

2016

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

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“We understand the concerns of patients, families and other stakeholders who are worried about health care costs, including the costs of prescription medications. They are calling on us to provide greater transparency about how we operate...”

At Janssen, the Pharmaceutical Companies of Johnson & Johnson, our mission is to transform lives by treating and curing some of the world’s most challenging diseases. Every day, we bring together cutting-edge science and the most creative minds in medical research to think differently about fighting disease.

We are passionate about this work because we know the dramatic impact medicines have on human life. All of us have benefitted from extraordinary medical advances over the past few decades — whether personally or through the experiences of loved ones who are now living longer or better thanks to innovative medicines. In fact, medicines are responsible for 70 percent of recent gains in life expectancy.¹

That is why it is so important that patients who need a medicine can get that medicine. We understand the concerns of patients, families and other stakeholders who are worried about health care costs, including the costs of prescription medications. They are calling on us to provide greater transparency about how we operate — including disclosing more information on our pricing and marketing practices, our patient access programs, and our clinical trials.

At Janssen, we are proud of our legacy of leadership on transparency and responsible business operations. That is why we are pleased to release the first annual Janssen U.S. Transparency Report, providing information about our medicines — from discovery and development to commercialization:

- **Clinical Data Transparency:** Information about our recent efforts to make our clinical trial data more accessible and transparent.
- **Value & Pricing:** Our approach to pricing our medicines, disclosure of our list price increases over the past five years, the net impact of those increases on our business, and the amount of rebates and discounts we paid.
- **Access:** How we help patients who need our products, including details about our U.S. patient access programs and contributions to help improve patient access to medicines.
- **Our Investments:** How and why we provide information about our medicines to physicians and consumers, and disclosure of our sales and marketing expenses.

Our response to public questions does not end with increased transparency. As part of the world’s most broadly-based health care company, we are in a unique position to see the challenges in our current system — and to advocate for improvements, working in partnership with stakeholders throughout the health care system.





We hope that by providing even greater transparency into how we operate within the current health care system, we can advance the dialogue and sharpen the focus on the promise of a more value-based health care system.

The fact is, the U.S. health care system is extraordinarily fragmented and complex. In 2013 alone, wasted health care expenditures, such as excess administration and low-value care, cost the U.S. an estimated \$765 billion.² Meanwhile, many still cannot afford the care they need, which is why we advocate for policies that support expanded coverage and assistance for patients.

Ultimately, however, ensuring that every American has access to affordable health care, including medicines, will require changes to how our country covers and pays for medical care. Instead of paying for volume in health care — the number of procedures performed or prescriptions filled — we should be paying for the value such care delivers. Every part of the health care system, including pharmaceutical companies like Janssen, should be held accountable for the value it delivers.

We believe this approach has tremendous potential to improve patient health, increase access to medicine, and limit costs. That is why we have entered into and continue to explore value-based arrangements with payers, aimed at containing costs and supporting patient population health goals. Such arrangements include, for example, contracts based on improving patient population outcome measures, lowering overall health care expenditures (such as inpatient hospitalization costs), or achieving treatment objectives. It is also why we recently became the first

pharmaceutical company to join the Department of Health and Human Services' Health Care Payment Learning and Action Network (LAN), which is focused on accelerating our health care system's transition to value-based care.

We recognize that we are just one company, and that our actions and disclosures alone cannot resolve all the challenges patients face in our health care system. We hope that by providing even greater transparency into how we operate within the current health care system, we can advance the dialogue and sharpen the focus on the promise of a more value-based health care system.

Sincerely,

Jennifer Taubert
Company Group Chairman,
The Americas, Pharmaceuticals

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

Section References:

1. Frank R. Lichtenberg, "Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009," National Bureau of Economic Research, (2012), doi:10.3386/w18235.
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CLINICAL DATA TRANSPARENCY

The patients and health care professionals who rely on our medicines place their trust in our clinical research and development. At Janssen, we believe making clinical trial data available furthers understanding of diseases, expands the base of knowledge needed to develop new treatments, and provides relevant information to help health care providers and patients make better health care decisions. Sharing information about clinical trials also helps patients identify clinical studies that may be appropriate for them.

We are proud of our history of transparency when it comes to clinical trial data. Here is a summary of how Janssen discloses information about our clinical trials:

- **Registration and Disclosure of Clinical Trial Results:**

Janssen provides information about our clinical trials in the largest U.S. public registry, [ClinicalTrials.gov](#). Our disclosures, which comply with U.S., European Union and other global laws, include listing our controlled interventional studies conducted in patients — which are used to test the efficacy and safety of medicines — and, after the studies are completed and the medicine is approved for sale, revealing the results of the studies.

- **Publication of Clinical Trial Results in Peer-Reviewed Journals:** We seek to publish the results of all company-sponsored interventional pharmaceutical clinical trials in patients in peer-reviewed journals. This includes those studies that are positive as well as those that are negative, those that end early, and those from discontinued research programs. We also seek to publish health

economic studies and other forms of our research that may be useful in advancing public health. The quality and rigor of our R&D efforts is reflected in the publication of many of our studies in top-tier peer-reviewed medical journals.

- **Sharing of Participant-Level Data and Clinical Study Reports:** In January 2014, Janssen R&D entered into a first-of-its-kind agreement with Yale University School of Medicine to establish a pioneering clinical data-sharing initiative. Under the agreement, the Yale Open Data Access (YODA) Project serves as an independent review panel to evaluate and make decisions regarding requests from researchers to access summary and participant-level data from Janssen's clinical trials. These data, which are not available through registries and scientific literature, include clinical study reports (CSRs) and participant-level data. Participant-level data provides de-identified data at the individual or study participant level, while CSRs are extensive reports summarizing the aggregate results of a trial. YODA enables researchers to





access and review such additional data from clinical trials for approved Janssen medicines for purposes of conducting their own scientific or medical research — with the goal of increasing medical knowledge and improving public health.

We believe granting an independent, academic group ultimate authority to determine how we respond to requests for access to participant-level data or CSRs from Janssen's clinical trials is a fair and unbiased approach.

YODA enables researchers to access and review such additional data from clinical trials for approved Janssen medicines for purposes of conducting their own scientific or medical research — with the goal of increasing medical knowledge and improving public health.

YODA Update

In 2015, we expanded our agreement with YODA to include not only pharmaceutical but also medical device clinical trial data. Just recently, in February 2017, we expanded our agreement again to include clinical trial data for consumer products.

To date, the YODA Project has approved more than 60 research proposals for Janssen data as well as one request for medical device data. In 2016, the YODA program received 36 requests for data from researchers and physicians at institutions and academic centers in the U.S. and worldwide, including the Mayo Clinic, Mount Sinai Medical Center, the Harvard School of Public Health, Johns Hopkins University, McGill University, University College London and the Princess Margaret Cancer Centre, among others. All of these requests were approved. In addition, two papers were published this past year as a result of data we have shared via the YODA Project.

Researchers interested in requesting access to data from Janssen's clinical trials can do so via the [YODA Project portal](#). ■



YODA Project 2016



36 researcher requests for data received



36 requests approved

OUR LEADERS DISCUSS



Joanne Waldstreicher, M.D., Chief Medical Officer, Johnson & Johnson, discusses the importance of clinical data sharing and our company's novel collaboration with Yale School of Medicine to make data available to academic investigators.



VALUE & PRICING

At Janssen, we have maintained a responsible approach to pricing our medicines. At the same time, we recognize that patients and other stakeholders are seeking more transparency around how our medicines are priced.

That is why this section of our U.S. Transparency Report provides context about pharmaceutical pricing and our business as well as additional information about our price increases.

In this section, we detail the complex pharmaceutical purchasing and payment system in the U.S. We talk about the difference between a “list price” and a “net

price” — and how much Janssen’s total portfolio of medicines changed in price over the last five years.

The data presented in this section demonstrate that the net price of Janssen’s medicines increased 3.5 percent over the past year. To put this in context, the medical care inflation rate — or the average price increase of medical care services and goods to consumers — was 4.1 percent in 2016.¹



The Value of Medicines

While drug price increases are a topic of much discussion, medicines in fact account for just 14 percent of total health care spending in the United States.² This percentage has been relatively stable over the last several decades, and is expected to remain so³ — even as the value of medicines to patients and society has increased:



Just 18 months after the introduction of highly active antiretroviral therapies to treat HIV, hospital spending on HIV patients decreased by 43 percent, and total health spending on HIV patients decreased by nearly \$300 per patient per month.⁴



New therapies have contributed to a 23 percent decline in the cancer death rate since its peak in 1991.⁵



Over time, as lower-cost generics become more widely available, prices are reduced by an average of 90 percent for oral medicines.⁶



9 out of 10 prescriptions in the U.S. are for lower-cost, generic medicines.⁷



Our Pricing Principles

When we price a new medicine, we take into account:

1. **Its value to patients and society.** We consider not just health and productivity benefits to patients, but also the medicine's potential to reduce other costs — like surgeries, hospital stays, or long-term care — and the improvement it represents to the existing standard of care.
2. **The importance of maintaining affordable access to medicines for people who need them.** We consider not just the list price, but also the negotiated discounts and rebates we will provide to insurers and governments to support broad access to our products.
3. **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 to continue to invest in tomorrow's cures through research and development.

Drug Pricing in the U.S.

The list price for medicines is a starting point and is ultimately reduced by discounts and rebates. We provide these discounts and rebates to insurance companies, pharmacy benefit managers, hospitals, clinics and others. We also pay fees to pharmaceutical wholesalers to distribute our medicines. However, these discounts, rebates and fees are often not visible to patients.

In fact, while the list price set by pharmaceutical manufacturers plays a role, patients' out-of-pocket costs for medicines are ultimately determined by payers, including insurers, pharmacy benefit managers and the government. Here is more information about how these discounts, rebates and fees work:

- **Private Insurance:** Commercial health insurance companies and pharmacy benefit managers (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.
- **Public Programs:** We are also 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 minimum mandatory discounts on medicines in order to participate in these programs. For example, companies are required to provide a discount of at least 23.1 percent⁸ off list price for medicines provided to people in traditional Medicaid programs. On top of that, many state Medicaid programs receive additional discounts for specific medicines either directly or by contracting with private insurers. Discounts and rebates are also paid in the drug coverage programs for seniors under Medicare Part D or Managed Medicare (Part C and Part D).

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 through these public programs.

The payers that administer Part D benefits represent as many as 40 million covered lives,⁹ meaning they are powerful negotiators with leverage to secure large discounts and rebates on behalf of Part D plans.



What Is the Difference Between a Discount and a Rebate?

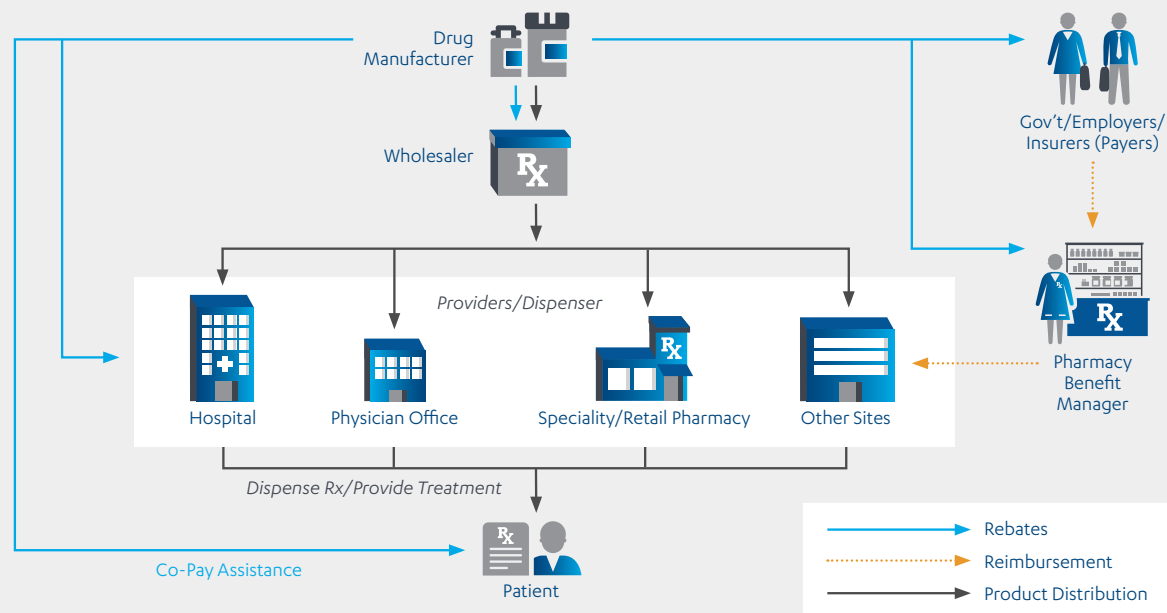
Discount: A reduction in the amount that an insurer or other entity is charged for a medicine at the time of sale.

Rebate: A reduction from the price of a medicine, paid to an insurer or other entity retroactively, after the medicine is dispensed. This rebate is typically paid at the end of some defined period of time.





AN EXAMPLE OF THE PHARMACEUTICAL SUPPLY CHAIN*



* Actual distribution dynamics can vary at every level.

- **Hospitals and Clinics:** We provide discounts on our products to hospitals and clinics for inclusion in their formularies and utilization of our medicines. In addition, under a federal program known as the 340B Drug Discount Program, we provide significant discounts for medicines purchased by certain kinds of hospitals, particularly those that provide care for low-income patients.
- **Wholesalers and Distributors:** We pay fees to pharmaceutical wholesalers and distributors, which are companies that buy medicines in bulk and distribute them to pharmacies and other health care providers.

Why do all these negotiations, rebates and discounts exist? There are often many medicine options available for a particular condition, so insurers and pharmacy benefit managers create competition among pharmaceutical

LEARN MORE

For more detailed information about the pharmaceutical supply chain, [click here](#) to watch the Biotechnology Innovation Organization video, "Understanding Your Drug Costs: Follow the Pill."

What Is a Drug Formulary?

A **drug formulary** is a list of prescription medicines that are approved to be prescribed by a particular health insurance plan. The insurer or the pharmacy benefit manager develops and manages their formulary. In the U.S., **tiered formularies** are a common practice, where out-of-pocket costs vary depending on the tier in which the medicine is placed. An example of a four-tier formulary follows:

TIER 1:

Generic

Lowest cost tier of prescription drugs; most are generic

TIER 2:

Preferred Brand Name

Second-lowest cost tier; some medicines are generic and some are brand name

TIER 3:

Non-Preferred Brand Name

Second-highest cost tier; most are brand name medicines, some are specialty

TIER 4:

Specialty

Highest cost tier; most are specialty medicines





companies for more favorable placement on their formulary. They do this by placing one or two medicines for a particular condition on lower formulary tiers that require a lower patient out-of-pocket payment, while placing other treatment options on higher tiers or excluding them altogether. Companies offer discounts and rebates on their products in order to gain favorable formulary placement and ensure more patients are able to access their medicines.

Patient Out-of-Pocket Costs

For someone with health insurance, the cost of a medicine is set by his or her payer (commercial insurance company, pharmacy benefit manager or the government), who determines the out-of-pocket payment for the medicine. After the patient meets his or her deductible, the patient pays either a co-pay or co-insurance for medicines.

Patients pay on average about 20 percent out-of-pocket for medicines, compared to just five percent for doctor

visits or hospital stays.¹⁰ One reason patients may feel that prices for their medicines are increasing is due to changes in how their insurance is designed and, specifically, how their pharmaceutical benefits are managed.

For example, according to a recent study by IMS Health, the average patient's out-of-pocket cost rose more than 25 percent, to \$44 per prescription, between 2010 and 2015.¹¹ In addition, the use of co-insurance rather than a flat co-pay amount is increasing. Among Medicare Part D plans, the percentage of medicines requiring co-insurance as opposed to co-pays increased from 35 percent in 2014 to 45 percent in 2015.¹²

Like many, we recognize that increasing out-of-pocket costs can be a burden to patients. To help make sure high out-of-pocket costs do not prevent patients from getting the medicines they need, Janssen offers a variety of cost support options through our Janssen CarePath program. In addition, uninsured patients are often eligible for patient assistance to help with out-of-pocket costs. (For more information, see the ["Access"](#) section.)

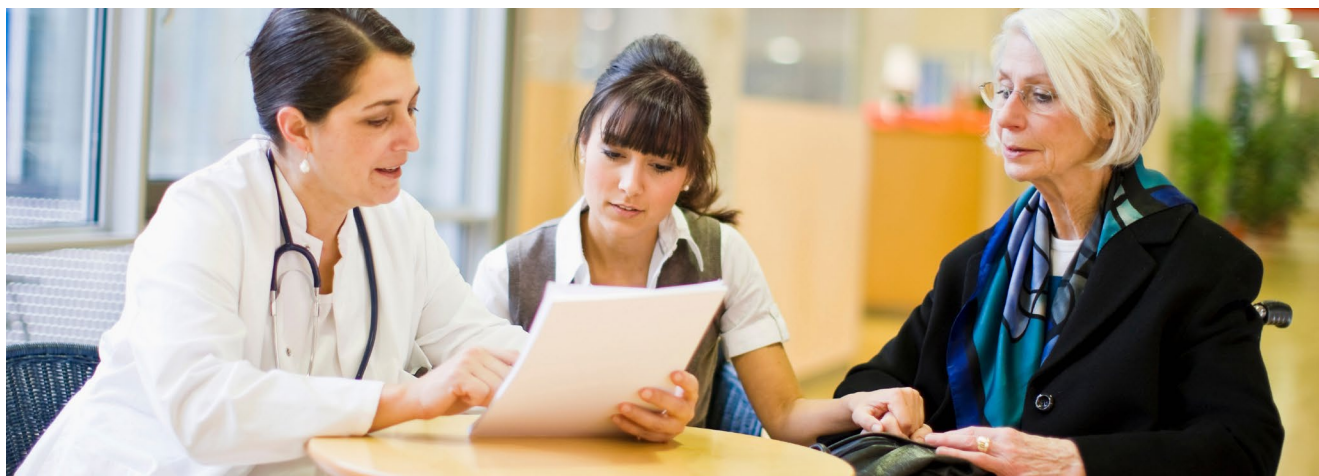
Rebates and Discounts Provided by Pharmaceutical Manufacturers

Mandatory:

- Medicaid
- U.S. Department of Veterans Affairs
- Federal 340B Drug Discount Program

Negotiated:

- Insurers & Pharmacy Benefit Managers (Including Commercial and Medicare Part D)
- Health Care Providers
- Pharmacies



What Is the Difference Between a Co-Pay and Co-Insurance?

Co-Pay: A flat amount paid by patients at the time they receive their medicine or other health care service.

Co-Insurance: A percentage of the cost of a medicine or other health care service paid by the patient.



The Net Price

When the rebates, discounts and fees provided to insurers, pharmacy benefit managers and others described previously are taken into account, we arrive at what is known as the net price. This is the best measure to assess the rate at which pharmaceutical prices are increasing.

“After accounting for discounts and rebates, we generally realize low- to mid-single digit percentages from our list price increases.”

Janssen’s Price Increases

At Janssen, we generally limit our annual aggregate list price increase to single digit percentages, below those of our competitive set.¹³ After accounting for discounts and rebates, we generally realize low- to mid-single digit percentages from our list price increases. The past five years reflected these trends.

As the chart at the right shows, in 2016, after taking into account discounts and rebates to insurers, pharmacy benefit managers and others — a total of approximately \$11 billion in the U.S., or a discount rate of 35.2 percent — the aggregate net impact of price on our U.S. business was 3.5 percent. This is lower than the total rate of medical inflation in the U.S. in 2016, which was 4.1 percent.¹⁸ ■

U.S. Product Portfolio,¹⁴ % Change v. Prior Year¹⁵

	List Price Change—Average ¹⁶	Net Price Change—Average ¹⁷
2012	7.6%	4.3%
2013	9.0%	4.8%
2014	8.3%	2.5%
2015	9.7%	5.2%
2016	8.5%	3.5%

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2. “A 10-Year Projection of the Prescription Drug Share of National Health Expenditures, Including Nonretail,” Altarum Institute, published October 2014 and addendum added August 2015, <http://altarum.org/sites/default/files/uploaded-publication-files/Non-Retail%20Rx%20Forecast%20Data%20Brief%2010-14-14.pdf>.
3. Ibid. 4. Samuel A. Bozzette, M.D., Ph.D., et al., (2001). “Expenditures for the Care of HIV-Infected Patients in the Era of Highly Active Antiretroviral Therapy,” *New England Journal of Medicine*, 344(11), (2001): 817-823, doi:10.1056/nejm200103153441107. 5. Rebecca Siegel et al. “Cancer Statistics, 2016,” *CA: A Cancer Journal for Clinicians* 66(2016): 7–30. 6. “Price Declines after Branded Medicines Lose Exclusivity in the U.S.,” IMS Institute for Healthcare Informatics, January 2016, https://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Price_Declines_after_Branded_Medicines_Lose_Exclusivity.pdf. 7. “Generic Drug Savings in the U.S. Seventh Annual Edition: 2015,” Generic Pharmaceutical Association, (2016), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf. 8. Manufacturers must provide a discount of either 23.1 percent or the lowest price they offer the drug to others in the marketplace (known as best price). 9. “The Medicare Part D Prescription Drug Benefit,” The Henry J. Kaiser Family Foundation, September 26, 2016, <http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/>. 10. “Prescription Medicines: Costs in Context,” chart, PhRMA analysis based on Medical Expenditure Panel Survey (MEPS), <http://www.phrma.org/sites/default/files/pdf/prescription-medicines-costs-in-context.pdf>. 11. “Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,” IMS Health, April 2016, <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>. 12. “Majority of Drugs Now Subject to Coinsurance in Medicare Part D Plans,” Avalere, March 10, 2016, <http://avalere.com/expertise/managed-care/insights/majority-of-drugs-now-subject-to-coinsurance-in-medicare-part-d-plans>. 13. Based on internal calculations using Janssen financial data and data from Analysource, IMS. We compare our aggregate list price increase against aggregate key competitor price increase for branded products in those therapeutic areas in which we market our products. 14. U.S. Product Portfolio includes pharmaceutical products marketed by the company. Products are primarily in the areas of Immunology, Oncology, Cardiovascular Metabolics, Infectious Diseases and Central Nervous System. 15. Annual percent change vs. prior year calculated at product level and weighted across company’s U.S. Product Portfolio. 16. Represents the year-over-year change in the average list price, or wholesale acquisition cost (WAC). 17. Represents the year-over-year change in the average net price, which is WAC less rebates, discounts and returns. The data presented are based upon our internal analysis of product rebates and discounts. The analysis 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. 18. “Consumer Price Index - December 2016,” news rel., U.S. Bureau of Labor Statistics, https://www.bls.gov/news.release/archives/cpi_01182017.htm.

OUR LEADERS DISCUSS



Blasine Penkowski
Chief Strategic Customer Officer

Blasine Penkowski, Chief Strategic Customer Officer for Janssen North America, discusses our company’s approach to pricing medicines and how patient cost is determined.





ACCESS

Medicines contribute tremendously to individual health and to the health of our society, which is why we believe it is so important for patients to have access to the medicines their health care professionals prescribe. As discussed earlier in the Value & Pricing section, patients today are paying more out-of-pocket for medicines, creating access challenges for many Americans. For example, you may recall that, according to a recent study, the average patient's out-of-pocket cost increased more than 25 percent, to \$44 per prescription, between 2010 and 2015.¹

This section of the Transparency Report describes our efforts to address barriers to access to our medicines. We negotiate and partner with private and public payers and health care systems to support availability of our products. In addition, since patient coverage and financial circumstances vary, we support a variety of programs and services to assist with access to medicines. While we recognize that these programs are not a long-term solution for all patients, they are one way we aim to meet the needs of the patients we serve.

Here, we highlight Janssen programs and donations that support U.S. patient access to approved medicines — and disclose the impact of these programs and donations.

To help ensure high out-of-pocket costs do not prevent patients from getting the medicines they need, Janssen offers a variety of support options ...

2016 Disclosures: Access to Medicines

To help ensure high out-of-pocket costs do not prevent patients from getting the medicines they need, Janssen offers a variety of support options, including:

- **Janssen CarePath helps patients understand their health insurance coverage for Janssen therapies and identify options that may help make Janssen products more affordable.** For commercially insured patients who meet our criteria, we offer our Janssen CarePath Savings Programs to reduce co-pays. For a list of all of Janssen CarePath's services, see the box on the right, or visit www.janssencarepath.com for more information.

In 2016, we helped approximately one million patients through the Janssen CarePath program.² Of that number, we helped approximately 870,000 commercially insured patients reduce their out-of-pocket spend through the Janssen CarePath Savings Program.³



About Janssen CarePath

Once your health care professional has prescribed a Janssen medicine for you, Janssen CarePath can provide resources that may help you get started and stay on your medicine.

Our Janssen CarePath coordinators can assist patients with:

- Reviewing health plan benefits to help answer questions about insurance coverage for our medicines
- Identifying options that may help make Janssen products more affordable, if needed
- Reviewing available services and providing support for patients to choose the services that best meet their needs
- For some medications, locating centers near the patient to receive treatment
- Providing treatment education and support

We also support health care providers through our Janssen CarePath program, offering services to help their patients, including:

- Conducting reviews of patient health benefits and providing insurance coverage information
- Offering access to our online provider portal, where providers can request and review benefits investigations
- Providing online resources to help keep track of Patient Savings Program enrollments, benefits and payments (medication dependent)





- **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 2016, approximately 12,000 patients enrolled in these programs, gaining access to information, education and adherence support throughout their journey of managing their schizophrenia.⁴

Janssen also supports independent programs and foundations that aim to assist patients in the U.S. For example:

- **We donate medicines and funding to the Johnson & Johnson Patient Assistance Foundation, Inc.,** an independent, nonprofit organization that provides Janssen medicines to U.S. patients who do not have insurance coverage for these products and do not have adequate financial resources. More information about the Johnson & Johnson Patient Assistance Foundation is available at www.jjpaf.org.

We donated medicines valued at approximately \$620 million⁵ to support 2016 operations of the Johnson & Johnson Patient Assistance Foundation, enabling the Foundation to provide medicines at no cost to approximately 75,000 patients.⁶

- **We make financial donations to independent charitable foundations that assist patients who are underinsured and in financial need with treatment-related expenses.** In 2016, our donations to these independent co-pay foundations helped patients with cancer and autoimmune diseases get financial support for medication-related expenses.

In 2016, we donated over \$47 million to independent charitable foundations,⁷ enabling them to provide assistance with medication-related co-pays to approximately 5,550 patients for any medicine prescribed by their physician.⁸ ■



Section References:

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More Information on Our Giving

In 2008, Janssen began voluntarily disclosing our charitable giving on our [website](#). Each year, this information is updated to reflect the previous year's giving.





Access to Investigational Medicines

Our mission is to develop, gain regulatory approval for, and bring to market important medicines that make a difference for patients around the world. While there have been improvements in shortening the time it takes to make new investigational medicines available, some seriously ill patients who have exhausted all available treatment options request, through their physicians, access to investigational medicines that are not yet approved by health authorities, including the U.S. Food and Drug Administration (FDA). There are three pathways to requesting what is known as “pre-approval access” to investigational medicines:

- **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 a health authority as part of the request for approval of a medicine. They are one of the most important steps in bringing new medicines to patients.
- **Expanded Access Programs:** Patients may sometimes obtain access to an investigational medicine through “expanded access programs” (EAPs), which provide a pathway for patients to get investigational medicines for serious diseases or conditions. At Johnson & Johnson, generally we consider opening an EAP in the U.S. when our clinical studies are completed and we are awaiting approval of our investigational medicine from government health authorities. However, an EAP is not opened for every investigational medicine, and we do not offer EAPs when investigational medicines are in early testing. The list of Janssen EAPs can be found at www.clinicaltrials.gov.
- **Individual Patient Requests or Compassionate Use:** For some patients who are not eligible for clinical trials or EAPs, and for whom no other alternative therapy exists, physicians — in discussion with patients — may make a “compassionate use” request to our company.

About Compassionate Use

There are important factors we consider when determining whether or not we can fulfill compassionate use requests. Johnson & Johnson follows three important principles when deciding whether or not we can provide compassionate access to investigational medicines:

- We must not put patients at risk of unnecessary harm.
- We must ensure all patients are treated fairly and equally.
- Compassionate use should not impede efforts to conduct thorough scientific studies to understand the potential risks and benefits of any investigational medication.

To enhance our long-standing commitment to ethical and patient-centered decision-making, Janssen Research & Development, LLC, in partnership with the New York University (NYU) School of Medicine’s Division of Medical Ethics, in 2015 launched a first-of-its-kind pilot program, The Compassionate Use Advisory Committee, to obtain independent input to assist in evaluating these requests.

The Compassionate Use Advisory Committee (CompAC)

The Compassionate Use Advisory Committee, or CompAC, was established for the purpose of independently reviewing compassionate use requests and providing external, objective recommendations to Janssen R&D. For each compassionate use request evaluated by CompAC, NYU assembles a committee of internationally recognized medical experts, bioethicists and patient representatives with knowledge of the relevant disease area. CompAC makes recommendations regarding individual requests for compassionate use in accordance with the considerations and principles outlined previously. The committee’s recommendations inform Janssen R&D physicians, who make the final decision on each request.

CompAC began in 2015 as a pilot for one medicine under development at that time, daratumumab. In September 2016, Janssen and NYU agreed to expand CompAC to include additional investigational medicines in late-stage development by Janssen R&D. Since the start of the program in July 2015, CompAC has reviewed 182 requests from around the world for compassionate use, seventeen (17) of which originated in the U.S. The results of these 17 requests are outlined below:*

- 12 requests were recommended by CompAC for approval
- Four were deemed to have an unfavorable risk-benefit profile
- One was eligible for an expanded access program, clinical trials or other approved therapies

Janssen followed 100% of the CompAC U.S. recommendations.

How to Get More Information

The best and fastest way to get more information on accessing Janssen investigational medicines, or to make a request, is to have your doctor call Janssen Medical Information at 1-800-Janssen or email us at janssenmedinfo@its.jnj.com.

LEARN MORE

[Click here](#) to watch **Dr. Amrit Ray, Chief Medical Officer, Janssen**, discuss our company’s approach to access to investigational medicines.

* Data based on Janssen’s Pre-Approval Access global tracking system.





OUR INVESTMENTS

At Janssen, we focus our investment on research and development (R&D) to discover and develop differentiated medicines that address many of the most serious unmet medical needs of our time. After we have U.S. Food and Drug Administration approval to bring an innovative medicine to market, we invest in providing accurate, up-to-date information about the medicine to health care professionals and patients through marketing and sales activities. We are sometimes asked if these activities are necessary and how our investment in R&D compares to the amount we spend on marketing our medicines. This section of the Transparency Report directly answers these questions.

Sales and Marketing to Health Care Professionals

One way we market to physicians and other health care professionals is through visits by our sales representatives. Our sales representatives provide information about our medicines' effectiveness, approved uses, side effects, benefits and risks. They may also raise awareness of current clinical practice standards and guidelines. In addition, we consult with health care professionals to gather information about how they are using our medicines and engage physicians to educate their colleagues about the approved uses of our medicines.

In fact, research has shown that health care professionals value information provided by pharmaceutical representatives; please refer to the box on the right.

Marketing to Patients and Caregivers

For consumers in the United States, marketing and promotional activities consist of educational materials we provide to help patients better understand their conditions and treatment options, as well as direct-to-consumer (DTC) advertising that provides information about our medicines.

The Social Benefit of Direct-to-Consumer Advertisements

Pharmaceutical DTC advertisements raise awareness about diseases and available treatments, may encourage people to get treatment, and may prompt more informed conversations between patients and their doctors or nurses. The time physicians have to

Physicians Value the Resources Provided by Pharmaceutical Company Representatives¹

In one study, physicians characterized the usefulness of resources provided by pharmaceutical company representatives as follows:

■ ALWAYS USEFUL ■ OFTEN USEFUL ■ SOMETIMES USEFUL

Provide information about drug interactions, side effects, and contraindications



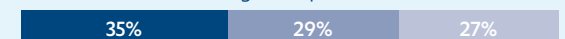
Provide information about the latest drugs and treatments, including information about clinical trials and new research studies



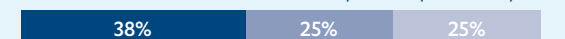
Provide information about assistance programs for patients without prescription coverage



Provide information to give to patients



Answer or find out the answers to specific questions you have



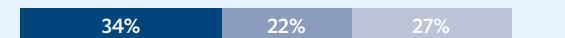
Provide free drug samples



Provide informational presentations for physicians and staff



Relay your reports of any side effects you have seen in your patients back to the pharmaceutical company





spend with patients is limited by desk work and record-keeping,² so it is especially important that patients have the information they need to have productive conversations with their doctors. Research shows that DTC advertising can enable these more informed conversations. In a 2010 survey among consumers:³

- 75-76 percent found the information they learned in DTC television ads — including benefit and risk information — “very or somewhat useful.”
- 33 percent of Americans reported speaking with their physicians about a condition after seeing a DTC advertisement.

Advertising and Marketing Standards that Protect Consumers

We believe acting ethically and responsibly is not only the right thing to do but also the right way to do business. We follow all relevant laws and regulations regarding the promotion of prescription drug products and submit promotional materials to the U.S. Food and Drug Administration at the time of initial publication or dissemination.

Our marketing and sales activities adhere to industry ethics standards and codes of conduct, including the PhRMA [Code on Interactions with Health Care Professionals](#) and the [Guiding Principles on Direct to Consumer Advertising about Prescription Medicines](#). In accordance with these guidelines, we may provide health care professionals with textbooks, medical journal articles and other educational resources, consulting-related travel, as well as modest meals if we are meeting with them during a mealtime. We do not provide

physicians and health care professionals with promotional or recreational items or entertainment.

Ongoing Open Payments Disclosures

In 2010, Johnson & Johnson began voluntarily disclosing payments made to physicians by our U.S. pharmaceutical companies and posting this information to our websites. Beginning in 2013, as required by the Physician Payment Sunshine Act — passed in 2010 as a part of the Affordable Care Act — we began annually disclosing payments and items of value we provide to health care professionals to the Centers for Medicare and Medicaid Services (CMS), part of the U.S. Department of Health and Human Services. CMS posts these disclosures on an online, publicly available database, referred to as “[Open Payments](#).”⁴ This data includes payments related to marketing activities. For example, all payments and items of value we provide to physicians when they are meeting with or consulting for us — such as modest meals or travel expenses — are disclosed in the Open Payments database.

The database also contains details about payments we make to physicians and teaching hospitals for their work in conducting clinical research. This work may include helping us design and conduct clinical trials. While these are not marketing activities, payments related to these activities are disclosed through the Open Payments database.

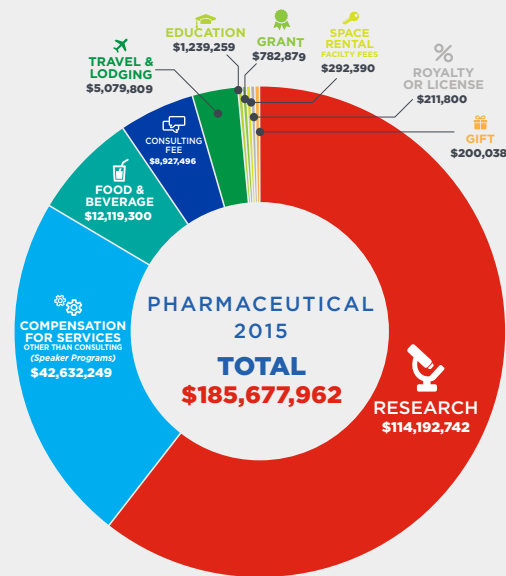
We anticipate that 2016 Open Payments data will be available through CMS on June 30, 2017. In this report we have included information on Janssen’s 2015 payments and transfers of value to physicians and other health care professionals. Importantly, research activities account for more than 60 percent of these payments.

“We believe acting ethically and responsibly is not only the right thing to do but also the right way to do business.”





2015 OPEN PAYMENTS SUMMARY



Click [here](#) to view the full J&J Open Payments summary.

	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.
	Meals, whether paid directly or reimbursed, may be provided in conjunction with: consulting services; training; educational and other business discussions with physicians.
	Product development; training; development of educational materials and disease management programs; unblinded market research.
	Travel, whether paid directly or reimbursed, in conjunction with: consulting services; product training.
	Medical textbooks; scientific journal articles.
	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); non-certified medical education activities.
	Space rental or facility fees (teaching hospital only); booth or exhibit space rental; facility rental for product training or clinical studies.
	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.
	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).

2016 Marketing and Sales Spending

In addition to the disclosures outlined above, here we provide data about our pharmaceutical sector marketing and sales expenses as compared to our R&D expenses.

In 2016, our global pharmaceutical marketing and sales expenditures were \$4.5 billion, and our global pharmaceutical R&D investment was \$7 billion.⁵ In other words, in 2016 we spent 55 percent more on developing medicines than we did on marketing and selling them. Of the \$4.5 billion, \$2.6 billion were U.S. pharmaceutical marketing and sales expenditures.⁶ (For information on what these expenditures and investments include, please refer to the box entitled "Definitions of Marketing and Sales and R&D Expenditures" on the following page.) ■

EXPENDITURES AND INVESTMENT

We spent **55% more** on developing medicines than we did on marketing and selling them.



OUR LEADERS DISCUSS



Dr. William N. Hait
Global Head, Janssen Research & Development

Dr. William N. Hait, Global Head, Janssen Research & Development, discusses our investment in R&D to bring transformational innovation to people in need of medical solutions.

In 2016, we invested 55% more in R&D than we spent on marketing and sales.

At Janssen, we are united by one mission — to discover and develop innovative medicines that transform individuals' lives. We leverage our world-class expertise to transform how diseases are prevented, treated and cured. We believe there are no limits to what science can do. And we never lose sight of those who rely most on our discoveries.





Understanding Our Financial Statements: Selling, Marketing and Administration vs. Marketing and Sales Expenses

Public companies like Johnson & Johnson disclose detailed financial information so that the investing public can make informed judgments about a company's performance. In our financial reporting, the marketing and sales expenses we describe above are combined with other items in a budget line item described as "Selling, Marketing and Administration" (SM&A). The SM&A figure reported in Johnson & Johnson financial documents accounts for much more than just 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, distribution and accounting functions.
- It pertains to all of Johnson & Johnson, which includes medical devices, consumer products, and over-the-counter medicines, as well as pharmaceuticals.
- It is global, not solely for the United States.

Section References:

1. "Survey of Physicians About Pharmaceutical and Biotech Research Company Activities and Information," KRC Research, commissioned by PhRMA, March 2011.
2. Christine Sinsky, et al., "Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties," *Ann Intern Med.* 165(11) (2016):753-760, doi: 10.7326/m16-0961. 3. "13th Annual National Survey: Consumer Reaction to DTC Advertising of Prescription Drugs," *Prevention Magazine*, (2010). 4. Johnson & Johnson has voluntarily posted the aggregated data for our companies covered by Open Payments, as submitted to CMS on March 31, 2016. Due to the CMS data review process, there may be differences between the aggregated totals for data posted here and aggregated totals derived from currently available data on the CMS website. 5. According to Janssen internal financial accounting. While we wish to provide as much detail to our stakeholders and consumers about our investments in R&D as possible, global R&D investment cannot be segmented by region. The R&D activities we undertake around the world collectively contribute to product development for the benefit of all consumers, regardless of market. 6. The financial figures in this section have not been audited and should not be read in conjunction with our filings with the Securities and Exchange Commission. 7. Ibid. 8. According to Janssen internal financial accounting.

OUR LEADERS DISCUSS



Michelle Goodridge, President of Central Nervous System at Janssen, discusses the value of our promotional efforts in informing health care providers and patients about our medicines.

Definitions of Marketing and Sales and R&D Expenditures

Marketing and sales expenditures include our sales force activities, market research, promotion and advertising, and marketing management.

Research and development expenditures relate to the processes of discovering, testing and developing new medicines; improving existing products; demonstrating product efficacy and regulatory compliance prior to the launch of a new drug; as well as safety monitoring and ongoing research post-launch.



