Johnson & Johnson
2017 Transparency Report
and Response to Blueprint

Michael Barnard – Director, Federal Affairs
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Overview

- 2nd annual U.S. Transparency Report includes information and disclosures on:
  - Investments
  - Value
  - Pricing & Patient Access
  - Resources for Patients

- Reflects commitment to responsible business practices

- Open dialogue can advance a more results-based health care system

![BY THE NUMBERS: JANSSEN IN 2017]

- $7.9 billion invested in research and development
- 88% more invested in R&D than we spent on marketing and sales
- 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
- 4 value principles that help us define the value of our medicines
- 8.1% average list price change
- -4.6% average net price change
- $15 billion approximate total discounts and rebates
- 610,000 commercially insured patients helped with out-of-pocket costs through the Janssen CarePath Savings Program
Our Investments

- Increased investment in R&D by ~$1B to total of $7.9B in 2017
- Invested 88% more in R&D than we spent on marketing and sales
- R&D accounts for 65% of all “Open Payments” to physicians
- Working to make R&D processes more efficient, patient-centered, transparent
Value

Aligning on measures of value critical to results-based care

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.
Pricing & Patient Access

U.S. Product Portfolio, \(^{59}\) % Change vs. Prior Year\(^{60}\)

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<thead>
<tr>
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<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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<tbody>
<tr>
<td>Average List Price Change(^{61})</td>
<td>9.0%</td>
<td>8.3%</td>
<td>9.7%</td>
<td>8.5%</td>
<td>8.1%</td>
</tr>
<tr>
<td>Average Net Price Change(^{62})</td>
<td>4.8%</td>
<td>2.5%</td>
<td>5.2%</td>
<td>3.5%</td>
<td>-4.6%</td>
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$15 billion approximate total discounts and rebates
Pricing & Patient Access, Continued

Janssen is advancing a more results-based approach through:

- Innovative Contracting Models
- Value-Based Partnerships
- Population Health Research
Resources for Patients

Programs We Offer

**Janssen CarePath:** ~1.2 million patients enrolled, including ~610,000 commercially insured patients who reduced out-of-pocket expenditures through the CarePath savings program.

**Janssen CONNECT:** ~10,000 patients enrolled

Programs We Support

**J&J Patient Assistance Foundation:** Donated ~$874M to JJPAPF, helping ~86,000 patients

**CoPay Foundations:** Donated ~$60 million to independent charitable foundations, helping ~9,750 patients

Access to Investigational Medicine

**Requests for Compassionate Use:** 161 global requests for compassionate use, 132 approved
Trump Administration’s “Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs”
Overview – Request for Information (RFI)

• **Improved Competition**
  – Addressing how the current market dynamics affect incentives and HHS’s ability to implement new Value-Based Arrangements

• **Better Negotiation**
  – Using new competition models, similar to the Competitive Acquisition Program from MMA and/or transferring drugs from Medicare Part B to Part D

• **Lower List Prices**
  – Looking at how rebates under the current system affect list pricing and whether the rebate system is beneficial/sustainable

• **Reduced OOP Costs**
  – Examining opportunities to lower patient costs at the counter via formulary changes, cost-sharing arrangement, etc.
Key Issue Areas for PhRMA Industry

• Rebates
  – Delink supply chain payments from the list price;

• 340B Program
  – Clarify patient definition, update eligibility standards for DSH hospitals, revisit contract pharmacy guidance;

• Medicare Part B
  – Don’t change coverage of physician-administered drugs from Part B to Part D, careful implementation of any updated CAP*;

• Value-Based Contracting
  – Address regulatory barriers that prevent the uptake of VBC in public health programs;
Key Issue Areas for PhRMA Industry, continued

• **Direct-to-Consumer Advertising**
  – Caution that putting list prices on DTC ads wouldn’t provide useful information to patients but cause confusion;

• **Medicaid**
  – Continue the current statutory rebate policy and ensure continued open formularies;

• **Medicare Part D**
  – Strengthen OOP protections, maintain formulary protections and ensure patient assistance counts towards TrOOP;

• **Global Free-Riding**
  – Enforce existing trade agreements, ensure foreign government transparency in pricing/reimbursement, secure strong trade commitments.
Johnson & Johnson’s Response to the RFI

• We share the Administration’s goals of reducing health care costs while improving the quality and efficiency of care.

• We will continue to seek opportunities to work with the Administration and others who share our commitment to developing a more results-based health system that delivers what we all want: greater access to care, at manageable cost, and most importantly, better health for all.
Johnson & Johnson’s Response to the RFI, continued

• We offer suggestions to achieve these goals, including:
  – a proposed model for reforming Medicare Part B reimbursement;
  – recommendations for policies that protect patient safety and choice;
  – That maintain a competitive, level playing field for biosimilars and their reference products.
Part B Market Competition Model

• We recommend an alternative to a Competitive Acquisition Program in Medicare Part B that we call a *Market Competition Model*. It features several advantages:
  – Balances savings from Medicare negotiations with access to medicines;
  – **Manufacturers** sell drugs to vendors at one percent below the Average Sales Price (ASP) to help offset costs of vendor distribution fees;
  – **Vendors** distribute drugs to providers and submit claims for reimbursement from Medicare at the acquisition cost of the drug plus a flat distribution fee
  – Participating **providers** compensated for drug administration and patient management activities.
Medicare Part B to Part D

• J&J has concerns with the proposal to shift some medicines from Medicare Part B to Part D
  – Such a move overlooks current Part B ASP pricing structures, which already reflects the weighted average of sales prices, net rebates and discounts;

• As a result, moving some drugs to Part D may not necessarily lower prices in Medicare, may result in an increase in Part D premiums, and could pose serious implications for patient access

• More than 1 in 4 Medicare beneficiaries do not have Part D coverage, and would therefore be unable to access drugs through Part D
Biosimilars

• J&J believes appropriate adoption of biosimilars and interchangeable biosimilars will depend in part on patient and provider confidence in their quality and safety

• We recommended HHS/FDA use caution against switching between biosimilars because of the lack of study in the effects of doing so

• We also encouraged FDA to require post-market monitoring of biosimilars, including switching between biosimilar products
The Role of Rebates in Drug Pricing

• The Administration, as well as some in Congress, have questioned the role that rebates play in affecting list prices for medicines
  – The RFI asks: should CMS restrict or reduce the use of rebates – or even prohibit them in Part D – and whether contracts between PBMs and manufacturers should be based solely on fixed-price contracts.

• These are important questions, especially since recent market trends have *not* resulted in savings for patients

• J&J hasn’t come to a catch-all answer to these questions, but we appreciate the Administration raising them and welcome the opportunity to be part of a broader policy discussion on alternative market-based solutions.
340B Drug Discount Program

• J&J has long supported the 340B drug discount program as an important part of a health care system that ensures that low-income, needy patients have appropriate access to medicine.

• We strongly support updated program guidance that modernizes key elements of the 340B program.
  – Updates to the “patient definition” and contract pharmacy guidance to ensure patients have a bona fide relationship with the covered entity, focusing the program more clearly on CEs that truly serve needy patients
Direct-to-Consumer Advertising

• We have concerns about including list prices in DTC advertising since it would be confusing and misleading for patients
  – Patient out-of-pocket costs vary significantly based on coverage
  – List prices are the “starting point” and are ultimately reduced significantly by discounts and rebates we provide

• We understand the need for greater transparency around healthcare costs. That’s why we provide information about how we price our medicines and invest our resources in an annual U.S. Transparency Report

• Price comparison websites already exist to help people determine their out-of-pocket costs with accuracy based on their specific insurance plan
Blueprint – Next Steps

• With more than 2,000 comments submitted, HHS is now tasked with reviewing, compiling, evaluating and implementing.
  – No official deadline for HHS/White House to implement, but political pressure is going to mount, especially leading up to the midterm election

• HHS officials need “a win” for the President to keep him from going rogue
  – They seem to be getting cold feet on Part B to Part D, but still ginning up DTC (Trump likes/understands it)
  – Recently announced plan to allow importation of certain generics
It All Comes Back to Our Principles

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… and Our Credo