DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

FOIA Case No.: 2019-00704-FOIA-OS
FOIA Case No.: 2019-00705-FOIA-OS
FOIA Case No.: 2019-00708-FOIA-OS
American Oversight v. HHS, 19-cv-2577-RCL

November 25, 2019

Sent via email
Sara Creighton
American Oversight
1030 15th Street NW, B255
Washington, DC 20005
foia@americanoversight.org

Dear Ms. Creighton:

This letter is in final response to the March 18, 2019, Freedom of Information Act (FOIA) requests to the U.S. Department of Health and Human Services (HHS). Specifically, you requested the following records:

1. FOIA 2019-00704: Ethics Request. All records from January 29, 2018, to the date the search is conducted, reflecting communications (including emails, email attachments, text messages, messages on messaging platforms (such as Slack, GChat or Google Hangouts, Lync, Skype, or WhatsApp), telephone call logs, calendar invitations, calendar entries, meeting notices, meeting agendas, talking points, any handwritten or electronic notes taken during any oral communications, summaries of any oral communications, or other materials reflecting communications) between Secretary Alex Azar or any person communicating on his behalf, such as schedulers or assistants, and any of the individuals or entities listed below:
    a. Eli Lilly and Company
    b. Lilly USA, LLC
    c. Healthcare Leadership Council
    d. HMS Holding, Inc.
    e. Biotechnology Innovation Organization
    f. Seraphim Strategies, LLC

2. FOIA 2019-00705: Brand-Name Drug Companies Request. All communications (including emails, email attachments, text messages, calendar invitations, calendar entries, meeting notices, meeting agendas, or talking points), as well as any summaries of or notes taken during any oral communications, between Secretary Alex Azar or any person communicating on his behalf, such as schedulers or assistants, and any individuals associated with the entities listed below:
    a. Johnson & Johnson
    b. Pfizer

c. Novartis
d. Sinopharm Group
e. Roche
f. Sanofi
g. GlaxoSmithKline
h. Merck & Co
i. Bayer
j. Gilead Sciences
k. AbbVie
l. Amgen
m. AstraZeneca
n. Bristol-Myers Squibb
o. Boehringer Ingelheim
p. Takeda

3. FOIA 2019-00708: Indiana Drug Companies Request. All communications (including emails, email attachments, text messages, calendar invitations, calendar entries, meeting notices, meeting agendas, or talking points), as well as any summaries of or notes taken during any oral communications) between Secretary Alex Azar or any person communicating on his behalf, such as schedulers or assistants, and any individuals associated with the entities listed below:
    a. Assembly Biosciences
    b. Apexian Pharmaceuticals
    c. Baxter BioPharma Solutions
    d. Catalent
    e. Endocyte
    f. Evonik
    g. Exelead
    h. KP Pharmaceutical Technology
    i. Lannett
    j. Mead Johnson
    k. Novo Nordisk
    l. PD Pharmatech
    m. IQVIA
    n. AIT Bioscience
    o. Anagin
    p. Maetrics
    q. Theratome Bio

In lieu of providing domain names to be searched, you subsequently requested a search for the names of the individuals and entities themselves in full-text in the "Subject" lines and body text of email communications, and also search for any additional domain names associated with the individuals or entities listed HHS may identify in the course of its search. Also the requests sought communications beyond emails, and thus HHS's search should include full-text searches of other record types as well.

In order to search for records responsive to your request, our office sent your request to several offices, including the HHS Office of the Chief Information Officer, Information Technology Infrastructure Operations, which conducted an electronic search for Outlook email messages.
For this response, the Department processed 222 pages of potentially responsive records captured in the agency's search. Of these 222 pages, I am releasing 52 pages in their entirety, 19 are being disclosed in part, with portions redacted pursuant to Exemptions 4 and 6 of the FOIA (5 U.S.C. §552 (b)(4); (b)(6)). I am withholding 19 pages in their entirety pursuant to Exemption 4 of the FOIA (5 U.S.C. §552 (b)(4)). Finally, I have determined that 128 pages are not responsive to your request.

FOIA exemption (b)(4) protects "trade secrets or commercial or financial information obtained from a person [that is] privileged or confidential." This exemption is intended to protect the interests of both the government and submitters/owners of information. The exemption covers two distinct categories of information in federal agency records: (1) trade secrets; and (2) information that is (a) commercial or financial, and (b) obtained from a person, and (c) privileged or confidential. Collectively, these two categories are commonly referred to as Confidential Business Information.

FOIA exemption (b)(6) permits a Federal agency to withhold information and records about individuals in "personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." The definition of "similar files" has historically been broadly interpreted to include a wide variety of files, and the United States Supreme Court has held that Congress intended the term "similar files" to be interpreted broadly, rather than narrowly. I have analyzed these records and find they meet the threshold requirement of this exemption. Additionally, I have reviewed and weighed the public interest in disclosure of this information against the privacy interest in nondisclosure, and found that the privacy interest outweighs the public's interest in disclosure.

Should you have questions or concerns regarding the Department's response and\or the processing of your request, any such issues should be communicated to your legal counsel and Department of Justice Attorney representing the Department in this matter.

Sincerely,

Brandon J. Gaylord
Supervisory Government Information Specialist and
HHS FOIA/PA Public Liaison

Enclosure: 90 Pages

From:	Manji, Husseini [JRDUS] <(b)(6)@its.jnj.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Important Potential G7 Mental Health Initiative
Date:	2018/02/20 10:33:19
Priority:	Normal
Type:	Note

Dear Secretary Azar,

Your speech last week addressing the tragedy in Parkland, Florida was a bright spot in the midst of all the terrible news. I was so heartened to hear you say that, under your direction, HHS will be "laser focused" on addressing serious mental illness in the United States. I am reaching out to you today specifically about a mental health issue that I hope is of mutual interest to us both.

(b)(6)

I should stress from the outset that while J&J has an outstanding request to meet with you, the purpose of my e-mail today is completely separate.

I wanted to apprise you of an important G7 Mental Health initiative that a group of committed multidisciplinary stakeholders is currently developing. The Initiative would benefit significantly from your support and attention.

The G7 Mental Health Initiative is patterned after the UK's G7 Dementia Initiative, spearheaded by Prime Minister Cameron. About four years ago, UK Prime Minister Cameron hosted a G7 Dementia Summit that I participated in. This effort galvanized the work being done in this area, and in a very short time produced numerous tangible advances in the research, treatment, and care of patients with Alzheimer's Disease (see a couple of brief attached slides). Many in the global mental health community believe that a G7 Mental Health Initiative would similarly produce worthwhile—perhaps even transformative—results in the field of mental health. Indeed a group of diverse stakeholders has already reached out to Canadian Government officials, including Prime Minister Justin Trudeau (Canada holds the G7 Presidency in 2018). We have also had a number of positive interactions with key figures in other G7 countries. While these officials have expressed widespread enthusiasm and recognition of the need for mental health reform, Canada has yet to name the Initiative as one of their formal G7 pillars.

The proposed initiative involves five major themes. The attached brief provides more details, but in summary they include:

1. • Addressing the impact of mental illness on **military service members, first responders, and their families**;
2. • Generating **sustainable funding** to advance biomedical and care research;
3. • Empowering youth and focusing on the growing **mental health demands of young people** as they build the foundation for successful careers and independent lives;
4. • Engaging employers to recognize the **impact of mental illness in the workplace** and respond to the needs of their employees dealing with mental illness personally or within their families;
5. • Constructing a comprehensive response to reduce mental illness in **vulnerable and underserved populations.**

The G7 Initiative represents one way for multiple stakeholders across multiple countries to come together to address the effects of mental illness across the globe, and has the potential to make a real difference in the lives of individuals with serious mental illnesses. Inadequate mental health diagnosis and care unfortunately have such a deep and multi-faceted societal impact. I believe that it is imperative to do more to address these unmet medical needs, and my interactions with so many other concerned parties leads me to believe that there is considerable global support for such an initiative.

As we move forward with the G7 Initiative, we certainly hope to have your support. Perhaps the next step could be to arrange a meeting with the global health leaders in HHS in order to discuss the Initiative further, particularly how you personally, and the HHS more globally, could participate. For instance, we would ideally hope that you would be willing to reach out to your counterparts in the Canadian government, Minister of Health Petitpas Taylor ((b)(6)@canada.ca), and Peter Boehm ((b)(6)@international.gc.ca), Deputy Minister for the G7 Summit and Personal Representative of the Prime Minister.

I would welcome any opportunity to further discuss this Initiative—and any other topics of mutual importance to both of us—at your convenience.

Kind regards

Husseini K Manji, MD, FRCPC
Global Therapeutic Head, Neuroscience
Johnson &Johnson Pharmaceuticals Group
1125 Trenton-Harbourton Road, E32000
Titusville, NJ 08560

Phone: 609-730-2968
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E-mail: (b)(6) @its.jnj.com

Sender:	Manji, Husseini [JRDUS] <(b)(6)@its.jnj.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2018/02/20 10:13:00
Delivered Date:	2018/02/20 10:33:19

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February 20, 2018

Re: G7 Mental Health Initiative

Dear Secretary Azar,

Your speech last week addressing the tragedy in Parkland, Florida was a bright spot in the midst of all the terrible news. I was so heartened to hear you say that, under your direction, HHS will be "laser focused" on addressing serious mental illness in the United States. I am reaching out to you today specifically about a mental health issue that I hope is of mutual interest to us both.

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Kind regards

Husseini K Manji, MD, FRCPC
Global Therapeutic Head, Neuroscience

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State of Public Policy – Achievements Since G8/G7 Leadership

G8 Dementia Summit Declaration Commitments	Examples of Outcomes
Greater innovation	• Accelerated Medicines Partnership (AMP) (US) launched • GAP, EPAD, JPAD and TRC-PAD formed
Increase funding	• UK and industry collaborate to form The Dementia Discovery Fund; Bill Gates joins • £250m UK Dementia Research Institute (alongside AS, ARUK) • US funding increases from approx $500M in 2013 to approx $1.3B in 2017
Sharing information	• GAAIN is launched • Canadian Consortium on Neurodegeneration in Aging is launched • OECD, with International Neuroinformatic Coordinating Facility, convene policy-makers, funders, scientists and publishers to consider the barriers to data sharing in relation to dementia research and identify practical steps to promote data sharing
Co-ordinated international research plan	• WHO surveyed government agencies to map research landscape and hosted 2,000 person research forum • JPND 2015 call for collaborative research proposals (EUR $40M) and increases number of countries engaged • ResearchersAgainstAlzheimer's expands to focus on G7 (and now G20) and develops annual pipeline report
Open access to research	• NIH launches The National Institute on Aging *Genetics of Alzheimer's Disease Data*
Examine national incentive structure for research	• OECD completes analysis of current research funding levels and identifies challenges • NIA investment in prevention trials begin • IMI Alzheimer's Research platform launched

State of Public Policy – Achievements Since G8/G7 Leadership

G8 Dementia Summit Declaration Commitments	Examples of Outcomes
Hold a series of high-level legacy events	• Held in UK, Japan and Canada (with France) • First WHO Ministerial held (Mar 2015) • Annual convenings and scientific symposia expand focus on G7 priorities (e.g., AAIC, CTAD, Lausanne Dialogues)
WHO and OECD attention to dementia	• WHO Action Plan • The OECD and WHO develop a framework to support countries in improving their policies for people with dementia • 'New perspectives and approaches to understanding dementia and stigma' issued by the OECD in Japan in November 2014
Call upon the UN Independent Expert to integrate dementia into their work	• UN adds dementia as part of the position's mandate
All sectors to treat people affected with dignity and respect	• Dementia Friendly Cities expands (Japan) and launches in new countries (UK, US and others) • New Orange Plan (JAP) is announced
Global efforts to reduce stigma	• GAP, EPAD and JPAD address barriers to clinical trials, including stigma • Recruiting Older Adults into Research (ROAR) (US) launched • Increased trial participation in the UK through Join Dementia Research launched in UK – 20% PWD recruited by 2020 • Dementia Envoy appointed and World Dementia Council formed
Meet in the US in February 2015 to review progress	• Completed

The Global Initiative to Transform Mental Health

A Global Movement at the Most Critical Time

There is no health or economic development without mental health, yet mental illness is *the* leading cause of both human suffering *and* global economic loss. The costs for mental disorders are greater than the costs of diabetes, respiratory disorders, and cancer *combined*. Fortunately, advances in neuroscience, technology, and policy, combined with a growing mental health advocacy movement, especially among youth, have set the stage for dramatic change across the world. **What's needed now is a sustained commitment from governments across the globe, leading global organizations such as the Group of Seven (G7) and Group of 20 (G20) or other international leaders to translate these positive trends into a cascade of progress.**

Mental health has an irrefutably deep impact on the economy and is a barrier to achieving inclusive and sustainable economic growth. A group of health economists commissioned by the World Economic Forum estimated mental disorders as the largest cost driver at $2.5 trillion in global costs in 2010 and projected costs of $6 trillion by 2030. This is partly because mental illness is very common – one out of four people experience mental illness at some point in their lives – but also because most do not receive adequate treatment due to stigma, lack of access, and other factors. Because most mental illness begins in adolescence, these effects can last a lifetime, resulting in loss of hope, productivity, and economic growth that is further amplified in our increasingly knowledge-based economy.

Leadership to Effect Change

To this end, *The Global Initiative to Transform Mental Health* seeks to build a multi-sectoral alliance of governments, civil society, academia and private sector dedicated to providing leadership on mental health. The goal is that, through this collaboration, the *Global Initiative* **will reduce suicide, psychosis, and mental illness-related disability by 50% by 2030**. Through extensive consultations with leading mental health experts, the following five areas have been identified for focus and will lay the foundation for achieving this goal, including:

1. Addressing the impact of mental illness on **military service members, first responders and their families**;
2. Generating **sustainable funding** to advance biomedical and care research;
3. Empowering youth and focusing on the growing **mental health demands of young people** as they build the foundation for successful careers and independent lives;
4. Engaging employers to recognize the **impact of mental illness in the workplace** and respond to the needs of their employees dealing with mental illness personally or within their families;
5. Constructing a comprehensive response to reduce mental illness in **vulnerable and underserved populations**

These five areas represent a starting point for building a comprehensive response to mental illness, but this does not represent the full focus. As the *Global Initiative* moves forward and gains additional input the reach will increase as well.

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*For the first time in recorded history, **the leading cause of death** for girls ages 15-19 worldwide is suicide.*

Why Now? The Opportunity to Improve Mental Health and Wellness

Growing awareness of the scope and scale of mental health challenges has led to the emergence of many innovative efforts that address mental health stigma and foster inclusive growth. For instance, millennials and their families are using social media to counter the stigma that for generations has prevented people from talking about their illnesses and seeking treatment. In the scientific community, the secrets of the brain are rapidly yielding to what is already being called "the golden age of neuroscience." The importance of mental health during and following pregnancy has improved maternal and child wellbeing thanks to the leadership of The World Health Organization in some of the hardest hit geographies in the developing world. In the workplace, public and private employers are seeking to improve employee engagement and wellbeing through healthy, culturally safe workplaces that enable inclusive growth amongst the middle-class. Lastly, policymakers and payers are eager to develop preventive treatments that bend the long-term cost curve.

The World Health Organization estimates that mental illness generates $2.5 trillion in annual global costs. And this number is set to grow to $6 trillion by 2030 if we don't act. ***The goal of reducing death and disability by 50% would be a global economic driver.***

Reflecting these developments, the World Bank and the World Health Organization held the first-ever joint conference on mental health, looking at ways for finance and health ministers to work together to address this international economic and health challenge. The United Nations also recently included mental health for the first time in its global development goals.

The truly good news is that previous experience and action on mental health has revealed what works: greater awareness and anti-stigma campaigns, early intervention, integration of primary and specialty care, and using data and technology to drive better outcomes and more fruitful research. While it's true we still don't know enough about mental illness, we also don't do enough with what we already know. In fact, with comprehensive, science-based treatments, most people with mental illness recover. Knowing this makes the current data about lack of treatment especially unacceptable. In contrast to so many areas of medicine in which our biggest burden is lack of effective treatments, the area of mental illness presents the challenge of bridging the gap between what we already know and what we *actually do* with that knowledge.

With the right kind of leadership, the *Global Initiative* can ensure that recent positive developments are ignited to reduce stigma and trigger a cascade of progress in the treatment of mental health disorders, which have emerged as the public policy challenge of the 21st century.

Transforming Mental Health on a Global Scale

When global leaders commit to our largest societal issues, important progress is made. For example, the global fund for HIV-AIDS was critical to driving down the prevalence of this infectious disease. The creation of a new Alzheimer's research platform resulted in new funding (see case study below).

Through coordinated, comprehensive collaboration, the *Global Initiative* can formalize a mutual commitment to mental health and inspire innovation and action. Without this catalyst, we will continue to see loved ones suffer from mental illness, families struggle to respond, and governments fail to meet the growing needs of this community

G7 Alzheimer's Leadership: A Case Study

In 2013, faced with the rising rates of Alzheimer's disease and dementia and lack of global action, Prime Minister Cameron leveraged his then-G8 presidency to create a global, multi-sectoral group of leaders from government, academia, the research community, the private sector, finance, medicines regulation, patient advocacy, and, critically, persons with lived experience of dementia. Britain's Minister of Health was appointed as liaison, and the group was tasked with developing a work program to identify areas where a global effort could have the most impact. As a result, G7 countries and multi-sectoral leaders from around the world committed to innovation and investing in and collaborating towards a cure. Immediate and notable success included: rapid increase in research funding in UK, but also roughly doubling the US Alzheimer's research budget, the creation of a global public-private research fund and a multi-country commitment to de-stigmatization campaign. Progress continues as new funds flow to Alzheimer's biomedical and care research. And most recently, in May 2017, WHO led a declaration committing all WHO member states to make dementia a priority.

The *Global Initiative's* goal is bold. But it is also important and achievable with concerted effort and high-level leadership and critical to the goal of fostering inclusive growth and reducing mental health stigma. **You can support *The Global Initiative to Transform Mental Health* by calling for increased global action, driving new collaborations and encouraging others to do so as well.**

From:	Marlene Colucci <(b)(6)@businesscouncil.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
CC:	Adams, Jane [JJCUS] <(b)(6)@its.jnj.com>; Adrienne Ball <(b)(6)@businesscouncil.com>; HHS Secretary (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e3fce8f00194d8d94fc91094888d811-HHS Secreta>
Subject:	Invitation to the Business Council Spring Reception/Dinner on Thursday May 17 at 6:30pm - Secretary Alex Azar
Date:	2018/05/04 21:56:18
Priority:	Normal
Type:	Note

Dear Secretary Azar,

On behalf of the Chairman of The Business Council, Henry Kravis, and Vice Chairman, Alex Gorsky, I would like to extend an invitation to you and your spouse to join us as a "special guest" for our reception and dinner at the National Museum of African American History and Culture on Thursday, May 17.

Our members would welcome the opportunity to spend time with you while they are in town.

I am attaching a formal letter of invitation as well as a list of members scheduled to attend and a one pager for your ethics department.

Please let me know if you are able to join us at your earliest convenience.

Warmest regards,

Marlene

Sender:	Marlene Colucci <(b)(6)@businesscouncil.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Adams, Jane [JJCUS] <(b)(6)@its.jnj.com>; Adrienne Ball <(b)(6)@businesscouncil.com>; HHS Secretary (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e3fce8f00194d8d94fc91094888d811-HHS Secreta>
Sent Date:	2018/05/04 21:54:17
Delivered Date:	2018/05/04 21:56:18

THE BUSINESS COUNCIL

May 2, 2018

The Honorable Alex M. Azar II
Secretary of Health & Human Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary,

The Spring Business Council meeting is taking place in Washington, DC from May 17-18, 2018. Our meeting with the CEOs of the world's most important business enterprises will examine the future of democracy and explore the major policy shifts taking place in our nation's capital over the past year.

We would be honored to have you and your spouse join us for our Spring Reception and Dinner on Thursday May 17, 2018 at the National Museum of African American History. The reception will begin at 6:30 PM and the seated dinner at 7:30 PM followed by a "fireside chat" with a special guest. Dinner is by assigned seating so we will need to know by Friday, May 11th if you are able to join us.

As you know, The Business Council is comprised of the chief executive officers of America's largest corporations, representing all sectors of the economy (*see attached list of members*). Created in 1933 by President Roosevelt, the Council seeks to foster understanding through discussion, best practice sharing and networking by its members with a view to making a contribution to our society, the global economy and to business generally. All conversations are off the record and closed to press. For your convenience, I have attached some information that I hope will be helpful to your Ethics Counsel.

I very much appreciate your consideration of my invitation. If you have any questions please contact me or our Executive Director, Marlene Colucci, at (b)(6) @businesscouncil.com or (202) 298-7650.

Regards,

Alex Gorsky
Vice Chair

Name	Title & Company
Richard C. Adkerson	President & CEO, Freeport-McMoRan Inc.
Samuel R. Allen	Chairman & CEO, Deere & Company
Mukesh D. Ambani	Chairman & Managing Director, Reliance Industries Limited
Stephen F. Angel	Chairman, President & CEO, Praxair, Inc.
Craig Arnold	Chairman & CEO, Eaton
Douglas M. Baker , Jr.	Chairman & CEO, Ecolab Inc.
Ajay S. Banga	President and CEO, MasterCard
Mary T. Barra	Chairman & CEO, General Motors Company
Alain Bellemare	President & CEO, Bombardier
Marc Benioff	Chairman & CEO, Salesforce.com
Aneel Bhusri	Co-Founder and Chief Executive Officer, Workday, Inc.
Lloyd C. Blankfein	Chairman & CEO, The Goldman Sachs Group, Inc.
Gail K. Boudreaux	President & CEO, Anthem, Inc.
Gregory H. Boyce	Retired Chairman & CEO, Peabody Energy Corporation
Thierry Breton	Chairman and CEO, Atos
Bruce D. Broussard	President and CEO, Humana
Steven A. Burd	CEO, Burd Health
Debra A. Cafaro	Chairman & CEO, Ventas, Inc.
Marc N. Casper	President & CEO, Thermo Fisher Scientific Inc.
Andrew Cecere	President and CEO, U.S. Bancorp
Michael L. Corbat	Chief Executive Officer, Citigroup Inc.
David M. Cordani	President & CEO, Cigna Corporation
Marijn E. Dekkers	Chairman, Unilever
Michael S. Dell	Chairman & CEO, Dell Technologies
David B. Dillon	Retired Chairman & CEO, The Kroger Co.
Mary Dillon	Chief Executive Officer, Ulta Beauty
James Dimon	Chairman & CEO, JPMorgan Chase & Co.
Arnold W. Donald	President & CEO, Carnival Corporation
John J. Engel	Chairman, President & CEO, WESCO International, Inc.
Roger Ferguson ,Jr.	President & CEO, TIAA
Lance M. Fritz	Chairman, President and CEO, Union Pacific Corporation
Seifi Ghasemi	Chairman, President and CEO, Air Products
Daniel Gilbert	Founder and Chairman, Quicken Loans
Gregory J. Goff	Chairman, President & CEO, Andeavor
James Goodnight	Chairman, President and CEO, SAS Institute Inc.
Ilene S. Gordon	Chairman, Ingredion Incorporated
James P. Gorman	Chairman & CEO, Morgan Stanley
Alex Gorsky	Chairman & CEO, Johnson & Johnson
Donald E. Graham	Chairman of the Board, Graham Holdings Company
John H. Hammergren	Chairman & CEO, McKesson Corporation
Gregory J. Hayes	Chairman & CEO, United Technologies Corporation
John B. Hess	CEO, Hess Corporation
Daniel R. Hesse	Former CEO, Sprint Corporation
Jacqueline C. Hinman	Former Chairman and Chief Executive Officer, CH2M

Name	Title & Company
Vicki Hollub	President & CEO, Occidental Petroleum Corporation
Mark Hurd	Chief Executive Officer, Oracle
Pablo Isla	Chairman & Chief Executive Officer, Inditex, S.A.
Bradley S. Jacobs	Chairman & CEO, XPO Logistics
Robert L. Johnson	Founder & Chairman, The RLJ Companies
Josef Kaeser	President & CEO, Siemens AG
Steven A. Kandarian	Chairman, President & CEO, MetLife, Inc.
Robert A. Kotick	President & CEO, Activision Blizzard Inc.
Henry R. Kravis	Co-Chairman and Co-CEO, Kohlberg Kravis Roberts & Co.
Ellen J. Kullman	Retired Chair of the Board & CEO, DuPont
Michael Lamach	Chairman & CEO, Ingersoll-Rand
Ryan M. Lance	Chairman and Chief Executive Officer, ConocoPhillips
Andrew N. Liveris	Chairman and CEO, The Dow Chemical Company and Director and Former Executive
David H. Long	Chairman & CEO, Liberty Mutual Insurance
Mario Longhi	Retired President & Chief Executive Officer, United States Steel Corporation
Michael H. McGarry	Chairman and CEO, PPG Industries, Inc.
W. James McNerney ,Jr.	Retired Chairman & CEO, The Boeing Company and Senior Advisor, Clayton, Dubilier &
Ken Moelis	Chairman & Chief Executive Officer, Moelis & Company
Beth E. Mooney	Chairman & CEO, KeyCorp
Shantanu Narayen	Chairman, President and CEO, Adobe Systems Incorporated
Robert L. Nardelli	Founder, XLR-8, LLC
Robert A. Niblock	Chairman & CEO, Lowe's Companies, Inc.
Takeshi Niinami	President & CEO, Suntory Holdings Limited
Bhavesh V. Patel	Chief Executive Officer, LyondellBasell Industries
Charles Phillips	Chief Executive Officer, Infor
Patrick Pouyanné	Chairman & CEO, Total S.A.
Azim H. Premji	Chairman, Wipro Limited
Denise L. Ramos	Chief Executive Officer and President, ITT Inc.
Ian C. Read	Chairman and Chief Executive Officer, Pfizer Inc.
Matthew K. Rose	Executive Chairman, BNSF Railway Company
David M. Rubenstein	Co-Founder and Co-Executive Chairman, The Carlyle Group
Stephen W. Sanger	Retired Chairman & CEO, General Mills, Inc.
Alan D. Schnitzer	Chairman and Chief Executive Officer, The Travelers Companies, Inc.
David T. Seaton	Chairman and Chief Executive Officer, Fluor Corporation
Frederick W. Smith	Chairman, President & CEO, FedEx Corporation
Brad Smith	Chairman & CEO, Intuit Inc.
Nancy C. Southern	Chair, President & CEO, ATCO Ltd. & Canadian Utilities Limited
Lee J. Styslinger III	Chairman & CEO, Altec, Inc.
Mark S. Sutton	Chairman & CEO, International Paper
Lip-Bu Tan	Chief Executive Officer, Cadence Design Systems
James Teague	Chief Executive Officer, Enterprise Products Partners L.P.
Kent J. Thiry	Co-Chairman and CEO, DaVita Inc.
Bernard J. Tyson	Chairman and CEO, Kaiser Permanente
Ben van Beurden	Chief Executive Officer, Royal Dutch Shell plc

Name	Title & Company
Al Walker	Chairman, President & CEO, Anadarko Petroleum Corporation
Lisa W. Wardell	President & CEO, Adtalem Global Education
Wendell P. Weeks	Chairman & CEO, Corning Incorporated
Darryl White	Chief Executive Officer, BMO Financial Group
James Whitehurst	President & CEO, Red Hat
Maggie Wilderotter	Chairman & CEO, The Grand Reserve Inn
Thomas L. Williams	Chairman & CEO, Parker-Hannifin Corporation
Michael K. Wirth	Chairman & CEO, Chevron Corporation
Patricia A. Woertz	Retired Chairman & CEO, Archer Daniels Midland Company

INFORMATION FOR GOVERNMMENT INVITEES

The following information is provided for government officials invited to attend Business Council receptions and dinners to assist them, and their designated ethics officials, in determining whether their acceptance of the invitation would comply with applicable gift, conflicts of interest and other ethics-related laws, rules and policies. Included below is the information typically sought in connection with making these determinations, but if any additional information is required, please contact the Business Council's Executive Director, Marlene M. Colucci, at 202.298.7650 or (b)(6)@businesscouncil.com.

- The Business Council ("Council") is a membership organization comprised of chief executive officers representing a cross-section of *Fortune 500* companies (membership list attached). It is a nonprofit corporation exempt from taxation under Section 501(c)(6) of the Internal Revenue Code.

- The purpose of the Council is to provide its membership with a medium to interact, share information and exchange views regarding corporate "best practices" and consequential public policy issues. In regards to the latter, the Council seeks to enhance member understanding and facilitate a constructive dialogue that will lead members to reach a consensus position. The Council accomplishes this through its sponsorship of three programs a year, each focused on a different issue. Each program includes a reception immediately followed by a dinner for Council members and guests.

- In addition to Council members, other attendees typically include Council staff, and a number of "special guests," who are invited because of their expertise and experience to present their perspective on the program topic and to engage with Council members. The Council's special guests have included high-level government officials (*e.g.*, senior White House and Cabinet officials and members of Congress), noted academics, scientists, and physicians, and other leading business and social innovators.

- The Council is not a federally registered lobbying organization. It does not advocate for or against *any* policy or position; rather, it serves as a catalyst for promoting informed discussion and developing a consensus view among members on select public policy issues.

- Invitations to Council dinners and receptions are extended by Council staff or designated Council members acting as such -- not by lobbyists or other third parties.

- Those attending Council dinners and receptions are generally accompanied by a spouse or other guest.

- All event costs are paid with Council dues and by no other persons (*i.e.*, individuals, corporation or organizations). Tickets are not sold for Council events, and there is no charge or registration fee for attendance. The combined estimated fair market value, based on the per person cost, of the food and refreshment offered at the dinner and reception on Thursday evening is approximately [$130.00].

- Government attendees are not provided or reimbursed for their travel to the event.

From:	Gorsky, Alex [JJCUS] <(b)(6)@its.jnj.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
CC:	Fowler, Liz [JJCUS] <(b)(6)@ITS.jnj.com>; Torok, Kathy [JJCUS] <(b)(6)@its.jnj.com>
Subject:	Meeting with Johnson & Johnson
Date:	2018/07/23 17:05:13
Priority:	Normal
Type:	Note

Dear Secretary Azar:

I am writing to follow up on conversations that some of our Johnson &Johnson leaders have been having with HHS leaders about improving affordable patient access to medicines. As you know, we strongly share the Administration's goals of reducing healthcare costs while improving quality and efficiency of care, and we have been developing innovative reform proposals to achieve these goals. I would appreciate an opportunity to meet with you as soon as possible to discuss these ideas.

At J&J, we take a responsible approach to prescription drug pricing. We have not recently taken list price actions, and we have no imminent plans to take price actions. In 2017 the average net price change of our medicines in the U.S. was -4.6 percent. More information about our approach to pricing and our investment in discovering and developing transformational medicines for patients facing some of the world's most challenging diseases is available in our second annual Janssen U.S. Transparency Report.

I look forward to the opportunity to discuss our innovative ideas for improving patient access and healthcare quality with you and your team.

Best regards,

Alex

Alex Gorsky
JNJRED
Chairman and Chief Executive Officer
Tel: (732) 524-6814
Fax: (732) 524-1318
New E-mail: (b)(6)@its.jnj.com

Sender:	Gorsky, Alex [JJCUS] <(b)(6)@its.jnj.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Fowler, Liz [JJCUS] <(b)(6)@ITS.jnj.com>; Torok, Kathy [JJCUS] <(b)(6)@its.jnj.com>
Sent Date:	2018/07/23 17:04:01
Delivered Date:	2018/07/23 17:05:13

From:	Fowler, Liz [JJCUS] <(b)(6)@ITS.jnj.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Janssen Drug Pricing and Transparency report
Date:	2018/03/08 22:50:59
Priority:	Normal
Type:	Note

Alex—
Congratulations again on becoming HHS Secretary. I know you are inundated with interesting (and controversial) policy issues, but I have faith in you and your team to do the right thing for patients and the programs that HHS oversees.

I wanted to make sure you saw the 2017 Janssen drug pricing and transparency report. (You can also find a copy of the report on our website here.) The upshot is that **our aggregate net price change in 2017 was -4.6%** (compared to average list price increase of 8.1%). That compares to 3.5% net and 8.5% list from the 2016 report (which I can also send if you're interested). Additionally, **we paid out $15 billion in discounts and rebates in 2017 (for an overall discount rate of 42%)**, which is an increase from $11 billion in 2016 (and discount rate of 35.2%).

Jennifer Taubert and a couple of her senior team are meeting with Peter and John O'Brien to talk further about drug pricing policy on Tuesday March 20 at 3:00. We would welcome the opportunity to meet with you as well to discuss the report, our philosophy on drug pricing and our policy ideas to address access and affordability for prescription drugs.

Thanks and hope you are well!

Liz Fowler
Vice President, Global Health Policy

JNJRED
Worldwide Government Affairs &Policy
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Sender:	Fowler, Liz [JJCUS] <(b)(6)@ITS.jnj.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>

Sent Date:	2018/03/08 22:48:54
Delivered Date:	2018/03/08 22:50:59

2017 JANSSEN U.S. TRANSPARENCY REPORT

janssen

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

HHS-19-0361, 19-0362 and 19-0363-A-000021

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

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 ...

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

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 development[1]

88% more
invested in R&D than we spent on marketing and sales[2]

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 approved[3]

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

8.1%
average list price change[4]

-4.6%
average net price change[5]

$15 billion
approximate total discounts and rebates

610,000
commercially insured patients helped with out-of-pocket costs through the Janssen CarePath Savings Program[6]

Our Investments

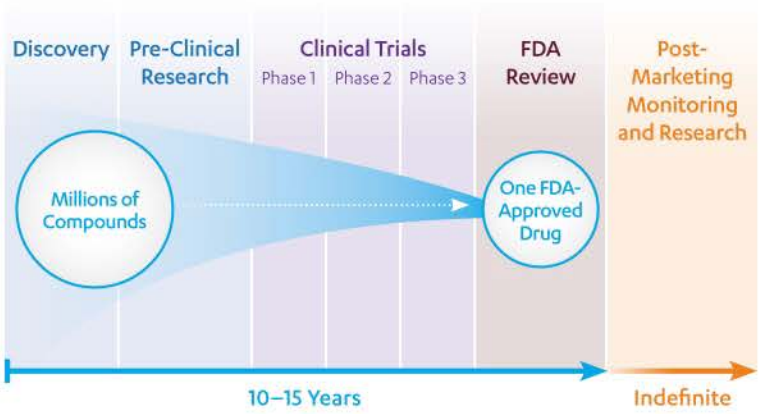
At Janssen, we are committed to delivering transformational medical innovation that can change the trajectory of health for humanity. To achieve this purpose, we combine our strong internal capabilities with the most compelling available external science to transform how diseases are prevented, intercepted, 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.

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 years[7] 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

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.

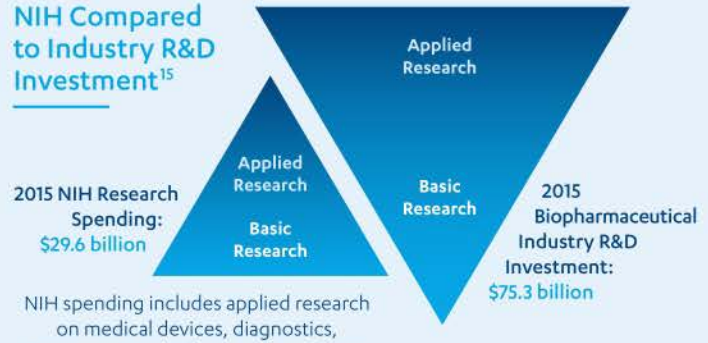
The Role of the NIH in Medical Research

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 Investment[15]



NIH spending includes applied research on medical devices, diagnostics, prevention, and other areas in addition to spending on basic research and biopharmaceutical-related research.

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 2017[25]

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 2017[26]

8
FDA Breakthrough Therapy Designations for indications for three of our investigational medicines in the last 5 years[27]

- 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.

> "We're honored to be recognized in the top spot for the Good Pharma Scorecard for the second year in a row. At Johnson &Johnson, we believe sharing clinical trial data honors the patients who participated in the trial, and contributes to improving patient care."
>
> **— Joanne Waldstreicher, M.D.,**
> Chief Medical Officer of Johnson & Johnson

Clinical Data Transparency

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]

BY THE NUMBERS: 2017 YODA RESULTS[29]

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

Janssen Global Trial Finder

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.

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]

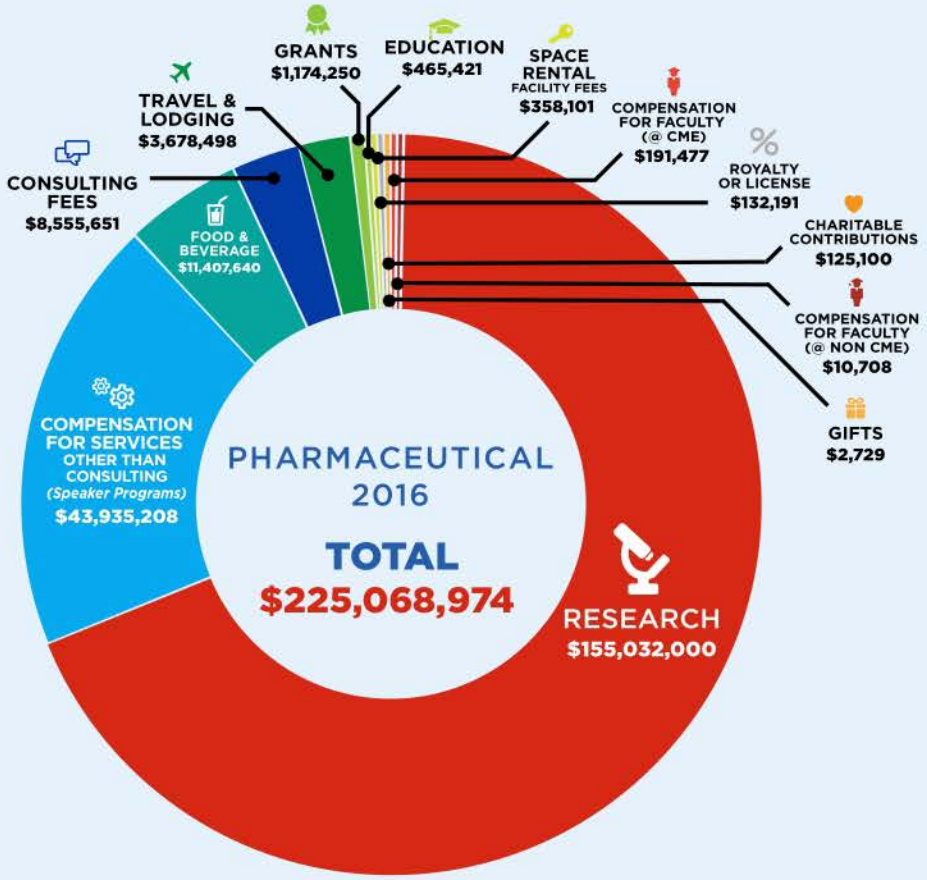
Open Payments: R&D Accounts for 65 Percent of Our Payments to Physicians

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 a non-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 jnj.com/our-giving.
- Indirect payment by a third party organization to speakers at an 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.



Value

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 medicines[40]

25% decline
in the cancer death rate since 1991 is credited, in part, to innovative cancer medicines, including new targeted therapies[41]

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 placebo[42]

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

$213 billion
in U.S. health care costs could be saved with correct use of medications for chronic conditions[44]

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 so[45]

Over 90%
of prescriptions today are for generic medicines, which are typically lower cost[46] 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.

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

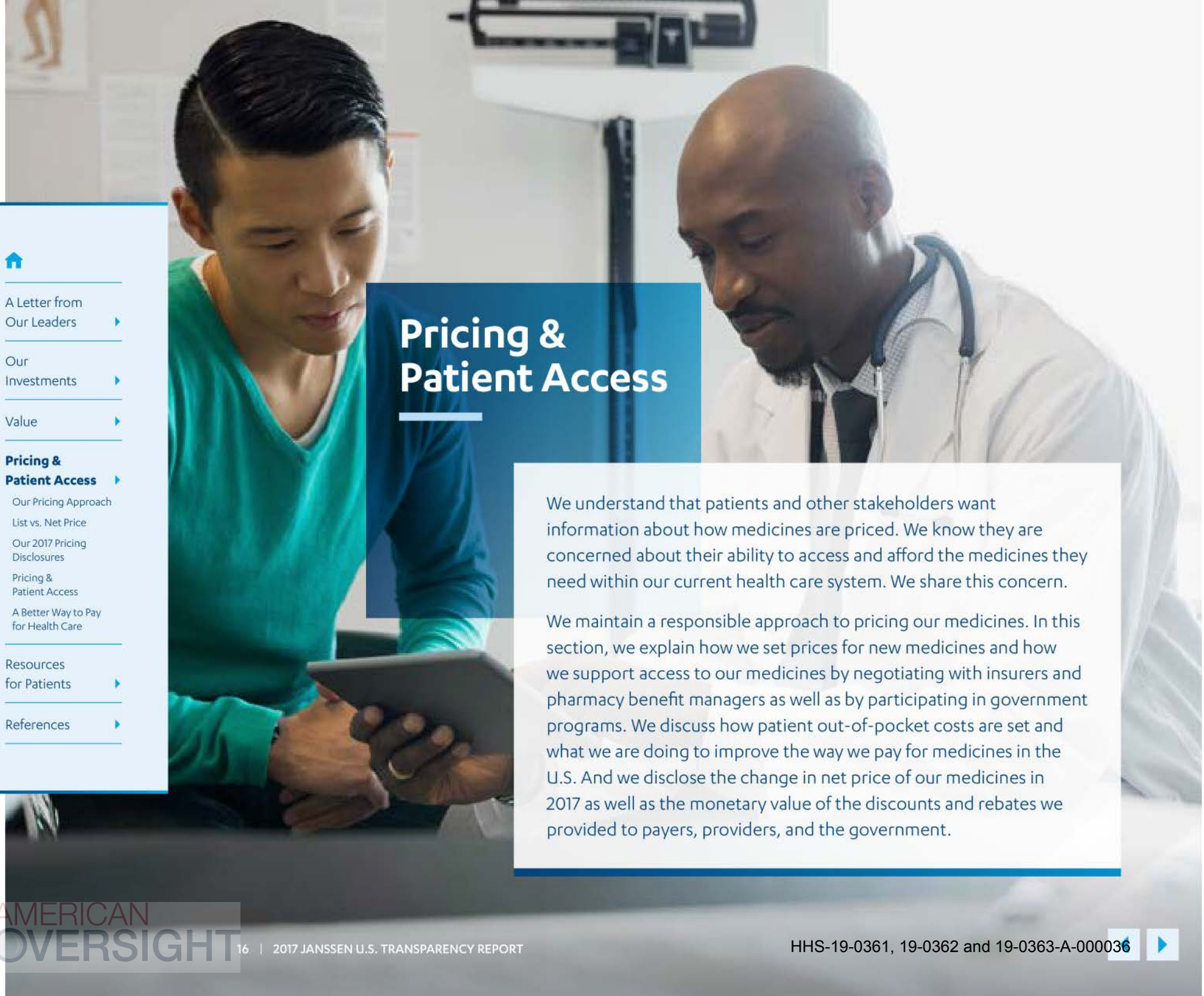
Measuring and defining the value of medicines has been the subject of much discussion. In the U.S., several organizations have introduced frameworks and methodologies to assess the relative value of medicines. These approaches, or "value assessment frameworks," can be helpful, but many of them fail to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



Pricing & Patient Access

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.

Our Pricing Approach

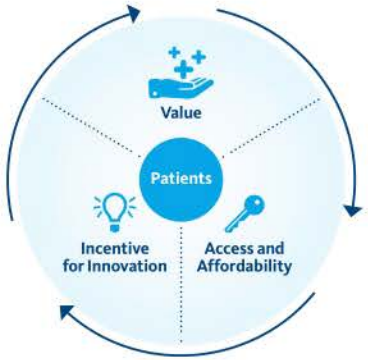
When we set an initial list price for our medicines following FDA approval, we balance the following considerations:

- **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



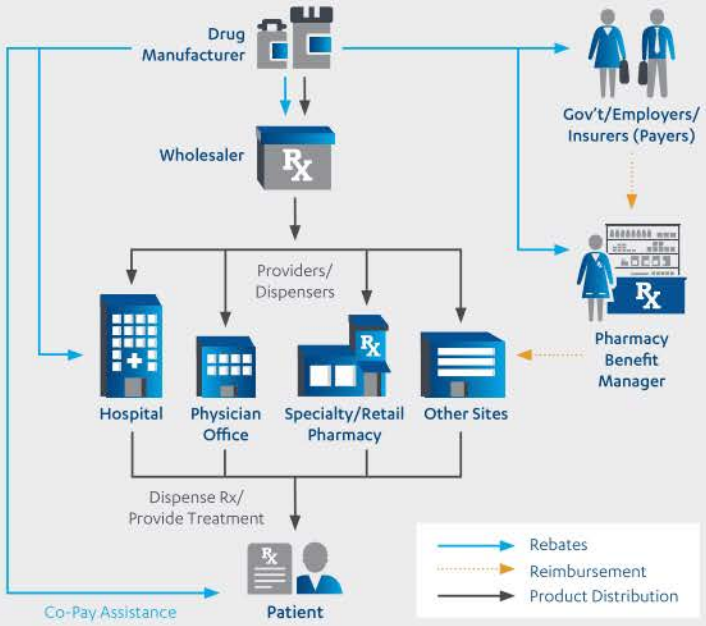
When determining an initial list price, we go through a lengthy process to gather the information necessary to assess the medicine on the basis of these principles. We review clinical data; we use health economic research to assess how our medicines may affect other health care costs arising from things 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.

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

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 percent[55] 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 percent[56] 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.

Our 2017 Pricing Disclosures

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 Year[60]

	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 medicines[64] — 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.

Pricing & Patient Access

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 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]

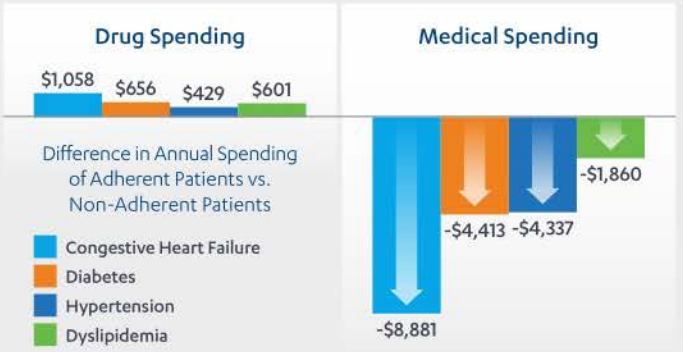
Research shows that when patients pay a greater share for their medicines, patient health can suffer, and health system costs don't necessarily go down.[82] For example, when diabetes patients' out-of-pocket costs rise, they are less likely to adhere to their medicines, meaning they are less likely to 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]

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]



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.

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. ■

Resources for Patients

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.

Janssen CarePath

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 patients[94] 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 patients[97] 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.

Independent Program & Foundation Support

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 pm to 6 pm ET).

  We donated approximately $875 million[100] 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.

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.

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.

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.

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About This Report

1. Figure is according to Janssen internal financial accounting. Our R&D investment figures are global because 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.
2. 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.
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102. According to internal financial accounting.

103. This estimate is based on assessment of donation amounts and publicly available data on approximate levels of patient assistance.

104. According to Janssen's Pre-Approval Access global tracking system.

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From:	Fowler, Liz [JJCUS] <(b)(6) @ITS.jnj.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Kalavritinos, Jack (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c96066167294edc816e7c273fddf342-Kalavritino>; O'Brien, John (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a55d8875a4fc1b4a57afa34e1df5c-Obrien, Joh>
CC:	Duato, Joaquin [JJCUS] <(b)(6) @its.jnj.com>; Taubert, Jennifer [JJCUS] <(b)(6) @its.jnj.com>
Subject:	RE: Thank you
Date:	2018/12/21 17:51:26
Priority:	Normal
Type:	Note

Alex, Jack and John,
Could you please use these slides and delete the previous version I sent? The version attached to this email includes the appropriate legal language about confidentiality that was not on the previous version sent earlier this afternoon. Thanks for your consideration, and sorry about that!

Happy holidays,
Liz

On Dec 21, 2018, at 2:40 PM, Fowler, Liz [JJCUS] <(b)(6) @ITS.jnj.com>wrote:

> Secretary Azar, John and John—
>
> Before too much time passes, we wanted to send the attached slides as follow up to our discussion last Friday. We hope this information is helpful and would be happy to answer any questions or discuss in more detail. Please also let us know if there is any additional information that might be useful as you continue to explore and refine policy options related to payment for Part B drugs.
>
> The deck includes the following:
>
> - (b)(4)

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of the Freedom of Information Act

From: Duato, Joaquin [JJCUS]
Sent: Friday, December 14, 2018 7:39 PM
To: Alex.Azar@HHS.GOV
Cc: John.Kalavritinos@hhs.gov; John.Obrien@hhs.gov; Fowler, Liz [JJCUS] <(b)(6) @its.jnj.com>; Taubert, Jennifer [JJCUS] <(b)(6) @its.jnj.com>
Subject: Thank You

Dear Mr. Secretary,

Thank you very much for taking time out of your day to meet with us and hear our ideas for addressing drug prices. As a company that has taken a responsible approach to pricing, we applaud you for taking steps to bring more competition to the market and bring costs down for U.S. patients and Medicare beneficiaries.

Under your leadership, we believe that we have a unique opportunity to come to the table with new ideas to improve the system in a responsible and thoughtful way. To that end, we look forward to working with John and others on your team to address some of the follow up items we discussed. Specifically, we will come back to you with more information on discounts and rebates currently offered in Part B, additional detail on our proposal to bring competitive forces to the buy and bill model, and how our Part B proposal would impact prices. We would also be pleased to share more detail on the price information we are considering adding to our DTC TV ads for 2019.

Thank you again for your time, and we look forward to seeing you again soon.

Sincerely,

Joaquin Duato	**Jennifer Taubert**
Vice Chairman of the Executive Committee	*Worldwide Chair, Pharmaceuticals*
Johnson &Johnson	**Johnson &Johnson**

Sender:	Fowler, Liz [JJCUS] <(b)(6)@ITS.jnj.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Kalavritinos, Jack (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c96066167294edc816e7c273fddf342-Kalavritino>; O'Brien, John (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a55d8875a4fc1b4a57afa34e1df5c-Obrien, Joh>; Duato, Joaquin [JJCUS] <(b)(6)@its.jnj.com>; Taubert, Jennifer [JJCUS] <(b)(6)@its.jnj.com>
Sent Date:	2018/12/21 17:46:37
Delivered Date:	2018/12/21 17:51:26

From:	AWOT (Amy Wotring) <(b)(6)@novonordisk.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Gottlieb, Scott (FDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e702dccfa254c91a581411243f513f1-scott.gottl>
Subject:	Diabetes Advocacy Alliance letter on blood glucose monitor accuracy
Date:	2018/10/23 15:35:46
Priority:	Normal
Type:	Note

Good afternoon Secretary Azar and Commissioner Gottlieb –

On behalf of the Diabetes Advocacy Alliance please see the attached letter addressed to the two of you sharing the DAA's concerns with findings from a recent study highlighting accuracy issues with certain blood glucose testing systems.

Please let me know if you have any questions.

Best,
Amy

Amy Wotring
Associate Director, External Relations

Novo Nordisk Inc.
920 Massachusetts Ave
Suite 500
Washington, DC 20001
USA
202-626-5646 (direct)
(b)(6) (mobile)

Sender:	AWOT (Amy Wotring) <(b)(6)@novonordisk.com>
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Sent Date:	2018/10/23 15:33:18
Delivered Date:	2018/10/23 15:35:46

October 23, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20301

The Honorable Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Secretary Azar and Dr. Gottlieb:

The Diabetes Advocacy Alliance (DAA) is writing to echo concerns raised in a recent study highlighting accuracy issues with certain blood glucose testing systems furnished to people with diabetes. We urge you to take necessary steps to ensure all people with diabetes have access to safe and accurate blood glucose testing systems.

The DAA is a coalition of 24 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes.

A study[1], published in *Diabetes Care* in May 2018, assessed the accuracy of 18 blood glucose testing systems cleared by the U.S. Food and Drug Administration (FDA) which represented 90% of commercially available systems used from 2013-2015. The study found only six of the 18 systems met the accuracy standards in all three of the separate accuracy tests conducted; four systems did not meet the accuracy standards in any of the three studies conducted. It is alarming that so few systems met the accuracy standards in all three tests and that four did not meet the accuracy standards in any of the tests.

As you know, more than 30 million Americans have diabetes including approximately 12 million Medicare beneficiaries (nearly 30 percent). People with diabetes use and rely on blood glucose testing systems to manage their chronic disease to avoid the costly complications of diabetes with the expectation that they are accurate. HHS, and relevant agencies like the FDA and CMS, should strive to ensure that blood glucose testing systems, especially those covered by federal programs like Medicare and Medicaid, consistently meet accuracy and safety standards.

The undersigned organizations strongly urge you to acknowledge the issue of blood glucose testing system accuracy and its potential implications for people with diabetes including seniors with diabetes and take the necessary steps to ensure people with diabetes have access to safe and accurate testing systems. We look forward to continuing to engage with HHS and FDA on this issue. If you have any questions or need additional

[1] Klonoff DC, Parkes JL, Kovatchev BP, Kerr D, et al. Investigation of the accuracy of 18 marked blood glucose monitors. Diabetes Care May 2018, dc171960; DOI: 10.2337/dc17-1960.

information, please free to contact one of the DAA's co-chairs: Meghan Riley at (b)(6) @diabetes.org, Meredith Dyer at (b)(6) @endocrine.org, or Karin Gillespie at (b)(6) @novonordisk.com.

Sincerely,

Academy of Nutrition and Dietetics
American Association of Clinical Endocrinologists
American Association of Diabetes Educators
American Diabetes Association
American Optometric Association
Diabetes Patient Advocacy Coalition
Endocrine Society
Novo Nordisk Inc.

From:	David Lachmann <(b)(6)@bio.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Letter to the Secretary re: Rep. Khanna's letter on 29 USC 1498
Date:	2018/03/13 16:02:52
Priority:	Normal
Type:	Note

David Lachmann
Senior Director, Federal Government Relations
Biotechnology Innovation Organization
1201 Maryland Avenue, SW, Suite 900
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Office Phone: 202-747-1286
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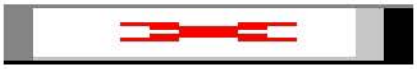
https://www.bio.org/

Join me in celebrating BIO's 25th Anniversary.
Visit https://www.bio.org/history for details.



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Sender:	David Lachmann <(b)(6)@bio.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2018/03/13 16:02:14
Delivered Date:	2018/03/13 16:02:52

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AMERICAN OVERSIGHT

Bio Biotechnology Innovation Organization

25 YEARS OF INNOVATION

Biotechnology Innovation Organization

March 12, 2018

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar:

I write to you on behalf of the Biotechnology Innovation Organization (BIO) concerning a February 15 letter sent to you by Representative Ro Khanna and 17 Members of the House of Representatives. The letter's signatories urge you to invoke 28 U.S.C. §1498 to authorize unlicensed generic manufacturers to copy patented innovative treatments for chronic Hepatitis C infections and sell them without the patent holder's consent, with the end goal being imposition of indirect Government pricing controls. I write to point out certain inaccuracies in Rep. Khanna's letter, and to correct misperceptions about the feasibility of using 28 U.S.C. §1498 in the procurement of innovative, patented drugs for general healthcare delivery.

28 U.S.C. §1498 originated as wartime legislation in 1918 and was last substantively amended in 1942. The statute confirms the Government's sovereign power to authorize the production or use of a patented invention for the exercise of Federal Government functions without the consent of the owner of the intellectual property, subject to the patentee's right to "reasonable and entire compensation." Because it is limited to the operations of the Federal Government, the provision provides no authority for the use of infringing products by or on behalf of states, municipalities, or private actors. Over the past 100 years, §1498 has been applied predominantly in the contexts of defense procurement and national security. Instances of applying this authority to prescription drug procurement were rare, and predate the modern Food, Drug and Cosmetic Act. To our knowledge, there has been no instance since the Vietnam War in which Federal procurement officials have invoked §1498 in the prescription drug context, and for good reasons. Contrary to the suggestion of Rep. Khanna's letter, §1498 is in no way a feasible tool to regulate the cost of prescription drugs.

First, the statute creates liability for the Federal Government to pay the patent owner "reasonable and entire compensation." Thus, Federal authorization under §1498 to dispense large amounts of patent-infringing medicines would expose the Federal Government to potentially large and unpredictable financial liability, the full extent of which would be determined by judges and become

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clear only after years of litigation.[1] It is hard to imagine a worse tool for planning healthcare budgets.

Second, the exercise of §1498 in the context of patent-infringing medicines would clash with the provisions of the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act. These carefully-crafted statutes directly regulate the approval of low-cost follow-on medicines by reference to the innovator's data protection periods and patent rights. In neither statute did Congress provide a Federal Government use exemption that would allow for market entry of follow-on drugs that could not otherwise be approved. Thus, even if the Federal Government were to exercise its rights under §1498 with respect to a patent-infringing drug, the standard regulatory approval timelines for such a drug (including patent linkage and reference product data protection) would still need to be followed, and the drug would not become available for general patient use any sooner than those statutory regimes allow.

Third, some proponents have argued, and Rep. Khanna's letter suggests, that by invoking §1498 the Federal Government could define broad swaths of the US healthcare system to be a Federal Government function, thus clearing Medicare contractors, state Medicaid programs, state prison systems and private healthcare programs to dispense patent-infringing drugs for general patient use "on behalf of the United States." Even if this were possible, it bears repeating that under §1498 the Federal Government would expressly assume legal liability for the actions of these third parties. In other words, coverage decisions would be made by private and state actors while the Federal Government would be on the hook for the required reasonable and entire compensation to the patent owner. The result would be a massive and uncontrolled shift of cost and liability from the states and the private sector to the Federal Government.

Finally, I ask you to consider the impact of Rep. Khanna's proposal on biomedical innovation and patient care in the United States. One in 10 Americans is affected by a rare disease, yet 95% of rare diseases have no approved treatment option. New therapeutic options are also urgently needed in more common disease areas, such as cancer and Alzheimer's. And innovative solutions will be required to combat the threat of drug-resistant infectious diseases that used to be treatable, but that can now once again kill. Biotech companies who pursue such innovation already must make enormous investments, knowing that future returns on their investments cannot be predicted and may never materialize. It takes on average over 2 billion dollars and close to 10 years of R&D, at a 90% failure rate, before a new investigational drug can be approved and made available for patient

[1] This is not a new concern. The former Comptroller General of the United States, Elmer B. Staats, testified before the Monopoly Subcommittee Select Committee on Small Business in 1971 that the Federal Government's exposure to liability under §1498 contributed to the minimal use of foreign-sourced drug products as an alternative to purchasing such drugs from U.S. patent holders.

care. And returns on such investments are highly skewed towards a minority of successful and important products, whose revenues must make up for development failures and the many new drugs that, despite approval, fail to recover their R&D costs.

Against this backdrop, the coercive use of §1498 as a tool for drug price-setting would send a terrible signal to investors deciding whether to commit the necessary R&D expenditures for future therapeutic breakthroughs. Under Rep. Khanna's proposal, the rate of return on research investment would effectively be decided in protracted, unpredictable §1498 litigation against an adversarial government, and the value of biomedical innovation would be determined by judges and lawyers instead of health economists, payors, professional societies and health officials. Other governments would be encouraged to expropriate American IP without fear of repercussions at a time when the Trump administration is seeking to persuade these same governments to contribute a fairer share to the cost of biomedical innovation and is insisting in trade negotiations that these governments respect the intellectual property rights of U.S. firms abroad. Faced with such prospects, R&D funding opportunities, especially for high-risk, high-reward biomedical research ventures, would dry up.

The BIO community is eager to partner with you on responsible solutions for providing greater access to affordable prescription medicines and lowering healthcare costs. We believe that your Department has tremendous opportunities to address our Nation's healthcare challenges by fueling, not stifling, the development of new therapies and competition in the market for biomedical innovation. Coercive measures however, such as those proposed by Rep. Khanna and his colleagues, may have an outward appearance of simplicity but are actually harmful, unworkable, counterproductive, and would prove costly to taxpayers.

With Sincerest Regards,

James C. Greenwood
President and CEO

From:	James C. Greenwood <(b)(6) @bio.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
CC:	Verma, Seema (CMS/OA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e36583cd19bb453997718e4ca9ac8a93-SeemaVermaP>; Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>; Tom Dilenge <(b)(6) @bio.org>; Crystal Kuntz <(b)(6) @bio.org>; Dan Durham <(b)(6) @bio.org>
Subject:	BIO concerns - Step Therapy for Part B Drugs in Medicare Advantage
Date:	2018/09/10 15:20:09
Priority:	Normal
Type:	Note

Secretary Azar,

Attached please find a letter expressing the concerns that BIO has with the recent decision by CMS to reverse long-standing policy and now allow MA plans to utilize step therapy requirements for Medicare Part B drugs.

Happy to discuss further.

Jim

Hon. James C. Greenwood
President and CEO
Biotechnology Innovation Organization (BIO)
Member of Congress, 1993-2005

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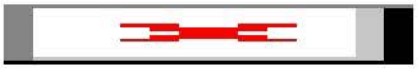

BIO_Action_468x60

Sender:	James C. Greenwood <(b)(6) @bio.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Verma, Seema (CMS/OA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e36583cd19bb453997718e4ca9ac8a93-SeemaVermaP>;

	Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>; Tom Dilenge <(b)(6)@bio.org>; Crystal Kuntz <(b)(6)@bio.org>; Dan Durham <(b)(6)@bio.org>
Sent Date:	2018/09/10 15:18:01
Delivered Date:	2018/09/10 15:20:09

Biotechnology Innovation Organization

James C. Greenwood
President & CEO

September 10, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, D.C. 20201

RE: Step Therapy for Part B Drugs in Medicare Advantage

Dear Secretary Azar:

The Biotechnology Innovation Organization (BIO) is writing to express our strong concern with the recent decision by the Centers for Medicare and Medicaid Services (CMS) to reverse long-standing policy and now allow Medicare Advantage (MA) plans to utilize step therapy requirements for Medicare Part B drugs. Because of the serious harm that such a policy could cause to some of the sickest and most vulnerable Medicare populations, I respectfully request that the Administration reverse, or at least suspend, this new policy, pending further discussions with stakeholders on whether such a policy should be implemented and if so, how to do so in a manner that is fully transparent to and protective of Medicare beneficiaries.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced other healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. To that end, we closely monitor changes to Medicare's reimbursement and coverage policies for the potential impact on patient access to drugs and biologicals. We therefore have significant concerns with CMS' recent changes to its utilization management policies for Part B drugs.

CMS' August 7, 2018 memo to MA plans rescinded a 2012 memo that explicitly prohibited plans from imposing additional requirements for accessing Part B drugs such as step therapy. The 2012 memo specifically noted plans' statutory requirement to provide "equal access to items and services covered by Original Medicare in their service area."[1] Despite this clear statutory requirement, CMS has abruptly reversed course. According to the newly issued guidance, MA plans are now permitted to implement step therapy for Part B drugs, beginning January 1, 2019.

[1] CMS Memo to Medicare Advantage Organizations. 17 September 2012.

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Additionally, MA prescription drug plans are permitted to require use of a Part D therapy prior to providing coverage for a Part B therapy.

This sudden reversal of long-standing Medicare policy, without any statutory change or opportunity for public comment, raises significant concerns. As an initial matter, CMS has not identified how this new policy change can be squared with the mandate for parity in covered benefits between Medicare Advantage and original Medicare that was clearly articulated and defended in the now-rescinded 2012 memo.

But more fundamentally, allowing MA plans to utilize step therapy for Part B drugs effectively puts insurers between providers and their patients – restricting patient access to the drugs their providers believe they need and potentially increasing patient costs and overall healthcare spending as well. Imposing these stringent requirements can be unduly burdensome on patients, subjecting them to potentially harmful side effects and diminished health outcomes. These potential consequences are especially concerning when considering that this new policy is intended to impact those Medicare beneficiaries seeking treatment for the most serious, often life-threatening conditions, such as cancer, autoimmune disorders, ESRD, and hemophilia – conditions that already are complex for providers and patients to manage appropriately and that often can require immediate access to the most effective therapy available in order to avoid life-threatening or irreversible negative complications. Policies such as step therapy that delay access to the most appropriate therapy in an effort to reduce upfront expenditures are not only a bad prescription for patients, but they are short-sighted, as there is substantial potential for increased overall healthcare costs and adverse patient outcomes due to avoidable hospitalizations, doctors' visits, and procedures.

Of additional concern is the complete lack of CMS oversight and beneficiary protections within CMS' new policy. In fact, CMS explicitly states that health plans ***are not required*** to submit their step therapy policies to CMS for review. In addition, health plans are required to include only a general disclosure in plan documents that Part B drugs ***may*** be subject to step therapy, but plans do not have to specify whether step therapy will indeed be required or for which drugs. Essentially, CMS will not know which plans are implementing step therapy and in what manner. More troubling, nor will beneficiaries. This lack of oversight and transparency is simply unacceptable.

We strongly urge the Agency to reverse course on this new policy, given its potential for serious negative impacts for Medicare beneficiary access to timely and appropriate treatment. However, if CMS insists on proceeding with this new policy, we recommend that the Agency pause implementation of the guidance until 2020, and work with affected stakeholders to address critical implementation issues, including ensuring: sufficient oversight by CMS; clear clinical criteria for step therapy policies; transparency of step therapy policies to beneficiaries and robust beneficiary protections; timely exceptions and appeals processes; sufficient protections for those on existing therapies; and protection for beneficiaries from higher cost-sharing. Our more detailed comments follow.

Lack of CMS Oversight. CMS places virtually no requirements on plans that want to establish step therapy requirements in Part B. CMS merely "encourages" MA-PD plans to use Part D pharmacy

and therapeutics (P&T) committees "to determine when it is medically appropriate to use step therapy."[2] Further, even if a P&T process is used, such recommendations are not binding on the plan sponsor. And, CMS will not know what process the plan has gone through – if any – to institute step therapy requirements. CMS states that plans **are not** required to submit their step therapy requirements to CMS for review.[3] This is inconsistent with requirements in Part D, where plans must submit step therapy protocols to CMS for review of their clinical appropriateness. Further, without submission of any information to CMS, the Agency will not even know which plans are requiring Part B step therapy and for which drugs.

Lack of Transparency to Beneficiaries. CMS states that the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents can list each Part B drug subjected to step therapy ***or it can be more general***.[4] This more general option is troubling as beneficiaries will not know if a Part B drug is subject to step therapy, as the plan is only required to say such drugs "may" be subject to step therapy. In addition, if step therapy is used, plans are not required to list the specific drugs for which this requirement applies. Further, CMS notes that plans can add or change step therapy mid-year but does not outline detailed parameters plans must follow to implement such changes or to notify beneficiaries of the changes. At a minimum, plans implementing step edits should be highlighted on the Medicare plan finder during open enrollment. Further, more specificity should be included in the ANOC and EOC documents than is currently required, and CMS should outline additional avenues for ensuring that critical information is communicated to beneficiaries, such as posting requirements on a health plan's website in a clear, accessible manner.

Insufficient Appeals Process. CMS states that a request for a Part B drug is an "organization determination request under Part C" and therefore is subject to a timeframe of 14 calendar days for standard requests and 72 hours for expedited requests (Q/A #11). CMS also states that it "strongly encourages" plans to expedite requests consistent with timelines under Part D (where standard requests are reviewed within 72 hours and expedited requests 24 hours). Given the vulnerability of the beneficiary population receiving coverage of drugs under Medicare Part B, CMS should ***require*** plans to follow the same timelines under Part D to ensure beneficiary access to needed medications without delay. CMS also should outline how it will ensure plan compliance with these standards.

Lack of Protections for Those on Existing Therapy. CMS states that step therapy may only be applied to "new prescriptions or new administrations of Part B drugs" and requires a look-back period of at least 108 days to determine whether the enrollee is eligible for a new start prescription. It is insufficient to apply the 108-day look-back required for Part D step edits to Part B patients. For many conditions commonly treated by Part B drugs, patients may experience a treatment free interval, following which they may return to treatment. For these drugs, the length of time that is treatment-free often can exceed the 108-day look-back period. It is essential that these patients can return to the treatment initially prescribed without being required to go through

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[2] CMS Memo to Medicare Advantage Organizations. 7 August 2018.

[3] CY 2019 Step Therapy Qs & As. 29 August 2018. See Question #6.

[4] CY 2019 Step Therapy Qs & As. 29 August 2018. See Question #5.

a step edit process. This look-back period should be extended (e.g., at least 12 months). In addition, if a plan is not able to determine whether a requested drug is, in fact, part of an ongoing course of therapy, the plan should be required to provide the enrollee with the drug without subjecting the drug to any step therapy. And, in the interest of beneficiary safety, MA plans should not be permitted to force patients first to take a repackaged drug or a medicine that is used off-label, which undermines the role of the Food & Drug Administration in determining safety and efficacy of products for specific indications.

Cost Sharing Implications. CMS also must address the higher out-of-pocket cost exposure that can occur for those patients forced to try a Part D drug before a Part B therapy. Cost-sharing for Part B medicines is set at 20 percent of the Medicare reimbursement rate. A majority of beneficiaries (more than 80 percent) carry supplemental coverage that helps defray their out-of-pocket costs for Part B medicines.[5] A recent Avalere analysis found that, as a result of supplemental coverage, beneficiaries typically have lower out-of-pocket costs for oncology medicines in Part B than in Part D plans.[6] Cost-sharing differences between the Part B and Part D programs have real-world implications for treatment decisions. CMS should clarify that a patient's out-of-pocket cost burden cannot increase due to a step edit requirement.

BIO supports policies that increase patient access, decrease patient cost-sharing, and reduce overall healthcare spending. Unfortunately, the new CMS policy will have the opposite effects. Accordingly, I strongly urge the Agency to halt implementation of this policy until critical issues such as those highlighted in this letter are addressed. I also request the opportunity to meet with you or Deputy Secretary Hargan to further discuss these issues at your earliest convenience.

Sincerely,

James C. Greenwood
President & CEO

cc: Eric Hargan, Deputy Secretary, U.S. Department of Health and Human Services
Seema Verma, Administrator, Center for Medicare & Medicaid Services

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[5] Analysis of the 2013 Medicare Current Beneficiary Survey conducted by The Moran Company for PhRMA. June 2017.
[6] Avalere Health. Moving Certain Part B Drugs to Part D, A Proposal Being Evaluated by The Trump Administration, Would Have Disparate Financial Impacts on Patients. May 2018.