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Drug Pricing in America: A Prescription for Change, Part II

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Chairman Grassley, Ranking Member Wyden, and Members of the Committee, thank you for the opportunity to be here to discuss how we can ensure that Americans have affordable access to the best healthcare today and to the extraordinary medical breakthroughs of tomorrow.

I am Jennifer Taubert, and I lead the Janssen Pharmaceutical Companies of Johnson & Johnson. At Janssen, we focus on discovering and developing transformational medicines that treat and cure some of the world's most challenging diseases, including blood cancers like multiple myeloma, chronic lymphocytic leukemia, and mantle cell lymphoma; prostate cancer; HIV; schizophrenia and other serious mental illnesses; cardiovascular diseases; rheumatoid arthritis; Crohn's Disease and other destructive gastrointestinal illnesses; and pulmonary hypertension, among others.

Like many of you, I know what it's like when a loved one faces a serious disease. My own mother died of lung cancer in 1988, in her 40s. At the time, there was very little that could be done for my mom. I've committed my career to bringing families genuine, meaningful hope – hope for years of life, hope for the chance to be there for a daughter's wedding or the birth of a grandchild.

Commitment to Innovation

Last year Janssen invested $8.4 billion globally in research and development,[1] making Janssen one of the world's top research and development ("R&D") investors in any industry, anywhere in the world.[2] In fact, our investment in R&D last year was 86 percent more than we spent on sales and marketing. This substantial investment has enabled us to research and develop more than 100 medicine candidates last year; and, over the past five years, we have introduced six innovative products in the U.S.[3] The nine

[1] Johnson & Johnson, FY18-Q4 Form 10-K for the Period Ending December 31, 2018 (filed February 20, 2019).
[2] PricewaterHouseCoopers. "2018 Global Innovation 1000 Study." https://www.strategyand.pwc.com/innovation1000.
[3] U.S. Food and Drug Administration Center for Drug Evaluation and Research." NDA and BLA Approval Reports – New Molecular Entity (NME) Drug and New Biologic Approvals." https://wayback.archive-it.org/7993/20170404174205/https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/ucm373420.htm.

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Breakthrough Therapy Designations we have received from the Food and Drug Administration ("FDA") reflect the significance of the advances we are pursuing in areas of profound unmet medical need.[4]

Our investment changes lives. It has helped turn HIV from a death sentence into a manageable disease. Today, people with HIV can have a near-normal life expectancy.[5] And we are working on a vaccine with the potential to eliminate HIV altogether. Our biologic therapies have transformed the lives of patients with Inflammatory Bowel Disease by dramatically improving their quality of life. Our therapies have reduced major bowel surgeries for patients with Crohn's Disease by 82 percent and cut hospitalizations by 65 percent.[6] In ulcerative colitis patients, our therapies have reduced the need for total colectomy by 41 percent.[7] One of our earliest pharmaceutical innovations enabled people with serious mental illness to be treated at home and in their communities rather than in psychiatric institutions, and today our innovative first and only 4-time-a-year schizophrenia treatment is improving adherence and breaking the cycle of hospitalization so that people with schizophrenia can live their best lives.[8] In the area of mental health, we are also investigating a new medicine for people suffering from treatment-resistant depression, which profoundly impacts these patients and their families and loved ones as well. Our first-in-class cancer medicines have helped patients with some of the most common and deadly types of cancer live longer, in some cases for many additional years.[9,10] In multiple myeloma, one of our medicines has more than doubled the length of time patients live without return of their disease.[11,12] We recently launched a new prostate cancer treatment that delays the spread of the disease by over an additional two years versus the prior standard of care.[13]

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[4] U.S. Food and Drug Administration Center for Drug Evaluation and Research. "CDER Breakthrough Therapy Designation Approvals."
https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM481542.pdf.

[5] Trickey, Adam, Margaret T. May, Jorg-Janne Vehreschild, Niels Obel, M. John Gill, Heidi M. Crane, Christoph Boesecke et al. "Survival of HIV-positive patients starting antiretroviral therapy between 1996 and 2013: a collaborative analysis of cohort studies." The Lancet HIV 4, no. 8 (2017): e349-e356. doi: 10.1016/S2352-3018(17)30066-8.

[6] Lichtenstein, Gary R., Songkai Yan, Mohan Bala, Marion Blank, and Bruce E. Sands. "Infliximab maintenance treatment reduces hospitalizations, surgeries, and procedures in fistulizing Crohn's disease." Gastroenterology 128, no. 4 (2005): 862-869. doi: 10.1053/j.gastro.2005.01.048.

[7] Sandborn, William J., Paul Rutgeerts, Brian G. Feagan, Walter Reinisch, Allan Olson, Jewel Johanns, Jiandong Lu et al. "Colectomy rate comparison after treatment of ulcerative colitis with placebo or infliximab." Gastroenterology 137, no. 4 (2009): 1250-1260. doi:10.1053/j.gastro.2009.06.061.

[8] INVEGA TRINZA U.S. Prescribing Information, January 2019. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+TRINZA-pi.pdf.

[9] IMBRUVICA U.S. Prescribing Information, January 2019.
https://www.imbruvica.com/docs/librariesprovider7/default-document-library/prescribing-information.pdf.

[10] ZYTIGA U.S. Prescribing Information, April 2019. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ZYTIGA-pi.pdf.

[11] Bahlis, Nizar, Meletios A. Dimopoulos, Darrell J. White, Lotfi Benboubker, Gordon Cook, Merav Leiba, P. Joy Ho et al. "Three-Year Follow up of the Phase 3 Pollux Study of Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) Versus Lenalidomide and Dexamethasone (Rd) Alone in Relapsed or Refractory Multiple Myeloma (RRMM)." (2018): 1996-1996. doi: 10.1182/blood-2018-99-112697.

[12] DARZALEX U.S. Prescribing Information, June 2018. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/DARZALEX-pi.pdf.

[13] ERLEADA U.S. Prescribing Information, February 2018. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ERLEADA-pi.pdf.

This progress against some of the world's most challenging diseases is heartening but hard-won. Continued advancement will require perseverance and dedication. For example, we remain very committed to continuing research exploring new approaches and investigational medicines to prevent Alzheimer's dementia, which starts many years before the full onset of disease. In fact, we have invested billions of dollars in this area, and despite some significant projects that were halted because of lack of efficacy or a newly identified imbalance in benefit-risk, we continue to invest with the goal of conquering this major public health challenge in our lifetimes.

Defeating Alzheimer's would not only change the lives of millions of patients and their families, it would dramatically change the economic burden of the disease. According to one analysis, if a new treatment that delays the onset of Alzheimer's by just five years were approved by 2025, the U.S. would save an estimated $367 billion each year by 2050.[14]

In fact, across a wide range of conditions, prescription medicines play a key role in keeping people well and productive and preventing the need for costly procedures and hospitalizations. For example, since the introduction of antiretroviral therapies, we've seen up to a $402,000 lifetime cost savings for each HIV patient diagnosed at an early stage.[15] Cardiovascular medicines have led to a 27 percent reduction in costs for hospitalizations and procedures.[16] In fact, the U.S. healthcare system could save $213 billion annually with the correct use of prescription medications.[17][18]

But medicines can't make a difference if patients who need them can't get them. We understand concerns about the cost of healthcare. Although prescription medicines represent only 14 percent of overall healthcare spend – a figure that has remained relatively steady for the past decade and is projected to

[14] Alzheimer's Association. "Changing the Trajectory of Alzheimer's Disease: How a Treatment by 2025 Saves Lives and Dollars." May 2015. https://www.alz.org/media/Documents/changing-the-trajectory-r.pdf.
[15] Farnham, Paul G., Chaitra Gopalappa, Stephanie L. Sansom, Angela B. Hutchinson, John T. Brooks, Paul J. Weidle, Vincent C. Marconi, and David Rimland. "Updates of Lifetime Costs of Care and Quality-of-Life Estimates for HIV-Infected Persons in the United States: Late Versus Early Diagnosis and Entry Into Care." Journal of Acquired Immune Deficiency Syndromes 64, no. 2 (2013): 183-189. doi: 10.1097/QAI.0b013e3182973966.
[16] Gotto, Antonio M., Stephen J. Boccuzzi, John R. Cook, Charles M. Alexander, James B. Roehm, Gregg S. Meyer, Michael Clearfield, Stephen Weis, and Edwin Whitney. "Effect of Lovastatin on Cardiovascular Resource Utilization and Costs in The Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS)." The American Journal of Cardiology 86, no. 11 (2000): 1176-181. doi:10.1016/s0002-9149(00)01198-x.
[17] IMS Institute for Healthcare Informatics, "Avoidable Costs in U.S. Healthcare" (June 2013). http://offers.premierinc.com/rs/381-NBB-525/images/Avoidable_Costs_in%20_US_Healthcare-IHII_AvoidableCosts_2013%5B1%5D.pdf.
[18] Roebuck, M. C., J. N. Liberman, M. Gemmill-Toyama, and T. A. Brennan. "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending." Health Affairs 30, no. 1 (2011): 91-99. doi:10.1377/hlthaff.2009.1087.

remain so into the future[19] – and 90 percent of prescriptions are filled with generics[20], managing the cost of medicines, particularly what patients pay at the pharmacy counter, is important.

Our Approach to Pricing

At Janssen, we take a responsible approach to pricing that recognizes our dual responsibility to patients today and patients tomorrow. Patients today need access to our medicines. Patients tomorrow count on us to deliver cures and treatments for the most challenging, intractable diseases. When we set an initial price for our medicines, we balance:

- **Value to patients, the healthcare system, and society**. We consider how the medicine will improve patient health and assess its 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.
- **Affordable access to medicines for people who need them.** We want to ensure appropriate insurance coverage so that patients who are prescribed our medicines can get them.
- **Ability to develop future groundbreaking cures and treatments.** We have an obligation to ensure we have the resources necessary to invest in future R&D to address serious unmet medical needs.

The list price of a medicine is a starting point that is ultimately reduced by the substantial discounts, rebates, and fees we provide to insurance companies, pharmacy benefit managers ("PBMs"), government programs, and others. We pay required discounts to government programs, and we negotiate with private payers so that they will cover our medicines and make them available to patients with lower out-of-pocket cost. In 2018, we provided approximately $21 billion in discounts and rebates on our medicines – an overall reduction from list price of 47 percent. For some of our medicines, and for some of our customers, we pay discounts, rebates, and fees totaling well over 50 percent of our list price – so middlemen in the supply chain in those cases realize a majority of the revenue.

All told, while our 2018 aggregate list price increase was 6.3 percent,[21] for the second year in a row discounts and rebates outweighed that increase, and aggregate net price – in other words, the real price – decreased by 6.8 percent.[22]

[19] Altarum Institute, Center for Sustainable Health Spending Data Brief. "A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail." 2014 & Addendum update August 2015. http://altarum.org/sites/default/files/uploaded-publication-files/Non-Retail%20Rx%20Forecast%20Data%20Brief_with%20Addendum.pdf.

[20] IQVIA. "2017 Medicine Use and Spending in the U.S. a Review of 2017 and Outlook to 2022." April 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf.

[21] Represents the year-over-year change in the average list price, or wholesale acquisition cost ("WAC").

[22] Represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns.

Trends in Pharmaceutical Spending

The fact is that across the industry net prices for branded medicines have increased below the rate of medical inflation in 2013, 2014, and 2016.[23,24,25,26] In 2017, the total expenditure on pharmaceuticals in the U.S. grew by only 0.4 percent, compared to a 3.9 percent increase in overall health spending and a 4.6 percent increase in hospital spending.[27]

Unfortunately, these trends are not reflected in many patients' experiences at the doctor's office or pharmacy counter. According to IQVia (formerly QuintilesIMS), out of pocket costs for branded medicines increased 48% from 2013-2016.[28]

One reason patient out-of-pocket spending has grown is due to changes in how health insurance is designed and, specifically, how pharmaceutical benefits are managed. As one recent analysis shows, patients are required to pay 13 percent of overall pharmaceutical costs versus only 3 percent of hospital costs – even though medicine can help keep patients out of the hospital.[29]

The reality is that our health coverage system simply wasn't built in anticipation of medicines that treat diseases previously only treated with surgeries, hospitalizations and other complex interventions. Medicines today can extend and transform life for people facing very challenging, often relatively rare, diseases. It's critical that we work together to ensure that today's medicines are more accessible and affordable for patients while at the same time preserving the incredible ecosystem of medical innovation that has delivered so much and promises so much more.

Solutions to Address the Challenges We Face

Above all, we need an American solution to this American challenge. We must maintain the hallmarks that make American healthcare remarkable: access to innovative therapies, personal choice, and doctors and patients making decisions based on what is right for each individual.

At Janssen, we are committed to being part of the solution.

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[23] IQVIA INSTITUTE for Human Data Science. The Global Use of Medicine in 2019 and Outlook to 2023. Report. January 2019. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf.

[24] U.S. Department of Labor. Bureau of Labor Statistics. "CONSUMER PRICE INDEX – DECEMBER 2016." News release, January 18, 2017. https://www.bls.gov/news.release/archives/cpi_01182017.pdf.

[25] U.S. Department of Labor. Bureau of Labor Statistics. "CONSUMER PRICE INDEX – DECEMBER 2017." News release, January 12, 2018. https://www.bls.gov/news.release/archives/cpi_01122018.pdf.

[26] U.S. Department of Labor. Bureau of Labor Statistics. "CONSUMER PRICE INDEX – DECEMBER 2018." News release, January 11, 2019. https://www.bls.gov/news.release/pdf/cpi.pdf.

[27] U.S. Centers for Medicare and Medicaid Services. "NHE Fact Sheet." December 06, 2017. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.

[28] IQVIA INSTITUTE for Human Data Science. Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021. Report. May 2017. https://www.iqvia.com/institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016.

[29] PhRMA. "PhRMA Chart Packs: Biopharmaceuticals in Perspective." Report. 2018. https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018.

We believe open dialogue and partnership is essential to addressing the challenges in our healthcare system. That's why in 2016 we began issuing an annual Janssen U.S. Transparency Report, sharing information about how we invest our resources, price our medicines, and help people who need Janssen medicines get access to them. Just recently, we expanded our commitment to transparency, announcing plans to voluntarily include list price and potential patient out-of-pocket costs in our pharmaceutical direct-to-consumer TV advertising, starting with our most frequently prescribed medicine.

These more recent steps build on a legacy of commitment to transparency at Janssen. For example, we believe that making clinical trial data available 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 healthcare decisions for patients. In a first-of-its-kind agreement with the Yale University School of Medicine, we share clinical trial data through the Yale Open Data Access (YODA) Project. Since 2014, YODA Project has served 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 research to increase medical knowledge and improve public health.

In the same spirit of open dialogue and partnership, we have consistently brought forward ideas and perspectives to both Congress and the Administration, with the goal of building on what is working in our healthcare system while fixing what is not:

Part D Out-of-Pocket Cap

While Medicare Part D is working for many seniors and has been effective in containing costs, we believe an out-of-pocket cap in Medicare Part D is a needed protection. Without a cap, Medicare beneficiaries face unlimited out-of-pocket expenses, and, as research shows, high out-of-pocket costs reduce patient adherence to prescribed treatments and make them more likely to abandon their prescriptions. Poor patient outcomes related to lack of adherence or abandonment of prescribed treatments can lead to an increase in overall healthcare costs.

Individual and group health insurance policies are already required to have out-of-pocket caps. We believe that Medicare, which serves some of the sickest and most vulnerable patients and is essential to the health of American seniors, should also have that protection. We have been working on policy approaches that would make it possible to implement an out-of-pocket cap in a fiscally responsible way without creating new costs or access barriers for patients. As Congress considers any changes to Part D, we look forward to discussing these ideas in more depth.

Medicare Part B Reform

We believe policy solutions in Medicare Part B should meet three objectives: 1) reduce cost and spending; 2) increase competition; and 3) remove incentives to prescribe higher cost therapies without causing significant disruption to physicians or patient care.

As changes to Part B are contemplated, it is important to remember that Medicare currently benefits from aggressive negotiations in the commercial market through the Average Sales Price (ASP) mechanism. Any reform should therefore leverage the benefits of the existing system.

In our response to the Health and Human Services advance notice of proposed rulemaking regarding Part B, we proposed an option that would allow Medicare to continue to achieve the negotiated cost savings of the free market, reduce Part B acquisition cost under the ASP-based model, and reimburse all stakeholders on a fee-based mechanism aligned with the services that they provide. Our proposal aims to eliminate incentives for selecting higher list price drugs while maintaining current Part B patient access to appropriate clinical care.

Rebate Reform

We support reforms to the rebate system that restructure incentives to ensure patients benefit from a competitive marketplace and see lower out-of-pocket costs. In 2017, the pharmaceutical industry paid $150 billion in negotiated rebates and discounts.[30] As we have noted, too often these rebates and discounts are not shared with patients, leaving the sickest patients paying higher out-of-pocket costs. We anticipate eliminating rebates could result in lower list prices, provided these rebates and discounts are not replaced with equally high fees or other payments demanded by middlemen. We also strongly advocate that beneficiary copays be based on net price.

Altering the current rebate structure would be a major change to the entire pharmaceutical supply chain. It would need to be done thoughtfully and carefully to avoid disruption for patients. We look forward to commenting on the Administration's proposed rule in this area.

Value-Based Care

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 surgeries that provide limited value or may not even be needed, driving up healthcare costs without actually improving patient health.

At Janssen, we're working with partners throughout the healthcare system to encourage more results-based healthcare approaches. While we have negotiated several value-based contracts, current policy often limits our ability to implement creative solutions. To address policy barriers, we support the following measures:

- Establish safe harbors in the federal Anti-Kickback Statute that better enable manufacturers to partner with payors and share risk; and,
- Clarify Medicaid pricing treatment, including existing Medicaid best price requirements that inhibit companies from offering arrangements that may yield lower price in some circumstances.

Promoting Competition on a Level Playing Field

Biosimilars – near copies of biologic medicines – have the potential to increase competition and bring down costs, which is why Janssen has long supported a patient-focused, science-based regulatory framework for biosimilars.

[30] Adam J. Fein. "The Gross-to-Net Bubble Topped $150 Billion in 2017." Drug Channels (April 24, 2018) (citing IQVIA INSTITUTE for Human Data Science. Medicines Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022. Report. April 2018. https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

Some stakeholders have called for government to drive uptake by creating further incentives for biosimilars. But policies designed to increase share for biosimilar manufacturers would distort the competitive environment and risk limiting the savings biosimilars deliver to patients and taxpayers. We saw this risk realized most recently in the 340B Drug Discount Program, where policy designed to encourage the use of biosimilars had the unfortunate effect of increasing cost to patients, including low-income patients who can least afford it, and to taxpayers.[31]

When it comes to making more biosimilars available for patients and their physicians, competition, not government intervention, is the best approach. And that approach is working. Not only is competition driving prices down for both innovator biologics and biosimilars, the biosimilars pipeline is strong. Competition on a level playing field will keep it that way.

340B Policy

At Janssen, we recognize that the 340B Drug Discount Program plays an important role in the healthcare system, helping to ensure that low-income, needy patients have appropriate access to medicine. However, Congressional oversight, proper implementation, and equitable application of the program are essential to ensuring the 340B program is helping those it was designed to help.

Under the 340B Drug Discount Program, we are required to provide significant discounts on certain medicines purchased by 340B covered entities (comprised of specific categories of hospitals, clinics, and health centers that meet federal eligibility requirements). Growth in the 340B program has been well documented, and Janssen has experienced significant growth in this highly discounted channel as well. Although the program was intended to benefit needy patients, the facilities themselves receive the discounts. There is no requirement that 340B covered hospitals pass along those discounts to patients. 340B covered hospitals can therefore access 340B pricing on outpatient drugs for all of their patients, including wealthy and well-insured patients.

A more direct and accountable link between the provision of the discount and patient access is needed. We believe the benefits of the program should flow more directly and transparently to needy patients. We support efforts to strengthen the 340B program through greater transparency and increased clarity and accountability for all stakeholders. These goals can be achieved through the establishment of clear, reasonable and auditable rules including a clear definition of “patient” as well as hospital eligibility criteria.

Conclusion

We are here today at a moment of incredible hope, on the verge of extraordinary progress that could change our lives and the lives of our children and grandchildren. We have the opportunity to get this right for Americans today and for future generations. At Janssen, we are committed to bringing that promise to life with transformational medical innovation.

[31] Center for Biosimilars. “340B Changes: What Biosimilar Manufacturers Need to Know.” Feb. 19, 2018 https://www.centerforbiosimilars.com/contributor/amanda-forys/2018/02/340b-changes-what-biosimilar-manufacturers-need-to-know.