

2017

JANSSEN U.S. TRANSPARENCY REPORT

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PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

A Letter from Our Leaders



Jennifer Taubert
Company Group Chairman,
The Americas, Pharmaceuticals,
Johnson & Johnson



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

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At the Janssen Pharmaceutical Companies of Johnson & Johnson, we're conquering sickness with science and hopelessness with heart. We're committed to discovering and developing transformational medicines that make a difference for patients facing some of the world's most challenging diseases.

In order for society, communities, and individuals to benefit from breakthrough medicines, we must ensure that the people who need medicines can get them. We know that in today's complex health care system patients and families are increasingly concerned about their ability to access and afford health care, including prescription medicines. These concerns have rightfully led to calls for greater transparency into the business of health care.

At Janssen, we are proud of our leadership in transparency and responsible business practices. With the release of the second annual Janssen U.S. Transparency Report, we continue to hold ourselves accountable to those we serve by providing more information about how we operate. This includes expanding on last year's report to include new information and disclosures related to our research and development process, the value of medicines, and the advantages of moving to a more results-based health care system. As you read the report, here is what you will learn:

- **Our Investments:** How we invest our resources in the development of new medicines and how this investment compares with what we spend to market and sell our medicines.
- **Value:** Our principles for determining the value of our medicines and the role value assessments should play in shaping decisions about health care.
- **Pricing & Patient Access:** Our approach to pricing, the monetary value of rebates and discounts we paid, and the net impact of price on our business; how we work with health insurers and other payers to make our medicines available to patients; and what we are doing to implement results-based health care solutions that deliver better care at a lower cost.
- **Resources for Patients:** What we do to help patients access our medicines and the resources that are available to them.

We hope that by providing even more transparency into how we operate, we can continue to make progress toward a more results-based health care system that meets the needs of patients ...



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We want this information to be useful to all our stakeholders: **patients, families, caregivers, and advocates**, who are asking questions about out-of-pocket costs for medicines and what resources are available to help them; **health care professionals**, who are increasingly being asked to consider the overall value of the medicines they prescribe; **policymakers**, who are working to make policy changes to help their constituents get the care they need; and **others in the health care system, like payers**, who consider value and price information when they make decisions about coverage and access.

Addressing the challenges in our health care system will require more than just greater transparency. Our current system rewards the quantity or volume of care delivered, regardless of the results of that care. Consequently, sometimes we spend money on treatments, diagnostic procedures, and interventions that provide limited value or may not even be needed, driving up health care costs without actually improving patient health. And when we waste money on what doesn't work, we have less money to spend on what does work — meaning that patients increasingly struggle to access the care and treatments they need.

As part of the world's most broadly based health care company, we apply our expertise and resources to find solutions that reward results rather than quantity of care. If every stakeholder in the health care system, including pharmaceutical companies like ours, were held accountable for results, we could improve the quality of and access to care — and deliver it at a more manageable cost.

At Janssen, we stand as a committed partner in advancing a more results-based health care system. We are working with payers to pilot new ways to pay for medicines based on the results they deliver. We are partnering with government and provider organizations to explore outcomes-based care models. We are conducting population health research to address quality, such as reducing hospital readmission rates. And, most importantly, we continue to research and develop medicines that have a meaningful impact on the lives of patients and improve the value of health care overall.

Spurring this kind of change is not easy and will take time, but we are heartened by the progress of these initiatives and partnerships. We hope that by providing even more transparency into how we operate, we can continue to make progress toward a more results-based health care system that meets the needs of patients today and patients tomorrow.

Sincerely,

Jennifer Taubert

Company Group Chairman, The Americas, Pharmaceuticals, Johnson & Johnson

Anastasia G. Daifotis, M.D.

Chief Scientific Officer, Janssen North America Pharmaceuticals

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About This Report

The 2017 Janssen U.S. Transparency Report is our second annual report providing greater transparency into our business operations. The report provides an inside look at how we at the Janssen Pharmaceutical Companies of Johnson & Johnson put our values into practice across our U.S. business, from how we choose to invest our resources in the development of new treatments, to how we value and price our medicines, to how we work to support access to our medicines.

The information provided in this report pertains to Janssen's U.S. operations, except where indicated otherwise. In June 2017, Johnson & Johnson completed the acquisition of Actelion Ltd, a leader in pulmonary arterial hypertension. The data and disclosures in this report do not include information about Actelion, as integration was underway throughout 2017. U.S. Actelion information will be incorporated into the 2018 Janssen U.S. Transparency Report, which will reflect Actelion's first full year as part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

All financial data in this report follow the concept of a fiscal year, which normally consists of 52 weeks. Other disclosures in this report cover the period between January 1, 2017 and December 31, 2017; any exceptions are noted. Analyses conducted for the purposes of this report may be different from the methodologies used by other companies. The data have not been audited and should not be read in conjunction with our filings with the Securities and Exchange Commission.

This report is not intended to address all our corporate disclosures, though throughout this report we refer to additional resources where readers can find more information about specific Janssen and Johnson & Johnson programs and disclosures. Financial performance information of our parent company, Johnson & Johnson, and its subsidiaries can be found in Johnson & Johnson Annual Reports, available at jnj.com/about-jnj/annual-reports. Information on Johnson & Johnson environmental, social, and governance measures can be found in the Johnson & Johnson Health for Humanity Report, available at healthforhumanityreport.jnj.com.

This report and a one-page executive summary are also available to read and download at janssen.com/2017ustransparencyreport.

BY THE NUMBERS: JANSSEN IN 2017

\$7.9 billion
invested in research and development¹

88% more
invested in R&D than we spent on marketing and sales²

100+
medicine candidates in development as a result of our investments in R&D

~150
active R&D collaborations from discovery to late stage development

23
clinical data transparency requests to the Yale Open Data Access (YODA) Project, all approved³

4
value principles that help us define the value of our medicines

8.1%
average list price change⁴

-4.6%
average net price change⁵

\$15 billion
approximate total discounts and rebates

610,000
commercially insured patients helped with out-of-pocket costs through the Janssen CarePath Savings Program⁶





Our Investments

At Janssen, we are committed to delivering transformational medical innovation that can change the trajectory of health for humanity. To achieve this purpose, we combine our strong internal capabilities with the most compelling available external science to transform how diseases are prevented, intercepted, treated, and cured. We focus our research and development (R&D) investments on serious unmet medical needs where we can make an enduring, meaningful impact, including oncology, immunology, cardiovascular and metabolic diseases, neuroscience, infectious diseases and vaccines, and pulmonary hypertension.

Here, we describe our investments in R&D, including our efforts to improve the process and make it more transparent. We also demonstrate that the investments we make in R&D far exceed what we spend to market our medicines.

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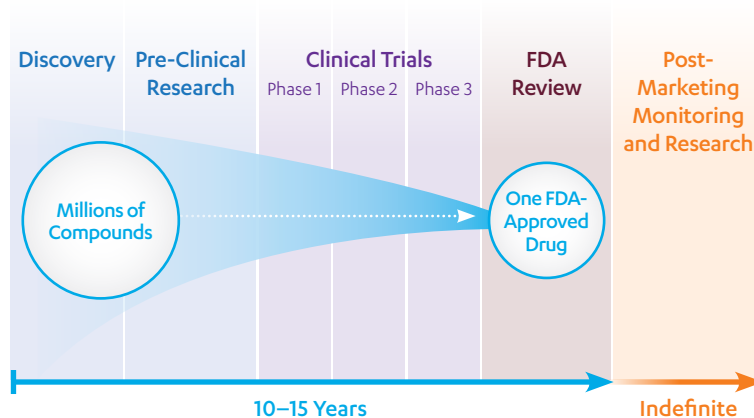
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Research & Development

Developing new and innovative medicines that extend and enhance the quality of people's lives is our greatest reward. The process to develop a new medicine is expensive, financially risky, and entails several stages of research conducted over many years. Typically, it takes 10–15 years⁷ to discover and develop a medicine and gain approval from the U.S. Food and Drug Administration (FDA), enabling us to make it available to patients. This process includes:

The Research & Development Process



- **Discovery:** We start by working to understand the molecular and cellular pathways together with the genetic and environmental influences that drive disease. In the early stages of discovery, scientists evaluate millions of compounds to identify those with the most promise to stop or alter a disease process. Extensive design, optimization, and investigation of the molecules is undertaken to determine their mechanism of action and assess any undesirable effects before advancing to clinical development.
- **Pre-Clinical Research:** Each potential new medicine undergoes “pre-clinical” laboratory research to determine whether it is reasonable to proceed with human clinical trials.⁸ Many potential medicines do not proceed past this point.⁹
- **Clinical Trials:** Clinical trials for the development of new medicines are typically conducted in phases and often involve thousands of patients from multiple countries. Through these studies, we obtain preliminary information about whether a potential medicine is safe and effective — that is, whether its benefits exceed its risks. In Phase I, we study the medicine in a small group of volunteers, usually healthy, to learn more about the safety of the medicine and how it interacts in the body. In Phase II, we evaluate the medicine’s effectiveness and side effects, often in several hundred patients who have the disease the medicine is intended to treat. In Phase III, the medicine is given to larger groups of people with an aim to confirm its effectiveness, evaluate how it works in different populations, compare it to commonly used treatments, and collect information that will allow the medicine to be used safely. For

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some medicines, such as oncology treatments, these development phases may be blended in order to get medicines to patients faster, with traditional Phase III studies sometimes completed after regulatory approval. A potential new medicine may fail at any stage of clinical trial development — for example, in Phase I if it proves to be unsafe, or in Phase II or III if it is not effective or is found to have an unsatisfactory side effect profile.

- **Approval:** If research shows that a medicine makes a real difference to patients facing serious illness, and its benefits outweigh its risks, we seek approval from the FDA to introduce the medicine to patients. The FDA's team of scientists, physicians, statisticians, and other experts analyze the condition for which the medicine is intended and patient experience with the condition, assess the medicine's benefits and risks based on the manufacturer's research data and proposed labeling, and consider strategies for managing risk. If the FDA determines that the medicine's benefits outweigh its risks, it approves the medicine, which then can be made available to patients.¹⁰ During this stage, we may also conduct additional research to determine the impact of the new medicine on a patient's quality of life, how it compares to existing therapies or treatments, and other ways the medicine could affect the health care system — information payers can use to compare treatment choices and make decisions about coverage.
- **Continuing Research:** After we receive FDA approval to bring a medicine to patients, we conduct studies to: understand how the product works in a real-world setting; explore expanded indications, dosages, or product formulations; monitor safety; and better understand the value our medicine has for patients, providers, and the health system at large. Investments in this stage of research may lead to product improvements or expanded indications that deliver additional benefits to patients.

We recognize that the best science does not always reside in a single company. Bringing new medicines to patients requires collaboration and partnership. A large part of our success stems from the work we do with dynamic, diverse partners, including startup companies, academic centers, hospitals, government agencies, biotech organizations, and other large pharmaceutical companies.

These collaborative opportunities allow us to accelerate the process of developing breakthrough medicines to create real value for patients within Janssen's defined therapeutic areas. Of the seven new medicines that we have brought to market in the last five years, many were the result of collaborations. Today we have approximately 150 active collaborations from discovery to late stage development.

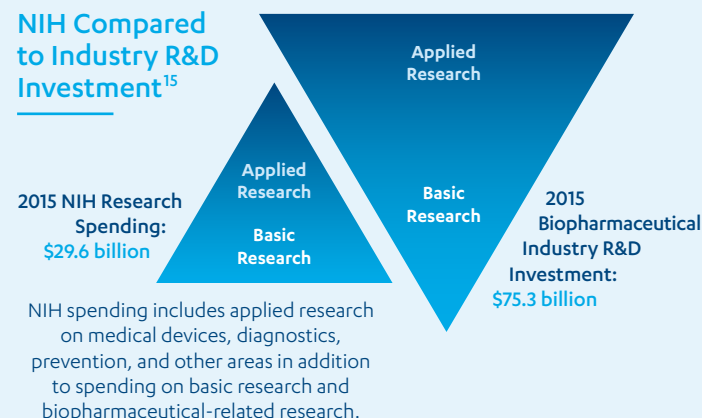
The Role of the NIH in Medical Research

The National Institutes of Health (NIH) and other U.S. government agencies play an important role in medical research, primarily funding basic research — the exploration of the cellular and molecular changes involved in the development of disease.¹¹

Basic research furthers our understanding of disease and can help identify potential targets for medicine development. Occasionally, research by government institutions like the NIH leads directly to the discovery of a molecule or technology platform that has the potential to become a novel medicine or vaccine, although this happens infrequently.¹²

The biopharmaceutical industry also conducts basic research and may purchase or license rights to basic research as a starting point. Notably, the industry is responsible for the majority of the investment in the long, financially risky, and costly process to discover and develop new medicines that meet the stringent safety and efficacy requirements of the FDA. In 2015 alone, industry investments exceeded \$75 billion.¹³ In fact, the amount of research biopharmaceutical companies undertake to bring new medicines to patients makes us one of the most research-intensive sectors in the United States.¹⁴

NIH Compared to Industry R&D Investment¹⁵



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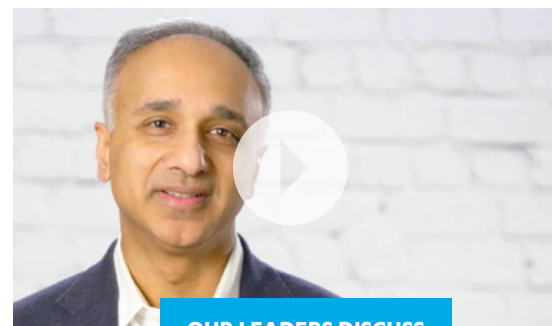
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In 2017, Janssen invested \$7.9 billion in R&D — an increase of \$0.9 billion from 2016.¹⁶ This investment has enabled us to research and develop more than 100 medicine candidates. Over the past five years (2013-2017), we have been an industry leader in New Molecular Entity (NME) approvals with a total of seven new medicines approved by FDA during this time.¹⁷ During this same time period, we received eight FDA Breakthrough Therapy Designations for indications for three of our investigational medicines.¹⁸ A Breakthrough Therapy Designation is a process that expedites the development and review of an investigational medicine that is intended to address a serious condition when preliminary clinical evidence indicates that the medicine may demonstrate a substantial improvement over other available treatments.¹⁹

Janssen's investment represents a portion of Johnson & Johnson's overall 2017 R&D investment of \$10.1 billion — an increase of \$1 billion from 2016, a year in which Johnson & Johnson was among the top ten investors in R&D in the world and number one among U.S. health care companies.²⁰

We are excited by the potential in our current pipeline, and we are working to make our R&D process more efficient. By streamlining our process, we can better leverage our investment resources, increase the speed of innovation, and potentially bring more transformational medicines to patients. In fact, between 2011 and 2015, we more than tripled the rate at which our potential new medicines under study were ultimately approved for use as new medicines.²¹ During this period, our success rate was more than double the industry average.²² Here are some examples of what we are doing:

- We are working to embed biomarker strategies early in clinical trial designs to enable rapid, efficient, and economical drug development as well as better targeted use. Biomarkers, which are measurable characteristics of biological processes, help us understand how well a medicine is working and if a disease is progressing.²³ For example, we can use HbA1c as a marker for diabetes control.²⁴ We are a member of [The Biomarkers Consortium](#), a public-private partnership managed by the Foundation of the U.S. National Institutes of Health that brings together the expertise and resources of various partners to rapidly identify, develop, and qualify potential high-impact biomarkers particularly to enable improvements in drug development, clinical care, and regulatory decision-making.
- We are adopting different technologies to optimize workflow, improve communication, and expedite data reporting, all of which play critical roles in the success of clinical trials.



OUR LEADERS DISCUSS

Mathai Mammen, Global Head of R&D at Janssen, discusses our strategy for bringing forward new medicines that make a real difference for patients.

BY THE NUMBERS: JANSSEN R&D

\$7.9 billion
invested in pharmaceutical
R&D in 2017²⁵

100+
medicine candidates
currently in development

400+
clinical trials in 2017,
with **116,000** patients
at **16,000+** trial sites
in **60+** countries around the world

~150
active collaborations in 2017
with academia, pharmaceutical
and biotech peers, and
public/private sector partners

6
R&D focus areas:
oncology, immunology,
cardiovascular and metabolic
diseases, neuroscience,
infectious diseases & vaccines,
and pulmonary hypertension

7
new Janssen medicines
approved in the last 5 years;
an industry leader in U.S.
FDA New Molecular Entity
(NME) approvals between
2013 and 2017²⁶

8
FDA Breakthrough Therapy Designations for indications
for three of our investigational medicines in the last 5 years²⁷

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- We are members of a number of collaborative initiatives focused on accelerating biopharmaceutical innovation across the continuum of R&D, from basic science to pre-clinical research to clinical development. These initiatives convene diverse partners, including pharmaceutical manufacturers, venture capitalists, nonprofits, and governments, to solve key R&D challenges. For example, we are a founding member of [TransCelerate Biopharma](#), a not-for-profit industry collaborative that aims to identify and overcome common challenges in the medicine development process; we are a part of the [Accelerating Medicines Partnership](#), a public-private venture with the National Institutes of Health focused on identifying biological targets for new medicines; and we are affiliated with the Duke Margolis [Real-World Evidence Collaborative](#) focused on advancing methods and policies related to the regulatory acceptability of real-world evidence.

Partnering with Patients

Patients have always been at the heart of everything we do, and we are partnering with them and their caregivers to better understand and meet their needs as we develop medicines, improve clinical trials, and create educational materials and support programs. We are incorporating patient perspectives early and often in the following ways:

- **Incorporating patient perspectives into clinical trial procedures.** Only 3 to 5 percent of patients who are eligible to participate in clinical trials actually enroll, which is why we want to design trials that are less burdensome for patients and rooted in the reality of their day-to-day lives. Our efforts led one Janssen R&D team to cut the length of patient visits in half, provide transportation to and from the trial site, and make informed consent available on a computer monitor and paper instead of a tablet to reduce glare for visually-impaired patients. After seven months, no trial

drop-outs were reported. Fifteen similar projects are underway, which may lead to better data collection and accelerate our ability to bring therapies to the patients who need them.

- **Including patient-reported outcomes in medicine labels.** When our researchers were developing a plaque psoriasis medicine, they worked with patients and other stakeholders to create the Psoriasis Symptoms and Signs Diary (PSSD), a tool that measures symptoms that matter to patients and lets them record their own symptoms. In clinical studies of moderate to severe plaque psoriasis, clinician-reported outcomes are typically used to assess the extent and severity of the disease as well as the patients' response to therapy. But plaque psoriasis often comes with symptoms that are best assessed by patients themselves, such as itching, pain, stinging, burning, and skin tightness. The PSSD tool, several years in the making, was a significant development in our quest to develop and convey patient-focused product information. The information we gathered from patients who used PSSD in clinical trials is now part of the FDA-approved U.S. Prescribing Information for the medicine.²⁸
- **Modifying product design for administering a medicine currently in development based on patient input.** One Janssen team worked with patients and health care professionals through studies to optimize the design of a device for administering a particular type of medicine. The modified design helps patients insert the device properly, shows whether the full dose has been administered, and comes with improved instructions, including questions and answers based on patient insights.



OUR LEADERS DISCUSS

Katherine Capparella, Global Patient Engagement Leader at Janssen, shares how we're using patient feedback to improve our medicines.

— Joanne Waldstreicher, M.D.,
Chief Medical Officer of Johnson & Johnson

The patients and health care professionals who rely on our medicines place their trust in our clinical research and development.

We believe making clinical trial data available advances science and benefits public health in important ways: it promotes the understanding of disease, expands the knowledge needed to develop new treatments, and generates new insights and more complete evidence that lead to better health care decisions for patients. Like others in our industry, we disclose 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 medical journals.

We have also pioneered new initiatives to further enhance clinical trial data transparency. In a first-of-its-kind agreement with the Yale University School of Medicine, we share pharmaceutical, 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 these clinical trial data in their own scientific or medical research to increase medical knowledge and improve public health. Launched in 2014 to share pharmaceutical clinical trial data, the YODA Project expanded to include Johnson & Johnson medical devices and consumer clinical trial data in 2016 and 2017 respectively.

In 2017, the YODA Project received 23 requests for data from researchers and physicians at institutions and academic centers in the U.S. and around the world, all of which were approved. Additionally, two papers were published this past year as a result of data we shared.³⁰ For more information about the YODA Project and to request access to data from Janssen's clinical trials, please visit yoda.yale.edu.

Our leadership in clinical data transparency has been recognized by external organizations like Bioethics International. For the second consecutive year, Johnson & Johnson achieved the highest overall clinical trial transparency score — 100 percent — from Bioethics International in its second Good Pharma Scorecard (GPS), an annual index that ranks large pharmaceutical companies and new drugs on their clinical trial transparency.³¹ The 2017 GPS report evaluated clinical trial registration, results reporting, clinical study report synopsis sharing, and journal article publication rates for new drugs approved by the FDA in 2014 that were sponsored by large drug companies.³²

In addition to advancing science, sharing information about clinical trials helps patients identify clinical studies that may be appropriate for them. We developed the Janssen Global Trial Finder to help people find information on Janssen clinical trials around the world. The interface makes it easy to search for Janssen clinical trials that are accepting new participants. People interested in enrolling in a clinical study can use the Janssen Global Trial Finder, available at globaltrialfinder.janssen.com/about-clinical-trials, to search for Janssen clinical trials by medical condition and geographic location.

BY THE NUMBERS: 2017 YODA RESULTS²⁹

23 requests for data 100% requests approved 2 papers were published using YODA data

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Sales & Marketing

After we have FDA approval to bring an innovative medicine to patients, we invest in providing accurate, up-to-date information about the medicine to health care professionals and to patients. These activities include communications with health care professionals about the medicine's effectiveness, approved uses, side effects, benefits and risks, as well as patient education and direct-to-consumer communication.

We follow all laws and regulations regarding the promotion of prescription medicines and submit all promotional materials to the FDA. We have a robust medical review process to ensure the quality and accuracy of information, and our marketing and sales activities adhere to industry ethics standards and codes of conduct, including the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Health Care Professionals.

In addition to the marketing and sales figures we are required to disclose by law, which include payments we make to physicians in accordance with the Physician Payment Sunshine Act (see "[Open Payments](#)"), in this report we voluntarily disclose global and U.S. marketing and sales figures. In 2017, our global pharmaceutical marketing and sales expenditures were \$4.2 billion. Of the \$4.2 billion, \$2.5 billion were U.S. pharmaceutical marketing and sales expenditures.³³

We disclose global and U.S. sales and marketing in this report because we are sometimes asked how much we spend on these activities, and our standard financial reporting does not cover these expenses specifically. Johnson & Johnson financial statements combine marketing and sales expenses with other items in a line item described as "Selling, Marketing and Administrative Expenses" (SM&A). In other words, the SM&A figure accounts for much more than marketing and sales expenses. It includes administrative and overhead activities that are not related to marketing or sales, such as expenses for insurance, legal, finance, and distribution; it pertains to all of the businesses in the Johnson & Johnson Family of Companies, which, in addition to pharmaceuticals, include medical devices, consumer products, and over-the-counter medicines; and it is a global, not U.S., figure.

Our Relative Investment

We spent \$4.2 billion on global marketing and sales activities in 2017. When compared to our global R&D investment of \$7.9 billion, our disclosures demonstrate that in 2017 we spent 88 percent more on R&D than we did on marketing and sales.³⁴

We make this comparison using global figures because our investment in R&D cannot be segmented by region. The R&D activities we undertake around the world collectively contribute to medicine development, regardless of market. ■

FAST FACT

In 2017, we invested **88% more** in R&D than we spent on marketing and sales.³⁵



Open Payments: R&D Accounts for 65 Percent of Our Payments to Physicians

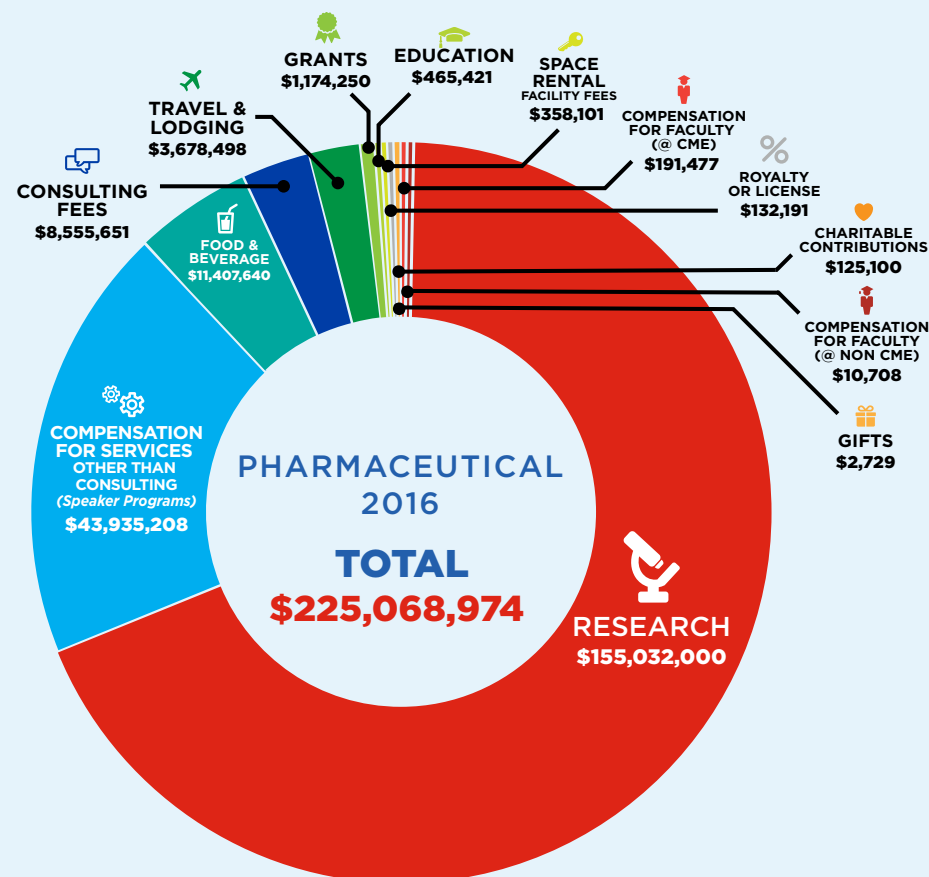
In accordance with the Physician Payment Sunshine Act, we disclose to the U.S. Centers for Medicaid and Medicare Services (CMS) the compensation or transfers of value that we provide as a part of our sales and marketing outreach to educate health care professionals about our medicines. These transfers of value include, but are not limited to, meals, travel expenses, medical textbooks, and scientific articles for health care professionals.

We also disclose payments we make to physicians and teaching hospitals for their R&D-related work, which can include helping us design and

conduct clinical trials. Research activities account for more than **65 percent** of our 2016 payments to physicians and teaching hospitals. While these are not marketing activities, payments related to these activities are also disclosed through the Open Payments database.

We anticipate that 2017 Open Payments data will be available through CMS on June 30, 2018. Here, we include information on Janssen's 2016 Open Payments disclosures.³⁶

	Clinical studies and research that provide valuable scientific and clinical information about the medicines and medical devices that improve patients' lives.
	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, and acquisition payments.
	Meals, whether paid directly or reimbursed, may be provided in conjunction with: consulting services, trainings, and educational and other business discussions with physicians.
	Product development, training, development of educational materials and disease management programs, and unblinded market research.
	Travel, whether paid directly or reimbursed, in conjunction with: consulting services or product training.
	Sponsorships 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); or non-certified medical education activities.
	Medical textbooks and scientific journal articles.
	Space rental or facility fees (teaching hospital only), booth or exhibit space rental, or facility rental for product training or clinical studies.
	Indirect payment by a third party organization to speakers at an accredited educational program, funded by an educational grant from a J&J company.
	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.
	Monetary donation (only represents charitable contributions required to be disclosed under Open Payments). For more on J&J charitable contributions, visit jn.com/our-giving .
	Indirect payment by a third party organization to speakers at a non-accredited educational program, funded by an educational grant from a J&J company.
	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 more appropriate category available.





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We are passionate about our work to develop transformational medicines because we have all experienced, personally or through loved ones, the devastation of disease and the dramatic impact medicines can have on human life. In this exciting era of medical innovation, it is helpful to consider the many and varied ways new therapies translate into longer, healthier lives for patients.

Our Value Assessment Principles

How does Janssen define and measure the value a medicine will have for patients and society? We employ our Janssen Value Assessment Principles to help us.

Janssen's Four Value Assessment Principles

- 1 What matters most in determining a medicine's value is its **impact on patients**.
- 2 The value of a medicine includes its **impact on the health care system and society**.
- 3 Treatment outcomes should be assessed over an appropriate timeframe to **capture all the benefits and risks for patients, the health care system, and society**.
- 4 Evidence considered in assessing the value of a medicine should be **high-quality, current, and relevant**.

1. What matters most in determining a medicine's value is its impact on patients.³⁷ First, we look at a medicine's clinical profile — its effectiveness, ability to improve health-related quality of life, tolerability, side effects, etc. — compared with alternative treatments for the same condition or disease. We also look at how the medicine will be administered, and in what setting; the length or difficulty of the regimen; and whether the treatment requires any diagnostic tests — all factors that matter to patients. We consider the importance patients and their families 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. And because patients respond differently to different medicines, even those within the same class, we think about the benefit of having a variety of treatment options from which to choose.

2. The value of a medicine includes its impact on the health care system and society.³⁸ Medicines have impacts that go beyond patient health. They can generate health care savings by reducing the need for future doctor visits, emergency room use, hospitalizations, nursing home stays, and procedures or operations. Medicines can add value to the broader economy by improving workplace productivity, reducing disability, and preventing health-related interruptions in work or education. And in cases of serious mental illness like schizophrenia, medicines can delay or reduce relapses, which may result in less frequent use of law enforcement or justice system resources.³⁹

BY THE NUMBERS: THE VALUE OF MEDICINES

Medicines not only save and improve lives, but also may help reduce the costs of disease:

Over 70%
of recent gains
in life expectancy
are attributable
to medicines⁴⁰

25% decline
in the cancer death rate since 1991
is credited, in part, to innovative
cancer medicines, including
new targeted therapies⁴¹

27%
reduction
in direct medical costs
from fewer cardiovascular-disease
related hospitalizations and
procedures is the result
of cardiovascular medicines, like
statins, when compared to a placebo⁴²

43%
decrease
in hospital spending
on HIV patients, with overall
expenditures declining by
16%, just 18 months after the
introduction of highly active
antiretroviral therapies⁴³

\$213 billion
in U.S. health care costs
could be saved
with correct use
of medications
for chronic conditions⁴⁴

14%
of total health care dollars
are spent on medicines, a
percentage that has been relatively
stable over several decades and
is expected to remain so⁴⁵

Over 90%
of prescriptions today are for generic medicines,
which are typically lower cost⁴⁶ and would not exist were it not
for the original branded medicine, underscoring the ongoing
contribution new medicines make for generations to come

Medicines have impacts that go beyond patient health. They can generate health care savings by reducing the need for future doctor visits, emergency room use, hospitalizations, nursing home stays, and procedures or operations.

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3. Treatment outcomes should be assessed over an appropriate timeframe to capture all the benefits and risks for patients, the health care system, and society.⁴⁷ Some medicines have an immediate benefit that lasts a lifetime. Some medicines significantly extend a lifetime. Others have a more moderate benefit or a benefit over a shorter period. Our assessment of a medicine's value considers the time needed to fully realize all its outcomes for all stakeholders, not just the first few months or a year or two.

4. Evidence considered in assessing the value of a medicine should be high-quality, current, and relevant.⁴⁸ We evaluate clinical trial data and real-world evidence from a variety of sources, including academic medical centers, government agencies, and health care systems, as well as our own research. We know evidence can vary in quality and certainty, which is why we strive to fully evaluate all the evidence to confirm its credibility, identify uncertainties, and determine how best to address differences in conclusions. Quality evidence, regardless of its source, makes clear study methods, assumptions, and limitations, and is transparent about any uncertainties in the data.

Measuring the Value of Our Medicines

At Janssen, we generate clinical information on the use, risks, and benefits of a medicine derived from data on how the medicine is being used in the real world, outside of a clinical trial.⁴⁹ We use this "real-world evidence" to better understand the value our medicines bring to patients and the health care system. These data allow us to see how our medicines affect people in their everyday lives. For example, through real-world studies, we have found that:

- Patients taking one of our medicines for schizophrenia were hospitalized less frequently than patients taking different medications for the same serious mental illness. This reduced rate of hospitalizations produced savings of greater than \$8,500 per patient per year for the specific health care system that was our partner on this research.
- Patients taking our medicine for diabetes were less likely to stop taking the medicine as prescribed, to change to another medicine, or to need a second medicine in order to achieve the desired health outcome. This is important because adherence — taking a medicine as prescribed — can result in better long-term health outcomes.

Our assessment of a medicine's value considers the time needed to fully realize all its outcomes ...

Value is one of several factors we consider when we determine the price of a new medicine. For more information on our pricing approach, please see the ["Pricing and Patient Access"](#) section.

The Role of Value Assessment

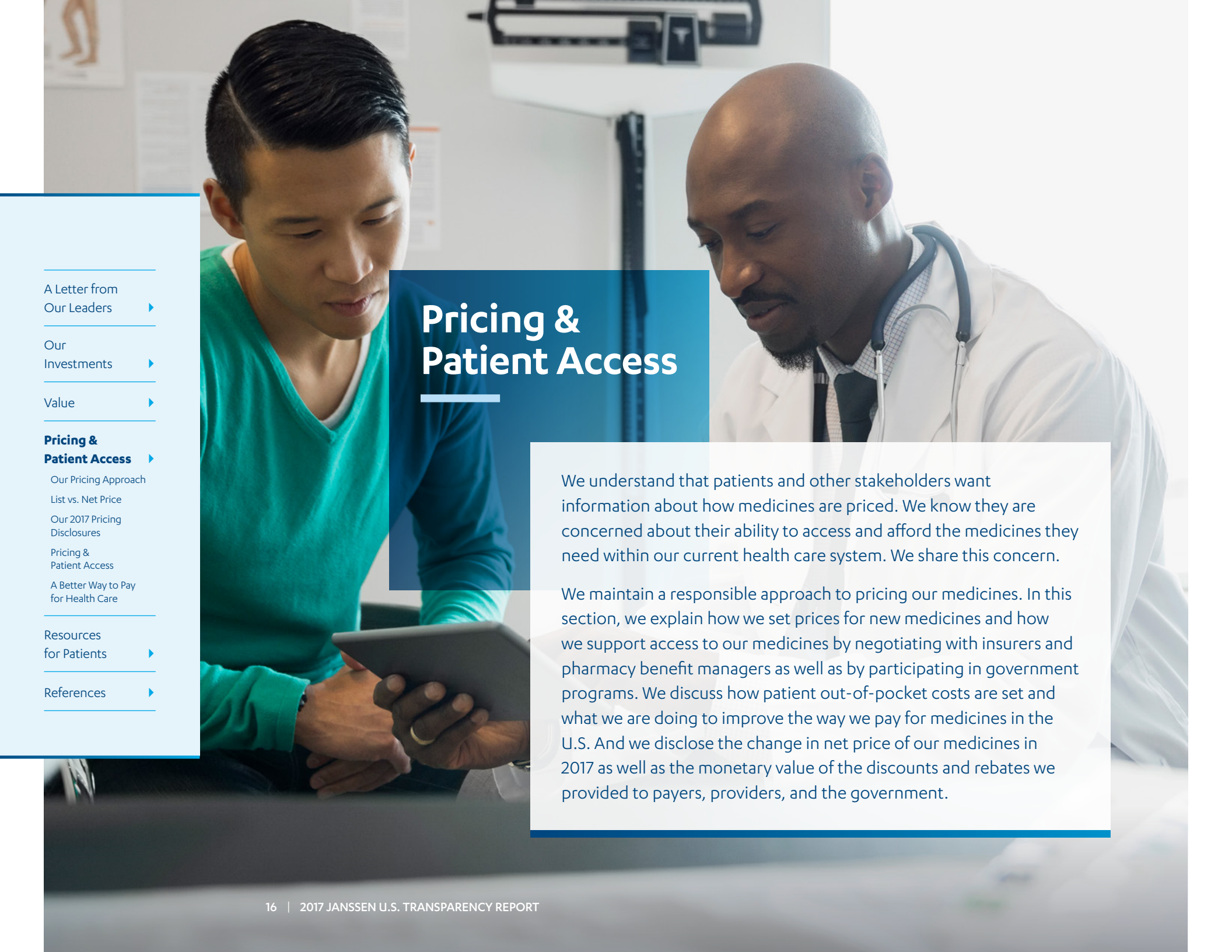
Measuring and defining the value of medicines has been the subject of much discussion. In the U.S., several organizations have introduced frameworks and methodologies to assess the relative value of medicines. These approaches, or "value assessment frameworks," can be helpful, but many of them fail to include factors that are critical to fully assessing value.

Most of these frameworks do consider important measures like how well the medicine works compared to other existing treatments and how much the medicine drives down more costly forms of health care spending. But some take a short-term view of value — for example, considering only the period in which the patient is being treated or the time it takes to see if a treatment is working — that fails to reflect the full benefits a medicine can provide to a patient over a lifetime.⁵⁰ And some frameworks focus heavily on the impact a medicine has on health care budgets, not on the value it brings to individual patients.⁵¹

Most importantly, value assessment frameworks need to measure value according to factors that matter most to patients — for example, improved quality of life, the ability to be productive at work, or the chance to remain independent for a longer period of time. But these types of factors are not reflected in many of the current value frameworks.⁵²

Value assessment frameworks are still evolving, and developers should address these and other important limitations before they are widely accepted. Doing so will allow us to have more informed conversations about health system costs and the respective value of health care interventions, including medicines.

In the next section, we further explore the importance of defining and measuring the value of medicines (see ["A Better Way to Pay for Health Care"](#)). ■



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We understand that patients and other stakeholders want information about how medicines are priced. We know they are concerned about their ability to access and afford the medicines they need within our current health care system. We share this concern.

We maintain a responsible approach to pricing our medicines. In this section, we explain how we set prices for new medicines and how we support access to our medicines by negotiating with insurers and pharmacy benefit managers as well as by participating in government programs. We discuss how patient out-of-pocket costs are set and what we are doing to improve the way we pay for medicines in the U.S. And we disclose the change in net price of our medicines in 2017 as well as the monetary value of the discounts and rebates we provided to payers, providers, and the government.

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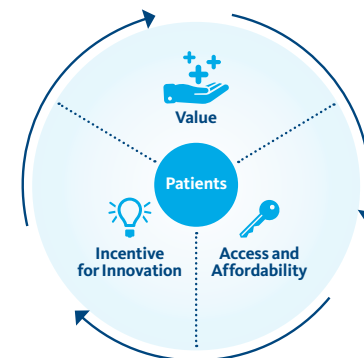


Our Pricing Approach

When we set an initial list price for our medicines following FDA approval, we balance the following considerations:

- **Value to patients, the health care system, and society.** We consider how the medicine will improve patient health. We also assess the medicine's potential to reduce other costs — surgeries, hospital stays, or long-term care, for example — and the improvement the medicine represents over the existing standard of care. (For more about our Value Assessment Principles, please see the [“Value”](#) section.)
- **The importance of maintaining affordable access to medicines for people who need them.** We consider not just the list price, but also the discounts and rebates we provide insurers, pharmacy benefit managers, governments, hospitals, physicians, and other providers of care to support broad access to our medicines.
- **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 resources necessary to invest in future research and development to address serious, unmet medical needs.

Janssen's Patient-Centered Approach to Pricing



When determining an initial list price, we go through a lengthy process to gather the information necessary to assess the medicine on the basis of these principles. We review clinical data; we use health economic research to assess how our medicines may affect other health care costs arising from things like hospitalizations or long-term care and we analyze existing therapies, current standards of care, and potential future therapies. We use this information to determine the value of our medicine compared to what is or will be available to treat the same condition — be it other medicines, surgery, or other forms of health care — and price accordingly. We also seek input on our pricing approach from external experts who provide feedback to help us make sure the price we set is appropriate.

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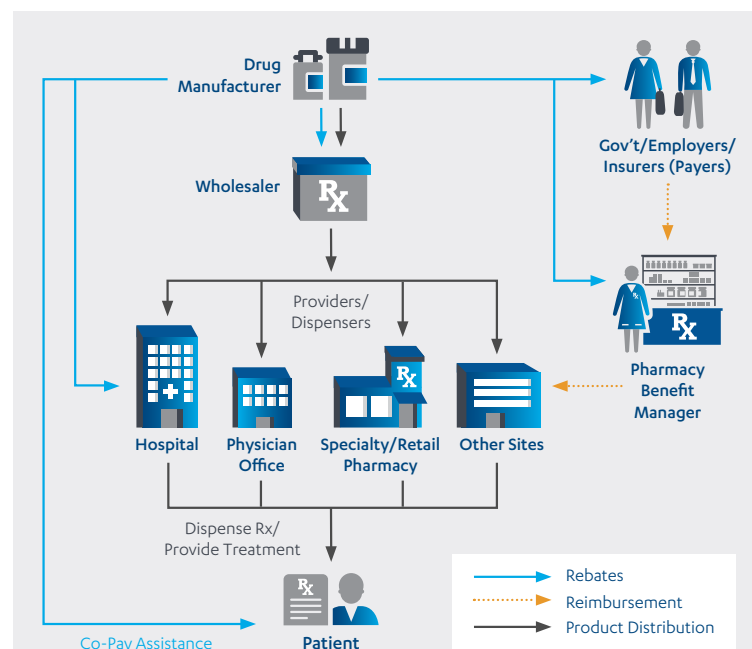
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List vs. Net Price

The list price for medicines is a starting point and is ultimately reduced by the discounts and rebates we provide to insurance companies, pharmacy benefit managers (PBMs), hospitals, clinics, the government, and others. We also pay fees to pharmaceutical wholesalers to distribute our medicines. Here is more information about how these discounts, rebates, and fees work:

- **Private Insurance:** Commercial health insurance companies and PBMs manage the purchase of medicines for those with private insurance coverage. They determine what medicines will be included on their formulary (the list of products they cover) and the out-of-pocket amounts patients will pay for those medicines. Formulary determinations are based in part on payers' negotiations with pharmaceutical companies. These negotiations result in rebates from the pharmaceutical company to the payer.

An Example of the Pharmaceutical Supply Chain*



* Actual distribution dynamics can vary at every level.



- **Public Programs:** We are required to give substantial discounts to government insurers such as state Medicaid departments and the U.S. Department of Veterans Affairs. The government requires that pharmaceutical companies provide specific mandatory discounts on medicines in order to participate in these programs. In addition, we provide discounts and rebates through negotiations with the private health insurance companies and pharmacy benefit managers who administer benefits for Medicaid and Medicare. (See [“Discounts and Rebates in Federal Health Programs”](#) and [“Negotiations in Medicare Part D”](#) for more information.)
- **Hospitals and Clinics:** We provide discounts on our products to hospitals and clinics for inclusion on their formularies. Also, under a federal program known as the 340B Drug Discount Program, we are required to provide significant discounts on certain medicines purchased by specific categories of hospitals, clinics, and health centers that meet federal eligibility requirements.
- **Wholesalers and Distributors:** We pay fees to pharmaceutical wholesalers and distributors — companies that buy medicines in bulk and distribute them to pharmacies and other health care providers.

LEARN MORE

For more information about patient out-of-pocket costs, please visit the following resources:

- Biotechnology Innovation Organization’s Understanding Your Drug Costs: [Follow the Pill](#)
- The Pharmaceutical Research & Manufacturers of America’s [Let’s Talk About Cost](#) & [Follow-the-Dollar](#)

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Why do we negotiate with private payers? For many conditions multiple treatment options exist, so payers create competition among pharmaceutical companies, who are all vying for favorable positions on their formularies. (See [“What Is a Formulary?”](#)) Payers designate certain medicines as “preferred” and place them on lower formulary tiers that require smaller patient out-of-pocket payments. “Non-preferred” treatment options get placed on higher tiers or are excluded altogether. Usually, the lower the medicine’s tier, the lower the patient’s out-of-pocket cost.

In contract negotiations, we give payers information they can use to evaluate the overall value of our medicine, and we offer discounts and rebates on our medicines in an attempt to gain favorable formulary placement. We are competitive in these negotiations because we want patients who need our medicines to have affordable access to them.

What Is a Formulary?

A drug formulary is a list of prescription medicines that a particular health insurance plan will pay for. The payer develops and manages the formulary. In the U.S., tiered formularies, in which out-of-pocket costs vary depending on where the medicine is placed, are a common practice. Here’s an example of a four-tier formulary:

Tier 4: Specialty Brands	Highest-cost tier; most are specialty medicines
Tier 3: Non-Preferred Brands	Second-highest cost tier; most are brand-name medicines, some are specialty medicines
Tier 2: Preferred Brand	Second-lowest cost tier; some medicines are generic and some are brand name
Tier 1: Generic	Lowest cost tier; most medicines on this tier are generic

This is a simplified example. Common drug plans in Medicare Part D include five tiers.⁵³

Negotiations in Medicare Part D

Pharmaceutical companies negotiate rebates on medicines purchased by Medicare through the Part D benefit and through Medicare Advantage plans. These negotiations occur with the private health insurance companies and pharmacy benefit managers who administer benefits for these public programs.

The payers that administer Part D benefits represent as many as 40 million covered lives,⁵⁴ meaning they are powerful negotiators with leverage to secure large discounts and rebates on behalf of Part D plans.

Discounts and Rebates in Federal Health Programs

Medicaid: As required by law, we provide a minimum discount of 23.1 percent⁵⁵ to states for brand medicines provided to people in traditional and managed Medicaid programs. On top of that, many state Medicaid programs receive additional rebates for specific medicines.

Department of Veterans Affairs and Department of Defense: We are required to provide a discount of at least 24 percent⁵⁶ for medicines provided through the Department of Veterans Affairs (VA) and the Department of Defense. In addition, pharmaceutical companies may provide further discounts to the VA to secure formulary placement.

340B Drug Discount Program: Under this program, we provide significant mandated and supplemental discounts for certain medicines purchased by specific categories of hospitals, clinics, and health centers that meet program eligibility requirements set by the federal government.

Medicare: Pharmaceutical companies negotiate rebates on medicines purchased by Medicare through the Part D benefit and through Medicare Advantage (Part C) plans. These negotiations occur with large private health insurance companies and pharmacy benefit managers that administer benefits for these public programs.

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In 2017, we provided approximately \$15 billion in discounts and rebates on our medicines — or a discount rate of 42 percent. As in past years, we limited our annual aggregate list price increase to single-digit percentages.⁵⁷ Despite this modest increase in list price, today's vigorously competitive marketplace drives deep discounts and rebates to payers and providers. In fact, the discounts and rebates we provided outweighed our increase in list price. As a result, the aggregate net impact of price on our business was -4.6 percent.⁵⁸ Our business remained strong because of increased use of our medicines, demonstrating the value of our innovations to patients and health care providers. In the chart below, you will see list and net price changes of our medicine portfolio for the past five years.

U.S. Product Portfolio,⁵⁹ % Change vs. Prior Year⁶⁰

	2013	2014	2015	2016	2017
Average List Price Change ⁶¹	9.0%	8.3%	9.7%	8.5%	8.1%
Average Net Price Change ⁶²	4.8%	2.5%	5.2%	3.5%	-4.6%

Price Increases Explained

There are many factors that contribute to price increases. We continue to conduct research on our medicines after we receive FDA approval, including: studies to understand how the medicine works in a real-world setting; to monitor for safety; and to develop new indications, dosages, or improved product formulations — an investment that enhances the medicine's value for patients and society. Additional regulatory requirements, upgrading or building new manufacturing facilities, an increase in the cost of goods, or other market dynamics can also play a role. And we must ensure we continue to generate a return in order to attract the capital to maintain our R&D activities.

It's important to remember that biopharmaceutical innovation paves the way for the introduction of generic and biosimilar medicines. In the U.S., medicines lose patent protection on average about 12 years after they are introduced.⁶³ When that happens, prices generally drop significantly — an average of 90 percent within two and a half years for oral medicines⁶⁴ — giving patients ongoing access to breakthroughs at a lower cost.

Why Do U.S. Medicine Prices Differ from Prices in Other Countries?

We are sometimes asked why patients in the U.S. pay more for medicines than patients in other countries. The fact is, most cross-country comparisons focus solely on the list prices of medicines and do not account for the significant discounts required for participation in U.S. public programs, such as Medicaid and the 340B Drug Discount Program, as well as the discounts and rebates negotiated by private payers, all of which narrow international price differences.⁶⁵

In the U.S., we have a market-based system that provides financial incentives for innovation while managing access and cost through intense competition, payer negotiations, and the high use of generics. In other countries, medicine prices are achieved through national regulation, which restricts access to innovative medicines and gives patients fewer choices. For example:

- Compared to patients in the U.S., the typical wait time for patients in five European Union countries to gain access to cancer medicines ranges from seven months to a year and a half longer.^{66,67}
- Of 45 cancer medicines approved by the FDA from 2009 to 2013 and available through the Medicare program in the U.S., only 58 percent were made available by government health authorities in the United Kingdom, 42 percent in France, 29 percent in Canada, and 24 percent in Australia.⁶⁸

FAST FACT

In 2017, the average net price change of our portfolio was **-4.6%**⁶⁹ while the total rate of U.S. medical inflation rose by **1.8%**.⁷⁰

Our 2017 decrease in net price contrasts with the total rate of medical inflation (the average price increase of medical care services and goods to consumers), which rose by 1.8 percent in the U.S. in 2017.⁷¹

In 2017, REMICADE® (infliximab), our largest-selling product in recent years, faced increased marketplace competition and corresponding downward pricing pressure. However, even excluding REMICADE®, our 2017 net price change for our portfolio of medicines was negative.

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In 2017, the average aggregate net price of our medicines decreased, and total prescription drug spending rose by just 1.3 percent.⁷² Across the entire industry, in four years alone, total discounts, rebates, and fees provided by pharmaceutical companies grew from an estimated \$59 billion in 2012 to \$127 billion in 2016,⁷³ while average net prices for branded medicine grew just 3.5 percent in 2016.⁷⁴

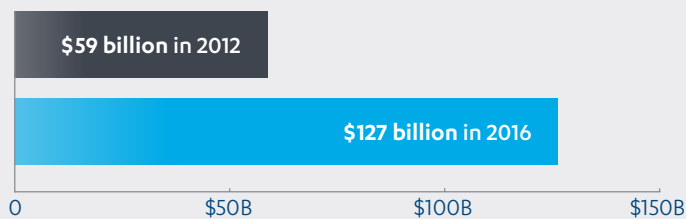
Meanwhile, patient out-of-pocket costs for medicines are rising. According to a recent study by QuintilesIMS (now IQVIA), out-of-pocket costs for branded medicines increased 48 percent from 2013 to 2016.⁷⁵

One reason patients may feel that prices for their medicines are increasing is changes in how their health insurance is designed and, specifically, how their pharmaceutical benefits are managed. The number of commercially insured patients under the age of 65 who are enrolled in high deductible health plans, which require greater initial out-of-pocket costs before coverage begins, has increased in recent years.⁷⁶ So too has the use of coinsurance, where patients are charged a percentage of a medicine's list price, as opposed to a fixed dollar amount or copayment.⁷⁷ For example, the average percentage of covered medicines with coinsurance among Medicare Part D plans rose from 35 percent in 2014 to 58 percent in 2016.⁷⁸

Payers — insurers, pharmacy benefit managers, and the government — ultimately determine which medicines will be included on formularies and what patients will pay for them, often referred to as their share of costs. These decisions

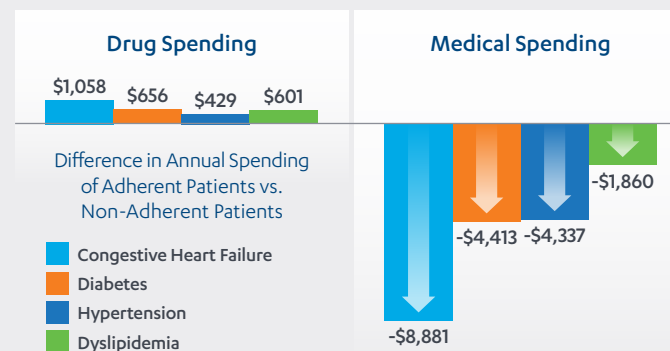
FAST FACT

Pharmaceutical company discounts, rebates, and fees have increased from an estimated **\$59 billion** in 2012 to **\$127 billion** in 2016.⁷⁹



FAST FACT

Adherence to medicines **lowers total health spending** for chronically ill patients.⁸⁰



are based on many factors including negotiated price. Patient cost sharing may not reflect the discounts and rebates provided by pharmaceutical companies. In fact, a recent study found that many patients' share of a medicine's cost is based on list — not net — price, particularly when patients pay for prescriptions in their deductible period or when their medicines are subject to coinsurance. More than half of all patient out-of-pocket spending on branded medicines is a result of prescription medicines filled in the deductible period or in the form of coinsurance.⁸¹

Research shows that when patients pay a greater share for their medicines, patient health can suffer, and health system costs don't necessarily go down.⁸² For example, when diabetes patients' out-of-pocket costs rise, they are less likely to adhere to their medicines, meaning they are less likely to take them as directed.⁸³ Patients with rheumatoid arthritis who are facing higher out-of-pocket costs may also forego filling their prescriptions or abandon their disease-modifying treatments altogether.⁸⁴ Such decisions may reduce payer and health system pharmacy costs in the short term, but, over the long term, lack of adherence results in poorer health outcomes and higher overall system costs.⁸⁵ According to one study, the U.S. could save \$213 billion annually if medicines were used appropriately,⁸⁶ and the Congressional Budget Office has estimated that for every 1 percent increase in the number of prescriptions filled by Medicare beneficiaries, spending on medical services decreases by about 0.2 percent.⁸⁷

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A Better Way to Pay for Health Care

Like many others, we are concerned about the rising costs of health care in the U.S. and are committed to working with others throughout the health care system to find ways to lower costs while improving care.

Our fragmented and complex health care system is fraught with wasteful spending. In 2012 alone, U.S. expenditures related to failures of care coordination, administrative complexity, and fraud and abuse were an estimated \$1 trillion.⁸⁸ By some estimates, system waste accounts for more than 20 percent of the total cost of health care.⁸⁹ Meanwhile, many still cannot afford the care they need.

We strongly believe that addressing our health care system's inefficiencies while ensuring every American has access to affordable health care, including medicines, means making changes to the way we cover and pay for medical care. Our country needs a new approach that prioritizes health care interventions — whether medicines, surgeries, in-office visits, or other forms of care — that deliver the best results at the best value. Instead of paying for volume, we should be paying for the value that the health care intervention delivers. Everyone who plays a role in the health care system should be held accountable for the results or outcomes they deliver, including pharmaceutical companies.

As discussed in the "Value" section, we are working to more clearly define and measure the value of our medicines. And we are taking steps to advance a more results-based approach in three distinct ways: through the establishment of innovative contracting models, also known as value-based contracts; through partnerships that explore value-based care models; and through population health research that seeks to address quality and cost challenges in today's health care system.

FAST FACT

Janssen is advancing a more results-based approach through:



**Innovative
Contracting Models**



**Value-Based
Partnerships**



**Population
Health Research**

Innovative Contracting Models

Innovative contracting models can allow the insurer and pharmaceutical company to share risk, with the goal of providing better outcomes for patients at a lower overall cost of care. These arrangements can be structured in a variety of ways, including:

- **Contracts tied to measurable medical outcomes:** In this type of contract, the pharmaceutical company and payer agree on a measurable medical outcome that both parties are trying to achieve. The contract is based on achieving this shared goal, which would result in beneficial outcomes for the payer's patient population and reduced health care costs overall. If the medicine doesn't meet the goal — or in other words, doesn't work as expected — the pharmaceutical company will pay a rebate to the insurer.
- **Contracts to help insurers better predict costs:** Pharmaceutical companies might cover unexpected costs of providing a medicine to a patient. For example, if a patient needs a higher dose of a medicine than the average patient, the pharmaceutical company might agree to cover part of the cost of the additional medication. This type of arrangement allows insurers to better anticipate costs and manage risk over a large population of patients and, as a result, enables them to provide better access to that medicine.
- **Contracts tied to offsets of other health care expenditures:** The insurer provides better access to a medicine with the expectation the medicine will reduce the need for other costly health care interventions, such as surgeries, physician visits, and hospital stays. If such health care expenditures are reduced, the pharmaceutical company is paid more; if they increase, the pharmaceutical company agrees to provide more rebates.

We are enthusiastic about the potential of innovative value-based contracting models, but there are a number of technological and policy barriers that can make these agreements challenging to implement. To address policy barriers, we support the following measures: establishing safe harbors to better enable manufacturers to partner with payors and share risk; clarifying Medicare and Medicaid pricing treatment; and making comparative formulary and cost-sharing information readily available to give patients what they need to make better decisions. To address technological barriers, we advocate modernizing our health care data system to make it easier to track patient outcomes.

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Janssen's Value-Based Contracts

We have established several value-based contracts with insurers and continue to explore new opportunities. Here are two examples:

Oncology: We have partnered with public and private payers on novel contracts for patients with prostate cancer. In one contract, we have agreed to provide additional rebates to the insurer for plan members who meet eligibility criteria and whose treatment duration is shorter than a predetermined period of time. If the patient stops treatment, most likely because the treatment isn't working as expected, we rebate a portion of the cost of that treatment to the payer. In this case, treatment duration is being used as a proxy for an outcomes-based measure of efficacy.

Type 2 Diabetes: We have partnered with a leading payer on a contract under which we are paid more if data show our medicine that treats adults with type 2 diabetes contributed to lowering other identified health care costs, such as the use of additional medicines. If those costs increase, we pay additional rebates. We have also partnered with several payers on results-based contracts tied to clinical outcomes for that medicine. Under such agreements, we provide additional rebates if the agreed-upon health outcome is not achieved.

Value-Based Partnerships

We continue to participate in partnerships to explore value-based care models. We were the first health care manufacturer to join the Health Care Payment Learning and Action Network (LAN), an initiative of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. The LAN, which brings together the private, public, and nonprofit sectors, is focused on accelerating our health care system's transition to alternative payment models that reward value — the difference a treatment makes for patients — rather than volume. We are also pleased to support a multi-stakeholder effort established by Value Based Insurance Design (VBID) Health that is working to identify, measure, and eliminate low-value health care services.



Population Health Research

We are working to advance results-based health care at the population level. In an effort to contribute to the "Triple Aim" goals of improving patient care and population health while reducing the per capita cost of health care,⁹⁰ our pioneering Population Health Research team is engaged in a number of unique research partnerships with a variety of health care stakeholders to find evidence-based solutions to population health challenges. Here are some examples:

- **Hospital readmissions are a significant health system cost driver.** We collaborated with Sharp Healthcare to use real-world data to better understand the impact of behavioral health factors on predicting re-hospitalizations within 30 days and how to proactively identify patients at higher risk for readmissions for any cause.⁹¹
- **Type 2 diabetes is a chronic and progressive disease.** Patients with type 2 diabetes often do not reach recommended HbA1c targets, a measure of diabetes control. In partnership with researchers at the University of Utah and SelectHealth, the insurance division of Intermountain Healthcare, we identified a broad set of patient-level factors associated with failure to achieve HbA1c goals. This analysis of real-world data will enable better identification of high-risk patients and help guide patient- and physician-targeted interventions.⁹²

We are engaged in these efforts because we believe a more value-based health care system has tremendous potential to improve patient health, increase access to care, and curb the increase in health care spending. The transition to this value-based approach will require pharmaceutical companies, payers, providers, and policy makers to work together, and we will continue to look for ways to help lead in this effort. ■



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Patients should have access to affordable medicines. In the previous section, we discussed how we contract with insurers to support the availability of our medicines. We also help patients obtain appropriate access to our medicines, as we know that insurance coverage can be complicated and finding financial assistance can be challenging.

In this section we describe the services we provide to patients, caregivers, and health care providers through our Janssen CarePath and JANSSEN CONNECT® programs. We also include information about our support for charitable organizations and foundations that help patients get the medicines they need.

While we recognize these programs are not a long-term solution for all patients, they are one way we strive to meet the needs of the patients we serve and the health care professionals who care for them.

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Even with health insurance, some patients experience high prescription medication out-of-pocket expenses. Others are limited in the types of medicines they can access due to medication management measures like prior authorization and step therapy. (See "[Medication Management Tools](#)" for more information.) For patients facing these challenges, we've created some tools to help.

Janssen CarePath provides access, affordability, and treatment-support resources to help patients get started on, and stay on, the Janssen medicines their health care providers prescribe. Janssen CarePath program coordinators offer various forms of patient access support: they answer questions about insurance coverage for Janssen medicines; locate nearby treatment centers for certain medicines; provide education to help patients take their medicines as directed; and, if needed, identify options that may help make the medicines more affordable.

For commercially insured patients who meet our criteria, we also offer our Janssen CarePath Savings Programs to reduce copays. Such programs — which provide copay coupons to help reduce out-of-pocket costs — are an important tool for helping patients gain access to the medicines prescribed by their health care provider. A recent study found that 51 percent of all copay coupons were offered for medicines that had either no generic equivalent or no generic substitute — meaning that the only option for these patients was a branded medicine. This finding suggests that copay coupons continue to play a critical role in making out-of-pocket costs more manageable for patients.⁹³

Medication Management Tools

Insurers use various tools to manage the costs of medicines. These include:

- **Prior authorization**, in which doctors are required to obtain approval from an insurer before a patient can receive a particular medicine. While prior authorization helps make sure patients get the insurer-preferred medicine, the practice can result in delays that cause some patients to forego their treatment altogether.
- **Step therapy**, also known as "fail first," in which insurers require that patients try medicines on an insurer's preferred list of prescriptions before the insurer will cover the cost of another medicine.
- **Non-medical switching**, in which insurers eliminate coverage for a patient's current medicine, switching them to treatment that has a lower cost for the insurer. While some patients can switch to a different treatment without issue, this practice may be harmful to some patients, especially those with complex, chronic, or rare conditions, who have found that one medication works better for them than another.



OUR LEADERS DISCUSS

Gina Giordano, Director for Patient Access Solutions for Oncology at Janssen, discusses how our Janssen CarePath Program helps support patient access and affordability of our medicines.

FAST FACT

In 2017, we helped approximately **1.2 million** patients⁹⁴ through the Janssen CarePath program.

This includes approximately **610,000** commercially insured patients who reduced their out-of-pocket expenditures through the Janssen CarePath Savings Program.⁹⁵

Janssen CarePath also helps health care providers focus on treating patients. For health care providers, navigating complex insurance benefits adds to their administrative burden. According to a survey by the American Medical Association, physicians and staff spend more than 16 hours a week seeking pre-approval — also known as prior authorization — from insurers to prescribe medicines, with 75 percent of physicians saying such requests impose a “high” or “extremely high” burden.⁹⁶ Janssen CarePath helps 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 2017, we helped approximately 1.2 million patients⁹⁷ through the Janssen CarePath program. This includes approximately 610,000 commercially insured patients who reduced their out-of-pocket expenditures through the Janssen CarePath Savings Program.⁹⁸

JANSSEN CONNECT®

JANSSEN CONNECT® and JANSSEN CONNECT® ACCESS & CARE TRANSITIONS are two programs offering comprehensive information and assistance to help patients with schizophrenia initiate and maintain their health care professional-prescribed Janssen long-acting injectable atypical antipsychotic therapy. In 2017, approximately 10,000 patients enrolled in these programs, gaining access to information, education, and adherence support throughout their journey of managing their schizophrenia.⁹⁹

Janssen CarePath helps by verifying patients’ health insurance benefits to make sure providers are familiar with their patients’ coverage for Janssen medicines ...



Why We Can't Offer Copay Cards to Seniors

The Social Security Act restricts the kinds of benefits pharmaceutical manufacturers can provide patients enrolled in federal and state-subsidized health care programs, including Medicare. Savings card programs are one such restriction. As a result, only patients who are privately and commercially insured are eligible for pharmaceutical savings cards.

While we can't help seniors directly through copay cards, we contribute to foundations and independent charitable organizations that can assist seniors with medication-related copays. (See more information on our charitable contributions later in this section.) In addition, Medicare patients may be eligible for one or more programs not affiliated with Janssen such as the [Medicare Savings Program](#), [Medicare Extra Help](#) (Part D), and [state-sponsored programs](#). More information is available at: [medicare.gov/your-medicare-costs/help-paying-costs/get-help-paying-costs.html](https://www.medicare.gov/your-medicare-costs/help-paying-costs/get-help-paying-costs.html).

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

- **We donate medicines and funding to the Johnson & Johnson Patient Assistance Foundation, Inc.,** an independent, nonprofit organization that provides Janssen medicines to eligible U.S. patients. More information about the Johnson & Johnson Patient Assistance Foundation is available at jjpaf.org or by calling 1-800-652-6227 (9 am to 6 pm ET).

We donated approximately \$875 million¹⁰⁰ to support 2017 operations of the Johnson & Johnson Patient Assistance Foundation, enabling the Foundation to provide medicines at no cost to approximately 86,000 patients.¹⁰¹

- **We make financial donations to independent charitable foundations** that assist underinsured and financially needy patients with treatment-related expenses.

In 2017, we donated approximately \$61 million to independent charitable foundations,¹⁰² enabling them to provide assistance with medication-related copays to an estimated 9,750 patients for any medicine prescribed by their physician.¹⁰³

The programs offered or supported by Janssen are one way to meet the needs of the patients we serve and the health care professionals who care for them. In addition to the programs and services we offer, patients and providers should be aware of the many other resources and programs available to help patients access medicines. (See [“Other Patient Programs and Resources”](#) for more information.) ■

Other Patient Programs and Resources

In addition to the programs and services we offer, patients and providers should be aware of the many other resources and programs available to help patients access medicines. Some include:

The Partnership for Prescription Assistance (PPA):

This organization helps patients who are uninsured or underinsured access the medicines they need through a program that is right for them. Since 2005, PPA has helped more than 10 million people get their prescriptions for free or nearly free. Visit pparx.org to find out whether PPA can help you or someone you know.

Healthcare Ready: Through collaboration between the public health and private sectors, Healthcare Ready helps address pressing health issues before, during, and after major natural disasters. Visit healthcareready.org to learn about the resources that may be available to help those affected by hurricanes and other natural disasters.

Clinical Trials: Patients and health care professionals can visit ClinicalTrials.gov to view a database of clinical studies being conducted around the world. We also developed the Janssen Global Trial Finder to help individuals easily access information on Janssen clinical trials. People interested in enrolling in a clinical study can use the Janssen Global Trial Finder, available at globaltrialfinder.janssen.com, to search for Janssen clinical trials by medical condition and geographic location.

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Requests for Access to Medicines in Development

Our mission is to develop, gain regulatory approval for, and bring to market important medicines that make a difference for patients around the world. Pre-approval access, also known as expanded access or compassionate use, is a way for eligible patients to request investigational medicines that have not yet been approved by health authorities. **We provide three pathways to pre-approval access:**

1. Clinical Trials

The primary method for gaining access to Johnson & Johnson's investigational medicines is to enroll in a clinical trial. Clinical trials are scientific studies that evaluate the effectiveness and safety of medicines and, ultimately, are submitted to health authorities as part of the request for approval of a medicine.

2. Expanded Access Programs

Patients may sometimes obtain access to an investigational medicine through expanded access programs. At Johnson & Johnson, we typically consider opening an expanded access program in the U.S. when our clinical studies are complete and we are awaiting approval from the FDA. We do not, however, open an expanded access program for every investigational medicine or offer investigational medicines when they are in their early testing. The list of expanded access programs for the Janssen Pharmaceutical Companies of Johnson & Johnson can be found at clinicaltrials.gov.

How to Get More Information

The best and fastest way for patients to get more information on how to access Janssen investigational medicines, or to submit a request for access, is for their physicians to call 1-800-JANSSEN or email janssenmedinfo@its.jnj.com. For information about how we process requests, please visit our website at janssen.com/compassionate-use-pre-approval-access.

3. Individual Patient Requests for Compassionate Use

Patients who are not eligible for clinical trials or expanded access programs, and for whom no other alternative therapy exists, can make a "compassionate use" request to our company through their physician.

The evaluation of individual requests for compassionate use are guided by three important ethical principles:

1. That we are not putting patients at risk of unnecessary harm.
2. That we continue to conduct thorough scientific studies to understand the potential benefits of new medicines to acquire the fundamental information needed to obtain approval from government health authorities and bring new medicines to all patients who need them.
3. That we treat all patients fairly and equally.

In 2017, Janssen received and reviewed 161 global requests for compassionate use, 132 of which were approved.¹⁰⁴

The Compassionate Use Advisory Committee (CompAC)

The Compassionate Use Advisory Committee, or CompAC, is an innovative approach that the Janssen Pharmaceutical Companies of Johnson & Johnson employs globally to help provide a

fair, ethical evaluation of compassionate use requests. Developed in collaboration with New York University Langone Health, CompAC facilitates the review of compassionate use requests by an independent, external body of internationally recognized medical experts, bioethicists, and patient representatives. After a successful pilot that began in 2015, CompAC was expanded to include additional investigational medicines in development at Janssen.

For every compassionate use request, our physicians conduct an initial review to identify patients who may be immediately eligible for a clinical trial or expanded access program, and they direct those requests accordingly. If a patient has exhausted all available treatment options, and does not qualify for any established pre-approval access program, the request will be assessed internally and may also be forwarded to CompAC based on pre-established criteria. CompAC evaluates such requests and provides a recommendation to Janssen. A Janssen physician makes the final decision on patient access for all compassionate use requests.

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About This Report

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