



PHARMACEUTICAL COMPANIES OF
Johnson & Johnson



TRANSFORMING LIVES, ADVANCING HOPE

2019 JANSSEN U.S. TRANSPARENCY REPORT

NOTES ON THIS REPORT

INTRODUCTION

Notes on This Report

A Letter From
Our Leaders

2019 in Summary

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES



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 December 31, 2018 and December 29, 2019, 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,” 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.

Hyperlinks in this report connect you to additional information. This report and a one-page executive summary are also available at janssen.com/ustransparencyreport.

A LETTER FROM OUR LEADERS

INTRODUCTION

Notes on This Report

**A Letter From
Our Leaders**

2019 in Summary

**TRANSFORMING
LIVES FOR
PATIENTS TODAY**

**ADVANCING HOPE
FOR PATIENTS
TOMORROW**

REFERENCES

IN OUR WORK EVERY DAY, WE WITNESS INTELLECT, EMPATHY,

and courage united in the service of patients. Our colleagues include researchers, pharmacists, medical doctors, policy analysts, commercial experts, and manufacturing engineers—professionals of all types who develop transformational medicines and work tirelessly to ensure they reach the people who need them.

We know our healthcare system has significant strengths. Thanks to an open and competitive marketplace, it offers an array of treatment options and generates groundbreaking discoveries that are typically available in the United States before anywhere else in the world. But all too frequently we're reminded that affordability remains a significant challenge for patients and their families. They want to know what they can expect to pay for their care, including their medicines, and what can be done to lower those costs.

In our fourth annual Janssen U.S. Transparency Report, we explain factors in our health system that influence the accessibility and affordability of medicines. As in years past, we offer information about our responsible business practices that put patients first:

- Since the beginning of 2016, the first year covered by this report, the compound net price decline of Janssen medicines was **-9.2%**¹
- We provided **\$24.5 billion** in discounts, rebates, and fees to government and private payers, as well as hospitals and others in the supply chain. In fact, for the first time, these discounts, rebates, and fees totaled **more than half the list price (51%)** of our medicines.²
- Globally, we invested **\$8.8 billion** in discovering and developing new medicines³—**91%** more than we spent on sales and marketing.⁴
- Over the last five years, we've spent **\$39.4 billion** on R&D,⁵ resulting in **7** new medicines⁶ and **38** new indications.⁷
- We helped **1.3 million** patients with access, affordability, and treatment support through Janssen CarePath.⁸
- We contributed practical policy solutions designed to bring down costs for patients and to make these costs more predictable, while supporting continued progress in the fight against disease.

Beyond providing a window into how we operate, we issue this Report because meaningful transparency is critical to the current discussion about healthcare. We aim to highlight what's at stake with the choices before us and show why it's important to preserve the parts of the U.S. system that patients count on—care when it's needed, innovative medicines, and progress in the fight against disease.



A LETTER FROM OUR LEADERS

INTRODUCTION

Notes on This Report

A Letter From Our Leaders

2019 in Summary

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

Historic advances in medicine—including cell and gene therapies that have the potential to cure rare and hard-to-treat diseases—promise to improve the lives of patients and increase the overall sustainability of healthcare in the U.S. Our Janssen therapies have made a significant impact. For example, one of our biologic therapies has been shown to reduce major bowel surgeries and cut hospitalizations for patients with Crohn's disease. Our first-in-class cancer medicines can help extend the lives of patients with some of the most common and deadly types of cancer.⁹ Important as they are, these numbers don't reflect the full impact such medicines can have: joy when health is regained; relief when the burdens of caregivers are lifted; pride when returning to work.

We want this Report to be useful to everyone with a stake in the future of our healthcare system—to policymakers, payers, providers, and most of all, patients. We hope the conversations it starts will bring us closer to a healthcare system that delivers greater access to care at a more manageable cost and, most important, better health for all.



Scott White

Company Group Chairman
North America Pharmaceuticals
Johnson & Johnson



Anastasia G. Daifotis, M.D.

Chief Scientific Officer
Janssen North America
Pharmaceuticals



2019 IN SUMMARY: TRANSFORMING LIVES FOR PATIENTS TODAY

INTRODUCTION

Notes on This Report

A Letter From
Our Leaders

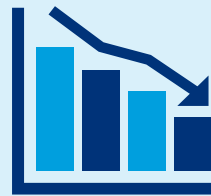
2019 in Summary

TRANSFORMING
LIVES FOR
PATIENTS TODAY

ADVANCING HOPE
FOR PATIENTS
TOMORROW

REFERENCES

NET PRICES FOR OUR MEDICINES HAVE DECLINED



-9.2%

compound net price decline of Janssen medicines since the beginning of 2016,¹⁰ the first year covered by this report. In 2019, our average aggregate **net price decline was -1.2%**¹¹

\$24.5 billion

total amount Janssen paid in rebates, discounts, and fees in 2019¹²

51%

more than half the list price of our medicines went to intermediaries in the system¹³

NATIONWIDE, MEDICINE PRICES REMAIN FLAT, BUT PATIENTS ARE PAYING MORE

0.3%

Growth of net prices for brand medicines across the industry in 2018; less than the rate of inflation¹⁴

67%

increase in patient healthcare spending from 2008-2018¹⁵

1 in 4

American adults reported difficulty in affording prescription medicines in 2019¹⁶



WE'RE SUPPORTING PATIENTS TODAY AND WORKING TOWARD SUSTAINABLE SOLUTIONS FOR TOMORROW

1.3 million

patients helped with access, affordability, and treatment support through the Janssen CarePath program in 2019¹⁷



540,000

Commercially insured patients who reduced their out-of-pocket costs¹⁸ through the Janssen CarePath Savings Program in 2019*

*Included in the 1.3 million patients helped, above

2019 IN SUMMARY: ADVANCING HOPE FOR PATIENTS TOMORROW

INTRODUCTION

Notes on This Report

A Letter From
Our Leaders

2019 in Summary

TRANSFORMING
LIVES FOR
PATIENTS TODAY

ADVANCING HOPE
FOR PATIENTS
TOMORROW

REFERENCES

WE MAINTAINED OUR INVESTMENT IN DISCOVERING AND DEVELOPING NEW MEDICINES

\$8.8 billion
invested globally in pharmaceutical R&D¹⁹

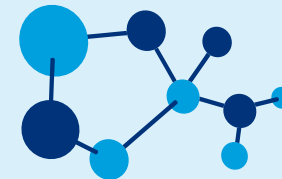
91% more
invested in global R&D than in global sales and marketing²⁰



OUR SUSTAINED COMMITMENT TO R&D IS LEADING TO MEANINGFUL ADVANCES FOR PATIENTS

IN 2019:

2 new medicines and 9 new indications
approved by the U.S. Food & Drug Administration (FDA)^{*,21,22}



OVER THE PAST FIVE YEARS:

\$39.4 billion
invested in R&D²³

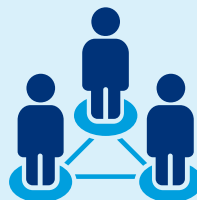
7 new medicines
approved by FDA²⁴

38 new indications
approved by FDA²⁵

7 FDA Breakthrough
Therapy Designations received^{26,27}

WE ARE HARD AT WORK DELIVERING THE NEXT GENERATION OF MEDICINES

140+
active collaborations
with universities,
biopharmaceutical
firms, academic medical
centers, and other
scientific organizations



80+
medicine
candidates in
development as
a result of our
investments
in R&D

120,000+
patients enrolled
worldwide in more
than **400 clinical**
trials. We launched
more than **100** new
clinical trials in 2019

640+
start-up companies in
the Johnson & Johnson
Innovation—JLABS
incubator community,
58% of which are run by
first-time entrepreneurs²⁸

*New therapeutic uses for previously approved medicines

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

TRANSFORMING LIVES FOR PATIENTS TODAY

“Patients and families in the United States continue to be concerned about their ability to access and afford medicines. We share these concerns and are working toward solutions.”

— Scott White, Company Group Chairman, North America Pharmaceuticals, Johnson & Johnson

When people are sick, they should have affordable access to the medicines they need. But many in the U.S. do not.

Access to medicines is critical. Medicines have dramatically improved patient health²⁹ and reduced the need for surgeries, physician visits, hospital stays, long-term care, and other costly healthcare interventions.^{30,31,32} This brings down the total cost of treating patients, ultimately benefitting the entire U.S. healthcare system and our society as a whole.

In this section, we look at factors that affect medicines’ affordability, including how medicines are distributed and paid for, and how insurance benefits work.

We explain why patients do not often see the benefits of discounts and rebates we provide to insurers.

We also explain steps we’re taking to address access and affordability challenges, including appropriately providing financial assistance to eligible patients and working with policymakers to advance solutions that maintain what’s distinctive about American healthcare: access to innovative therapies, choice, and care that’s focused on the individual.

MEDICINES ARE MAKING A DIFFERENCE

Innovative medicines have fueled dramatic health gains in the U.S.

- Cancer death rates **decreased 27%** from 1991 to 2017³³
- Heart disease death rates **decreased 64%** since 1980³⁴
- **39 years:** Increase in the average lifespan for a person with HIV who takes current medicines³⁵

Earlier availability of these innovative medicines is a strength of the U.S. healthcare system

- Of new medicines launched worldwide between 2011-2018, **88%** were available in the U.S. vs. **46-59%** in the United Kingdom, France, and Canada³⁶
- Compared to patients in these same countries, cancer patients in the U.S. have **10-20% higher survival rates**^{37,38}

UNDERSTANDING THE PRICE OF MEDICINES

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

Empowering patients to make informed decisions about their healthcare starts with helping them understand more about the cost of their medicines.

HOW A LIST PRICE BECOMES A NET PRICE

The list price of a medicine is a starting point that is ultimately reduced to a net price by the substantial discounts, rebates, and fees pharmaceutical companies provide to payers and other intermediaries. These include government programs, insurance companies, and employers, as well as the pharmacy benefit managers (PBMs) who administer benefits on their behalf. Hospitals, clinics, physician offices, and others may also receive discounts and rebates. We also pay fees to pharmaceutical wholesalers to distribute our medicines. In 2019, we paid \$24.5 billion in rebates, discounts, and fees—more than half the list price of our medicines (51%).³⁹

We provide or pay these discounts and rebates to support broad access to our medicines, as outlined below:

- **Public and Private Payers.** To participate in public programs, we are required to give specific mandatory discounts to government insurers such as state Medicaid departments and the U.S. Department of Veterans Affairs. In addition, we provide discounts and rebates through negotiations with the private health insurance companies and PBMs who administer benefits for Medicaid and Medicare.

We also work with commercial health insurance companies and the PBMs that manage the purchase of medicines for individuals with private insurance

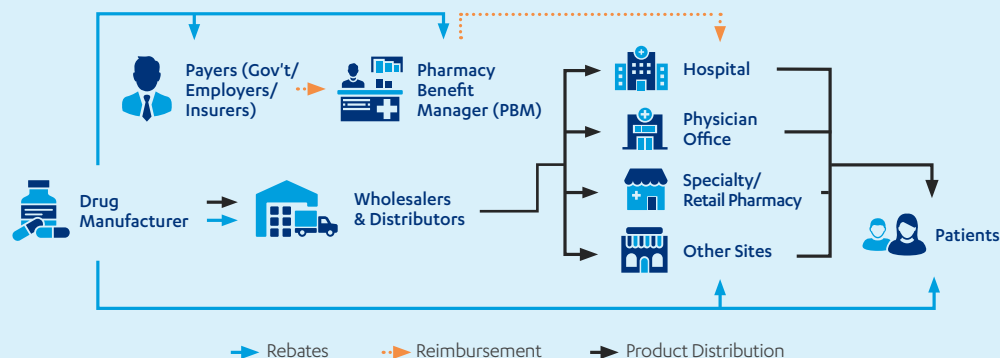
coverage. Private insurance companies determine which medicines will be included on their formulary (the list of medicines they cover) and the out-of-pocket amounts patients will pay for those medicines. Formulary determinations are based in part on pharmaceutical companies' negotiations with payers, which result in rebates from the pharmaceutical company to the payer.

- **Wholesalers and Distributors.** Pharmaceutical companies pay fees to wholesalers and distributors—companies that buy medicines in bulk and distribute them to pharmacies and healthcare providers.
- **Hospitals, Clinics, Physicians' Offices, and Other Dispensers of Medicines.** Pharmaceutical companies provide discounts on medicines to hospitals and clinics for inclusion on their formularies. In addition, we provide discounts and rebates to physicians' offices where certain medicines are administered. Under a federal program known as the 340B Drug Discount Program, we also are required to provide significant discounts on certain medicines purchased by specific categories of hospitals, clinics, and health centers that meet certain eligibility requirements set forth by the federal government.

Within the formularies of various payers, medicines are placed on tiers that correspond with patients' out-of-pocket costs. Because for many conditions there are multiple treatments available, payers create competition among pharmaceutical companies seeking to have their medicines placed on tiers with lower copays. We offer discounts and rebates to gain payer coverage and favorable formulary placement so our medicines are accessible and affordable. However, the amount a patient pays often does not reflect the discounts and rebates we give payers, as we explain in the next chapter. ●

THE PATH TO THE PATIENT

Many entities are involved in getting a medicine from the pharmaceutical company to the patient. Together, they make up the pharmaceutical supply chain. This chart depicts a typical route a medicine takes from drug manufacturer to patient. In 2018, about 46% of the money spent in the U.S. on brand name medicines across the pharmaceutical industry went to players in this supply chain, up from 33% in 2013.⁴⁰



HOW PATIENT COSTS ARE DETERMINED

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

A recent survey reported that one in four Americans finds it “very difficult” or “difficult” to afford their medicines.⁴¹ Why is that?

The amount insured patients pay out-of-pocket for their medicines is determined by how their health insurance is designed and how their pharmaceutical benefits are managed. Notably, on average, patients pay 12% of their prescription drug costs compared to 4% of their hospital care costs.⁴²

While many patients receive insurance through government programs or by purchasing it themselves, roughly half of all Americans receive insurance benefits from their employers.⁴³ Their employers choose plans with designated coverage levels, including copays, deductibles, coinsurance amounts, and out-of-pocket maximums for medicines.

One force driving up patients’ out-of-pocket spending is the use of high-deductible health plans, which are increasingly prevalent among employers and individuals. These plans offer lower monthly premiums but require more out-of-pocket costs, or a higher deductible, before coverage begins.⁴⁴ In 2019, the number of workers enrolled in high-deductible health plans increased to 30%, up from 4% in 2006.⁴⁵ For all people with employer-provided insurance, average deductibles more than quadrupled between 2006 and 2019.⁴⁶

FAST FACT

39%

of large employers now offer only **high-deductible healthcare plans**, up from **7%** in 2009.⁴⁷

34%

of insured adults find it **difficult to pay their deductible** before their insurance kicks in.⁴⁸



accumulator adjustment programs. These programs prevent copay assistance—provided to patients by manufacturers, often in the form of savings cards—from applying toward patients’ out-of-pocket maximums or deductibles. This can result in additional and unexpected costs for patients, which make it harder for them to stay on their medications.⁴⁹

For specific illustrations of how copays, coinsurance, accumulator adjustment programs, and high-deductible healthcare plans can affect out-of-pocket costs for patients enrolled in plans with different benefit levels, please visit page 26 of our [2018 Janssen U.S. Transparency Report](#). ●



Other factors in healthcare benefit design can increase the amounts patients pay out-of-pocket. These include coinsurance, where insurers charge patients a percentage of the medicine’s list price instead of a fixed-dollar copay, and the addition of formulary tiers with higher cost sharing. Payers also can put in place

HOW UTILIZATION MANAGEMENT IMPACTS PATIENTS AND PROVIDERS

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES



UTILIZATION MANAGEMENT TOOLS

Payers also employ various “utilization management tools” to ensure physicians adhere to their formularies. Aimed at steering patients to insurers’ preferred therapies, utilization management tools include:

- **Prior Authorization**, which requires physicians to obtain approval from an insurer before a patient can receive a prescribed medicine.^{50,51}
- **Step Therapy (also known as “fail first”)**, which requires patients to try medicines on an insurer’s preferred list of prescriptions before the insurer will cover the cost of another medicine.
- **New-to-Market Block**, where insurers delay coverage for newly approved medicines, sometimes for significant amounts of time.
- **Non-Medical Switching**, which happens when insurers eliminate coverage for a patient’s current medicine (sometimes within a plan year) requiring a clinically stable patient to switch from one branded medicine to another for non-medical reasons. Non-medical switching differs from a situation where a patient changes treatment for a medical reason.

Significantly, utilization management tools add to a physician’s administrative burden, taking time and attention from patient care.⁵² Across specialties, physicians report spending an average of 15 hours a week seeking authorizations from insurers.⁵³ ●

OUR POSITION ON NON-MEDICAL SWITCHING

We believe treatment decisions belong in the hands of patients and their healthcare professionals, which is why we are concerned about medically stable patients being switched to other therapies for non-medical reasons.

Because our first responsibility is to patients who use our medicines, we oppose non-medical switching even when it works to our advantage, as in cases where a Janssen medicine is the lowest-cost therapy on a payer’s formulary for a given condition. We do not proactively seek arrangements with payers that require patients who are clinically stable to switch to a different medicine.

HOW COSTS AND OTHER ACCESS HURDLES AFFECT PATIENT HEALTH

Research shows that patients' health can suffer when they face obstacles to getting the medicines they need,⁵⁴ such as high out-of-pocket costs^{55,56} or barriers put up by insurers.

Patients with higher out-of-pocket costs are more likely to abandon their new prescriptions at the pharmacy.⁵⁷ Similarly, high out-of-pocket costs can contribute to medication “non-adherence,” as has been shown in patients with rheumatoid arthritis⁵⁸ or breast cancer.⁵⁹

FAST FACT

69%

of patients **did not fill a new prescription** when faced with out-of-pocket costs exceeding **\$250**.⁶⁰



Utilization management tools can cause delays in care and lead patients to report worse health outcomes.

In a survey carried out by the American Medical Association, nine out of ten physicians said the process of navigating prior authorization requirements may delay patients' access to necessary care.⁶¹ At the same time, studies have found

prior authorization requirements to be associated with worse health outcomes and increased healthcare costs in such areas as diabetes and mental health.^{62,63,64}

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. Three out of five reported complications and two out of five said they stopped taking their medication altogether. In another survey, 70% of patients said that when they were switched to different medications for non-medical reasons, they considered their new medications less effective.⁶⁵

ACCESS HURDLES THAT DELAY THERAPY CAN LIMIT THE LONG-TERM BENEFITS OF MEDICINES

Over the long term, medicines bring significant benefits to patients, the health system, and society. More than half of the improvements in patient outcomes since 1990 can be attributed to medicines, according to physicians surveyed.⁶⁶ When patients gained access to prescription drug coverage through the Medicare Part D benefit, it resulted in decreases in hospital admissions and inpatient charges.⁶⁷ More recently, novel treatments for hepatitis C have cured patients of what was once a chronic disease. These treatments are projected to save Medicaid an estimated \$12 billion from 2013-2022, despite initial concern about their cost.⁶⁸ For our medicines specifically, data shows they can improve long-term health outcomes, reducing costs to patients and to the health system. For more information, visit page 33 of our [2018 Janssen U.S. Transparency Report](#).

Beyond reducing costs to the healthcare system, medicines provide benefits to society more broadly. Patients taking one of our medicines to treat schizophrenia (a long-acting injectable) were significantly less likely to have an encounter with the criminal justice system in the 12-month period after starting the medicine than in the 12-month period before.⁶⁹ The results suggest that these medicines could reduce costs associated with the criminal justice system, including costs related to incarceration.⁷⁰

These benefits underscore the importance of access to medicines—the key factor in our responsible approach to pricing, which we discuss in the following section. ●



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

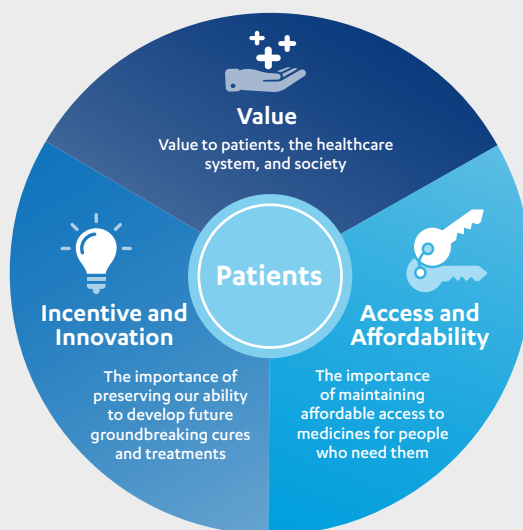
ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

OUR RESPONSIBLE APPROACH TO PRICING

At Janssen, our approach to pricing recognizes our dual responsibility to patients today and patients tomorrow. Patients today need access to our medicines. Patients tomorrow count on us to deliver cures and treatments for challenging diseases.

JANSSEN'S PATIENT-CENTERED APPROACH TO PRICING



In setting an initial list price for a medicine, we balance:

- **Its value to patients, the healthcare system, and society.** What matters most is how the medicine will improve patient health. We also assess the medicine's potential to reduce a variety of costs—surgeries, hospital stays, or long-term care, for example—and the improvement the medicine represents over the existing standard of care. We consider the importance patients, their families, and their caregivers place on having additional months or years of life; being able to avoid disability, hospitalization, and extensive medical procedures; and not having to depend on others for daily care.

- **The importance of ensuring affordable access to medicines for people who need them.** We work closely with insurers, pharmacy benefit managers, governments, hospitals, physicians, and other providers of care so patients who are prescribed our medicines can get access to them.
- **The importance of preserving our ability to develop future groundbreaking cures and treatments.** We have an obligation to ensure that the sale of our medicines provides us with the necessary resources to invest in R&D to address serious, unmet medical needs.

Some observers propose a different approach. They argue that the price of medicines should be pegged to the costs of developing or manufacturing them. However, pricing a medicine based on its R&D or manufacturing costs alone would not take into account the full range of benefits a medicine provides. It would also leave out investments that we must make in drug candidates that fail in development. Pharmaceutical companies and the rest of the scientific community can learn from these failures to improve the research process.



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

OUR RESPONSIBLE APPROACH TO PRICING

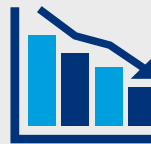
OUR NET PRICES DECLINED IN 2019

After we set an initial list price for our medicines, it is substantially reduced by rebates, discounts, and fees, leading to a net price. In 2019, our average aggregate net price decline was -1.2%.⁷¹ The approximately \$24.5 billion in discounts, rebates, and fees we provided to payers, providers, and other intermediaries outweighed our single-digit list price increases.⁷² The total average amount provided off of our list price to health system intermediaries has grown by 44% since 2016, the first year we began disclosing approximate total discounts, rebates, and fees.⁷³

Although our net prices declined this year, our business has continued to grow and remains strong because of increased use of our medicines—growth that reflects their value to patients and healthcare providers. Our net price decline comes as the total rate of medical inflation in the U.S. rose approximately 4.6% in 2019.⁷⁴ ●

FAST FACT

Between 2016 and 2019, the **compound net price decline** of our medicines was **-9.2%.**⁷⁵



JANSSEN U.S. PRICING OVERVIEW

Year	List Price Change ⁷⁶	Net Price Change ⁷⁷
2019	5.1%	-1.2%
2018	6.3%	-6.8%
2017	8.1%	-4.6%
2016	8.5%	3.5%
2015	9.7%	5.2%

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES



OUR PROGRAMS TO SUPPORT PATIENTS TODAY

Patients should have affordable access to medicines. We offer and support programs that can help.

As noted, the primary way we support patient access to our medicines is by negotiating with payers for preferred placement on their formularies. However, even with health insurance, some patients face high out-of-pocket costs for

prescription medicines, and finding financial assistance can be challenging. In compliance with relevant laws, we take additional steps to help patients obtain access to medicines. While we recognize these programs are not long-term solutions, they are one way we strive to meet the needs of the patients we serve and the healthcare professionals who care for them.

JANSSEN CAREPATH

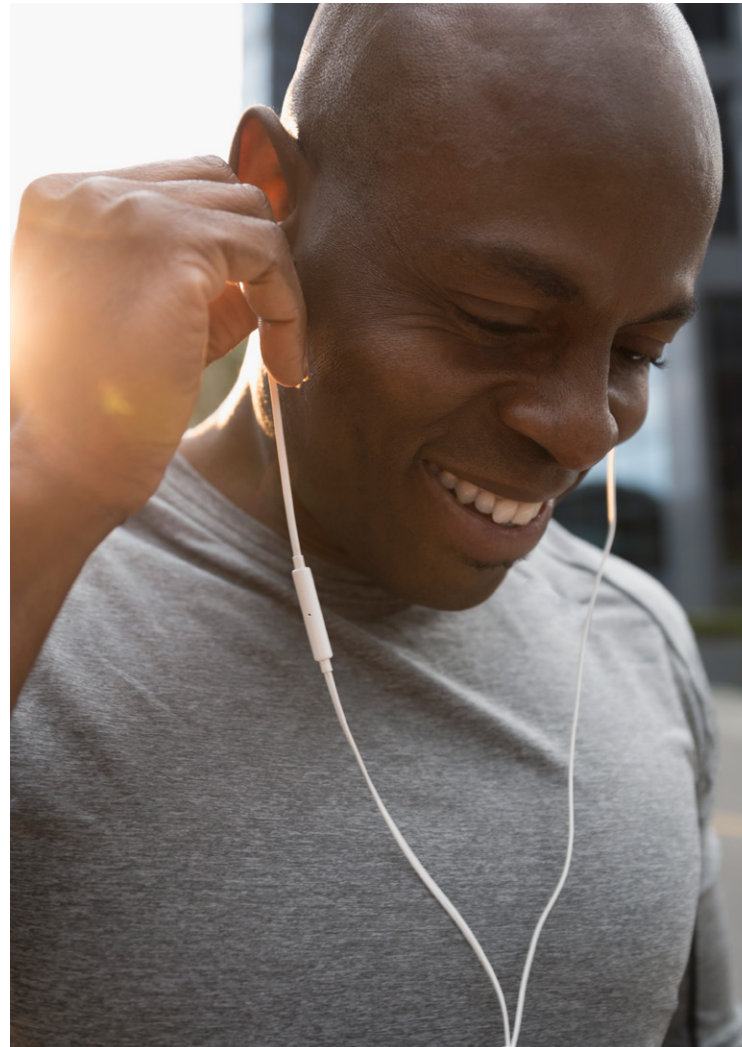
Janssen CarePath provides access, affordability, and treatment support resources to help patients get started on, and stay on, the Janssen medications their healthcare providers prescribe. Janssen CarePath Care Coordinators offer various forms of patient support: they answer questions about insurance coverage for Janssen medications and potential patient out-of-pocket costs; locate nearby treatment centers for certain medications; provide resources to help patients take their Janssen medications as prescribed; and if needed, they identify options that may help make the medications more affordable. These resources are available for patients who are prescribed Janssen medicines in the following therapeutic areas: cardiovascular and diabetes, dermatology, gastroenterology, infectious diseases, neuroscience, oncology, and rheumatology.

For commercially insured patients who meet the program requirements, we offer the Janssen CarePath Savings Program to help reduce patient out-of-pocket medication costs for prescribed Janssen medications. Such programs—sometimes referred to as “copay cards” or “copay coupons”—play a critical role in making out-of-pocket costs more manageable for patients by helping them gain access to the medicines prescribed by their healthcare providers.⁷⁸

Additionally, Janssen CarePath helps healthcare providers find access solutions for their patients by verifying patients’ health insurance benefits to make sure providers are familiar with their patients’ coverage for Janssen medicines and any requisite prior authorization, step therapy, or other payer policies.

In 2019, we helped approximately 1.3 million patients through the Janssen CarePath program.⁷⁹ This includes approximately 540,000 commercially insured patients who reduced their out-of-pocket expenditures through the Janssen CarePath Savings Program.⁸⁰

To learn more, please visit [JanssenCarePath.com](https://www.JanssenCarePath.com) or call 1-877-CarePath (1-877-227-3728).



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the
Price of Medicines

How Patient Costs
Are Determined

How Utilization
Management Impacts
Patients and Providers

How Costs and Other
Access Hurdles Affect
Patient Health

Our Responsible
Approach to Pricing

Our Programs to Support Patients Today

Advocating for
Patient-Centered
Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

OUR PROGRAMS TO SUPPORT PATIENTS TODAY

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

INDEPENDENT PROGRAM AND FOUNDATION SUPPORT

We also support independent programs and foundations that help patients in the U.S.:

- Janssen donates medicines and funding to the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF), an independent, nonprofit organization committed to helping eligible patients without insurance coverage receive prescription products donated by Johnson & Johnson operating companies.
- In 2019, we donated approximately \$1.2 billion⁸¹ in free products and financial support to the JJPAF, enabling the Foundation to provide medicines at no cost to approximately 82,000 patients.⁸² More information is available at jjpaf.org.
- We also make financial donations to independent charitable foundations that assist underinsured and financially needy patients with treatment-related expenses.
- In 2019, we donated approximately \$220 million to independent charitable foundations,⁸³ enabling them to assist an estimated 30,000 patients with medication-related copays for any physician-prescribed medicines that treat certain diseases covered by the foundations.⁸⁴

ADDITIONAL RESOURCES FOR PATIENTS

In 2019, we joined other leading pharmaceutical companies to create the Medicine Assistance Tool (MAT) program, connecting patients, caregivers, and providers with hundreds of different financial assistance programs that may help them afford their medicines. MAT also provides patients with more transparency about medicine costs, helping them to make more informed healthcare decisions. For more information, please visit mat.org.

While all of these programs provide meaningful support for patients today, we believe more sustainable solutions can be achieved through patient-centered policy reforms. ●



ADVOCATING FOR PATIENT-CENTERED POLICY REFORMS

“We strive for a healthcare system that delivers affordable access for patients today and greater hope for patients tomorrow.”

—Scott White, Company Group Chairman, North America Pharmaceuticals, Johnson & Johnson

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

The U.S. healthcare system has many strengths. But as patients have made clear, the need for improvement is urgent.

At Janssen, we are committed to generating sustainable policy solutions that put patients first and build on the strengths of the U.S. healthcare system, which prioritizes treating patients as individuals, and fostering the development and rapid approval of new medicines.

OUR HEALTHCARE POLICY PRINCIPLES



Affordable Access. Policies should support broad patient access to appropriate, affordable, high-quality treatment options.



Choice. Policies should safeguard the physician-patient relationship and keep treatment decisions in the hands of patients and their healthcare professionals; clinically stable patients should not be switched to other therapies for non-medical reasons.



Patient Safety. Policies should promote patient safety by ensuring consistently rigorous clinical and manufacturing quality standards.



Sustainability. Policies should lower overall costs to the system while sustaining a biomedical research ecosystem that continues to deliver transformative medical advances to society.

We support reforms that reward value and promote competition in the U.S. healthcare system.

Ensuring every American has access to affordable healthcare, including the medicines they need, means changing how we pay for healthcare. Shifting to an approach that makes value, not volume, the priority means that everyone who plays a role in the healthcare system is held accountable for the results or outcomes they deliver, including pharmaceutical manufacturers like Janssen. This approach focuses on healthcare interventions—whether medicines, surgeries, in-office visits, or other forms of care—that deliver the best results at the lowest cost.

Competition is also key—it spurs innovation, provides choices at prices that reflect value, and keeps costs down. That’s why we believe in a level playing field for all companies, including manufacturers of generics and biosimilars. Roughly nine in ten prescriptions written in the U.S. are for generics, and the use of biosimilars continues to grow.⁸⁵ From 2009-2018, generics reduced U.S. health spending by \$2 trillion.⁸⁶ These savings can be used for other kinds of care, including innovative new treatments.

Some proposals to control the price of medicines may not lower patients’ costs and would lead to fewer new medicines being developed.

Over the last few years, several policy proposals have been put forward to reduce the costs of medicines for the health system, including:

- Importing medicines from countries outside the U.S.
- Forcing companies to tie the price of their medicines in the U.S. to that of other countries (known as international reference pricing)
- Capping the amount of inflation in drug prices year-over-year

These proposals may not actually reduce out-of-pocket costs for patients because they do not address key drivers of patient costs in our system. Patient costs are largely determined by their insurance benefit design and the degree to which fees and discounts are passed through the supply chain, which is often limited.

ADVOCATING FOR PATIENT-CENTERED POLICY REFORMS

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

At the same time, these proposals could drastically reduce the incentives for innovation that benefit U.S. patients. In fact, recent analyses have found that under a proposal that includes reference pricing, between 50 and 100 fewer new medicines would be approved for patients over the next decade.^{87,88}

A better solution is to promote reforms that directly limit or lower patient out-of-pocket costs.

We support a cap on patient out-of-pocket costs, especially in Medicare Part D, and other proposals to increase the predictability of what patients pay month-to-month. More broadly, we believe patients should receive their fair share of the discounts and rebates that payers negotiate. Patient coinsurance and deductibles should be based on the net price the plan actually pays for the medicine, not its list price. And patients should not have to pay more in copays or coinsurance than their insurer pays for a given medicine.

Reforms must consider healthcare costs as a whole and the potential of medicines to manage those costs.

In the U.S., more than 85% of all healthcare spending goes to costs other than prescription medicines⁸⁹ and, as noted previously, medicines can reduce spending on hospitalization and other healthcare costs.^{90,91} In 2018, total retail prescription medicine spending grew 2.5% while overall healthcare expenditures increased 4.6%.⁹² More specifically, spending on hospital care and professional services grew by \$92.2 billion in 2018 compared to just \$8.3 billion in increased spending on outpatient prescription drugs.⁹³ As stakeholders seek ways to curb healthcare spending in the U.S., it is important to remember the limited role prescription medicines play in overall healthcare costs, especially given the tremendous value they bring.

We are listening, learning, and offering ideas.

We are committed to advancing the dialogue on healthcare reform. We have and will continue to share our perspective with state governments, Congress, and the Administration based on the beliefs we have outlined above. As we work toward practical solutions, it is important to remember we all share the same goal: building a more sustainable, affordable, and accessible healthcare system that improves the options for patients now—and in the future. ●

A CLOSER LOOK AT VALUE FRAMEWORKS

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—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.

Particularly concerning are value frameworks that use cost-effectiveness analyses and thresholds to determine whether or not patients should have access to medicines. Cost-effectiveness analyses attempt to quantify the level of health gained for each dollar spent on treatment. 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.⁹⁴

“Cost-effectiveness analyses generally use an input called the quality adjusted life year, or QALY. The QALY rates the value of human life relative to a subjective standard of perfect health, which is why its use may discriminate against populations such as the elderly, chronically ill, and disabled.⁹⁵ QALY-based frameworks place a lower value on treatments that extend and improve the lives of people who may never have perfect health—one of the main reasons they should not be used in valuing medicines.”^{96,97}

—Anastasia G. Daifotis, M.D.
Chief Scientific Officer, Janssen North America Pharmaceuticals

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach
to Research and
Development

Continually
Enhancing Discovery
and Development

Contributing to
a Stronger
R&D Ecosystem

The Complementary
Roles of Public
and Privately
Funded Research

Sustaining the
Engine of Biomedical
Innovation

Bringing Our Approved
Medicines to Patients:
Sales and Marketing

Fighting Sickness with
Science: An Alzheimer's
Disease Story

REFERENCES

ADVANCING HOPE FOR PATIENTS TOMORROW

“We issue this Report at a critical moment in U.S. healthcare. We need to ensure medical progress continues to give patients hope.”

— Anastasia G. Daifotis, M.D., Chief Scientific Officer, Janssen North America Pharmaceuticals

At Janssen, we invest in research that transforms human health. We strive to make our research as efficient and productive as possible so that new treatments can reach the patients who need them. This requires that we employ highly creative scientists and physicians, and that we collaborate with the best researchers throughout the scientific community.

In the section below, we explain our approach to research and development (R&D) and discuss the medical advances enabled by our R&D investment, which

exceeds what we spend on sales and marketing. We detail how the research data we share enhances the efforts of the scientific community at large. We also express our support for the intellectual property framework that helps the R&D ecosystem function, clarify the role of government funding in research, and explain why and how we educate prescribers.

CUTTING-EDGE RESEARCH TO ADDRESS SIGNIFICANT PATIENT NEEDS

Diseases like cancer, cardiovascular disease, diabetes, and dementia continue to take a human and economic toll. In the U.S., such diseases:⁹⁸

- Claim **1 million lives** each year
- Affect **191 million people**, with **75 million** having more than one disease
- Will cost **\$42 trillion** between 2016 and 2030

Scientists across our industry are tackling these challenges head-on for a variety of diseases.

- More than **8,000 new medicines** are in development globally, including **4,500** in the U.S.⁹⁹
- **74% of the new medicines** in clinical development would be first-in-class innovations¹⁰⁰

OUR APPROACH TO RESEARCH AND DEVELOPMENT

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

At Janssen, our scientists are working to create a future where disease is a thing of the past.

Our research and development is centered on six therapeutic areas and a number of diseases within those areas, all of which have significant unmet need:

- **Cardiovascular & Metabolism:** Chronic kidney disease, type 2 diabetes, non-alcoholic steatohepatitis, thrombosis, and retinal diseases
- **Immunology:** Inflammatory bowel diseases, including Crohn's and ulcerative colitis, psoriatic arthritis, lupus, lupus nephritis, atopic dermatitis, and psoriasis
- **Infectious Diseases and Vaccines:** HIV, hepatitis B, Ebola, *E. coli*, and respiratory infections such as RSV, influenza, and COVID-19
- **Neuroscience:** Schizophrenia, major depressive disorder, multiple sclerosis, and Alzheimer's disease
- **Oncology:** Hematologic malignancies such as multiple myeloma and acute myeloid leukemia, and solid tumors such as prostate, lung, colon, and bladder cancer
- **Pulmonary Hypertension:** Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension

Across these diseases, we use our expertise in small molecules, monoclonal antibodies, cell and gene therapies, RNA therapeutics, and vaccines to develop transformational medical innovations.



R&D BY THE NUMBERS

2 new medicines and 9 new indications
approved by the U.S. Food & Drug Administration (FDA) in 2019^{*101,102}

\$8.8 billion
invested globally in
pharmaceutical R&D¹⁰³



91% more
invested in global R&D than
in global sales and marketing¹⁰⁴

80+
medicine candidates in
development as a result
of our investments in R&D

140+
active collaborations with universities,
biopharmaceutical firms, academic medical
centers, and other scientific organizations

120,000+
patients enrolled
worldwide in more
than 400 clinical trials



640+
start-up companies in
the Johnson & Johnson
Innovation-JLABS
incubator community

*New therapeutic uses for previously approved medicines

In 2019, we increased our global investment in R&D to \$8.8 billion, up from \$8.4 billion in 2018.¹⁰⁵ This investment represents a significant portion of Johnson & Johnson's overall 2019 R&D investment of \$11.4 billion, which is among the highest in the world in any industry.¹⁰⁶

Our R&D expenditures enable us to discover, test, and develop new medicines as well as demonstrate the efficacy, safety, and regulatory compliance of our medicines before approval. We also use our R&D resources to improve and monitor the safety of existing, FDA-approved products, and explore possible new indications in additional patient populations.

OUR APPROACH TO RESEARCH AND DEVELOPMENT

In 2019, we had two new medicines approved by the FDA,¹⁰⁷ along with nine expanded indications that allow new groups of patients to benefit from our medicines.¹⁰⁸

Our investment, along with the passion, ingenuity, and insight of our researchers, has enabled us to advance more than 80 medicine candidates. Seven of these have been granted Breakthrough Therapy Designations by the FDA in the past five years.^{109,110} Medicines with this designation show early clinical evidence of a substantial improvement over current therapies to treat serious conditions.¹¹¹

Over the last five years (2015-2019), we invested \$39.4 billion in R&D.¹¹² In that same period, we had a total of seven new medicines approved by the FDA¹¹³ and received 38 approvals for expanded indications or new product formulations.¹¹⁴

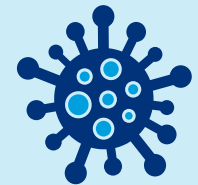
Our investment in global R&D (\$8.8 billion)¹¹⁵ significantly exceeds our spending in global sales and marketing (\$4.6 billion).¹¹⁶ In total we spent 91% more on R&D than we did on marketing and sales.¹¹⁷ We use global figures to make

this comparison because the R&D activities we undertake around the world collectively contribute to medicine development.

The Janssen sales and marketing figures in this report are even more specific than what is described in Johnson & Johnson's financial statements. Our financial statements combine sales and marketing expenses with other items in "Selling, Marketing, and Administrative Expenses" (SM&A). This SM&A figure accounts for much more than pharmaceutical sales and marketing expenses. It includes administrative and overhead activities that are not related to sales or marketing, such as operational expenses for insurance, accounting and product distribution. It is a global figure that pertains to all the businesses in the Johnson & Johnson Family of Companies, which include medical devices and consumer products in addition to pharmaceuticals. ●



MOBILIZING AGAINST THE COVID-19 CORONAVIRUS



Building on our experience and significant investment in vaccine research and development, we [launched a multipronged response](#) to address the global outbreak of a new form of coronavirus (also known as 2019-nCoV or COVID-19). We believe collaboration is key to combating this crisis, and that public-private partnerships and coordinated efforts among scientists, researchers, government, and academia will offer the most promising solutions. Our approach includes collaborations to develop a vaccine candidate against 2019-nCoV,^{118,119} and to screen a library of antiviral therapies to protect people from this serious and sometimes deadly disease.¹²⁰ We are expanding our global manufacturing capacity, including through the establishment of new U.S. vaccine manufacturing capabilities and scaling up capacity in other countries. The additional capacity will assist in the rapid production of a vaccine and will enable the supply of more than one billion doses of a safe and effective vaccine globally. We plan to begin production at risk, and are committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.¹²¹

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

CONTINUALLY ENHANCING DISCOVERY AND DEVELOPMENT

Bringing a new medicine to patients includes several stages of research conducted over many years and comes with significant cost and risk of failure. Developing a medicine and then gaining approval from the FDA typically takes 10-15 years¹²² and can cost billions of dollars.¹²³

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

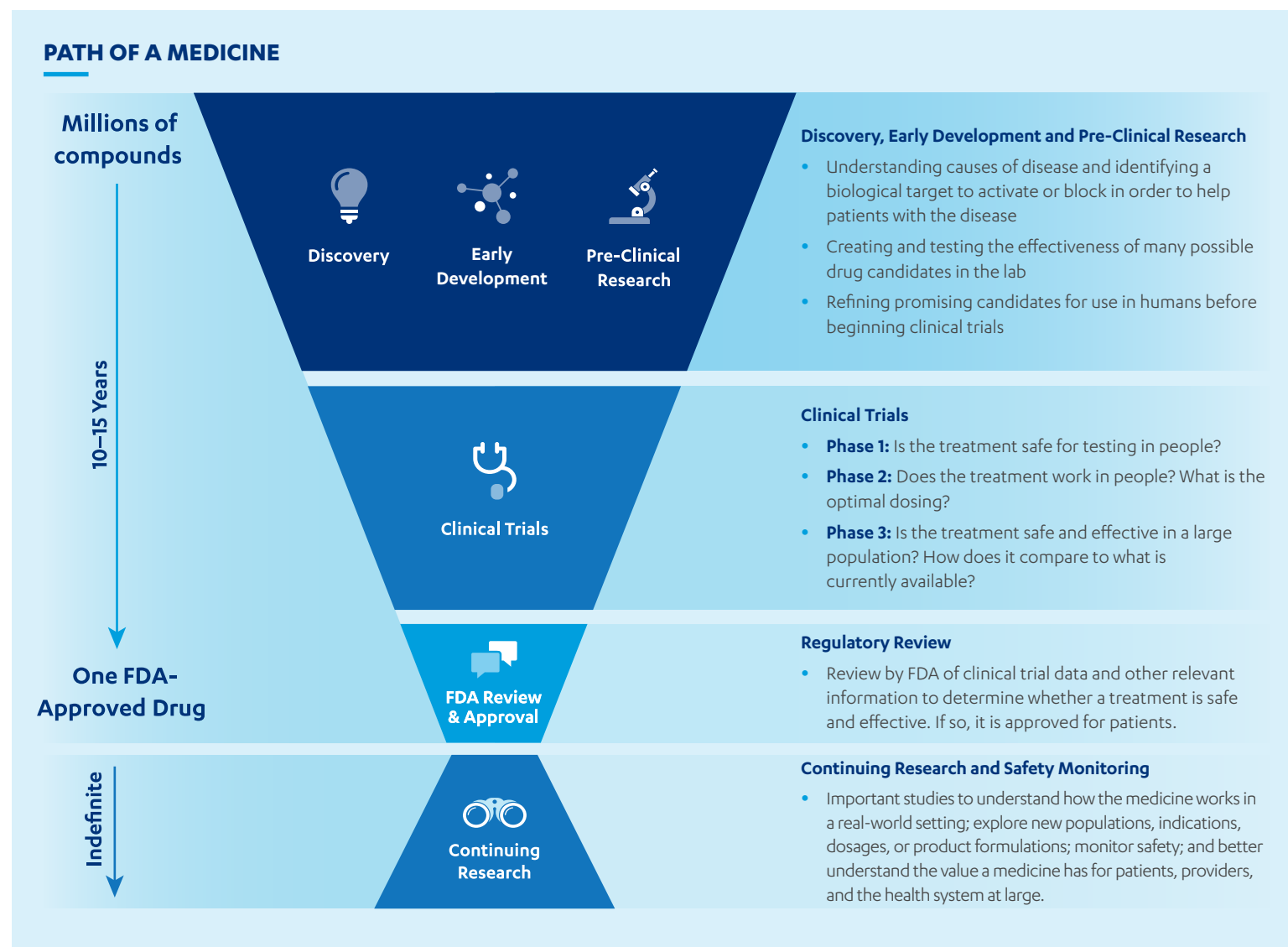
The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES



CONTINUALLY ENHANCING DISCOVERY AND DEVELOPMENT

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

The diagram on the previous page illustrates the journey of a new medicine from laboratory to launch. But no diagram can capture the full complexity of developing a new medicine and having it approved by regulators.

The process begins with millions of molecules being screened and investigated. These are winnowed to a few candidates selected for development, which are refined, characterized, tested, and further culled in the course of research. In the end, new medicines are approved infrequently, likely after a decade or more of research and billions of dollars in investment.



FAST FACT

We currently have more than **120,000 patients** enrolled worldwide in more than **400 clinical trials**. In 2019, we launched more than **100 new clinical trials**.



SPEEDING THE SCIENCE

Janssen is continually working to improve the medicine development process so we can more efficiently and effectively follow leads, strengthen our clinical data, and increase the number of medicines that gain approval by regulatory agencies, including the FDA and its counterparts in other nations. We are:

Investing in data science. We are harnessing cutting-edge analytical tools, including machine learning, deep learning, natural language processing, and more to analyze new and expanded sources of data. These include clinical trial data, physician notes, patient-reported outcomes, lab results, images, and data from wearable devices. These technologies can help us better identify targets, improve the probability of success in advancing promising candidates, reduce research timelines, and evaluate our medicines more efficiently and effectively than ever before.

Taking a more integrated view. By studying biological pathways that underpin more than one disease, we aim to speed the development of new therapies for multiple conditions, compared to previous efforts that focused on one disease in isolation.

Improving clinical trials. Clinical trials are often the longest and most expensive element of the development sequence. Each trial is designed in compliance with regulatory policies and conducted by independent investigators to maintain the quality and integrity of the data. To ensure the safety of patient volunteers, we work with top scientific experts to design, execute, and report data from our trials. These trials take months to design, months to years to enroll, and years to execute. We are working to improve our clinical trials in the following ways:

- We consider patient perspectives early in the process. Patients, caregivers, and patient advocacy groups provide critical perspectives and often help us clarify our research priorities and goals by contributing insights that improve the design of our clinical trials. For more information about our approach to patient engagement, visit page 12 of our [2018 Janssen U.S. Transparency Report](#).

CONTINUALLY ENHANCING DISCOVERY AND DEVELOPMENT

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

- We strive to make our clinical trial populations reflect the diversity of real-world patient populations. In 2019, we launched an effort to increase the diversity of clinical trial participants and build greater trust in the process. As an example, we enabled more members of under-represented populations to participate in one of our immunology clinical trials, by using machine learning and data science to address a longstanding challenge to recruitment—the choice of appropriate trial sites.
- We explore appropriate ways to supplement the clinical evidence generated by randomized controlled trials with real-world evidence. In 2019, we utilized data science and real-world data to streamline a clinical trial of one of our oncology medicines. ●

PIONEERING DIGITAL CLINICAL TRIALS

We are collaborating with Apple on the Heartline™ study to analyze the impact of wearable technology on the early detection and diagnosis of atrial fibrillation (Afib), a condition that can lead to stroke and other devastating health complications. To learn more about this study, visit heartline.com.



PRE-APPROVAL ACCESS PROGRAMS

The main pathway for gaining access to Janssen's investigational medicines is for a patient to enroll in a clinical trial. Pre-Approval Access (PAA) is the overarching term used for access to an investigational medicine outside of a clinical trial and prior to its approval by a health authority.

For patients with serious or life-threatening illnesses who cannot enroll in clinical trials, pre-approval access programs, such as "expanded access" programs and "named patient" programs for multiple patients, or "single-patient access" requests for individual patients, can be considered. Our policy for considering pre-approval access to investigational medicines is grounded in key ethical principles. Visit janssen.com/compassionate-use-pre-approval-access to learn more.

We typically consider making pre-approval access available when our clinical studies are complete, or when enough scientific evidence is available to inform careful review of requests prior to health authority approval. In 2019, Janssen provided access to 455 patients through PAA programs.¹²⁴

For more information, please visit janssen.com/compassionate-use-pre-approval-access. Healthcare providers may submit a request for access by calling 1-800-JANSSEN or email janssenmedinfo@its.jnj.com.



CONTRIBUTING TO A STRONGER R&D ECOSYSTEM

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

No single company has all the best ideas. Success in the discovery and development of new medicines and vaccines depends on collaborations between scientific organizations ranging from small startups to universities to large global companies.

We do our part to support science and accelerate the development of new medicines by:

- Making our clinical trial data more accessible
- Creating an infrastructure for other healthcare innovators to succeed
- Enabling and financing promising science

MAKING CLINICAL TRIAL DATA MORE ACCESSIBLE

Increasing the availability of our clinical trial results allows the scientific community to learn from efforts of other researchers and the patients who volunteer for clinical studies. This advances science and benefits public health in important ways.

Like others in our industry, we disclose summary information about our clinical trials on clinicaltrials.gov, the largest U.S. public registry, and we seek to publish the results of company-sponsored trials and health economic studies in peer-reviewed scientific journals. But we go beyond what's required.



In a first-of-its-kind agreement with Yale Medical School, we share pharmaceutical, medical device, and consumer product clinical trial data through the Yale Open Data Access (YODA) Project. Its mission is to advocate for the responsible sharing of clinical research data, open science, and research transparency.

The YODA Project serves as an independent review panel, evaluating researchers' requests for access to participant-level trial data and research reports, which provide extensive details about the methods and results of a clinical trial. Researchers can use this clinical trial data in their own scientific or medical research to increase medical knowledge and improve public health.

Our leadership in data sharing has been recognized by external organizations like Bioethics International.¹²⁵ For more information about the YODA Project and to request access to data from Janssen's clinical trials, please visit yoda.yale.edu.

BY THE NUMBERS: YODA RESULTS¹²⁶

IN 2019:

32
Requests for data



10
Papers published using YODA data

SINCE PROGRAM INCEPTION IN 2014:

154
Requests for data



27
Papers published using YODA data

CREATING AN INFRASTRUCTURE FOR INNOVATORS TO SUCCEED

In 1953, Janssen itself was a startup, with our namesake, Dr. Paul Janssen, working out of a space provided by his father. Today we remain faithful to our roots and are passionate about helping the next generation of biomedical innovators.

CONTRIBUTING TO A STRONGER R&D ECOSYSTEM

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

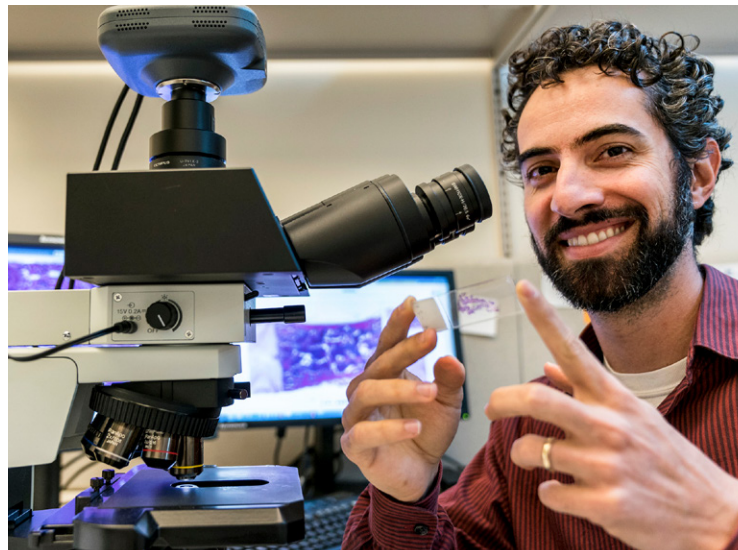
This is demonstrated through Johnson & Johnson Innovation – JLABS, our network of open innovation ecosystems. Through JLABS, we provide early-stage healthcare companies with access to the expertise, funding, services, and state-of-the-art equipment to get started and scale up. JLABS follows a “no-strings-attached” model, so entrepreneurs are free to develop their science while holding on to their intellectual property.

More than 640 companies are either current JLABS residents or alumni, 58% of which are first-time entrepreneurs. Collectively they have secured \$27.7 billion of investments in their companies through financing and strategic relationships.¹²⁷ To learn more, please visit jlabs.jnjinnovation.com/JLABSNavigator#.

ENABLING AND FINANCING PROMISING SCIENCE

Our partnerships and collaborations span the research spectrum, from licensing new drug targets to full-scale development partnerships. These relationships may entail upfront and milestone payments, royalty agreements, and R&D expense sharing.

In some cases, we work with academic institutes and biotech companies on early-stage research. For example, we have an ongoing collaboration with researchers at the Broad Institute of MIT and Harvard to discover new targets and develop therapeutics for immune-mediated diseases using cutting-edge genetics and innovative screening tools.



On the other end of the spectrum, we also collaborate with the world's largest private companies and government research organizations. In 2019, we joined with the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH), the HIV Vaccine Trials Network (HVTN), and the U.S. Army Medical Research and Development Command (USAMRDC) to launch the first large-scale Phase 3 clinical trial of our “mosaic-based” investigational vaccine aimed at preventing infections from multiple strains of HIV.¹²⁸ For more information about what a mosaic-based vaccine is, visit nj.com/innovation/what-is-a-mosaic-hiv-vaccine. ●

FAST FACT

We have more than **140 active collaborations** and partnerships. We formed **53 new ones** in 2019.



ADVANCING PERSONALIZED CANCER CARE

Every year in the U.S., more than 30,000 patients are diagnosed with multiple myeloma, and more than 12,000 patients die from the disease. Through a collaboration with Legend Biotech USA, Inc., Janssen is advancing the development of a chimeric antigen receptor T cell (CAR-T) therapy, which harnesses the body's own immune system to fight cancer. CAR-T therapy is a type of immunotherapy that involves extracting a patient's white blood cells, genetically modifying them in a laboratory, and re-administering the modified cells to the patient. In 2019, Janssen [received U.S. FDA Breakthrough Therapy Designation](#) for JNJ-4528, an investigational CAR-T therapy.¹²⁹ Additionally, we are investing in state-of-the-art supply chain capabilities in support of our ongoing clinical efforts and potential future needs. We are committed to advancing this novel therapy through clinical development and bringing this treatment to patients who are still in need of effective therapies.

THE COMPLEMENTARY ROLES OF PUBLIC AND PRIVATELY FUNDED RESEARCH

We are sometimes asked: Does Janssen benefit from research funded by U.S. taxpayers?

Government funding is a critical part of the nation's R&D ecosystem. The NIH provides the most public biomedical research funding of any government agency in the world.¹³⁰ The bulk of the NIH's budget is disbursed as grants to academic researchers,¹³¹ while just 7.6% of NIH's 2019 grant funding went to domestic for-profit companies.¹³²

Generally, the NIH funds early-stage, basic research to understand the causes of a disease or the mechanisms underlying a biological process, such as what makes cancer cells divide.¹³³ Academic scientists, biotechnology companies,

and large pharmaceutical companies work to translate that basic research into drug or vaccine candidates for development and clinical testing. As previously noted, it takes many years and billions of dollars to carry out the applied research to develop a new medicine, which is why it is typically conducted by companies such as Janssen.^{134,135} Sometimes, after a product is initially approved, government funders may support research by academics or other scientists to explore further uses that may or may not result in FDA-approved indications of the product.

In total, the biopharmaceutical industry's R&D investments in 2018 were approximately \$102.1 billion, more than 2.5 times the NIH's \$35.4 billion spending on research.¹³⁶ Both sources of research funding are critical to advancing patient care, and both should be encouraged.

PUBLIC FUNDING AND JANSSEN RESEARCH

U.S. government officials have recently stressed the importance of collaboration between the public and private sectors, academia, and others when dealing with public health threats.^{137,138} All of the government funding we received to support our research over the last five years is for a limited number of projects that supplement our investments to address public health threats. These projects are typically part of broader collaborations with support from additional institutions, including other governments, nonprofit funders, and more. The U.S. government funding we received from 2015-2019, which amounted to less than one percent of our global R&D investment, supported the following:¹³⁹

- A vaccine candidate for the prevention of Ebola currently being tested or provided in the Democratic Republic of Congo, Rwanda, and other countries
- A vaccine candidate for the prevention of HIV currently being tested in at-risk populations in the U.S., Africa, South America, and Europe
- Vaccine and therapeutic candidates for the prevention and treatment of emerging infectious disease, including pandemic influenza
- A therapeutic to treat acute radiation exposure

Separately, in the rare cases where Janssen developed and successfully commercialized a new medicine by building on research discovered and patented by the government, we pay royalty and commercial milestone payments back to the government. These payments to the NIH totaled more than \$242 million over the last five years.¹⁴⁰ ●



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

SUSTAINING THE ENGINE OF BIOMEDICAL INNOVATION

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach
to Research and
Development

Continually
Enhancing Discovery
and Development

Contributing to
a Stronger
R&D Ecosystem

The Complementary
Roles of Public
and Privately
Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved
Medicines to Patients:
Sales and Marketing

Fighting Sickness with
Science: An Alzheimer's
Disease Story

REFERENCES

Innovation is a strength of American healthcare. However, some have questioned whether the intellectual property (IP) protections in the U.S. prevent patients from attaining affordable access to these innovations. A closer look suggests otherwise.



IP protections include both patents and, in the pharmaceutical industry specifically, data exclusivity. Patents provide innovators with a limited time period where inventions that are considered new, useful, and non-obvious cannot be copied. In the pharmaceutical industry specifically, data exclusivity provides companies that conduct tolerability, safety, and efficacy testing on their products a limited time where only they can use their clinical data for regulatory approval. The strong IP protections in the U.S. benefit patients in numerous ways:

- **Promoting Innovation.** Time-limited patent protection enables innovators to receive a fair return for the extensive resources, time, and effort it takes to develop their current and future products. The patent system does not guarantee commercial success, but simply provides some certainty that if meaningful advances are made, the innovator's work will not be immediately copied. The comparative strength of the U.S. IP system is a key reason more new medicines are developed in the U.S. than in any other nation.¹⁴¹

- **Supporting Transparency and Competition.** In exchange for the limited window of protection provided by patents, researchers must publicly disclose information about their discoveries which others can use to develop the next generation of treatments. Even while a medicine is under IP protection, competing companies may be able to bring even better treatments to patients. In fact, most first-in-class medicines face competition from another branded product either when they are first approved, or within the first three years after introduction.¹⁴²
- **Fostering Generic and Biosimilar Entry.** After data exclusivity ends, generic and biosimilar manufacturers can gain approval of copies or near-copies of medicines without having to repeat costly clinical trials. This is because they can rely on the clinical data provided by the company that developed the original medicine. Without a stream of innovative new medicines, there would be no additional generics or biosimilars. Today, nine in ten prescriptions are for generic medicines.¹⁴³

Because an open, competitive market has proven to be the best model to support the development of new treatments for patients, we continue to support strong, reliable, and enforceable IP protections. ●



BRINGING OUR APPROVED MEDICINES TO PATIENTS: SALES AND MARKETING

After we have FDA approval for an innovative medicine, we invest in providing accurate, up-to-date information to healthcare providers and patients so it can be used appropriately.

RESPONSIBLE COMMUNICATIONS ABOUT OUR MEDICINES

In 2019, we spent \$4.6 billion globally (\$2.7 billion in the U.S.) on pharmaceutical sales and marketing activities,¹⁴⁴ including communications with healthcare professionals about our medicines' approved uses, effectiveness, side effects, benefits, and risks. These expenditures also include patient education and direct-to-consumer communication.

Our sales and marketing activities adhere to industry ethics standards and codes of conduct, including the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code on Interactions with Healthcare Professionals and the [PhRMA Guiding Principles on Direct-to-Consumer \(DTC\) Advertisements about Prescription Medicines](#). We view these guidelines as a starting point and challenge ourselves to deliver even more for patients.

We ensure the information we share with patients and healthcare professionals is balanced, accurate, current, and credible. We work with healthcare providers on peer-to-peer education with the goal of advancing the health of patients by sharing clinical outcomes through transparent, compliant activities. Healthcare providers with real-world clinical experience in specific therapeutic areas are uniquely qualified to provide education and insights into new advancements regarding our medicines. This type of interaction can address potential treatment gaps, as it allows providers to discuss important medical information about the appropriate use of our products.

Beyond educating healthcare professionals and informing patients about our medicines, our responsible approach to sales and marketing helps generate the revenues we need to fund research into future treatments and cures.



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach
to Research and
Development

Continually
Enhancing Discovery
and Development

Contributing to
a Stronger
R&D Ecosystem

The Complementary
Roles of Public
and Privately
Funded Research

Sustaining the
Engine of Biomedical
Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with
Science: An Alzheimer's
Disease Story

REFERENCES

BRINGING OUR APPROVED MEDICINES TO PATIENTS: SALES AND MARKETING

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach
to Research and
Development

Continually
Enhancing Discovery
and Development

Contributing to
a Stronger
R&D Ecosystem

The Complementary
Roles of Public
and Privately
Funded Research

Sustaining the
Engine of Biomedical
Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing









Fighting Sickness with
Science: An Alzheimer's
Disease Story

REFERENCES

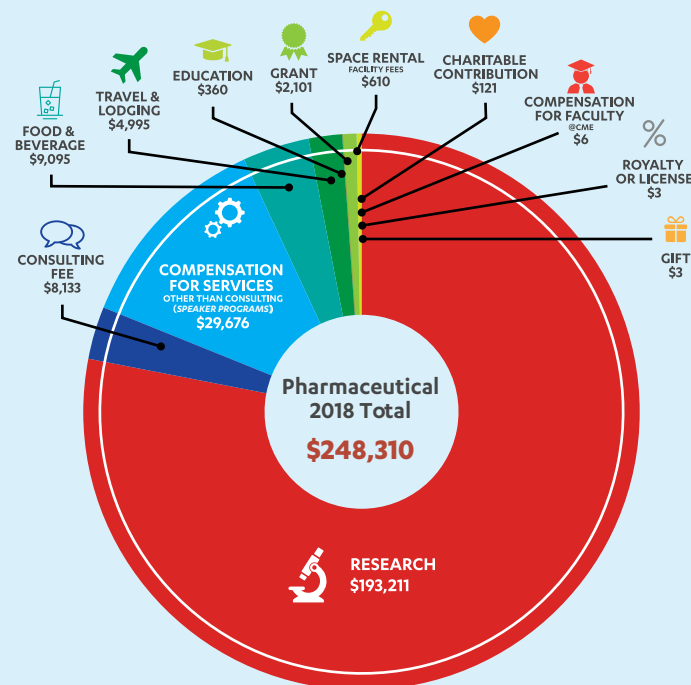
OPEN PAYMENTS: R&D ACCOUNTS FOR 77% OF OUR PAYMENTS TO PHYSICIANS

In compliance with Open Payments requirements, we report to the U.S. Centers for Medicare and Medicaid Services (CMS) the compensation or transfers of value that we provide as a part of our sales and marketing outreach to educate healthcare professionals about our medicines. These transfers of value include, but are not limited to, medical textbooks, scientific articles, meals, and travel expenses. This information is available through the CMS Open Payments database and we make this information available to the public on [njn.com](https://www.jnj.com). The great majority—77%—of our Open Payments disclosures in 2018, the latest reporting year, are research payments.¹⁴⁵ These include, but are not limited to, payments we make to healthcare providers and academic medical centers for conducting research during the multi-year medicine development process.





We anticipate that 2019 Open Payments data will be available through CMS on June 30, 2020.

 RESEARCH	Clinical studies and research that provide valuable scientific and clinical information about the medicines and medical devices that improve patients' lives
 CONSULTING FEE	Product development • Training • Development of educational materials and disease management programs • Unblinded market research
 COMPENSATION FOR SERVICES OTHER THAN CONSULTING (SPEAKER PROGRAMS)	Compensation for services other than consulting, including serving as faculty or a speaker at a venue other than a continuing education program • Fees for speaking at program on our company's behalf • Acquisition payments
 FOOD & BEVERAGE	Meals, whether paid directly or reimbursed, may be provided in conjunction with: Consulting services • Training • Educational and other business discussions with physicians
 TRAVEL & LODGING	Travel, whether paid directly or reimbursed, in conjunction with: Consulting services • Product training
 EDUCATION	Medical textbooks • Scientific journal articles
 GRANT	Sponsorship of an educational event, patient advocacy event, or publication • Sponsorship of fellowships for fellow and resident training • Certified independent educational activities (i.e., activities certified by a continuing medical education provider) • Non-certified medical education activities
 SPACE RENTAL FACILITY FEES	Space Rental or Facility Fees (Teaching Hospital Only) • Booth or exhibit space rental • Facility rental for product training or clinical studies

Numbers contained in the chart below are shown in thousands.



2018 data excludes late data, dispute resolutions, and Actelion data.

 CHARITABLE CONTRIBUTION	Monetary donation (only represents charitable contributions required to be disclosed under Open Payments); for more on J&J charitable contributions, visit: njn.com/our-giving
 COMPENSATION FOR FACULTY @CME	Indirect payment by a third-party organization to speakers at an accredited educational program, funded by an educational grant from a J&J company
 ROYALTY OR LICENSE	Payment of royalty or license fees for inventions or significant contributions towards the development of a new innovation, often based on product sales over a pre-determined period of time
 GIFT	Open Payments categories are specified by regulation and do not provide for an "other" category; the gifts category may be used when there is no appropriate category available

FIGHTING SICKNESS WITH SCIENCE: AN ALZHEIMER'S DISEASE STORY

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

Alzheimer's disease is the sixth-leading cause of death in the U.S. and has no existing cure. That's not for lack of trying.

For more than two decades, researchers have seen a series of promising therapies fail in clinical trials. In fact, from 1998 to 2017, there have been more than 140 failed attempts to develop a treatment for Alzheimer's disease, a medical condition whose causes are notoriously difficult to isolate and address.¹⁴⁶ Without further advances, Alzheimer's disease will affect nearly 14 million Americans over the age of 65 by 2060,¹⁴⁷ by which time the total cost of care for people with Alzheimer's and other dementias could top \$1.1 trillion.*¹⁴⁸

Despite some of our own setbacks in this space, we continue our R&D commitment to Alzheimer's disease because the need for treatment remains so great.

To speed advances against Alzheimer's, we share important data and samples with researchers outside our organization. In 2019, Janssen, Shionogi & Co., and the Alzheimer's Drug Discovery Foundation's Diagnostics Accelerator announced an initiative to share data and samples with researchers around the world. Our goal is to find new biomarkers—the telltale signs of disease that can be detected through tests. Finding additional biomarkers would be a major step toward novel treatment options and could be especially valuable in intercepting Alzheimer's disease before it does irreparable damage to the patient's brain. There is much work to do here, but we are up to the task of conquering this major public health challenge in our lifetimes.



WHEN THE QUEST FOR A CURE IS PERSONAL

Gayle Wittenberg, Ph.D., a Neuroscience Data Scientist at Janssen Research & Development, LLC, whose father passed away from Alzheimer's disease in 2019, tells us why we need to continue our quest for a cure.

"As it stands today, there is no cure for Alzheimer's disease, and that's not a legacy that we want to pass on to subsequent generations. If my dad were here today, he would look at the challenges involved in finding a cure for Alzheimer's disease and he would remind us, 'you can do hard things.' When things don't always go the way you would like, you don't let that break you. You stand back and you say, okay universe, challenge accepted, and then you find joy in the creative problem solving that comes next."



Patients like Gayle's dad are why we strive to deliver the medicines that will transform tomorrow—and why we work to make medicines that are available today accessible to all who need them.

We live in a moment of incredible hope, on the verge of extraordinary progress that could change our lives and the lives of our children and grandchildren. At Janssen, we are committed to bringing that promise to life. ●

*In 2018 dollars

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

REFERENCES

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INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

REFERENCES

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REFERENCES

INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

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INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

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