation of why this is, see Our Promise. At the state level, discounts to Medicaid reflect not only competition and statutory discounts, but also the extra, “supplemental,” discounts we and other manufacturers negotiate with individual states. Because of these factors, price concessions to government programs have grown substantially in recent years.

Notably, between 2015–2019, patients’ exposure to costs continued to rise, largely due to insurer practices, such as:<sup>40</sup>



**Not passing rebates** directly to patients.

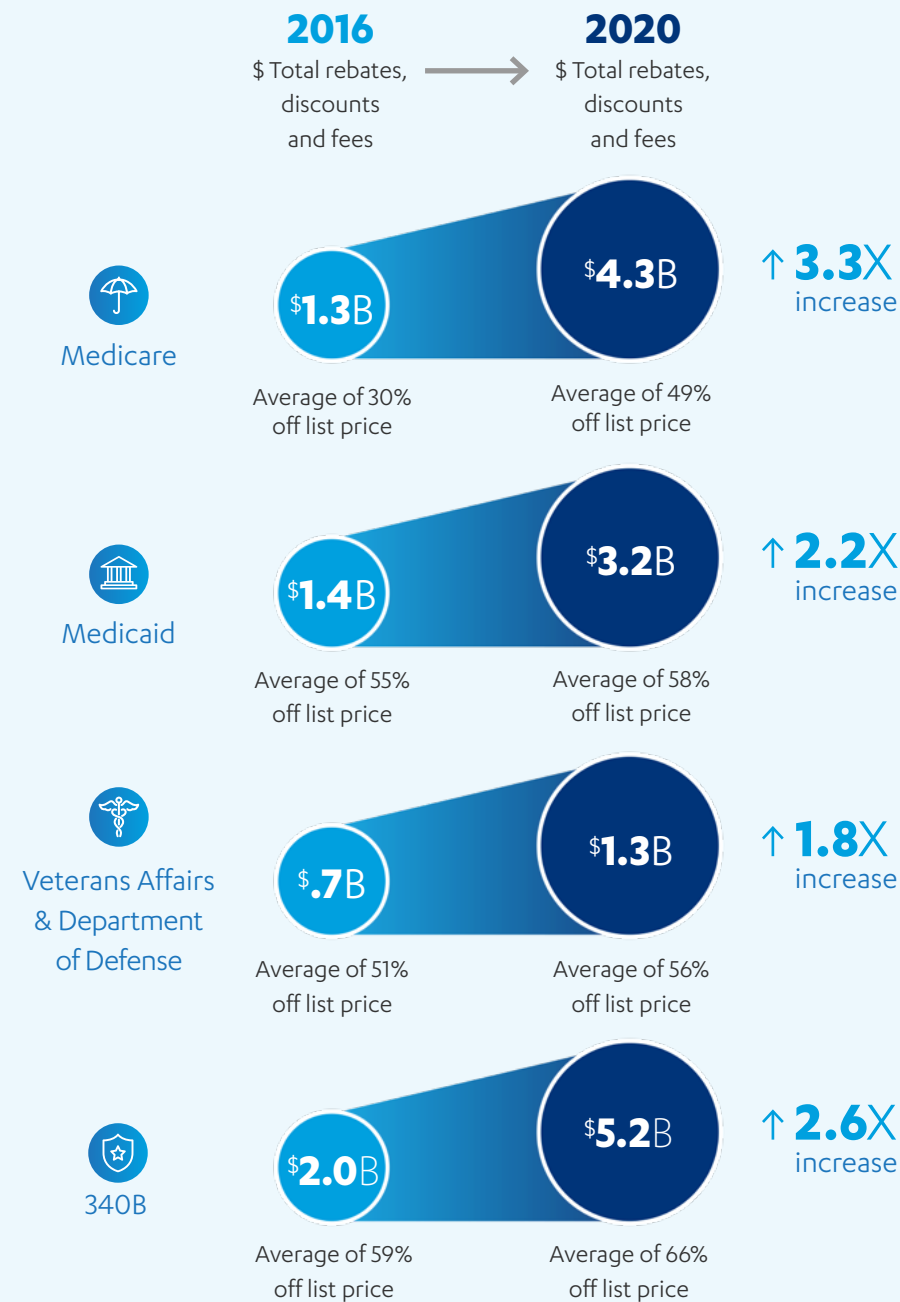


**Basing cost-sharing on list prices,** not net prices.

In the third chapter, Our Promise, we share our ideas for policies that put patients first and create a more accessible and affordable healthcare system.

[Read more about our policy issues >](#)

## OUR GROWING DISCOUNTS TO GOVERNMENT PROGRAMS<sup>41</sup>





## OUR PRIORITY: AFFORDABLE ACCESS FOR PATIENTS

### INCREASES IN OUT-OF-POCKET COSTS CAN HARM PATIENT CARE

The amount insured patients pay out-of-pocket for their medicines is determined by how their health insurance is set up—the co-pays, deductibles, co-insurance amounts and out-of-pocket maximums for which a patient is responsible.

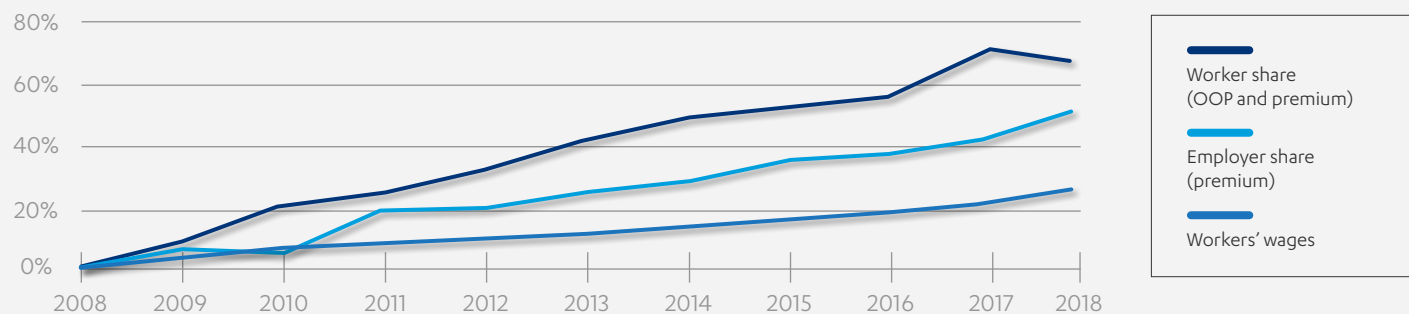
#### Patients' share of total spending:

**15%** of total outpatient prescription drug spending (\$53.7 billion)<sup>42</sup>      **3%** of total hospital care spending (\$35.9 billion)<sup>43</sup>

Patients are increasingly vulnerable to high out-of-pocket costs for medicines.

- In 2020, the share of U.S. workers' health plans with deductibles between \$2,349 (single) and \$4,601 (family)—known as high-deductible health plans (HDHPs)—**increased to 31%, up from 4% in 2006.**<sup>44</sup>
- For all people with employer-provided insurance, **the average deductible in 2020 was \$1,364**, which was 27% higher than 2015 (\$1,077) and 111% higher than 2010 (\$646).<sup>45</sup>
- Deductibles and co-insurance, which are based on a percentage of a drug's list price rather than a pre-set dollar amount, **have risen faster than wages and inflation** at the same time.<sup>46</sup>
- The doubling of co-pays has been found to **reduce patients' adherence to prescribed medicines by 25%–45%.**<sup>47</sup>

### 2008–2018: CUMULATIVE GROWTH IN PREMIUMS AND OUT-OF-POCKET (OOP) SPENDING FOR FAMILIES WITH LARGE EMPLOYER COVERAGE<sup>48</sup>



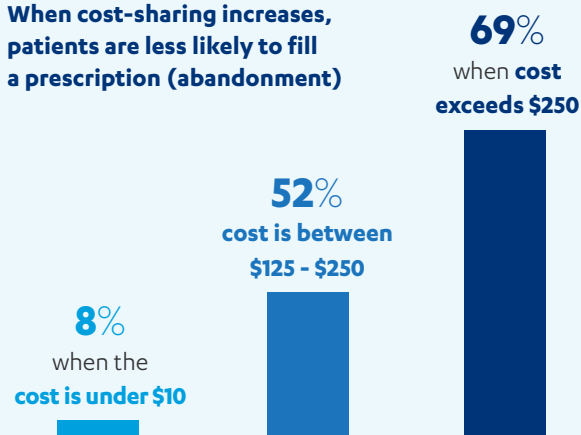
*Note: OOP costs are inflated from 2017 to 2018 because data are not yet available. Large employers are those with one thousand or more employees.*

Kaiser Family Foundation Brief

## OUR PRIORITY: AFFORDABLE ACCESS FOR PATIENTS

### PRESCRIPTION ABANDONMENT RATES FOR NEW PATIENTS<sup>49</sup>

When cost-sharing increases, patients are less likely to fill a prescription (abandonment)



### ACCESS HURDLES CAN LIMIT LONG-TERM BENEFITS OF MEDICINES

Patients' health can suffer when they face high costs. They are more likely to stop taking their medicine or to leave a new prescription unfilled. In 2017, prescription "abandonment" rates for new patients were 8% when the out-of-pocket cost was \$10 or less, but rose to 52% when the cost was between \$125 - \$250 and jumped to 69% when costs exceeded \$250.<sup>51</sup> A recent study of Medicare beneficiaries taking life-saving statins and anti-hypertensives showed that a \$10 increase in out-of-pocket costs led to 23% fewer patients filling their prescriptions and 33% more deaths.<sup>52</sup>

Three examples demonstrate why affordable access to treatments helps individuals, the healthcare system and society. Crohn's disease, a chronic inflammatory gastrointestinal disorder, often requires stays in the hospital and frequent visits to the emergency room (ER). A real-world study of one of our immunology therapies

### Fast Facts: Cost-Sharing Increases Affect Adherence

Doubling co-pays has been found to **reduce patients' adherence to prescribed medicines by 25%-45%.**<sup>50</sup>

found it was associated with reductions in ER visits, inpatient hospital stays and the use of corticosteroids that can be part of treatment regimens for Crohn's disease. Annual all-cause ER visits decreased by more than 20%, while inpatient stays decreased by more than 30%.<sup>53</sup>

In another study, we found that patients enrolled in Medicaid who started Janssen anti-retroviral therapy (ART) soon after an HIV diagnosis had better health outcomes and lower healthcare costs.<sup>54</sup>

We also found that patients taking one of our long-acting injectable medicines used to treat schizophrenia were significantly less likely to have an encounter with the criminal justice system in the 12-month period<sup>55</sup> after starting the medicine than in the 15-month period prior, potentially reducing costs associated with the criminal justice system, including incarceration.<sup>56</sup>

## OUR PRIORITY: AFFORDABLE ACCESS FOR PATIENTS

### OUR PROGRAMS TO SUPPORT PATIENTS

We continue to support patients through Janssen CarePath.

Janssen CarePath is 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 and stay on track, including sharing options to help manage out-of-pocket costs.

In 2020, Janssen CarePath helped almost 1.2 million patients through the Janssen CarePath program.<sup>57</sup>

**For more information, please visit [JanssenCarePath.com](https://JanssenCarePath.com) >**

### INDEPENDENT PROGRAM AND FOUNDATION SUPPORT

We also support independent programs and foundations that help patients. In the U.S., Janssen and other Johnson & Johnson operating companies donate medicines and funding to the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAPF)—an independent, nonprofit organization committed to helping eligible, low-income patients without insurance coverage. In 2020, Janssen donated approximately \$1.9 billion in products and financial support to JJPAPF,<sup>58</sup> enabling it to provide medicines at no cost to about 95,000 patients.<sup>59</sup>

In response to COVID-19, JJPAPF took action to ensure that qualifying patients in need of donated medicines could access those medicines and was able to support approximately 15% more patients in 2020 than in 2019.<sup>60</sup> JJPAPF will continue to monitor the COVID-19 pandemic to address any changes that are required, consistent with their charitable mission.

**For more information, please visit [jjpaf.org](https://jjpaf.org) >**



# OUR FOCUS: CREATING A FUTURE WHERE DISEASE IS A THING OF THE PAST

Society counts on us to deliver vaccines, treatments and cures to fight challenging diseases.

## SECTION HIGHLIGHTS:

-  In 2020, we **invested \$9.6 billion in R&D**<sup>61</sup>—more than twice (106%) what we spent on marketing and sales.<sup>62</sup>
-  Our R&D investment has **increased an average of 8.1%** for the past five years.<sup>63</sup>
-  **Since 2016, we've invested \$42.2 billion in R&D**<sup>64</sup>—86% more than we've spent on marketing and sales.<sup>65</sup>
-  When the pandemic struck, past R&D investment meant Janssen had a **ready technology platform to develop our COVID-19 vaccine**.



## OUR APPROACH TO RESEARCH AND DEVELOPMENT

We focus on the areas of medicine where we can make the greatest difference: cardiovascular and metabolism, immunology, infectious diseases and vaccines, neuroscience, oncology and pulmonary hypertension. Across these therapeutic areas, we use our expertise in small molecules, monoclonal antibodies, cell and gene therapies, RNA therapeutics and vaccines to develop transformational medical innovations.

In 2020, we increased our global investment in R&D to \$9.6 billion,<sup>66</sup> up from \$8.8 billion in 2019,<sup>67</sup> a substantial portion of Johnson & Johnson's \$12.2 billion global R&D budget across all sectors<sup>68</sup>—enabling us to discover, test and develop new medicines as well as demonstrate the efficacy, safety and quality compliance of our medicines before approval.

Over the last five years we've invested \$42.2 billion in R&D,<sup>69</sup> 86% more than we spent on marketing and sales.<sup>70</sup> This investment produced a total of four new Janssen medicines approved by the FDA<sup>71</sup> and an additional 42 approvals for expanded indications or new product formulations over the same five-year period.<sup>72</sup>

## Fast Facts: Driving Treatment Advances for Patients

Our **\$42.2 billion investment in R&D between 2016–2020<sup>73</sup>** produced:

- Four new FDA-approved prescription medicines.<sup>74</sup>
- Forty-two additional approvals for expanded indications or new product formulations.<sup>75</sup>



**OUR FOCUS: CREATING A  
FUTURE WHERE DISEASE  
IS A THING OF THE PAST**

**PAST INVESTMENT HELPED US BE PREPARED  
FOR COVID-19**

Janssen began to research potential vaccine candidates against COVID-19 in January 2020, as soon as the gene sequence for the novel coronavirus became available. Our ability to move quickly reflected our long-term commitment to innovation and the infrastructure we have invested in over many years, including our AdVac®-based vaccine technology. The same technology was used to develop Janssen's European Commission-approved Ebola vaccine regimen and construct our HIV, RSV and Zika vaccine candidates.<sup>76</sup>

In addition to leveraging our existing technologies and platforms, we also:

- Expanded our manufacturing and distribution capabilities to provide access to our COVID-19 vaccine;
- Committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use;
- Explored potential therapies by screening a library of compounds (ours as well as those of other companies) and where promising, initiated clinical trials; and
- Prepared for future pandemics by continuing to learn about immune response to respiratory pathogens and assessing combinations of different mechanisms of action.

The size, scale and global footprint of our organization enabled us to urgently address the crisis as it unfolded, committing \$50 million to support and supply frontline health workers with meals, protective equipment, extra training and mental health support.<sup>77</sup> This commitment expanded upon a \$250 million multi-year commitment made earlier in 2020.<sup>78</sup>

**FROM THE LAB TO THE REAL WORLD:  
OUR RESEARCH NEVER STOPS**

**We want healthcare decision makers to have a more complete picture of the value our medicines and vaccines deliver.**

An essential element of delivering transformational medical advances is studying how our innovations work in real-world settings after they are approved by the FDA, generating "real-world evidence." We examine how our medicines can improve healthcare delivery, enhance population health, reduce costs to the healthcare system and society, and make day-to-day living easier for patients and their caregivers. In a large private health group, inpatient admissions, re-admissions after 30 days and ER visits decreased after adult patients started a long-acting injectable (administered once a month rather than taken daily, like a pill) used to treat schizophrenia.<sup>79</sup> This helps patients stay on the medicine they started and as a result, led to less use of healthcare resources.

**Fast Facts: Our R&D  
Investment Exceeds Our  
Spending on Marketing and Sales**



Over the last five years we've invested **86% more in R&D (\$42.2B)<sup>80</sup> than marketing and sales.<sup>81</sup>**



Our R&D investment has **increased an average of 8.1%** for the past five years.<sup>82</sup>



Our global 2020 R&D investment **(\$9.6B)<sup>83</sup> was 106% more** than we spent on marketing and sales.<sup>84</sup>

# OUR PROMISE: CREATING A HEALTHIER FUTURE FOR ALL

A fair and equitable healthcare system is one in which all patients have affordable access to the medicines they need. Policies and laws need to be patient-centric to improve access and patients' health.

## SECTION HIGHLIGHTS:



We highlight our efforts to understand how race and socioeconomic factors impact access and health outcomes and to make our clinical trials more racially inclusive.



We explain how we engage with diverse patient populations to design studies for approval of our medicines and afterward through our Patient Engagement Research Councils.



We present policy principles to build a more accessible, affordable and equitable healthcare system.

## Johnson & Johnson Investment to Eliminate Health Inequities for People of Color

Racism is a public health threat. Johnson & Johnson announced \$100 million in commitments and collaborations over the next five years to promote health equity solutions for Black people and other communities of color in the U.S.<sup>85</sup>

Aiming to combat the disparities that threaten health in communities of color, our commitment prioritizes:

- **Healthier Communities:** Providing equitable healthcare for underserved communities.
- **Enduring Alliances:** Forging partnerships to reduce differences in socially determined health outcomes.
- **Diverse & Inclusive Corporate Culture:** Ensuring a diverse and inclusive workforce.

## Better Research Through More Inclusive Clinical Trials

To make R&D more equitable, we are improving how we collect real-world evidence and are working to better understand clinical effectiveness in diverse patient populations. We've modified our approach to trials to make them more broadly representative of the people we help. We have increased the number of investigators who work with diverse patient populations and provided tailored training to enable more physicians from underrepresented populations to lead clinical trial research. And we've addressed barriers to enrollment by patients in underrepresented communities, such as lack of transportation to a trial site.

## Examining Insurance Design and Health Disparities

At Janssen and across Johnson & Johnson, we seek to understand how race and socioeconomic factors determine access, so we are better equipped to combat systemic racism in healthcare.

We are researching how the design of insurance benefits exacerbates health disparities; for example, whether outcomes for patients enrolled in high-deductible health plans (HDHPs) vary based on race and ethnicity. A recent study published in the Journal of the American Medical Association found that among cancer survivors, 23% of Black survivors with an HDHP skipped medication to save money compared to 8% of White cancer survivors on the same plan.<sup>86</sup> Other research shows the most frequent high-cost prescription claims (claims greater than \$125) were for diseases that disproportionately affect African Americans, including diabetes, HIV, obesity, respiratory disease and stroke.<sup>87</sup>

## WHAT WE STAND FOR: POLICIES PUTTING PATIENTS FIRST

The U.S. health system has many strengths—especially when it comes to medical breakthroughs. Yet, too many barriers stand between patients and affordable access to advances.

**At Janssen, we are committed to advancing solutions that strengthen the U.S. healthcare system and enable the development and rapid approval of new medicines.**

*When we offer policy solutions and/or assess policy proposals, the following principles guide our thinking:*



Patients should have **affordable access to appropriate treatment options** and sites of care



Treatment decisions **belong in the hands of patients** and their healthcare providers



Clinically stable **patients should not be switched from their treatments for non-medical reasons** (unless deemed substitutable by the FDA)



Appropriate **clinical rigor and manufacturing quality standards** should be applied in all instances to ensure patient safety

**OUR PROMISE: CREATING A HEALTHIER FUTURE FOR ALL**

*We believe the healthcare system should support these principles by:*



Maintaining a **fair and competitive** marketplace



Fostering an environment that **supports future investment in innovation**



Ensuring **responsible pricing and appropriate transparency** system-wide



Determining value based on evidence that **incorporates the benefits and risks** for patients, the healthcare system and society

## OUR PROMISE: CREATING A HEALTHIER FUTURE FOR ALL

### BENEFIT DESIGN SHOULD ENABLE ACCESS TO MEDICINES AND TREATMENT CHOICE

When patients need medicines, their insurance should allow them to get the care they need. It should provide financial protection with predictable out-of-pocket costs. However, insurer programs and practices intended to reduce overall costs can add to patients' financial burden.

#### Accumulators

Accumulator adjustment programs prevent co-pay assistance provided to patients by manufacturers from applying toward patients' out-of-pocket maximums or deductibles. They can lead to additional and unexpected costs for patients and consequently, can potentially lead to reduced medication adherence. We have serious concerns about their impact on patient health.

#### Non-Medical Switching

We believe treatment decisions for all products belong in the hands of patients and their healthcare providers. We are concerned about clinically stable patients on any product being switched to other therapies for non-medical reasons. Non-medical switching also has impacts on patients. In a survey carried out by the Alliance for Patient Access (sponsored by Janssen Scientific Affairs, LLC), patients responded they experienced negative impacts on health outcomes and well-being because of non-medical switching.<sup>88</sup> Consistent with our position that no clinically stable patient should be switched from any medicine (not including medicines deemed substitutable by the FDA), regardless of whether it's a Janssen medicine or not, we do not proactively seek arrangements with payers that require patients who are clinically stable on a medicine to switch to a different medicine.

### ENSURING A LEVEL PLAYING FIELD WILL CONTINUE TO DRIVE BIOSIMILAR UPTAKE

Despite misconceptions, the uptake of biosimilars has been comparable to that of recently launched, competing innovator biologics and price reductions of both have resulted in significant savings to the healthcare system. Competition has reduced the price of REMICADE® (infliximab), a Janssen medicine used to treat immunological conditions like Crohn's disease and ulcerative colitis. Biosimilars and biologics should compete on a level playing field.

We have long supported a robust regulatory framework for biosimilars that promotes safety and confidence and does not have the unintended consequence of letting stable patients be switched from a medicine that is already working for them. Formulary policies that require failing on biosimilars before trying a branded biologic should not apply to patients whose treatment is working for them and who are stable on their current therapy.





## REFORMS TO MEDICARE SHOULD FOCUS ON PATIENT OUT-OF-POCKET COSTS

Medicare Part B and Part D are effective programs for ensuring seniors have access to the medicines they need and benefit from private market competition. While most seniors pay nothing directly out-of-pocket for Part B medicines—most have supplemental insurance—we support a cap on out-of-pocket costs in Medicare Part D.

### Medicare Part B

Medicare Part B covers physician-administered medications—typically infused medicines and biologics for treating chronic conditions. On average, the patient is responsible for 20% of all medication costs<sup>89</sup> incurred after an annual deductible has been met (\$198 in 2020).<sup>90</sup> Most Medicare beneficiaries have some type of supplemental insurance coverage that covers much of the patient's Part B cost-sharing requirements.<sup>91</sup>

The Medicare Part B program benefits from private-market negotiations between manufacturers and payers and covers patients' medicines without barriers to access like utilization management. For a medicine it covers, Medicare Part B pays based on the "average sales price" (ASP), which is an average of the net prices negotiated between manufacturers, commercial health insurers and others (and excludes 340B and Medicaid discounts). These negotiations are reflected in the declining ASP of REMICADE®, one of our medicines covered under Medicare Part B (see below):

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## MEDICARE PART B IS WORKING AS DESIGNED<sup>92</sup>

It benefits from competition and **nearly 9 out of 10 beneficiaries pay \$0 for their medicines.**

**\$500**

REMICADE®  
ASP

**\$522**

Provider  
Reimbursement  
(ASP + 4.3%)

**\$418**

Medicare Covers  
80% of  
Reimbursement  
Amount

### 20% Cost to Part B Beneficiaries

**89%**

with supplemental  
insurance pay

**\$0**

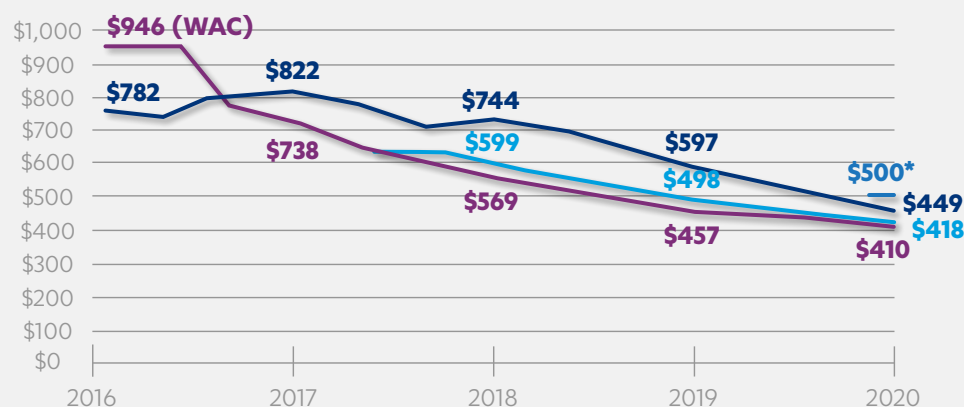
**11%**

without supplemental  
insurance pay

**\$104**

For 340B providers, reimbursement is ASP -22.5%.

## THANKS TO COMPETITION, PRICES ARE FALLING FOR REMICADE® (INFLIXIMAB) AND INFLIXIMAB BIOSIMILARS<sup>93</sup>



REMICADE® (ASP)	Inflectra® (ASP) (infiximab-dyyb)
Renflexis® (ASP) (infiximab-abda)	Avsola® (WAC) (infiximab-axxq)

\*Avsola® launched in July 2020 at a wholesale acquisition cost (list price) of \$500, lower than previous infliximab biosimilar launches. Renflexis® is a registered trademark of Merck Sharp & Dohme Corp. Avsola® is a registered trademark of Amgen Inc. Inflectra® is a registered trademark of Pfizer Inc.

### Medicare Part D

Medicare Part D covers self-administered medications (typically orally administered and some injectable therapies) and is offered through private insurers.

Despite misconceptions, the Medicare Part D program benefits from competitive negotiations, as the private insurers that manage Part D bargain directly with pharmaceutical manufacturers for larger discounts.

The table below shows how much Janssen pays in rebates to support access to INVOKANA®, (canagliflozin).

### Fast Facts: Reducing Patient Out-of-Pocket Costs in Part D

Tying cost-sharing to net price would result in:



**47%**

of Medicare beneficiaries seeing **reductions in out-of-pocket spending** (for those who do not receive low-income subsidies)<sup>95</sup>

### Fast Facts: Discounts to Government Programs Support Patient Access<sup>94</sup>

We give government programs deep discounts to support access to our medicines.

In 2020, for example, discounts on INVOKANA® (canagliflozin), were:

**72%**

for Medicare  
Part D

**100%**

for Medicaid

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HEALTHIER FUTURE FOR ALL**



## THE 340B DRUG DISCOUNT PROGRAM SHOULD BENEFIT NEEDY PATIENTS

The 340B Drug Discount Program is intended to increase access to medicines for needy patients. The program requires drug manufacturers to provide steep discounts on outpatient drugs to certain healthcare providers. To be eligible for program participation, providers must be one of six designated hospital types or be a designated federal grantee.

In recent years, the 340B Program has expanded at double-digit rates.<sup>96</sup> More than half of all hospital drug purchases are made at the discounted 340B Program prices,<sup>97</sup> and prescription drugs purchased at 340B Program discounts are estimated to account for about 14% of all branded outpatient drug purchases in the U.S.<sup>98</sup>

Unfortunately, the program is no longer working as intended. Hospitals and other covered entities under the 340B Program do not always pass along the discounted drug prices to uninsured and indigent patients.<sup>99</sup> Discounts can also be diverted from patients to for-profit intermediaries in the system, such as contract pharmacies owned by large pharmacy chains or PBMs.<sup>100</sup> The number of external pharmacies in the 340B Program has skyrocketed. Nearly half of the country's retail, mail and specialty pharmacies now profit from the 340B Program.<sup>101</sup> These contract pharmacy arrangements have increased 4,228% since 2010;<sup>102</sup> they are lucrative for both the contract pharmacies and for the covered entities, which can charge the patient list price of a medicine and split the 340B Program discount with the contract pharmacy that dispenses the prescription.

We support the 340B Program but want it to work as intended—to serve needy patients.

## DISCOUNTS IN GOVERNMENT PROGRAMS CAN GROW UP TO 100%<sup>103</sup>

### Medicaid

	\$519	INVOKANA® list price
—	\$519	Janssen discount on INVOKANA list price (100%)
	\$0	Net cost to Medicaid

### 340B

	\$519	INVOKANA list price for 30 pill bottle
—	\$518.70	Janssen discount on INVOKANA list price (~99%)
	\$.30	Cost to 340B provider site (e.g., For 30 pill bottle cost would be \$0.30)

## Fast Facts: Growth Rate of the 340B Program



The 340B Drug Discount Program, the second largest federal prescription drug program<sup>104</sup>, tripled in size between 2014 and 2019 to nearly \$30 billion.<sup>105</sup>

- Since 2010, the number of contract pharmacy arrangements with 340B covered entities has increased to: **28,000**<sup>106</sup>
- Average annual growth rate of purchases in the 340B Program from 2014-2019: **27%**<sup>107</sup>
- Percentage of total U.S. drug market accounted for by the 340B Program: **over 8%**<sup>108</sup>
- Average portion of total manufacturer discounts for brand name medicines that go to the 340B Program: **16%**<sup>109</sup>
- Portion of all branded outpatient drug purchases in the U.S. made at 340B Program discounts: **14%**<sup>110</sup>
- Majority of hospital drugs purchased at the discounted 340B Program prices: **57%**<sup>111</sup>

## POLICIES SHOULD TARGET THE TRUE SOURCES OF PATIENT BURDEN

U.S. policymakers have considered proposals that would peg prices for medicines in the U.S. to those of other economically similar countries, an approach known as “international reference pricing.”

These proposals also ignore important differences between the healthcare system in the U.S. and the rest of the world. In the U.S., patients expect timely access to new medicines, while patients outside our borders can face significant delays before treatments become available in their countries.<sup>112</sup> The U.S. system has many different payers, both public and private and most people are insured through their employer. Outside the U.S., healthcare is often funded by a single government payer. These differences reflect each countries’ specific histories, cultures and values.

International reference pricing would, in essence, give control of part of the U.S. healthcare system to other countries and subject U.S. citizens to the consequences of political decisions made in another country. It would hinder the development of new treatments, creating a potential vulnerability for response to future pandemics and could reduce the nation’s overall global competitiveness in an essential industry. No other healthcare service is benchmarked to payment rates in other parts of the world.<sup>113</sup>



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## VALUE ASSESSMENT SHOULD BE PATIENT-CENTRIC AND HOLISTIC

As healthcare decision makers' interest in value assessment has grown, so has our concern about the shortcomings of frameworks currently used to analyze the value of medicines. Typically, these frameworks fail to appropriately account for all the factors that make a medicine valuable, most notably to patients through improved quality of life, the ability to work and care for family, reduced burden on caregivers and the chance to remain independent for a longer period of time.<sup>114, 115, 116, 117</sup>

Particularly concerning are value frameworks that use cost-effectiveness analyses and thresholds to determine whether patients should have access to medicines. Cost-effectiveness analyses attempt to quantify the level of health gained for each dollar spent on treatment.<sup>118</sup> They are estimates that rest on numerous assumptions and rely on inputs from a wide variety of sources, some more credible than others.

These estimates deem a medicine "valuable" if the ratio of dollars spent to health gained stays below a limit, or threshold. In practical terms, that threshold is arbitrary and puts a monetary ceiling on the value of human health and life.<sup>119</sup>

Cost-effectiveness analyses generally use an input called the Quality Adjusted Life Year, or QALY. The QALYs rate the value of human life relative to a subjective<sup>120, 121</sup> standard of perfect health and their use may discriminate against populations such as the elderly, chronically ill and disabled.<sup>122</sup> QALY-based frameworks place a lower value on treatments that extend and improve the lives of people who may never have perfect health.<sup>123</sup>

Some countries use government-funded organizations to carry out assessments of health technologies (sometimes known as HTAs) before patients can access new treatments. This can result in a delay for patients accessing new medicines compared with the U.S.<sup>124, 125</sup> They may also recommend limits on the prices of medicines, as well as certain coverage restrictions. In the U.S., we have a highly segmented system with multiple payers<sup>126, 127</sup> who serve groups of patients with diverse needs. As a result, the value of new medicines (and other technologies) is evaluated locally, with those needs in view. Therefore, health technology assessments should be carried out independently by payers, academic institutions and clinical groups.

At Janssen we follow four key principles when we assess the value of our medicines:

- What matters most in determining a medicine's value is its impact on patients.<sup>128</sup>
- The value of a medicine should include its impact on the health system and society.<sup>129</sup>
- Treatment outcomes should be assessed over an appropriate timeframe to capture all the benefits and risks for patients, the healthcare system and society.<sup>130</sup>
- Evidence considered in assessing the value of a medicine should be high-quality, current and relevant.<sup>131</sup>

## National Commission on Disability

**"QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities."**

**Quality-Adjusted Life Years and the  
Devaluation of Life with Disability >**

# BUILDING A HEALTHIER FUTURE FOR ALL

We work with policymakers to address this country's healthcare challenges and build on its significant strengths, offering solutions that:

- Eliminate the barriers to access created by antiquated insurance design that include unaffordable cost-sharing.
- Ensure rebates negotiated by pharmaceutical manufacturers for payer coverage of medicines go directly to the patients who need them.
- Reduce racial and socioeconomic disparities standing in the way of better health outcomes that Americans have come to expect and on which, amid COVID-19, so many hopes depend.
- Preserve an environment that fosters medical advances and encourages investment in research and development necessary to discover and make these medical advances available to patients in need.

We believe affordable access to healthcare is critical to ensuring individuals can live their fullest lives and society continues to advance. While redesigning healthcare delivery and redirecting resources away from ineffective, wasteful care is challenging, we can and must, continue to seek solutions that benefit all of our communities. Because doing so means improving patients' health, saving lives and creating a stronger, healthier society.

## Advancing Patient-Centric Solutions for a Healthier Future for All



**Eliminate** Barriers  
to Access



**Reduce** Racial  
and Socioeconomic  
Disparities



**Ensure** Rebates  
are Shared Directly  
with Patients



**Preserve** Environment  
for Innovation

BUILDING A HEALTHIER  
FUTURE FOR ALL

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