

January 19, 2021

Via e-mail at shareholderproposals@sec.gov

Securities and Exchange Commission
Office of the Chief Counsel
Division of Corporation Finance
100 F Street, NE
Washington, DC 20549

Re: Request by Johnson & Johnson to omit proposal submitted by Oxfam America, Inc. and 12 co-filers

Ladies and Gentlemen,

This letter responds to the letter from Johnson & Johnson (“J&J”) dated January 12, 2021 (the “No-Action Reply”). In the No-Action Reply, J&J attacks the response (the “No-Action Response”) by Oxfam America, Inc. and 12 co-filers (together, the “Proponents”) to J&J’s request dated December 11, 2020 (the “No-Action Request”) that the Division concur that J&J is entitled to omit a proposal submitted by the Proponents (the “Proposal”) from J&J’s 2021 proxy materials because the Proposal deals with J&J’s ordinary business operations and because J&J has substantially implemented the Proposal. The Proposal asks J&J to report to shareholders on whether and how J&J subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

In the No-Action Reply, J&J objects that the No-Action Response’s discussion of the profound impacts of the COVID-19 pandemic and the role of widespread vaccination are irrelevant to whether the Proposal deals with a significant policy issue transcending ordinary business.¹ But a full understanding of the broader context in which COVID-19 vaccines and therapies are being developed is essential context for the debate over access to those products. Unlike other products manufactured and marketed by pharmaceutical companies like J&J, COVID-19 vaccines and therapies have the power, if deployed widely, not only to prevent suffering and death for

¹ See No-Action Reply, at 2.

individuals but also to create the herd immunity necessary to begin rebuilding the economy and mitigating the other impacts of the pandemic on society. The stakes here could not be higher.

J&J suggests that a proposal on drug pricing or access is excludable unless it has the broadest possible focus—a “broader notion of affordable access to healthcare” or a company’s “fundamental business strategy with respect to pricing policies.”² The “fundamental business strategy” language appears in the Gilead, Vertex, and Celgene proposals seeking disclosure of drug pricing risks, as well as earlier proposals seeking a policy of drug price restraint, but there is no reason to believe that this is the only way to establish that a proposal addressing drug pricing or access addresses a significant policy issue. While the Staff allowed exclusion of proposals in the 2017 season requesting specific information about companies’ ten best-selling medicines, the medicines themselves (which would have differed among companies) did not have a fraction of the importance to the public that COVID-19 vaccines and therapies do, as discussed in the No-Action Response. The public attention focused on the vital importance of access to these products and the government’s role in their development is unprecedented and support the conclusion that the Proposal deals with a significant policy issue.

J&J also reiterates that it has substantially implemented the Proposal, pointing again to general disclosures regarding pandemic pricing and support for government-facilitated access. J&J states that its existing disclosures “address specific details on how it plans to take into account government collaboration in setting the price for its COVID-19 vaccine.” Presumably, J&J is referring to the article linked from J&J’s websites in which the company’s CFO states that the “not-for-profit” price to which J&J has committed during the pandemic will be “based on a formula established and utilized by the Bill & Melinda Gates Foundation (BMGF) for vaccine product pricing in lower-income countries.” As discussed in the No-Action Response, that article does not state that the BMGF takes government support into account or describe how it does so. That information is the core request made in the Proposal, so its absence dooms J&J’s substantial implementation claim.

* * *

For the reasons set forth above and in the No-Action Response, J&J has not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7) or 14a-8(i)(10). The Proponents thus respectfully request that J&J’s request for relief be denied.

² No-Action Reply, at 3.

The Proponents appreciate the opportunity to be of assistance in this matter. If you have any questions or need additional information, please contact me at (907) 713-4963.

Sincerely,



Nicholas J. Lusiani
Senior Advisor, Private Sector Department
Oxfam America

cc: Marc S. Gerber, Esq.
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January 12, 2021

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Chief Counsel
100 F Street, N.E.
Washington, D.C. 20549

RE: Johnson & Johnson – 2021 Annual Meeting
Supplement to Letter dated December 11, 2020
Relating to Shareholder Proposal of
Oxfam America, Inc. and co-filers¹

Ladies and Gentlemen:

We refer to our letter dated December 11, 2020 (the “No-Action Request”), submitted on behalf of our client, Johnson & Johnson, pursuant to which we requested that the Staff of the Division of Corporation Finance (the “Staff”) of the U.S. Securities and Exchange Commission (the “Commission”) concur with Johnson & Johnson’s view that the shareholder proposal and supporting statement (the “Proposal”) submitted by Oxfam America, Inc. and co-filers (collectively, the “Proponents”) may be excluded from the proxy materials to be distributed by Johnson & Johnson in connection with its 2021 annual meeting of shareholders (the “2021 proxy materials”).

¹ The following shareholders have co-filed the Proposal: Achmea Investment Management; Benedictine Sisters of Boerne, Texas; Benedictine Sisters of Virginia, Inc.; CommonSpirit Health; Congregation of Divine Providence; Mercy Investment Services, Inc.; Monasterio De San Benito; PeaceHealth; Providence Trust; The Sisters of Charity of Saint Elizabeth; The Sisters of Providence, Mother Joseph Province; and Trinity Health.

This letter is in response to the letter to the Staff, dated January 4, 2021, submitted by Oxfam America, Inc. on behalf of the Proponents (the “Proponents’ Letter”), and supplements the No-Action Request. In accordance with Rule 14a-8(j), a copy of this letter also is being sent to the Proponents.

I. The Proposal Deals with Matters Relating to Johnson & Johnson’s Ordinary Business Operations.

As described below, the Proponents’ Letter attempts to recast the Proposal in order to evade exclusion but in so doing the Proponents disregard the plain text of their own Proposal. In addition, the Proponents’ Letter mischaracterizes the Staff’s position on Rule 14a-8(i)(7) as expressed in previous no-action letters. Nevertheless, because the Proposal deals with matters relating to Johnson & Johnson’s ordinary business operations and does not focus on a significant policy issue, the Proposal is excludable pursuant to Rule 14a-8(i)(7).

The Proponents’ Letter describes at great length the significance of the COVID-19 pandemic, the human tragedy, the economic impacts, the challenges faced by the healthcare system, the significant efforts to develop vaccines and secure FDA approval, and the important role that widespread vaccination will have on returning to some sense of normalcy. Johnson & Johnson does not dispute the human and economic toll of the pandemic, and the No-Action Request does not suggest otherwise. Indeed, Johnson & Johnson is very much in favor of widespread vaccination and, as described in the No-Action Request and in Johnson & Johnson’s public statements, has supported the plans of the U.S. and other governments to procure COVID-19 vaccines on behalf of their citizens.

That said, the wide ranging discussion contained in the Proponents’ Letter is largely not pertinent to the Proposal. The Proposal focuses instead on the specific question of whether and how government collaboration for the development and manufacture of vaccines and therapeutics for COVID-19 is taken into account in Johnson & Johnson’s pricing decisions for those products. This particular issue — unambiguously set forth in the text of the resolution contained in the Proposal — does not constitute a significant policy issue.

In addition, the Proponents’ Letter attempts to shoehorn the Proposal into a group of proposals that the Staff has determined focus on the significant policy issue of access to affordable health care. As discussed above and in the No-Action Request, however, the Proposal is focused on Johnson & Johnson’s pricing decisions with respect to a particular product and, specifically, “whether and how [Johnson & Johnson’s] subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.” Fairly read, there is no doubt that the Proposal’s focus

is on the particular issue of how government collaboration for the development and manufacture of vaccines and therapeutics for COVID-19 may influence Johnson & Johnson's pricing decision for those products, rather than on any broader notion of affordable access to healthcare.

The Proponents' Letter also mischaracterizes the Staff's historical view of proposals broadly involving drug pricing to suggest that "[p]roposals addressing prescription drug pricing and access" necessarily implicate a significant policy issue and cannot be excluded so long as they do not seek overly granular data. As explained in the No-Action Request, however, the fact that a proposal touches upon the pricing of pharmaceutical products does not alone render the proposal non-excludable. Rather, the Staff examines whether the substance of the proposal involves a matter of ordinary business. Contrary to the Proponents' Letter's characterization of *Gilead Sciences, Inc.* (Feb. 23, 2015), *Vertex Pharmaceuticals Inc.* (Feb. 25, 2015) and *Celgene Corp.* (Mar. 19, 2015), the Staff declined to permit exclusion of the proposals under Rule 14a-8(i)(7) in those instances because it determined that the requests for reports on the risks from rising pressure to contain U.S. specialty drug prices focused on the companies' "fundamental business strategy with respect to its pricing policies for pharmaceutical products." Here, unlike in those instances, the Proposal's request does not focus on Johnson & Johnson's fundamental business strategy with respect to its drug pricing policies. Instead, the request focuses on a particular group of products — COVID-19 vaccines and therapeutics — and on how one specific factor — government collaboration — factors into Johnson & Johnson's pricing decisions for those products. Thus, the Proposal's specific request demonstrates that the Proposal's focus is on how a particular factor impacts specific pricing decisions regarding certain pharmaceutical products and not on any more general notion of Johnson & Johnson's fundamental business strategy with respect to drug pricing policies.

Finally, the Proponents' Letter argues that the Proposal does not micromanage Johnson & Johnson because, among other things, the Proposal "does not identify specific details for inclusion in a report." This assertion, however, ignores the fact that the Proposal's request inherently seeks intricate details relating to Johnson & Johnson's pricing decisions for COVID-19 products. As described in the No-Action Request, in addition to the myriad factors Johnson & Johnson generally considers when pricing pharmaceutical products, the Proposal's focus on Johnson & Johnson's COVID-19 vaccines and therapeutics involves unique complexities related to, among other things, production timelines, intellectual property, patent rights, supply demands and distribution requirements, and Johnson & Johnson's relationship with the U.S. government. Moreover, given the rapid, emergency development process for COVID-19 products and the severity and magnitude of the pandemic, Johnson & Johnson's pricing decisions for those products involve more complexities than typical pharmaceutical pricing decisions. By requesting a report implicating those matters, the Proposal seeks to micromanage Johnson & Johnson's business.

Accordingly, the Proposal should be excluded from Johnson & Johnson's 2021 proxy materials pursuant to Rule 14a-8(i)(7) as relating to Johnson & Johnson's ordinary business operations.

II. Johnson & Johnson Has Satisfied the Proposal's Essential Objective.

As noted in the No-Action Request, the Staff has permitted exclusion under Rule 14a-8(i)(10) where a company already addressed the underlying concerns and satisfied the essential objectives of the proposal, even if the proposal had not been implemented exactly as proposed by the proponent.

In this instance, although the Proponents may have a particular interest in more detailed disclosure of how government collaboration for the development and manufacture of vaccines and therapeutics for COVID-19 may impact Johnson & Johnson's pricing decisions for those products, Johnson & Johnson's public disclosures already address its approach to pricing COVID-19 vaccines and therapeutics. Specifically, as described further in the No-Action Request, in addition to providing Johnson & Johnson's general approach to pricing its COVID-19 vaccine, Johnson & Johnson's public disclosures address specific details on how it plans to take into account government collaboration in setting the price for its COVID-19 vaccine. Johnson & Johnson also has disclosed its commitment to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use, how it intends to implement that commitment, and specific arrangements with governments for its COVID-19 vaccine and pricing for such arrangements. Thus, even though Johnson & Johnson's public disclosure may not be as detailed as the Proponents would prefer, Johnson & Johnson's public disclosures nevertheless address the underlying concern of the Proposal. Accordingly, Johnson & Johnson believes that it has satisfied the Proposal's essential objective and that its public disclosures compare favorably with the Proposal.

Therefore, as described in the No-Action Request, the Proposal is excludable under Rule 14a-8(i)(10).

III. Conclusion

For the reasons stated above and in the No-Action Request, Johnson & Johnson respectfully requests that the Staff concur that it will take no action if Johnson & Johnson excludes the Proposal from its 2021 proxy materials.

Should the Staff disagree with the conclusions set forth in this letter, or should any additional information be desired in support of Johnson & Johnson's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior

to the issuance of the Staff's response. Please do not hesitate to contact the undersigned at (202) 371-7233.

Very truly yours,



Marc S. Gerber

cc: Matt Orlando
Worldwide Vice President, Corporate Governance and Corporate Secretary
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Office of Chief Counsel
January 12, 2021
Page 6

David Neisius
Provincial Treasurer
The Sisters of Providence, Mother Joseph Province



January 4, 2021

Via e-mail at shareholderproposals@sec.gov

Securities and Exchange Commission
Office of the Chief Counsel
Division of Corporation Finance
100 F Street, NE
Washington, DC 20549

Re: Request by Johnson & Johnson to omit proposal submitted by Oxfam America, Inc. and 12 co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Oxfam America, Inc. and 12 co-filers (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to Johnson & Johnson ("J&J" or the "Company"). The Proposal asks J&J to report on whether and how its receipt of government financial support for the development and manufacture of vaccines and therapeutics for COVID-19 is being or will be taken into account when engaging in conduct that affects access to those products.

In a letter to the Division dated December 11, 2020 (the "No-Action Request"), J&J stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the 2021 annual meeting of shareholders. J&J argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), on the ground that the Proposal relates to J&J's ordinary business operations; and Rule 14a-8(i)(10), as substantially implemented. As discussed more fully below, J&J has not met its burden of proving its entitlement to exclude the Proposal on either of those bases, and the Proponents ask that its request for relief be denied.

The Proposal

The Proposal states:

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

Ordinary Business

J&J argues that the Proposal’s subject is a matter of ordinary business for the Company. Nothing could be further from the truth. Access to life-saving COVID-19 vaccines and therapies satisfies the Division’s standard for a significant policy issue that transcends ordinary business, as subject that is a “consistent topic of widespread public debate.” Proposals addressing prescription drug pricing and access have survived challenge on ordinary business grounds numerous times in the past three decades, provided they do not seek overly granular data. And access to the vaccines needed to end the COVID-19 pandemic and mitigate its devastating effects is now a consistent topic of widespread public debate, augmenting the longstanding public debate about drug pricing and access.

Access to Medicine and Risks Associated With High Drug Prices Are Significant Policy Issues Transcending Ordinary Business

J&J claims the Proposal’s subject does not transcend ordinary business because it addresses “pricing decisions regarding certain of [the Company’s] products.” The Proponents do not dispute that, without more, proposals requesting changes to, or information about, a company’s prices have generally been found by the Division’s Staff to address ordinary business matters. The determinations J&J cites dealt with such mundane pricing-related matters as giving shareholders the same discounts on products afforded to company employees,¹ providing senior citizens and shareholders with discounted hotel rates,² reporting on rent increases

¹ Verizon Communications, Inc. (avail. Jan. 29, 2019).

² Host Hotels & Resorts, Inc. (avail. Feb. 6, 2014).

in manufactured housing communities,³ allowing customers to buy a spare tire from an auto manufacturing company at cost,⁴ and comparing a company's fees, exchange rates and pricing structure with those of industry peers.⁵ The policy implications of each of these issues that the Staff determined constitutes "ordinary business" are of vastly less social import than those of COVID-19 vaccine access, as will be detailed below; this make them poor fits to offer as justification to reject the Proposal here.

All of those proposals sought to affect the kind of matters that are, in the Commission's words, "fundamental to management's ability to run a company on a day-to-day basis" and thus poorly suited for shareholder input.⁶ It is worth noting that the proponents of the Host Hotels, Equity LifeStyle, and Ford proposals did not even respond to the no-action requests, so no argument was ever made that those proposals addressed significant policy issues. The proponent of the Verizon proposal responded but did not claim that the proposal addressed a significant policy issue. Only the Western Union proponent asserted that the proposal's subject, the impact of the company's remittance practices on the communities it serves, was a significant policy issue, but it only pointed to few news articles or policy initiatives related to remittance pricing.

Proposals addressing access to prescription drugs, including drug prices, have consistently stood on a different footing than these sorts of proposals. Almost 30 years ago, the Staff declined to allow exclusion on ordinary business grounds of a proposal asking Eli Lilly to adopt a policy of pharmaceutical price restraint.⁷ Similar price restraint proposals at Bristol-Myers Squibb and Warner Lambert were deemed not to deal with ordinary business operations in the early 2000s.⁸

In 2015, proposals seeking disclosure of drug pricing-related risks (the "pricing risk proposals") survived challenge on ordinary business grounds. In the 2015 proxy season, proposals asked Gilead, Vertex and Celgene to report on the risks created by rising pressure to contain U.S. specialty drug prices. All three companies argued that the proposals addressed ordinary business matters because they concerned the prices the companies charged for their products; the proponent countered, and the SEC agreed, that high-profile controversies involving very expensive drugs sold by the companies supported a conclusion that the proposals addressed a significant policy issue.⁹

³ Equity LifeStyle Properties, Inc. (avail. Feb. 6, 2013).

⁴ Ford Motor Co. (avail. Jan. 31, 2011).

⁵ Western Union Co. (avail. Mar. 7, 2007).

⁶ See Exchange Act Release No. 40018 (May 21, 1998).

⁷ Eli Lilly and Company (avail. Feb. 25, 1993).

⁸ Bristol-Myers Squibb Company (avail. Feb. 21, 2000); Warner Lambert Company (avail. Feb. 21, 2000).

⁹ Gilead Sciences, Inc. (avail. Feb. 23, 2015); Celgene Corporation (avail. Mar. 19, 2015); Vertex Pharmaceuticals Inc. (avail. Feb. 25, 2015).

J&J claims that five determinations from 2017¹⁰ allowing exclusion of proposals requesting information on drug price increases (the “price increase proposals”) stand for the proposition that any proposal relating to pricing of specific products can be excluded as ordinary business. But that reading is too broad.. The price increase proposals differed from the Proposal in two important ways. First, they sought data on price trends over six years for each company’s 10 best-selling drugs by revenue, regardless of whether any controversy had attached to those drugs. Second, in addition to asking for an assessment of risks, which the pricing risk proposals also did, the price increase proposals sought granular data regarding the rationale and criteria for year-over-year price increases, and the rate of such increases, for the ten best-selling drugs. The more business-oriented focus created by these elements undermined the argument that they addressed a significant policy issue, and the Staff cited them in the determinations. By contrast, the Proposalthe Proposal seeks more general transparency around critical policy issues that are consistent subject of high-profile media coverage, and as such, attendant risk to investors.

The Proposal’s Focus on Products that Could End the COVID-19 Pandemic, Which Has Crippled the Healthcare System and Plunged the Economy Into Recession, Bolsters the Case that the Proposal Addresses a Significant Policy Issue

The Proposal, unlike some proposals the Staff has allowed companies to exclude on ordinary business grounds, focuses on products that treat or prevent COVID-19 and about which there has been consistent and widespread public debate.¹¹ It would be difficult to overstate the impact the COVID-19 pandemic has had on every aspect of life in the U.S.; the large volume of media coverage and policy initiatives, reflected in the footnotes below, evidences the seriousness and magnitude of these effects.

As of January 4, 2020, 20.6 million cases of COVID-19 have been reported in the U.S., and 351,682 people have died of the disease.¹² Health care resources have

¹⁰ AbbVie, Inc. (avail. Feb. 24, 2017); Biogen Inc. (avail. Feb. 23, 2017); Gilead Sciences Inc. (avail. Feb. 10, 2017); Johnson & Johnson (avail. Feb. 10, 2017); Pfizer Inc. (avail. Feb. 10, 2017).

¹¹ The Proposal does not focus on ordinary business matters despite touching on a significant policy issue, as J&J claims. (No-Action Request, at 6-7). The determinations J&J cites involved proposals that raised a significant policy issue but grafted on elements that implicated day-to-day management. For example, in PetSmart, Inc. (avail. Mar. 24, 2011), the proposal asked PetSmart to require its suppliers to attest that they had not violated certain laws related to animal cruelty. PetSmart pointed out that the laws in question governed not only animal cruelty, a significant policy issue, but also mundane matters such as record keeping. The Staff concurred and granted relief, citing the breadth of the laws referenced in the proposal. Here, by contrast, the Proposal’s subject—access to COVID-19 vaccines and therapeutics—is (and does not merely “touch on”) a significant policy issue, and no other matters are addressed.

¹² <https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?action=click&module=Top%20Stories&pgtype=Homepage>

been strained to the breaking point by the influx of severely ill COVID-19 patients. ICUs are full or nearly so in many places,¹³ which impairs the ability of non-COVID patients to obtain critical care.¹⁴ Health care workers are reporting severe burnout, and staffing shortages are limiting hospitals' ability to expand capacity.¹⁵ Approximately 41% of adults surveyed reported delaying or skipping medical care during the pandemic,¹⁶ which can result in delayed diagnosis and suboptimal management of existing conditions.¹⁷ What's more, the pandemic is disproportionately afflicting people of color, with Black, Hispanic, and Native Americans dying at a faster rates than their Caucasian counterparts.¹⁸

The economic crisis caused by COVID-19 is “unprecedented in its scale: the pandemic has created a demand shock, a supply shock, and a financial shock all at once,” according to the Brookings Institution.¹⁹ The 9.1% drop in economic output in the second quarter of 2020 is the largest on record, and industrial production has only partially recovered from a large drop in March 2020.²⁰ The Congressional Budget Office predicted in May 2020 that cumulative nominal output of the U.S. economy from 2020-2030 will be \$15.7 trillion less than forecast, due to the pandemic.²¹ States and municipalities are collecting much less revenue, which has precipitated budget crises.²²

The economic fallout has been especially damaging for women. According to the president and CEO of the Institute for Women's Policy Research, “There's no historic parallel for what's happening here for women. We have nothing to

¹³ <https://www.msn.com/en-us/news/us/icu-capacity-shrinks-at-hospitals-as-they-scramble-to-find-enough-staff-to-manage-covid-surge/ar-BB1cdqET>;
<https://www.nytimes.com/interactive/2020/us/covid-hospitals-near-you.html>;
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<https://intermountainhealthcare.org/blogs/topics/covid-19/2020/11/covid-19-what-it-means-for-a-hospital-icu-to-be-at-capacity/>; <https://www.npr.org/sections/health-shots/2020/12/09/944379919/new-data-reveal-which-hospitals-are-dangerously-full-is-yours>;
<https://abcnews.go.com/GMA/News/video/icu-beds-capacity-country-amid-covid-19-74645461>

¹⁴ <https://www.vox.com/22196119/icu-capacity-hospital-staffing-coronavirus-covid-19>;
<https://www.npr.org/sections/health-shots/2020/09/09/909669760/npr-poll-financial-pain-from-coronavirus-pandemic-much-much-worse-than-expected> (19% of New Yorkers reported that “at least one member of their household has been unable to get medical care for a serious problem when they needed it during the pandemic”);

¹⁵ <https://time.com/5914409/covid-19-health-care-worker-burnout/>;
<https://www.kansas.com/news/coronavirus/article246924192.html>

¹⁶ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6936a4.htm>

¹⁷ <https://www.southcoasttoday.com/story/news/2020/12/07/covid-fears-detering-patients-routine-check-ups-screenings-health/3812564001/>; <https://www.npr.org/sections/health-shots/2020/09/09/909669760/npr-poll-financial-pain-from-coronavirus-pandemic-much-much-worse-than-expected>

¹⁸ <https://covidtracking.com/race>

¹⁹ <https://www.brookings.edu/research/ten-facts-about-covid-19-and-the-u-s-economy/>

²⁰ <https://www.brookings.edu/research/ten-facts-about-covid-19-and-the-u-s-economy/>

²¹ <https://www.cbo.gov/system/files/2020-06/56376-GDP.pdf>

²² <https://www.cbpp.org/research/state-budget-and-tax/states-grappling-with-hit-to-tax-collections>

compare it to: not to the 2008 recession or the Great Depression.”²³ In August and September of 2020, 865,000 women, more than four times the number of men, dropped out of the workforce, according to Bureau of Labor Statistics data, which means they have given up looking for work.²⁴ Women “are more likely to have been laid off or furloughed during the Covid-19 crisis,” especially women of color.²⁵ By September, unemployment among white women had dropped to 6.9% while it was 11% for Black and Latina women.²⁶ Employment as “essential” workers prevented more job loss for women of color but brought increased risk of infection with COVID-19 for them and their communities.²⁷

Women are disproportionately shouldering the increased child care and education-related responsibilities resulting from K-12 remote learning and the closure of child care centers.²⁸ A McKinsey study of employees at 317 companies found that one in four senior women is considering “downshifting” their career—reducing work hours (including going part-time) or changing to a less demanding role—or leaving the workforce altogether as a result of the pandemic.²⁹ Many experts fear that these developments threaten to stall or reverse improvements in the wage gap and gender diversity in leadership made in recent years.³⁰

²³ <https://time.com/5900583/women-workforce-economy-covid/>

²⁴ <https://nwlc.org/resources/four-times-more-women-than-men-dropped-out-of-the-labor-force-in-september/>; <https://www.rand.org/blog/2020/10/sitting-it-out-or-pushed-out-women-are-leaving-the.html>;

²⁵ https://wiw-report.s3.amazonaws.com/Women_in_the_Workplace_2020.pdf, at 6; see also <https://www.americanprogress.org/issues/economy/reports/2020/10/22/492179/shambolic-response-public-health-economic-crisis-women-brink-job-recovery-stalls/>

²⁶ <https://www.smithsonianmag.com/smart-news/covid-19s-impact-working-women-unprecedented-disaster-180976084/>

²⁷ <https://www.americanprogress.org/issues/economy/reports/2020/10/22/492179/shambolic-response-public-health-economic-crisis-women-brink-job-recovery-stalls/>; <https://www.policylink.org/our-work/economy/national-equity-atlas/COVID-workforce>

²⁸ <https://time.com/5900583/women-workforce-economy-covid/>;
<https://www.brookings.edu/essay/why-has-covid-19-been-especially-harmful-for-working-women/>;
<https://www.forbes.com/sites/advisor/2020/10/19/women-are-leaving-the-workplace-in-record-numbers-and-we-dont-know-when-theyll-be-back/?sh=3f7d2d456ab5>;
<https://www.npr.org/sections/coronavirus-live-updates/2020/10/02/919517914/enough-already-multiple-demands-causing-women-to-abandon-workforce>;
<https://www.nytimes.com/2020/05/06/upshot/pandemic-chores-homeschooling-gender.html>;
<https://lernercenter.syr.edu/2020/06/04/ds-18/>;
<https://www.washingtonpost.com/business/2020/07/03/big-factor-holding-back-us-economic-recovery-child-care/>; <https://www.bloomberg.com/opinion/articles/2020-10-20/covid-19-explodes-the-myth-that-women-opt-out-of-the-workforce>

²⁹ https://wiw-report.s3.amazonaws.com/Women_in_the_Workplace_2020.pdf, at 6 & n.3; see also <https://www.weforum.org/agenda/2020/10/women-work-gender-equality-covid19/>;
<https://www.cnn.com/2020/08/19/economy/women-quitting-work-child-care/index.html>;
<https://www.usatoday.com/story/news/nation/2020/10/22/coronavirus-women-leaving-jobs-droves-amid-child-care-crisis/3727447001/>

³⁰ See, e.g., <http://www.bu.edu/articles/2020/pov-covid-19-and-resulting-school-closures-could-set-back-womens-gains-in-workforce-for-years-to-come/>; <https://www.mckinsey.com/about-us/new-at>

The Trump Administration viewed rapid development and deployment of a COVID-19 vaccine as sufficiently urgent to establish Operation Warp Speed (“OWS”), a public-private partnership whose “goal is to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).”³¹ OWS has provided over \$10 billion in support to vaccine makers for development and expansion of manufacturing capacity, and \$825 million in support for monoclonal antibody therapies.³²

Congressional hearings have explored various aspects of the debate over how best to control COVID-19 and mitigate its effects. Committees have held hearings on efforts to develop of safe and effective vaccines (some of which J&J participated in),³³ protecting nursing home residents,³⁴ COVID-19 outpatient treatment,³⁵ combatting COVID-19 in federal prisons³⁶ and ICE facilities,³⁷ the Administration’s performance in distributing PPE and modeling appropriate behaviors such as mask

mckinsey-blog/how-are-working-women-doing-during-covid-19-our-women-in-the-workplace-study-explores; <https://www.americanprogress.org/issues/women/reports/2020/10/30/492582/covid-19-sent-womens-workforce-progress-backward/>; <https://www.washingtonpost.com/us-policy/2020/07/29/childcare-remote-learning-women-employment/>; <https://journals.sagepub.com/doi/full/10.1177/2378023120947997>; <https://www.americanprogress.org/issues/economy/reports/2020/10/22/492179/shambolic-response-public-health-economic-crisis-women-brink-job-recovery-stalls/>; <https://www.rand.org/blog/2020/10/sitting-it-out-or-pushed-out-women-are-leaving-the.html>; <https://www.nytimes.com/2020/06/03/business/economy/coronavirus-working-women.html>; <https://www.nbcnews.com/know-your-value/feature/no-1-way-keep-covid-19-setting-women-back-work-ncna1248390>

³¹ <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>

³² <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>

³³ <https://www.c-span.org/video/?476344-1/house-hearing-covid-19-vaccine-development>; <https://www.c-span.org/video/?475442-1/nih-director-astra-zeneca-vaccine-trial-pause-reassuring>; <https://www.c-span.org/video/?473850-1/house-hearing-ensuring-safe-covid-19-vaccine>; <https://www.c-span.org/video/?473450-1/covid-19-vaccine-development>;

³⁴ <https://www.c-span.org/video/?473382-1/house-ways-means-subcommittee-hearing-covid-19-nursing-homes>

³⁵ <https://www.c-span.org/video/?478159-1/senate-hearing-covid-19-outpatient-treatment>

³⁶ <https://www.c-span.org/video/?506909-1/federal-bureau-prisons-us-marshals-service-oversight-hearing>

³⁷ <https://www.c-span.org/video/?473795-1/house-hearing-oversight-ice-detention-facilities-coronavirus-pandemic>

wearing,³⁸ the national strategy,³⁹ racial and health disparities in the pandemic,⁴⁰ and the Administration’s response to COVID-19 more generally.⁴¹

Federal legislation has aimed to ameliorate some of the pandemic’s economic damage. The Families First Coronavirus Response Act provided paid sick and caregiving leave, though many workers were not covered. The Coronavirus Economic Aid, Relief and Economic Security Act supplemented state unemployment insurance and provided assistance to states in dealing with education and child care disruptions.⁴² The Paycheck Protection Program (“PPP”) lent money to businesses to encourage them to keep workers on their payrolls.⁴³ Rep. Carolyn Maloney introduced the Pandemic Risk Insurance Act, which would “establish a Federal program that provides for a transparent system of shared public and private compensation for business interruption losses resulting from a pandemic or outbreak of communicable disease,”⁴⁴ and a hearing on the bill was held in November.⁴⁵ At the end of December 2020, Congress passed and the President signed a new relief package extending unemployment insurance for gig workers and independent contractors, providing ten weeks of supplemental \$300 unemployment insurance payment, and extending eviction protections.⁴⁶

Congress has also held hearings on the impact of COVID-19 on various aspects of the economy: the live event entertainment industry,⁴⁷ the pandemic and economic recovery,⁴⁸ the role of financial regulators⁴⁹ and oversight of financial regulation during the pandemic,⁵⁰ preventing fraud and abuse in the PPP,⁵¹

³⁸ <https://www.c-span.org/video/?476340-1/health-human-services-secretary-testimony-covid-19-response>

³⁹ <https://www.c-span.org/video/?474168-1/health-officials-national-strategy-combat-coronavirus-pandemic>

⁴⁰ <https://www.c-span.org/video/?473981-1/racial-health-disparities-covid-19-pandemic>

⁴¹ <https://www.c-span.org/video/?475764-1/coronavirus-vaccine-widely-late-2021-cdc-director>; <https://www.c-span.org/video/?473686-1/house-hearing-federal-response-coronavirus-pandemic-part-1>; <https://www.c-span.org/video/?473229-1/white-house-coronavirus-task-force-members-testify-federal-response-pandemic>

⁴² <https://www.brookings.edu/essay/why-has-covid-19-been-especially-harmful-for-working-women/>

⁴³ <https://www.c-span.org/video/?507170-1/senate-hearing-paycheck-protection-program>

⁴⁴ <https://maloney.house.gov/sites/maloney.house.gov/files/PRIA%20Section%20by%20Section.pdf>

⁴⁵ <https://www.c-span.org/video/?478218-1/insurance-coverage-coronavirus-pandemic>

⁴⁶ <https://www.cnn.com/2020/12/27/politics/trump-relief-bill-christmas-eve/index.html>

⁴⁷ <https://www.c-span.org/video/?507290-1/hearing-covid-19-impact-live-event-entertainment-industry>

⁴⁸ <https://www.c-span.org/video/?506828-1/treasury-secretary-federal-reserve-chair-testimony-coronavirus-pandemic-economic-recovery>; <https://www.c-span.org/video/?473448-1/fed-chair-powell-treasury-secretary-mnuchin-testify-coronavirus-response>

⁴⁹ <https://www.c-span.org/video/?478021-1/house-hearing-role-financial-regulators-pandemic>

⁵⁰ <https://www.c-span.org/video/?477933-1/senate-banking-hearing-financial-regulators-oversight>

⁵¹ <https://www.c-span.org/video/?476436-1/hearing-preventing-fraud-abuse-paycheck-protection-program>

COVID-19's impact on the food industry⁵² and restaurant operations,⁵³ numerous hearings on COVID-19 and the economy,⁵⁴ the impact on small businesses,⁵⁵ financial aid for states,⁵⁶ the impact on rural economies,⁵⁷ and protecting workers' pay.⁵⁸ Related topics such as reopening schools;⁵⁹ the availability of child care;⁶⁰ mental health issues;⁶¹ and the House-passed HEROES Act,⁶² providing additional support for workers, states/municipalities, businesses, and education and child care,⁶³ have also been addressed in hearings.

Responses to COVID-19 have not been limited to the federal government. States, largely left to their own devices in procuring supplies, establishing health protocols, and setting restrictions on activities, have adopted numerous initiatives. A database on the National Conference of State Legislatures web site captures COVID-19-related bills, which numbered a whopping 3,446 in 2020.⁶⁴ The subjects of these bills ranged from mortgage foreclosure and eviction moratoriums⁶⁵ to establishing a PPE stockpile for essential workers⁶⁶ to mandating frequent testing

⁵² <https://www.c-span.org/video/?476397-1/covid-19s-impact-food-industry>

⁵³ <https://www.c-span.org/video/?476228-1/house-hearing-coronavirus-impact-restaurant-operations>

⁵⁴ <https://www.c-span.org/video/?475827-1/treasury-secretary-federal-reserve-chair-testimony-covid-19-economy>; <https://www.c-span.org/video/?476127-1/federal-reserve-chair-jerome-powell-covid-19-economic-impact>; <https://www.c-span.org/video/?476055-1/treasury-secretary-mnuchin-fed-chair-jerome-powell-testify-pandemic-response>; <https://www.c-span.org/video/?473950-1/ben-bernanke-janet-yellen-testify-covid-19-economic-inequities>

⁵⁵ <https://www.c-span.org/video/?473822-1/treasury-secretary-small-business-administrator-testify-small-businesses-covid-19>; <https://www.c-span.org/video/?473867-1/house-hearing-small-business-covid-19-pandemic>; <https://www.c-span.org/video/?473528-1/small-business-loans-coronavirus-pandemic>

⁵⁶ <https://www.c-span.org/video/?475561-1/mexico-minnesota-kansas-guam-governors-testify-covid-19-aid>

⁵⁷ <https://www.c-span.org/video/?475605-1/house-panel-examines-coronavirus-pandemic-impact-rural-economy>

⁵⁸ <https://www.c-span.org/video/?473661-1/house-hearing-covid-19-jobs>

⁵⁹ <https://www.c-span.org/video/?474554-1/house-hearing-opening-schools-covid-19-pandemic>; <https://www.c-span.org/video/?473932-1/house-hearing-reopening-schools-pandemic>; <https://www.c-span.org/video/?473393-1/covid-19-response-reopening-schools>

⁶⁰ <https://www.c-span.org/video/?473308-1/house-hearing-child-care-amid-coronavirus-pandemic>

⁶¹ <https://www.c-span.org/video/?473502-1/house-hearing-covid-19-impact-mental-health>

⁶² <https://www.c-span.org/video/?474094-1/hearing-economic-recovery-coronavirus-pandemic>

⁶³ <https://appropriations.house.gov/news/press-releases/house-democrats-release-updated-version-of-the-heroes-act>

⁶⁴ <https://www.ncsl.org/research/health/state-action-on-coronavirus-covid-19.aspx>

⁶⁵ E.g.,

https://custom.statenet.com/public/resources.cgi?id=ID:bill:AK2019000H312&ciq=ncsl&client_md=1fdb614866d1596fb834807ee76554df&mode=current_text

⁶⁶

https://custom.statenet.com/public/resources.cgi?id=ID:bill:CA2019000S275&ciq=ncsl&client_md=c1b7227c80b0bffd71bde31e4b01884&mode=current_text

for nursing home residents and staff.⁶⁷ The National Governors Association web site maintains a database of state actions to mitigate COVID-19, such as stay-at-home orders, mask mandates, and limits on gatherings and indoor dining;⁶⁸ face covering policies;⁶⁹ travel quarantine orders/guidance;⁷⁰ and reopening documents for schools, child cares, and youth sports.⁷¹ Many of these state and local actions have been the subject of intense debate and, in some cases, armed confrontation.⁷²

No aspect of American life – our health, our economy, our community – has survived the unprecedented scale of this pandemic intact. COVID-19 is the epitome of a significant policy issue.

Widespread Vaccination is Key to Ending the COVID-19 Pandemic, Making Access to Vaccines is a Significant Policy Issue

Widespread vaccination is the key to reviving the economy, relieving the massive burdens on the health care system, and returning to some semblance of normalcy.⁷³ “[V]accines will be our way out of this pandemic,” virologist Kanta

⁶⁷

https://custom.statenet.com/public/resources.cgi?id=ID:bill:NY2019000S8385&ciq=ncsl&client_md=1f9f6aca494362bc9955fb01303ab1a6&mode=current_text

⁶⁸ <https://www.nga.org/coronavirus-mitigation-actions/>

⁶⁹ <https://www.nga.org/coronavirus-face-covering-policy/>

⁷⁰ <https://www.nga.org/traveler-quarantine-order-guidance-covid-19/>

⁷¹ <https://education.nga.org/#section-statetable>

⁷² See, e.g., <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2020/11/17/gop-lawsuits-restrain-governors-covid-19-actions>; <https://www.bbc.com/news/world-us-canada-52496514>; <https://www.nytimes.com/2020/12/21/world/oregon-coronavirus-protests.html>; <https://www.cnn.com/2020/08/26/politics/idaho-coronavirus-fight-brad-little/index.html>; <https://fox8.com/news/coronavirus/armed-protesters-gathered-outside-statehouse-demanding-dewine-reopen-ohio/>; <https://www.houstonchronicle.com/neighborhood/woodlands/article/Protest-over-COVID-restrictions-draws-hundreds-to-15782982.php>;

<https://www.rochesterfirst.com/rochester/maskless-protesters-rally-against-covid-19-restrictions-in-rochester/>; <https://www.thegardenisland.com/2020/12/03/hawaii-news/protesting-covid-restrictions/>

⁷³ See, e.g., <http://www.oecd.org/economic-outlook/december-2020/>;

<https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>; <https://www.usatoday.com/story/money/2020/11/30/covid-vaccine-news-viable-vaccine-may-already-lifting-spending-economy/6399117002/>;

<https://wgme.com/news/coronavirus/maines-economic-recovery-relies-on-vaccines-and-a-stimulus-in-2021> (“Public health and economic health are intertwined and until there is widespread vaccination against COVID-19, we will not be able to return to all of our typical economic activities.”);

<https://www.nga.org/center/publications/supporting-equitable-distribution-covid-19-vaccines/> (“Ensuring the rapid development, distribution, and widespread public uptake of a safe and effective COVID-19 vaccine will be a critical element in containing the COVID-19 pandemic and resuming normal economic, educational, and social activities.”); <https://www.reuters.com/article/health-coronavirus-europe-vaccines/the-beginning-of-the-end-europe-rolls-out-vaccines-to-see-off-pandemic-idUSKBN2910BQ?il=0>; <https://www.nga.org/memos/covid-19-vaccine-development-and-production/> (“Achieving broad immunity to COVID-19 is central to a return to normal life, and most experts maintain that this hinges on a widely available, safe, and effective vaccine.”)

Subbarao said recently.⁷⁴ As one prominent economist put it, “Only [when herd immunity is achieved] will we be able to resume normal family life, schooling, sports events and concerts, and patronize businesses on Main Street (what’s left of it.)”⁷⁵ Dr. Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases and chief medical adviser to President-elect Joe Biden, has estimated that 75-85% of Americans must be vaccinated in order to achieve herd immunity.⁷⁶ Herd immunity in the U.S. is not enough, though; a vaccine “will not end the pandemic unless it is within reach of all people in all countries.”⁷⁷

Equal access is critical to achieving these goals. As Julia Barnes-Weise, executive director of the Global Healthcare Innovation Alliance Accelerator, explained, “Nobody’s safe until everybody’s safe.”⁷⁸ Oxfam reported in September 2020 that “[w]ealthy nations representing just 13 percent of the world’s population have already cornered more than half (51 percent) of the promised doses of leading COVID-19 vaccine candidates.”⁷⁹

Substantial press attention has focused on questions of access, especially since news broke about the efficacy of the Pfizer/BioNTech, Moderna and AstraZeneca/Oxford vaccines. Many reports have addressed pricing, including prices paid by OWS and other government programs, differences between prices charged in the U.S. and those charged to other countries, and commitments regarding pricing such as J&J’s to use “not-for-profit pricing” and AstraZeneca’s to provide vaccines at cost “in perpetuity” to low- and middle-income countries.⁸⁰

⁷⁴ <https://www.theatlantic.com/health/archive/2020/11/vaccines-end-covid-19-pandemic-sight/617141/>

⁷⁵ <https://www.brookings.edu/blog/fixgov/2020/12/17/if-necessary-the-u-s-should-pay-people-to-get-a-covid-19-vaccine/>

⁷⁶ <https://www.npr.org/sections/coronavirus-live-updates/2020/12/15/946714505/fauci-predicts-u-s-could-see-signs-of-herd-immunity-by-late-march-or-early-april>

⁷⁷ <https://www.un.org/es/desa/vaccine-will-not-end-pandemic-unless-everyone-can-get-it>

⁷⁸ <https://www.marketplace.org/2020/12/15/could-relaxing-patents-help-poorer-countries-get-vaccines-faster/>; see also <https://www.forbes.com/sites/katiejennings/2020/11/17/how-much-will-a-covid-19-vaccine-cost/?sh=40084754576d> (“The ultimate value of this vaccine will really be determined by coverage”)

⁷⁹ <https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19>

⁸⁰ <https://www.forbes.com/sites/katiejennings/2020/11/17/how-much-will-a-covid-19-vaccine-cost/?sh=40084754576d>; <https://observer.com/2020/11/covid19-vaccine-price-pfizer-moderna-astrazeneca-oxford/>; <https://www.cnbc.com/2020/11/17/covid-vaccines-how-much-they-cost-whos-bought-them-and-how-theyre-stored.html>; <https://www.ft.com/content/80f20d71-d7eb-4386-b0f2-0b19e4aed94d>; <https://khn.org/news/analysis-how-a-covid-19-vaccine-could-cost-americans-dearly/>; <https://fortune.com/2020/12/10/covid-vaccine-pfizer-questions-biontech-how-effective-side-effects-approved-price-ingredients-doses-pandemic/>; <https://www.reuters.com/article/us-health-coronavirus-eu-vaccines/pfizer-irked-after-belgian-politician-publishes-covid-19-vaccine-prices-idUSKBN28S1T0>; <https://www.wsj.com/articles/covid-19-vaccine-makers-signal-prices-11596648639>; <https://www.marketplace.org/2020/11/12/how-much-could-pfizer-make-from-a-covid-19-vaccine/>; <https://www.nytimes.com/2020/12/18/upshot/coronavirus-vaccines-prices-europe-united-states.html>;

Potential access challenges in the U.S. other than pricing, such as transportation and healthcare infrastructure,⁸¹ as well as problems low- and middle-income countries are likely to experience in obtaining affordable vaccines,⁸² have also been discussed.

The fact that some vaccines were developed with significant government support figures in many accounts.⁸³ For example, a story on NPR's Weekend Edition related: "Given the upfront investment in the Moderna vaccine by the government, there are sharp questions about its eventual pricing. **'It's a classic example of taxpayers paying twice for medicines,'** says Zain Rizvi, a law and policy researcher at Public Citizen focused on pharmaceuticals. 'Now it wants to turn around and charge those very same taxpayers the highest public price for a potential COVID-19 [vaccine]. That's outrageous.'"⁸⁴ A recent op-ed in The New York Times urged: "Public support should mean a public vaccine, one that reaches people as quickly as possible — profitable or not. The pharmaceutical industry wouldn't be able to rake in its profits and restore its reputation without funding that comes from our tax dollars. We shouldn't let Big Pharma forget it."⁸⁵ An article about AstraZeneca in the Los Angeles Times made the connection to the broader

<https://www.firstpost.com/tech/science/oxford-astrazeneca-covid-19-vaccine-will-be-available-at-cost-price-across-world-says-pharma-head-olivier-nataf-9046111.html>;

<https://www.bloomberg.com/news/articles/2020-07-22/pfizer-biontech-receive-u-s-order-for-covid-vaccine>;

⁸¹ See, e.g., <https://www.cnn.com/2020/12/24/us/pharmacy-deserts-covid-19-vaccine/index.html>;
<https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01554>;
<http://richmondfreepress.com/news/2020/dec/10/officials-stress-equitable-access-blacks-latinos-c/>;
<https://www.nbcnews.com/news/us-news/how-get-covid-vaccine-everything-we-know-cost-effectiveness-n1250624>

⁸² <https://www.nature.com/articles/d41586-020-02684-9>; <https://www.reuters.com/article/us-health-coronavirus-vaccine-gdp-trfn/ensuring-global-covid-19-vaccine-access-seen-worth-billions-to-rich-nations-idUSKBN28D217>; <https://www.cnbc.com/2020/11/16/coronavirus-health-expert-says-vaccine-race-akin-to-law-of-the-jungle.html>; <https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive>; <https://www.bbc.com/news/world-54961045>

⁸³ <https://www.fool.com/investing/2020/12/16/heres-how-much-each-coronavirus-vaccine-will-cost/>;
<https://khn.org/news/analysis-how-a-covid-19-vaccine-could-cost-americans-dearly/> ("The United States instead has let business calculations drive drug price tags, forcing us to accept and absorb ever higher costs. That feels particularly galling for treatments and vaccines against COVID-19, whose development and production is being subsidized and incentivized with billions in federal investment."); <https://www.nytimes.com/2020/12/18/upshot/coronavirus-vaccines-prices-europe-united-states.html>; <https://www.latimes.com/politics/story/2020-09-14/drug-maker-got-1-billion-from-taxpayers-boosting-prices> ("One of the world's largest drug companies has been aggressively raising prices even as it received hundreds of millions of dollars of U.S. government aid to develop a COVID-19 vaccine."); <https://www.usatoday.com/story/news/health/2020/07/21/should-government-funded-covid-19-vaccine-free-all-americans/5426531002/> (quoting think tank spokesperson as arguing, "If American taxpayers are shouldering the financial risk of vaccine development, then American patients should be guaranteed that any resulting vaccines be affordable and accessible and that drug companies aren't allowed to profiteer from them.");

⁸⁴ <https://www.npr.org/sections/health-shots/2020/08/06/899869278/prices-for-covid-19-vaccines-are-starting-to-come-into-focus> (emphasis added)

⁸⁵ <https://www.nytimes.com/2020/12/17/opinion/covid-vaccine-big-pharma.html>

drug pricing issue, bemoaning that the company raised prices twice on some of its top-selling drugs in 2020 despite receiving substantial public support for its COVID-19 vaccine.⁸⁶ Further, the optimal allocation plan to ensure equitable access continues to be vigorously debated.⁸⁷

Legislative initiatives have addressed pricing and access concerns related specifically to COVID-19 products, which further underscores that this is indeed a significant policy issue. A bipartisan bill was introduced in the House and Senate, the “Make Medications Affordable by Preventing Pandemic Price Gouging Act of 2020,” which would “require any COVID-19 drug developed in whole or in part with Federal support to be affordable and accessible by prohibiting monopolies and price gouging.”⁸⁸ The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held a hearing in July 2020 on “Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine,” at which executives from AstraZeneca, J&J, Merck, Moderna and Pfizer testified.⁸⁹ Committee Chairman Frank Pallone, Jr. emphasized that “public health experts must ensure that [a vaccine] is safe, effective, and available to all who need it.”⁹⁰

Multilateral initiatives also aim to provide broad access. In April, the World Health Organization and several other organizations launched the Access to COVID-19 Tools (ACT) Accelerator. A study commissioned by the Bill and Melinda Gates Foundation estimated that giving low- and middle-income countries access to vaccines through the ACT Accelerator would benefit the economies of 10 high-income countries, including the U.S., by more than \$466 billion by 2025.⁹¹ One pillar of the ACT Accelerator, the COVAX facility, supports production of vaccines and negotiates their prices in order to provide equitable access across countries.⁹²

⁸⁶ <https://www.latimes.com/politics/story/2020-09-14/drug-maker-got-1-billion-from-taxpayers-boosting-prices> (“The company’s price hikes underscored the persistent inability of American policymakers, including Trump, to rein in drug prices, even during a public health crisis when pharmaceutical companies are getting substantial public assistance.”)

⁸⁷ See, e.g., <https://www.virginiamercury.com/2020/12/23/put-equity-first-in-access-to-the-covid-19-vaccine/> (“

⁸⁸ <https://www.govinfo.gov/app/details/BILLS-116hr7296ih/summary>;
<https://www.govinfo.gov/app/details/BILLS-116s4439is>

⁸⁹ <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-pathway-to-a-vaccine-efforts-to-develop-a-safe-effective-and>

⁹⁰

https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/2020.7.21.PALLONE.%20COVID-19%20Vaccine%20Hearing.OI_.pdf

⁹¹ <https://www.weforum.org/agenda/2020/12/who-covid-vaccines-equitable-access/>; see also <https://www.cnn.com/2020/12/10/business/melinda-gates-covid-vaccines/index.html> quoting Melinda Gates: “If we only get it to the high-income countries, this disease is going to bounce around. We’re going to see twice as many deaths. And our recovery of our economies is going to be much slower than if we get the vaccine out to everybody.”)

⁹² <https://www.gavi.org/vaccineswork/covax-explained>

The U.S.'s refusal to participate in or fund COVAX has spurred controversy.⁹³ The World Bank has committed \$12 billion to allow developing countries to buy and distribute COVID-19 vaccines.⁹⁴

Economists agree that equitable distribution of vaccines is key to economic recovery. In its 2020 World Economic Outlook, the International Monetary Fund ("IMF") stated, "A key aspect of combating the health crisis is to ensure that all innovations, be they in testing, treatments, or vaccines, are produced at scale for the benefit of all countries."⁹⁵ If access is unequal, according to the IMF, growth outcomes will be lower.⁹⁶ Indeed, when asked about what is top of mind for 2021, the IMF's Chief Economist Gita Gopinath responded without hesitation or prompting that it is universal availability of the COVID-19 vaccines to end the pandemic everywhere.⁹⁷ RAND Europe concluded that "vaccine nationalism," in which countries "push to get first access to a supply of vaccines or hoard key components of vaccine production," could trim up to \$1.2 trillion per year from global GDP.⁹⁸ The former Director-General of the World Trade Organization warned against inequitable access, stating: "a full resumption of international trade and economic activity will not be possible as long as some countries, populations and regions remain affected by the virus. Every additional month of delay in achieving immunisation coverage would translate into \$375 billion in losses to the global economy and tens of thousands of lost lives."⁹⁹

Inter-governmental organizations are also keenly focused on vaccine access. The United Nations General Assembly called its first special session in four years to address the pandemic. Many speakers emphasized the importance of equitable vaccine access in mitigating the pandemic's effects.¹⁰⁰ COVID-19 vaccine accessibility was a top agenda item in the most recent G-20 summit,¹⁰¹ and the World Health Organization (WHO), together with various governmental, private

⁹³ <https://www.axios.com/covax-initiative-vaccines-china-joins-trump-russia-26dce1f3-1b81-47af-8b7d-199900a928f3.html>; <https://globalbiodefense.com/2020/10/03/why-it-matters-that-the-u-s-is-not-supporting-covax/>; <https://foreignpolicy.com/2020/09/15/covax-vaccine-covid-19-trump-save-lives-equitable-distribution/>; <https://www.barrons.com/articles/the-u-s-snubbed-the-whos-covax-facility-that-could-be-dangerous-for-americans-51599298200>; <https://www.vox.com/21448719/covid-19-vaccine-covax-who-gavi-cepi>; <https://www.businessinsider.com/trump-refusal-to-join-who-vaccine-effort-hurts-us-2020-9>; <https://fortune.com/2020/12/17/covax-biden-why-the-us-needs-to-help-the-world-get-vaccinated-ceo-daily/>

⁹⁴ <https://www.worldbank.org/en/news/press-release/2020/10/13/world-bank-approves-12-billion-for-covid-19-vaccines>

⁹⁵ <https://www.imf.org/en/Publications/WEO/Issues/2020/09/30/world-economic-outlook-october-2020>, at xiii.

⁹⁶ <https://www.imf.org/en/Publications/WEO/Issues/2020/09/30/world-economic-outlook-october-2020>, at xvi.

⁹⁷ <https://www.imf.org/external/mmedia/view.aspx?vid=6216445696001>

⁹⁸ https://www.rand.org/pubs/research_briefs/RBA769-1.html

⁹⁹ <https://voxeu.org/article/production-and-equitable-access-covid-19-tests-treatments-and-vaccines>

¹⁰⁰ <https://www.un.org/press/en/2020/ga12293.doc.htm>

¹⁰¹ <https://www.cbsnews.com/news/g20-summit-2020-concludes-covid19-vaccine-for-all/>

and philanthropic partners, have convened the COVAX facility to boost global equitable access to COVID-19 vaccines.¹⁰²

Attention has also focused on the role intellectual property protections play in hindering access, which is mentioned in the Proposal's supporting statement. In October 2020, India and South Africa asked the World Trade Organization to adopt an intellectual property waiver that would allow member countries to refrain from enforcing patents for COVID-19 treatments, vaccines or diagnostics until widespread vaccination and immunity has been achieved; this request was supported by hundreds of advocacy groups.¹⁰³ The People's Vaccine Alliance is urging vaccine manufacturers to share intellectual property (and related proprietary information) through the World Health Organization's COVID-19 Technology Access Pool, to facilitate production of the number of doses needed to vaccinate people in poor countries as well as rich ones.¹⁰⁴

Members of the Global Development Policy Center argued that the waiver is necessary because intellectual property barriers have "led to limited product development worldwide and an inability to expand supply to meet the demand for effective medical technologies."¹⁰⁵ A December 2020 op-ed in The New York Times urged rich countries to drop their opposition, for their own sake as well as that of less affluent countries,¹⁰⁶ as has the humanitarian organization, Doctors Without Borders/Medicins Sans Frontieres.¹⁰⁷ The EU argued in the WTO General Council on December 18th that "[t]he best way of achieving [rapid scale-up] is by disseminating the technology and know-how of those who developed the vaccines, through collaboration with other companies that can contribute to the developers' manufacturing capacity."¹⁰⁸ Opposition by a few wealthy countries, including the U.S., has thus far led to a stalemate.¹⁰⁹

¹⁰² <https://www.who.int/initiatives/act-accelerator/covax>

¹⁰³ <https://www.wsj.com/articles/developing-nations-push-for-covid-vaccines-without-the-patents-11605614409>; <https://theconversation.com/covid-19-drug-and-vaccine-patents-are-putting-profit-before-people-149270>; <https://www.msf.org/covid-19-governments-must-build-consensus-around-waiver>; <https://www.statnews.com/pharmalot/2020/10/14/wto-patents-covid19-coronavirus-pandemic-vaccines/>; [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32581-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext); <https://www.theguardian.com/world/2020/nov/19/uk-faces-calls-drop-opposition-patent-free-covid-vaccines-wto>; <https://www.wsj.com/articles/covid-vaccine-shakedown-at-the-wto-11608160370>

¹⁰⁴ <https://www.amnesty.org/en/latest/news/2020/12/campaigners-warn-that-9-out-of-10-people-in-poor-countries-are-set-to-miss-out-on-covid-19-vaccine-next-year/>

¹⁰⁵ <https://www.bu.edu/gdp/2020/11/18/open-letter-to-trips-council-members/>

¹⁰⁶ <https://nyti.ms/33Py7Cp>

¹⁰⁷ <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-calls-governments-support-landmark-move-wto-suspend-patents-during>

¹⁰⁸ <https://medicineslawandpolicy.org/2020/12/decision-on-intellectual-property-waiver-over-covid-technology-on-hold-till-2021-what-are-the-next-steps/>

¹⁰⁹ <https://www.reuters.com/article/us-health-coronavirus-wto/wto-delays-decision-on-waiver-on-covid-19-drug-vaccine-rights-idUSKBN28K2WL>

The fact that many vaccine makers have received government support for research and development as well as manufacturing has been cited as a reason companies should be willing to share intellectual property. The NYT op-ed noted that Moderna, Pfizer, and AstraZeneca all benefited from government support: “In other words, the vaccines developed by these companies were developed thanks wholly or partly to taxpayer money. Those vaccines essentially belong to the people — and yet the people are about to pay for them again, and with little prospect of getting as many as they need fast enough.”¹¹⁰ The OECD has stated, “In the context of COVID-19, vast amounts of public funding have already allocated to R&D and, as argued above, more funding will be needed. Given that taxpayers already bear much of the risk and costs of R&D and that broad access to a new vaccine and effective treatments will be key to restoring social and economic life, [intellectual property rights] should not create financial access barriers and product prices will need to be close to the cost of production to ensure affordability.”¹¹¹

Given the massive debate and public discourse surrounding access and pricing of COVID-19 vaccines and treatment by global and national institutions alike, calling this a significant policy issue is an understatement; indeed, distribution and access has become one of the most critically important policy issues of our time.

In 2019, the pharmaceutical industry’s reputation, as measured in an annual Gallup poll, fell below that of all other industries and even the federal government, driven by its role in the opioid crisis and controversies regarding high drug prices.¹¹² Producing a vaccine to end the COVID-19 pandemic has been viewed, in part, as an opportunity to burnish the industry’s reputation.¹¹³ Eli Lilly’s CEO stated on an earnings call that the industry had a “once in a generation opportunity to reset” its reputation.¹¹⁴ Positive vaccine data has already begun to rehabilitate the industry

¹¹⁰ <https://nyti.ms/33Py7Cp>

¹¹¹ <https://www.oecd.org/coronavirus/policy-responses/treatments-and-a-vaccine-for-covid-19-the-need-for-coordinating-policies-on-r-d-manufacturing-and-access-6e7669a9/#section-d1e1763>

¹¹² <https://news.gallup.com/poll/266060/big-pharma-sinks-bottom-industry-rankings.aspx>

¹¹³ <https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html> (“For Pfizer, this is as much public relations as it is a financial return — they very much want to be seen as part of the solution,” said Geoffrey Porges, an analyst for SVB Leerink, an investment bank in Boston.); <https://scrip.pharmaintelligence.informa.com/SC143225/Can-Pharma-Rebuild-Its-Reputation-COVID19-Means-A-Big-Responsibility-And-Opportunity> (“The industry now hopes that if it is indeed successful at helping to end the global health crisis caused by COVID-19 through the development of treatments and vaccines, it will offset some of the bad press that has built over decades.”); <https://scrip.pharmaintelligence.informa.com/SC142130/Pharma-Can-Reset-Reputation-In-Pandemic-Says-Novartis-CEO>

¹¹⁴ <https://www.fiercepharma.com/pharma/amid-challenges-a-covid-19-opportunity-for-pharma-a-chance-to-bolster-its-reputation-lilly>

in the eyes of the public,¹¹⁵ but decisions affecting access, including pricing and willingness to share intellectual property, could not only frustrate efforts to end the pandemic but also reinforce public perceptions of pharmaceutical companies as price gougers.

Finally, access to COVID-19 treatments will continue to be important even as vaccination campaigns are deployed to achieve herd immunity. Some people cannot be vaccinated for medical reasons, and the types of access barriers discussed above will likely prevent vaccination of all eligible people. Further, the durability of immunity is still unknown, and so it is still quite possible that periodic – even annual – vaccinations will be necessary. Thus, the receipt of federal support for therapeutics, if J&J develops one or more, would create the same kinds of risks as are present in the vaccine context.

The Proposal Would Not Micromanage J&J

J&J contends that the Proposal would micromanage the Company because “any pricing decisions for COVID-19 vaccines and therapeutics are inherently complex matters upon which shareholders, as a group, are not in a position to make an informed judgment.”¹¹⁶ That assertion is contradicted by the extensive national and international dialogue and debate described above, which shows that the public, non-governmental organizations, and policy makers are capable of engaging on the subject. There is no reason to believe that shareholders are less capable of understanding the factors that go into pricing and access decisions than the non-specialists involved in the current debate. Accordingly, shareholders are in a position to make an informed judgment on the subject of the Proposal.

Moreover, J&J’s contention that the Proposal requests a “highly detailed report” on the relationship between its receipt of federal support and its pricing decisions is inaccurate because the Proposal does not identify specific details for inclusion in a report.

An argument much like J&J makes here was advanced in the unsuccessful requests to exclude the pricing risk proposals. Gilead claimed that the proposal sought to micromanage it, arguing that information on risks created by the relationship between prices and “clinical benefit, patient access, the efficacy and price of alternative therapies, drug development costs and the proportion of those costs borne by academic institutions or governments” was too complex and difficult for shareholders to understand.¹¹⁷ The Staff rejected this argument. This Proposal, like the pricing risk proposals, seeks to understand how government support of drug

¹¹⁵ <https://www.fiercepharma.com/marketing/pfizer-vaccine-awareness-and-reputation-rises-vaccine-news-harris-poll>

¹¹⁶ No-Action Request, at 8.

¹¹⁷ Gilead Sciences, Inc. (avail. Feb. 23, 2015).

development efforts may affect pricing and decisions related to access; unlike those proposals, however, the Proposal does not ask for disclosure regarding other, arguably more technical matters such as clinical benefit and competing therapies.

In sum, the Proposal should not be excluded on ordinary business grounds because:

1. Access to medicines and high drug prices have long been considered a subject of consistent and widespread public debate and thus rise to the level of a significant policy issue.
2. Widespread vaccination is critical to ending the COVID-19 pandemic, reviving the economy, relieving burdens on the health care system, and restoring normalcy, so the debate over access to COVID-19 vaccines, especially given the central role played by government support, should be deemed a significant policy issue.
3. The Proposal operates at a high level, seeking general information about the role of government support in pricing and access decisions and not requiring disclosure of detailed technical information; thus, it would not micromanage J&J.

Substantial Implementation

J&J claims that it has substantially implemented the Proposal through disclosures on its web site. Those disclosures, however, do not address key elements of the Proposal and thus cannot be said to “compare favorably” to the Proposal’s request or to accomplish the Proposal’s “essential objectives.”

J&J points to material on its web site that is not responsive to the Proposal: a description of general pricing considerations, a commitment to deliver up to 500 million doses to lower income countries, and support for governments’ plans to obtain vaccines to administer free of charge to their citizens.

In the article J&J references (also available as Exhibit F to the No-Action Request), Mr. Wolk explained that the “not-for-profit” price will be “based on a formula established and utilized by the Bill & Melinda Gates Foundation (BMGF) for vaccine product pricing in lower-income countries.” The article did not describe that formula, but J&J asserted in the No-Action Request, citing to the BMGF’s own web site, that under the BMGF formula all third-party contributions, including contributions from the government, that “directly related to the incremental production of the vaccine being assessed should be counted” toward reducing the manufacturer’s cost base.

Thus, the disclosure on J&J’s web site states that a “not-for-profit” price will be used for some period of time—we note that the phrase “emergency pandemic use”

is undefined—and that the BMGF formula will be used in determining that price, but it does not explain how government support is treated. Instead, readers must research BMGF’s formula elsewhere in order to obtain that information. Furthermore, claiming that the pricing will be “based on” the BMGF formula does not confirm that J&J will adopt an identical or even substantially similar approach, leaving shareholders in the dark as to how closely the Company will hew to that model. We also note that J&J does not claim to provide any information about how government support would be treated when setting prices or making other access-related decisions outside of the “emergency pandemic” window. In sum, stating that the Company’s COVID-19 pricing strategy is based on a particular formula - without providing any information about *how* government financial support will be taken into account now or in the future - leaves investors uninformed and unable to assess associated risks. Given that the Proposal’s core request is for information about how government support is taken into account in pricing decisions, J&J’s existing disclosures fall far short of satisfying the Proposal’s essential objective.

* * *

For the reasons set forth above, J&J has not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7) or 14a-8(i)(10). The Proponents thus respectfully request that J&J’s request for relief be denied.

The Proponents appreciate the opportunity to be of assistance in this matter. If you have any questions or need additional information, please contact me at (907) 713-4963.

Sincerely,



Nicholas J. Lusiani
Senior Advisor, Private Sector Department
Oxfam America

cc: Marc S. Gerber, Esq.
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BY EMAIL (shareholderproposals@sec.gov)

December 11, 2020

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Chief Counsel
100 F Street, N.E.
Washington, D.C. 20549

RE: Johnson & Johnson – 2021 Annual Meeting
Omission of Shareholder Proposal of
Oxfam America, Inc. and co-filers¹

Ladies and Gentlemen:

Pursuant to Rule 14a-8(j) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we are writing on behalf of our client, Johnson & Johnson, a New Jersey corporation, to request that the Staff of the Division of Corporation Finance (the “Staff”) of the U.S. Securities and Exchange Commission (the “Commission”) concur with Johnson & Johnson’s view that, for the reasons stated below, it may exclude the shareholder proposal and supporting statement (the “Proposal”) submitted by Oxfam America, Inc. (“Oxfam”) and co-filers from the proxy materials to be distributed by Johnson & Johnson in connection with its 2021 annual

¹ The following shareholders have co-filed the Proposal: Achmea Investment Management; Benedictine Sisters of Boerne, Texas; Benedictine Sisters of Virginia, Inc.; CommonSpirit Health; Congregation of Divine Providence; Mercy Investment Services, Inc.; Monasterio De San Benito; PeaceHealth; Providence Trust; The Sisters of Charity of Saint Elizabeth; The Sisters of Providence, Mother Joseph Province; and Trinity Health.

meeting of shareholders (the “2021 proxy materials”). Oxfam and the co-filers are sometimes collectively referred to as the “Proponents.”

In accordance with Section C of Staff Legal Bulletin No. 14D (Nov. 7, 2008) (“SLB 14D”), we are emailing this letter and its attachments to the Staff at shareholderproposals@sec.gov. In accordance with Rule 14a-8(j), we are simultaneously sending a copy of this letter and its attachments to the Proponents as notice of Johnson & Johnson’s intent to omit the Proposal from the 2021 proxy materials.

Rule 14a-8(k) and Section E of SLB 14D provide that shareholder proponents are required to send companies a copy of any correspondence that the shareholder proponents elect to submit to the Commission or the Staff. Accordingly, we are taking this opportunity to remind the Proponents that if they submit correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should concurrently be furnished to Johnson & Johnson.

I. The Proposal

The text of the resolution contained in the Proposal is copied below:

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

II. Bases for Exclusion

We hereby respectfully request that the Staff concur in Johnson & Johnson’s view that it may exclude the Proposal from the 2021 proxy materials pursuant to:

- Rule 14a-8(i)(7) because the Proposal deals with matters relating to Johnson & Johnson’s ordinary business operations; and
- Rule 14a-8(i)(10) because Johnson & Johnson has substantially implemented the Proposal.

III. Background

Johnson & Johnson received the Proposal on October 30, 2020, accompanied by a cover letter from Oxfam. On November 2, 2020, after confirming that Oxfam was not

a shareholder of record, in accordance with Rule 14a-8(f)(1), Johnson & Johnson sent a letter to Oxfam requesting a written statement from the record owner of Oxfam's shares verifying that Oxfam has beneficially owned the requisite number of shares of Johnson & Johnson common stock continuously for at least one year as of the date the Proposal was submitted (the "Deficiency Letter"). On November 9, 2020, Johnson & Johnson received a letter from Fidelity Investments verifying Oxfam's stock ownership. Copies of the Proposal, cover letter, the Deficiency Letter and related correspondence are attached hereto as Exhibit A. In addition, the co-filers' submissions are attached hereto as Exhibit B.

IV. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(7) Because the Proposal Deals with Matters Relating to Johnson & Johnson's Ordinary Business Operations.

Under Rule 14a-8(i)(7), a shareholder proposal may be excluded from a company's proxy materials if the proposal "deals with matters relating to the company's ordinary business operations." In Exchange Act Release No. 34-40018 (May 21, 1998) (the "1998 Release"), the Commission stated that the policy underlying the ordinary business exclusion rests on two central considerations. The first recognizes that certain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight. The second consideration relates to the degree to which the proposal seeks to "micro-manage" the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment. As demonstrated below, the Proposal implicates both of these two central considerations.

A. The Proposal relates to Johnson & Johnson's ordinary business matters.

The Commission has stated that a proposal requesting the dissemination of a report is excludable under Rule 14a-8(i)(7) if the substance of the proposal involves a matter of ordinary business of the company. *See* Exchange Act Release No. 34-20091 (Aug. 16, 1983) (the "1983 Release") ("[T]he staff will consider whether the subject matter of the special report or the committee involves a matter of ordinary business; where it does, the proposal will be excludable under Rule 14a-8(c)(7)."); *see also* *Netflix, Inc.* (Mar. 14, 2016) (permitting exclusion under Rule 14a-8(i)(7) of a proposal that requested a report describing how company management identifies, analyzes and oversees reputational risks related to offensive and inaccurate portrayals of Native Americans, American Indians and other indigenous peoples, how it mitigates these risks and how the company incorporates these risk assessment results into company policies and decision-making, noting that the proposal related to the ordinary business matter of the "nature, presentation and content of programming and film production").

The Staff has consistently permitted exclusion of shareholder proposals under Rule 14a-8(i)(7) when those proposals relate to how a company makes specific pricing decisions regarding certain of its products. *See, e.g., Verizon Communications Inc.* (Jan. 29, 2019) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company offer its shareholders the same discounts on its products and services that are available to its employees, noting that the proposal related to the company's discount pricing policies); *Host Hotels & Resorts, Inc.* (Feb. 6, 2014) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board consider providing senior citizens and stockholders discounts on hotel rates, noting that discount pricing policy determinations is an ordinary business matter); *Equity LifeStyle Properties, Inc.* (Feb. 6, 2013) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on, among other things, "the reputational risks associated with the setting of unfair, inequitable and excessive rent increases that cause undue hardship to older homeowners on fixed incomes" and "potential negative feedback stated directly to potential customers from current residents," noting that the "setting of prices for products and services is fundamental to management's ability to run a company on a day-to-day basis"); *Ford Motor Co.* (Jan. 31, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal seeking to allow shareholders who purchased a new vehicle and "had no spare tire and hardware for mounting [the spare tire] . . . be able to purchase same from Ford Motor at the manufacturing cost of same," noting that "the setting of prices for products and services is fundamental to management's ability to run a company on a day-to-day basis"); *Western Union Co.* (Mar. 7, 2007) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board review, among other things, the effect of the company's remittance practices on the communities served and compare the company's fees, exchange rates, and pricing structures with other companies in its industry, noting that the proposal related to the company's "ordinary business operations (*i.e.*, the prices charged by the company)").

In particular, the Staff has permitted exclusion of shareholder proposals under Rule 14a-8(i)(7) where the proposals related to the pricing of a particular group of prescription drugs. *See AbbVie Inc.* (Feb. 24, 2017) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on "the rationale and criteria used" to determine "the rates of price increases year-to-year of the company's top ten selling branded prescription drugs between 2010 and 2016," noting that the company's "rationale and criteria for price increases" of such prescription drugs related to ordinary business operations); *Biogen Inc.* (Feb. 23, 2017) (same); *Gilead Sciences, Inc.* (Feb. 10, 2017) (same); *Johnson & Johnson* (Feb. 10, 2017) (same); *Pfizer Inc.* (Feb. 10, 2017) (same).

In addition, the Staff has permitted exclusion of shareholder proposals under Rule 14a-8(i)(7) when those proposals request a report on how companies intend to respond to certain external pressures relating to pricing policies or price increases. *See Johnson & Johnson* (Jan. 12, 2004) (permitting exclusion under Rule 14a-8(i)(7) of a

proposal requesting that the board review pricing and marketing policies and prepare a report on how the company will respond to certain external pressures to increase access to prescription drugs); *see also UnitedHealth Group Inc.* (Mar. 16, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a board report on how the company is responding to certain external pressures to ensure affordable health care coverage and the measures the company is taking to contain price increases of health insurance premiums as relating to ordinary business matters).

We are aware that, under certain limited circumstances, the Staff has declined to permit the exclusion of proposals relating to the company's overall pricing policies for pharmaceutical products. In all of those instances, however, the proposals focused solely on the company's fundamental business strategy with respect to its pricing policies for pharmaceutical products, rather than on specific pricing decisions regarding particular products. *See Celgene Corp.* (Mar. 19, 2015) (declining to permit exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on the risks to the company from rising pressure to contain U.S. specialty drug prices, noting that the proposal focused on the company's "fundamental business strategy with respect to its pricing policies for pharmaceutical products"); *Vertex Pharmaceuticals Inc.* (Feb. 25, 2015) (same); *Gilead Sciences, Inc.* (Feb. 23, 2015) (same); *Bristol-Myers Squibb Co.* (Feb. 21, 2000) (declining to permit exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board create and implement a policy of price restraint on pharmaceutical products for individual customers and institutional purchasers to keep drug prices at reasonable levels and report to shareholders any changes in its pricing policies and procedures, noting that the proposal related to the company's "fundamental business strategy, i.e., its pricing for pharmaceutical products"); *Warner-Lambert Co.* (Feb. 21, 2000) (same); *Eli Lilly and Co.* (Feb. 25, 1993) (declining to permit exclusion under Rule 14a-8(i)(7) where the proposal asked the board "to seek input on its pricing policy from consumer groups, and to adopt a policy of price restraint," noting that the proposal related to "the [c]ompany's fundamental business strategy with respect to its pricing policy for pharmaceutical products").

In addition, the Staff also has permitted exclusion of shareholder proposals under Rule 14a-8(i)(7) when those proposals relate to a company's sources of financing. In *General Electric Co.* (Feb. 15, 2000), for example, the Staff permitted exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company report on the financial benefits received by the company from various government incentive programs, including direct subsidies and below-market financing backed by government funds or government guarantees. In the supporting statement of the proposal, the proponents argued that the company faced risks from relying on government financial assistance. In concurring with the company's view that the proposal could be excluded under Rule 14a-8(i)(7), the Staff noted that the proposal related to "a source of financing" and therefore to a matter of ordinary business operations. *See also, e.g., Pfizer Inc.* (Feb. 16, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting an

annual assessment and report of risks created by actions the company takes to avoid or minimize U.S. federal, state and local taxes, noting that the proposal related to “decisions concerning the company’s tax expenses and sources of financing”); *The TJX Companies, Inc.* (Mar. 29, 2011) (same); *Pfizer Inc.* (Feb. 5, 2003) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on “each tax break that provides the company with more than \$5 million of tax savings,” noting that the proposal related to the “disclosure of the sources of financing”).

In this instance, the Proposal concerns ordinary business matters related to Johnson & Johnson’s pricing decisions regarding particular products and the sources of financing for those products (in the form of research grants and advance purchases by the federal government). Specifically, the Proposal focuses on Johnson & Johnson’s pricing decision on “vaccines and therapeutics for COVID-19” and how government collaboration for their development and manufacture may influence such pricing decision. In this regard, the supporting statement asserts that Johnson & Johnson’s subsidiary “has received substantial government funding for research and development related to COVID-19” and questions how this collaboration will be taken into account in setting a price for COVID-19 products. This focus demonstrates a concern with the ordinary business matter of how, when and why Johnson & Johnson decides the prices of certain of its products and the relationship that certain sources of financing, and government research grants and advance purchases in particular, may factor into such decisions. These business and operational decisions are complex and fall squarely within the purview of management and could not, as a practical matter, be subject to direct shareholder oversight. In addition, unlike those proposals described above where the Staff was unable to concur in the company’s request for exclusion, this Proposal is not remotely concerned with Johnson & Johnson’s fundamental business strategy for all of its products. Instead, the Proposal features a singular focus on pricing for COVID-19 vaccines and therapeutics. For this reason, the Proposal is excludable under Rule 14a-8(i)(7).

We note that a proposal may not be excluded under Rule 14a-8(i)(7) if it is determined to focus on a significant policy issue. The fact that a proposal may touch upon a significant policy issue, however, does not preclude exclusion under Rule 14a-8(i)(7). Instead, the question is whether the proposal focuses primarily on a matter of broad public policy versus matters related to the company’s ordinary business operations. *See* the 1998 Release and Staff Legal Bulletin No. 14E (Oct. 27, 2009). The Staff has consistently permitted exclusion of shareholder proposals where the proposal focused on ordinary business matters, even though it also related to a potential significant policy issue. In *PetSmart, Inc.* (Mar. 24, 2011), for example, the proposal requested that the company’s board require suppliers to certify that they had not violated certain laws regulating the treatment of animals. Those laws affected a wide array of matters dealing with the company’s ordinary business operations beyond the humane treatment of animals, which the Staff has recognized as a significant policy

issue. In granting relief to exclude the proposal, the Staff noted the company's view that "the scope of the laws covered by the proposal is 'fairly broad in nature from serious violations such as animal abuse to violations of administrative matters such as record keeping.'" *See also, e.g., CIGNA Corp.* (Feb. 23, 2011) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the potential significant policy issue of access to affordable health care, it also asked CIGNA to report on expense management, an ordinary business matter); *Capital One Financial Corp.* (Feb. 3, 2005) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the significant policy issue of outsourcing, it also asked the company to disclose information about how it manages its workforce, an ordinary business matter).

In this instance, as described above, the Proposal focuses on the ordinary business matter of Johnson & Johnson's pricing decision for particular products—COVID-19 vaccines and therapeutics—and how government collaboration is taken into account when making those decisions. Therefore, even if the Proposal could be viewed as touching upon a significant policy issue, its focus is on ordinary business matters. Accordingly, the Proposal may be excluded under Rule 14a-8(i)(7).

B. The Proposal seeks to micromanage Johnson & Johnson.

The Staff has consistently agreed that shareholder proposals attempting to micromanage a company by probing too deeply into matters of a complex nature upon which shareholders, as a group, are not in a position to make an informed judgment are excludable under Rule 14a-8(i)(7). *See* the 1998 Release; *see also, e.g., Walgreens Boots Alliance, Inc.* (Nov. 20, 2018) (permitting exclusion under Rule 14a-8(i)(7) on the basis of micromanagement of a proposal that requested open market share repurchase programs or stock buybacks subsequently adopted by the board not become effective until approved by shareholders); *JPMorgan Chase & Co.* (Mar. 30, 2018) (permitting exclusion under Rule 14a-8(i)(7) on the basis of micromanagement of a proposal that requested a report on the reputational, financial and climate risks associated with project and corporate lending, underwriting, advising and investing on tar sands projects).

In Staff Legal Bulletin No. 14J (Oct. 23, 2018), the Staff reiterated that a proposal micromanages a company when it "involves intricate detail, or seeks to impose specific time-frames or methods for implementing complex policies." The Staff explained that the micromanagement basis of exclusion "also applies to proposals that call for a study or report" and, therefore, a proposal that seeks an intricately detailed study or report may be excluded on micromanagement grounds. Further, the Staff stated that it "would, consistent with Commission guidance, consider the underlying substance of the matters addressed by the study or report" to determine whether a proposal involves intricate detail, or seeks to impose specific time-frames or methods for implementing complex policies.

In this case, the Proposal attempts to micromanage Johnson & Johnson by requesting an intricately detailed report. In particular, the Proposal's resolution requests a report on how collaboration with the U.S. government is being or will be taken into account when setting prices for COVID-19 vaccines and therapeutics. The supporting statement goes on to discuss production timelines, intellectual property considerations, patent rights, and supply demands in relation to COVID-19 products. As exemplified by these varied features, any pricing decisions for COVID-19 vaccines and therapeutics are inherently complex matters upon which shareholders, as a group, are not in a position to make an informed judgment. Moreover, the scope of the report requested by the Proposal would be especially detailed.

As explained in the 2019 Janssen U.S. Transparency Report, Johnson & Johnson and its subsidiary Janssen take into account myriad factors when pricing pharmaceutical products. For instance, Johnson & Johnson considers the product's value to patients, the healthcare system and society, and preserving the ability to invest in future developments.² In this regard, Johnson & Johnson's pricing decision for a COVID-19 vaccine may involve even more complexities, given the rapid, emergency development process for the vaccine and the scale of the pandemic. Further, the Proposal requests a highly detailed report on the complex relationship between Johnson & Johnson's collaboration with the U.S. government and the pricing of a COVID-19 vaccine. By requesting such an intricately detailed report, the Proposal seeks to micromanage Johnson & Johnson's business. Therefore, the Proposal is precisely the type of effort that Rule 14a-8(i)(7) is intended to prevent.

Accordingly, the Proposal should be excluded from Johnson & Johnson's 2021 proxy materials pursuant to Rule 14a-8(i)(7) as relating to Johnson & Johnson's ordinary business operations.

V. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(10) Because Johnson & Johnson Has Substantially Implemented the Proposal.

Rule 14a-8(i)(10) permits a company to exclude a shareholder proposal if the company has already substantially implemented the proposal. The Commission adopted the "substantially implemented" standard in 1983 after determining that the "previous formalistic application" of the rule defeated its purpose, which is to "avoid the possibility of shareholders having to consider matters which already have been favorably acted upon by the management." *See* 1983 Release; Exchange Act Release No. 34-12598 (July 7, 1976). Accordingly, the actions requested by a proposal need not

² *See 2019 Janssen U.S. Transparency Report*, available at <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-v16.pdf> and attached hereto as Exhibit C.

be “fully effected” provided that they have been “substantially implemented” by the company. *See* 1983 Release.

Applying this standard, the Staff has consistently permitted the exclusion of a proposal when it has determined that the company’s policies, practices and procedures or public disclosures compare favorably with the guidelines of the proposal. *See, e.g., Devon Energy Corp.* (Apr. 1, 2020)*; *Johnson & Johnson* (Jan. 31, 2020)*; *Pfizer Inc.* (Jan. 31, 2020)*; *The Allstate Corp.* (Mar. 15, 2019); *Johnson & Johnson* (Feb. 6, 2019); *United Cont’l Holdings, Inc.* (Apr. 13, 2018); *eBay Inc.* (Mar. 29, 2018); *Kewaunee Scientific Corp.* (May 31, 2017); *Wal-Mart Stores, Inc.* (Mar. 16, 2017); *Dominion Resources, Inc.* (Feb. 9, 2016); *Ryder System, Inc.* (Feb. 11, 2015); *Wal-Mart Stores, Inc.* (Mar. 27, 2014).

In addition, the Staff has permitted exclusion under Rule 14a-8(i)(10) where the company already addressed the underlying concerns and satisfied the essential objectives of the proposal, even if the proposal had not been implemented exactly as proposed by the proponent. For example, in *Oshkosh Corp.* (Nov. 4, 2016), the Staff permitted exclusion under Rule 14a-8(i)(10) of a proposal asking the board to amend certain provisions of the company’s proxy access bylaw in accordance with the six “essential elements” specified in the proposal. In arguing that the proposal had been substantially implemented, the company explained that it had adopted three of the six proposed changes in the proposal. Although the proposal asked for the adoption of all of the proposed changes, the Staff concluded that the company’s bylaw amendments “compare favorably with the guidelines of the proposal” and that the company substantially implemented the proposal. Similarly in *PG&E Corp.* (Mar. 10, 2010), the Staff permitted exclusion under Rule 14a-8(i)(10) of a proposal requesting that the company provide a report disclosing, among other things, the company’s standards for choosing the organizations to which the company makes charitable contributions and the “business rationale and purpose for each of the charitable contributions.” In arguing that the proposal had been substantially implemented, the company referred to a website where the company had described its policies and guidelines for determining the types of grants that it makes and the types of requests that the company typically does not fund. Although the proposal appeared to contemplate disclosure of each and every charitable contribution, the Staff concluded that the company had substantially implemented the proposal. *See also, e.g., The Wendy’s Co.* (Apr. 10, 2019) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting a report assessing human rights risks of the company’s operations, including the principles and methodology used to make the assessment, the frequency of assessment and how the company would use the assessment’s results, where the company had a code of ethics and a code of conduct for suppliers and disclosed on its website the frequency and methodology of its human rights risk assessments); *MGM Resorts Int’l* (Feb. 28, 2012) (permitting exclusion under

* Citations marked with an asterisk indicate Staff decisions issued without a letter.

Rule 14a-8(i)(10) of a proposal requesting a report on the company's sustainability policies and performance, including multiple objective statistical indicators, where the company published an annual sustainability report); *Exelon Corp.* (Feb. 26, 2010) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting a report disclosing policies and procedures for political contributions and monetary and non-monetary political contributions where the company had adopted corporate political contributions guidelines).

In this instance, Johnson & Johnson has substantially implemented the Proposal, the essential objective of which is to report on Johnson & Johnson's approach to COVID-19 vaccine and therapeutic pricing. In particular, the Proposal requests a report on how government collaboration for the development and manufacture of vaccines and therapeutics for COVID-19 may influence Johnson & Johnson's pricing decision for those products.

Johnson & Johnson already has published information on its approach to COVID-19 vaccine and therapeutic pricing. In this regard, Johnson & Johnson maintains a portion of its corporate website dedicated to providing updates on its COVID-19 related initiatives and statements, a landing page titled "Our COVID-19 Efforts," which includes information detailing its pricing approach. These public disclosures address the underlying concerns and essential objectives of the Proposal. Specifically, as disclosed on Johnson & Johnson's website, in September 2020 Johnson & Johnson signed a Communiqué on Expanded Global Access for COVID-19, where it committed to ensure that people everywhere have access to the potential COVID-19 innovations under development at a number of companies regardless of their income level. In connection with the Communiqué, Johnson & Johnson committed to providing up to 500 million vaccine doses to lower income countries with delivery beginning mid next year.³ As further disclosed on Johnson & Johnson's website, since the beginning of its COVID-19 response Johnson & Johnson has been committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.⁴ Among other efforts, Johnson & Johnson has supported the plans of the U.S. and other governments to procure the vaccine on behalf of their citizens in order to ensure that the vaccine is provided free of charge. Further, in an interview published on Johnson &

³ See *Johnson & Johnson Joins Other Companies in Signing a Landmark Communiqué on Expanded Global Access for COVID-19*, available at <https://www.jnj.com/latest-news/johnson-johnson-signs-communicue-on-expanded-global-access-for-covid-19-vaccines> and attached hereto as Exhibit D.

⁴ See *Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use*, available at <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use> and attached hereto as Exhibit E.

Johnson's website, Johnson & Johnson's Chief Financial Officer, Joe Wolk, explained that providing a potential COVID-19 vaccine for emergency pandemic use on a not-for-profit basis entails "distributing the vaccine at a cost to payers that covers [Johnson & Johnson's] costs, such as development, clinical trials required and manufacturing and distribution."⁵ Moreover, Mr. Wolk explained that Johnson & Johnson's not-for-profit pricing will be "based on a formula established and utilized by the Bill & Melinda Gates Foundation (BMGF) for vaccine product pricing in lower-income countries." This formula provides that all third-party contributions, including contributions from the government, that "directly related to the incremental production of the vaccine being assessed should be counted" toward reducing the manufacturer's cost base for a product.⁶ Accordingly, Johnson & Johnson has not only reported on its approach to COVID-19 vaccine and therapeutic pricing, but it also has provided specific details on how it plans to take into account government collaboration in setting the price for a potential COVID-19 vaccine.⁷

Consistent with the precedent described above, Johnson & Johnson's public disclosures already have satisfied the essential objective of the Proposal by describing how Johnson & Johnson may take into account its collaboration with the government

⁵ See *The Impact of COVID-19 on a Company: 6 Questions for the Chief Financial Officer of Johnson & Johnson*, available at <https://www.jnj.com/latest-news/johnson-johnson-cfo-joe-wolk-on-business-impact-of-covid-19> and attached hereto as Exhibit F.

⁶ See Bill & Melinda Gates Foundation, *Production Economics for Vaccines* (2016), available at https://docs.gatesfoundation.org/Documents/Production_Economics_Vaccines_2016.pdf and attached hereto as Exhibit G.

⁷ In addition, Johnson & Johnson's subsidiary Janssen, which is responsible for developing COVID-19 vaccines and therapeutics, already discloses a significant amount of information with respect to its drug pricing in the 2019 Janssen U.S. Transparency Report. See *2019 Janssen U.S. Transparency Report*, *supra* note 2. In this regard, the report discusses, among other things:

- Janssen's investment of \$8.8 billion in 2019 alone and \$39.4 billion over the past five years for pharmaceutical research and development.
- Janssen's more than 140 active collaborations with universities, biopharmaceutical firms, academic medical centers, and other scientific organizations for discovering and developing new drugs.
- Janssen's discounts and rebate programs to payers and other intermediaries, including government programs, which reduce the list price of Janssen drugs to a lower net price paid by patients.
- Various factors that influence Janssen's approach to drug pricing, such as the product's value to patients, the healthcare system and society, and preserving the ability to invest in future developments.
- Information and statistics on the government funding Janssen received to support its research over the past five years, and, in particular, that all of such funding related to investments to address public health threats. In particular, the U.S. government funding Janssen received between 2015 and 2019 amounted to less than one percent of its global research and development investment.

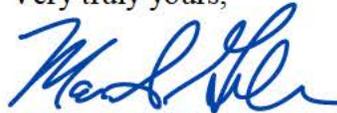
for pricing COVID-19 vaccines and therapeutics. Moreover, Mr. Wolk's interview and other public disclosures on Johnson & Johnson's corporate website compare favorably with the guidelines of the Proposal, as those disclosures provided details on the standard that Johnson & Johnson will use in providing a COVID-19 vaccine for emergency pandemic use on a not-for-profit basis and how Johnson & Johnson will take into account government collaboration for its COVID-19 vaccine and therapeutic pricing. Thus, Johnson & Johnson has substantially implemented the Proposal.

Accordingly, the Proposal should be excluded from Johnson & Johnson's 2021 proxy materials pursuant to Rule 14a-8(i)(10) as substantially implemented.

VI. Conclusion

Based upon the foregoing analysis, Johnson & Johnson respectfully requests that the Staff concur that it will take no action if Johnson & Johnson excludes the Proposal from its 2021 proxy materials. Should the Staff disagree with the conclusions set forth in this letter, or should any additional information be desired in support of Johnson & Johnson's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior to the issuance of the Staff's response. Please do not hesitate to contact the undersigned at (202) 371-7233.

Very truly yours,



Marc S. Gerber

Enclosures

cc: Matt Orlando
Worldwide Vice President, Corporate Governance and Corporate Secretary
Johnson & Johnson

Nicholas J. Lusiani
Senior Advisor, Private Sector Department
Oxfam America

Susan Mika, OSB
Benedictine Sisters of Boerne, Texas

Andrea Westkamp, OSB
Benedictine Sisters of Virginia

Patricia Regan, CDP
General Treasurer
Congregation of Divine Providence

Lydia Kuykendal
Director of Shareholder Advocacy
Mercy Investment Services

Rose Marie Stallbaumer, OSB
Investment Representative
Monasterio De San Benito

Judy Byron, OP
PeaceHealth

Ramona Bezner, CDP
Trustee
Providence Trust

David Neisius
Provincial Treasurer
The Sisters of Providence, Mother Joseph Province

EXHIBIT A

(see attached)



October 30th, 2020

BY EMAIL AND OVERNIGHT DELIVERY

Johnson & Johnson, Inc.
Attn: Assistant General Counsel and Corporate Secretary, Mr. Matt Orlando
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
Email: MOrland3@ITS.JNJ.COM

Re: Shareholder proposal for 2021 Annual Shareholder Meeting

Dear Mr. Orlando,

Enclosed please find a proposal of Oxfam America, Inc. (“Oxfam America”) and other co-filers to be included in the proxy statement of Johnson & Johnson, Inc. (the “Company”) for its 2021 annual meeting of shareholders.

Oxfam America has continuously held, for at least one year as of the date hereof, sufficient shares of **the Company’s common stock to meet** the requirements of Rule 14a-8 of the general rules and regulations of the Securities and Exchange Act of 1934, as amended. Verification of this ownership will be forthcoming. Oxfam America intends to continue to hold such shares through the date of the **Company’s 2021 annual meeting of shareholders.**

Oxfam America is the lead filer for this proposal and expects to be joined by other shareholders as co-filers. Oxfam America as lead filer is authorized to negotiate on behalf of each co-filer any potential withdrawal of this proposal.

Oxfam America welcomes the opportunity to discuss this proposal with representatives of the Company. Please feel free to contact me with any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "N. Lusiani".

Nicholas J. Lusiani
Senior Advisor, Private Sector Department
Oxfam America

[Enclosure]

CC: Ms Tina French, Assistant Corporate Secretary, tfrench1@its.jnj.com

SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

SUPPORTING STATEMENT

Janssen has received substantial government funding for research and development related to COVID-19. In February 2020, Janssen entered into a “collaborative partnership” pursuant to which the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) provided \$456 million to develop a vaccine candidate for COVID-19,¹ and BARDA agreed to pay \$152 million for Janssen and a partner to screen compounds for efficacy in treating COVID-19.² BARDA committed \$1 billion to Janssen in August to fund expansion of vaccine manufacturing capability; the agreement entitles the federal government to 100 million doses.³

JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

¹ <https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine>.

² <https://www.reuters.com/article/health-coronavirus-usa-funding/factbox-u-s-pours-billions-into-development-of-coronavirus-vaccines-tests-idINL4N2D32T5>.

³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

⁴ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁵ See e.g., <https://www.nature.com/articles/d41586-020-02278-5>.

If JNJ's vaccine is approved, scaling up production beyond JNJ's goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen's agreements with BARDA have been criticized for limiting the government's intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ's 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ's] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

⁶ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁷ <https://www.wsj.com/articles/covid-19-vaccine-deployment-would-give-global-economy-a-lift-next-year-11601820001>.

⁸ See <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>.

⁹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>, at 4.

¹⁰ See <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-v16.pdf>, at 11.



MATTHEW ORLANDO
WORLDWIDE VICE PRESIDENT
CORPORATE GOVERNANCE
CORPORATE SECRETARY

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-0026
(732) 524-3292
FAX: (732) 524-2185
MORLAND3@ITS.JNJ.COM

November 2, 2020

VIA EMAIL

Nicholas J. Lusiani
Senior Advisor, Private Sector Department
Oxfam America, Inc.
Nicholas.lusiani@oxfam.org

Dear Mr. Lusiani:

This letter acknowledges receipt by Johnson & Johnson, on October 30, 2020, of the shareholder proposal submitted by Oxfam America, Inc. (the “Proponent”) pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the “Rule”), for consideration at the Company’s 2021 Annual Meeting of Shareholders (the “Proposal”).

Paragraph (b) of the Rule provides that shareholder proponents must submit sufficient proof of their continuous ownership of at least \$2,000 in market value, or 1%, of a company’s shares entitled to vote on the proposal for at least one year preceding and including the date the shareholder proposal was submitted, which was October 30, 2020. The Company’s stock records do not indicate that the Proponent is a record owner of Company shares, and to date, we have not received sufficient proof that the Proponent has satisfied the Rule’s ownership requirements.

Accordingly, please furnish to us, within 14 days of your receipt of this letter, a written statement from the “record” holder of the Proponent’s shares (usually a broker or a bank) and a participant in the Depository Trust Company (“DTC”) verifying that the Proponent beneficially owned the requisite number of Company shares continuously for at least the one-year period preceding, and including, October 30, 2020, the date the Proposal was submitted. The Proponent can confirm whether a particular broker or bank is a DTC participant by asking the broker or bank or by checking DTC’s participant list, which is currently available on the Internet at: <http://www.dtcc.com/client-center/dtc-directories>.

If the Proponent’s broker or bank is not on the DTC participant list, the Proponent will need to obtain a written statement from the DTC participant through which the Proponent’s shares are held verifying that the Proponent beneficially owned the requisite number of Company shares continuously for at least the one-year period preceding, and including, October 30, 2020, the date the Proposal was submitted. The Proponent should be able to find who this DTC participant is by asking the Proponent’s broker or bank. If

Nicholas J. Lusiani

November 2, 2020

Page 2

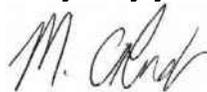
the broker is an introducing broker, the Proponent may also be able to learn the identity and telephone number of the DTC participant through the Proponent's account statements, because the clearing broker identified on the account statements will generally be a DTC participant. If the DTC participant knows the Proponent's broker or bank's holdings, but does not know the Proponent's holdings, the Proponent can satisfy the proof of ownership requirement by obtaining and submitting two proof of ownership statements verifying that, for at least the one-year period preceding and including October 30, 2020, the required amount of securities was continuously held – one from the Proponent's broker or bank confirming the Proponent's ownership, and the other from the DTC participant confirming the Proponent's broker or bank's ownership.

The SEC's rules require that any response to this letter be postmarked or transmitted electronically no later than 14 calendar days from the date you receive this letter. Please address any response to me at Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933, Attention: Corporate Secretary. For your convenience, a copy of the Rule is enclosed.

Once we receive any response, we will be in a position to determine whether the Proposal is eligible for inclusion in the proxy materials for the Company's 2021 Annual Meeting of Shareholders. We reserve the right to seek relief from the Securities and Exchange Commission as appropriate.

In the interim, you should feel free to contact either my colleague, Renee Brutus, Assistant Corporate Secretary, at (732) 524-1531 or me at (732) 524-2472 if you wish to discuss the Proposal or have any questions or concerns that we can help to address.

Very truly yours,



Matthew Orlando

cc: Renee Brutus



November 9, 2020

BY EMAIL AND OVERNIGHT DELIVERY

Johnson & Johnson, Inc.
Attn: Worldwide Vice President, Corporate Governance and Corporate Secretary,
Mr. Matthew Orlando
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
Email: MOrland3@ITS.JNJ.COM

Re: Ownership verification for shareholder proposal for 2021 Annual Shareholder Meeting

Dear Mr. Orlando,

Pursuant to your letter last week regarding our shareholder proposal submitted on October 30, 2020, attached please find verification of continuous ownership by Oxfam America, Inc. of the requisite shares in Johnson and Johnson, Inc. since October 26, 2011.

Please let me know if you have any questions or require any additional information.

Oxfam America welcomes the opportunity to discuss this proposal with representatives of the Company. Please feel free to contact me with any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "N. Lusiani".

Nicholas J. Lusiani
Senior Advisor, Private Sector Department
Oxfam America

Cc: Assistant Corporate Secretary, Ms Tina French



Fidelity Clearing & Custody Solutions®

100 Crosby Parkway KCIJ
Covington, KY 41015

November 09, 2020

Oxfam America Inc.
Activist Fund
226 Causeway St, Fl 5
Boston, MA 02114-2155

RE: 26 shares of Johnson & Johnson. - Account ending ***

To Whom It May Concern:

Please accept this letter as confirmation that National Financial Services (NFS) holds 26 shares of Johnson & Johnson (JNJ) for the benefit of Oxfam America, Inc. Per our records 55 shares were purchased on October 26, 2011. There were subsequent sells out of the account, 17 shares on July 29, 2014, 5 shares on February 4, 2020 and 7 shares on October 15, 2020, leaving a balance of 26 shares.

Certification of Beneficial Ownership

This Certification relates to the 26 shares of common stock (the "Shares") of Johnson & Johnson. (The "Issuer") owned beneficially by Oxfam America, Inc. (the "Proponent".)

This Certification is given in connection with the shareholder proposal submission on October 30, 2020 by the Proponent of the Issuer of a shareholder proposal under Rule 14a-8 under the Securities Exchange Act of 1934, as amended. The undersigned hereby certifies, as of the date set forth above, as follow.

I. The undersigned is and has been the record holder of the shares from and including the Proposal Submission Date and through and including the date hereof.

II. The proponent is the beneficial owner of the Shares and has owned 26 shares continuously since October 26, 2011.

The undersigned acknowledges and agrees that this Certification may be delivered to the Issuer as proof of the Proponent's beneficial ownership of the Shares pursuant to Rule 14a-8.

Sincerely,

A handwritten signature in cursive script that reads "Linda M. Gilman".

Linda Gilman
Client Services Manager

Our file: W843783-09NOV20

200 Seaport Boulevard, Boston, MA 02210

Fidelity Clearing & Custody Solutions® provides clearing, custody, or other brokerage services through National Financial Services LLC or Fidelity Brokerage Services LLC, Members NYSE, SIPC.

526665.6.0

EXHIBIT B

(see attached)



Handelsweg 2
3707 NH Zeist
The Netherlands

www.achmea.com

Achmea Investment Management, 3707 NH Zeist

BY EMAIL: MOrland3@ITS.JNJ.COM
AND DELIVERY MAIL

Johnson & Johnson, Inc.
Attn: Assistant General Counsel and Corporate Secretary,
Mr. Matt Orlando
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
UNITED STATES OF AMERICA

Date: 6th of November 2020

Handled by: Frank Wagemans
E-mail: Frank.Wagemans@achmea.nl
Phone: 00 31 (0) 6 22087929

Re: Shareholder proposal for 2021 Annual Shareholder Meeting

Dear Mr. Orlando,

Stichting Bewaarder Achmea Beleggingspools, being the legal owner of the assets of Achmea IM Global Enhanced Equity Fund EUR hedged, hereinafter represented by its sole statutory director Achmea Investment Management, hereby co-files a shareholder proposal submitted by lead filer Oxfam America, Inc. ("Oxfam America"), in accordance with SEC Rule 14a-8, to be included in the proxy statement of Johnson & Johnson, Inc. (the "Company") for its 2021 annual meeting of shareholders (see enclosure).

Stichting Bewaarder Achmea Beleggingspools has continuously held, for at least one year as of the date hereof, the number of shares (see enclosure) of the Company's common stock to meet the requirements of Rule 14a-8 of the general rules and regulations of the Securities and Exchange Act of 1934, as amended. Stichting Bewaarder Achmea Beleggingspools intends to continue to hold such shares through the date of the Company's 2021 annual meeting of shareholders.

Oxfam America is the lead filer for this proposal and is entitled to negotiate on behalf of Stichting Bewaarder Achmea Beleggingspools any potential withdrawal of this proposal.

We welcome the opportunity to discuss this proposal with representatives of the Company. Please feel free to contact me with any questions.

Sincerely, Stichting Bewaarder Achmea Beleggingspools, hereinafter represented by its sole statutory director Achmea Investment Management

Name:
Function: 
R.M. Krens
CIO

Name:
Function: 
J. de Wit
Directievoorzitter

[Enclosures]

CC: Ms Tina French, Assistant Corporate Secretary, tfrench1@its.jnj.com

SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

SUPPORTING STATEMENT

Janssen has received substantial government funding for research and development related to COVID-19. In February 2020, Janssen entered into a “collaborative partnership” pursuant to which the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) provided \$456 million to develop a vaccine candidate for COVID-19,¹ and BARDA agreed to pay \$152 million for Janssen and a partner to screen compounds for efficacy in treating COVID-19.² BARDA committed \$1 billion to Janssen in August to fund expansion of vaccine manufacturing capability; the agreement entitles the federal government to 100 million doses.³

JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

¹ <https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine>.

² <https://www.reuters.com/article/health-coronavirus-usa-funding/factbox-u-s-pours-billions-into-development-of-coronavirus-vaccines-tests-idINL4N2D32T5>.

³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

⁴ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁵ See e.g., <https://www.nature.com/articles/d41586-020-02278-5>.

If JNJ's vaccine is approved, scaling up production beyond JNJ's goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen's agreements with BARDA have been criticized for limiting the government's intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ's 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ's] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

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⁷ <https://www.wsj.com/articles/covid-19-vaccine-deployment-would-give-global-economy-a-lift-next-year-11601820001>.

⁸ See <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>.

⁹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>, at 4.

¹⁰ See <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-v16.pdf>, at 11.



BNY MELLON

To whom it may concern:

Amsterdam, 6 November 2020

Subject: Positions in JOHNSON & JOHNSON (US4781601046)

The Bank of New York Mellon SA/NV
Amsterdam Branch
WTC building, Podium office, B Tower
Strawinskylaan 337
1077 XX Amsterdam
The Netherlands

P.O. Box 79007
1070 NB Amsterdam
The Netherlands

t: +31 (0)76 760 2308
e: Stephen.Noteboom@BNYMellon.com

www.bnymellon.com

Dear Sirs,

BNY Mellon is the custodian bank for the Achmea IM Wereldwijd Aandelen Fonds ("the Fund"), managed by Achmea Investment Management BV.

We are writing to confirm that the Funds have had beneficial ownership of a least \$2,000 in market value of the voting securities of the JOHNSON & JOHNSON and that such beneficial ownership has existed continuously for one or more years.

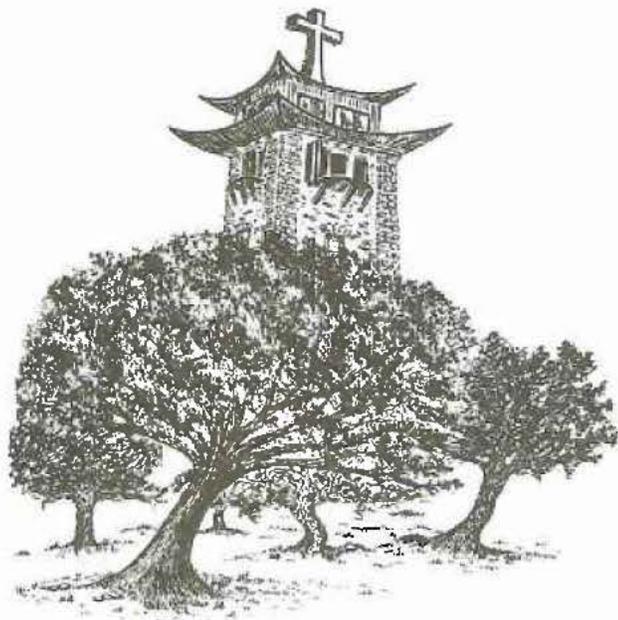
I/we hereby certify that the transactions shown in the attached Exhibit A concerning securities of JOHNSON & JOHNSON truly and accurately reflect the transactions in or for the Achmea Investment Management account/fund, held by us in custody, during the relevant period.

BNY Mellon is a DTC participant.

Sincerely,

Stephen Noteboom
Relationship Executive
The Bank of New York Mellon SA/NV

The Bank of New York Mellon SA/NV is a Belgian limited liability company, authorized and regulated as a significant credit institution by the European Central Bank and the National Bank of Belgium under the Single Supervisory Mechanism. In the Netherlands, The Bank of New York Mellon SA/NV is trading as the Bank of New York Mellon SA/NV, Amsterdam Branch on an EU passported basis. The Amsterdam branch is registered at the chamber of commerce under company no. 34363596 and has its registered office at WTC Building, Strawinskylaan 337, 1077 XX, Amsterdam, the Netherlands.



Benedictine Sisters

285 Oblate Drive
San Antonio, TX 78216

210-348-6704 phone
210-341-4519 fax

November 10, 2020

Michael H. Ullmann
Vice President, General Counsel, Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Email: mullman@corus.jnj.com

Dear Mr. Ullmann:

I am writing you on behalf of Benedictine Sisters, Boerne, Texas to co-file the stockholder resolution on COVID-19 Proposal. In brief, the proposal states: **RESOLVED**, that shareholders of Johnson & Johnson ("JNJ") ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen's receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Oxfam America. I submit it for inclusion in the 2021 proxy statement for consideration and action by the shareholders at the 2021 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. We are the beneficial owner, as defined in Rule 13d-3 of the Securities Exchange Act of 1934, of \$2,000 worth of the shares.

We have been a continuous shareholder for one year of \$2,000 in market value of Johnson & Johnson stock and will continue to hold at least \$2,000 of Johnson & Johnson stock through the next annual meeting. Verification of our ownership position will be sent by our custodian. A representative of the filers will attend the stockholders' meeting to move the resolution as required by SEC rules.

We truly hope that the company will be willing to dialogue with the filers about this proposal. We consider Oxfam America the lead filer of this resolution. As such, Oxfam America, serving as the primary filer, is authorized to act on our behalf in all aspects of the resolution, including negotiation and deputize them to withdraw the resolution on our behalf if an agreement is reached. Please note that the contact person for this resolution/proposal will be Diana Kearney, of Oxfam America who may be reached by email: diana.kearney@oxfam.org. As a co-filer, however, we respectfully request direct communication from the company and to be listed in the proxy.

Sincerely,

Sr. Susan Mika
Sr. Susan Mika, OSB
Director, Corporate Responsibility

2021 Johnson & Johnson COVID-19 Proposal

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

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JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

If JNJ’s vaccine is approved, scaling up production beyond JNJ’s goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen’s agreements with BARDA have been criticized for limiting the government’s intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ’s 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ’s] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

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³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

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⁵ See e.g. <https://www.nature.com/articles/d41586-020-02278-5>.

⁶ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

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November 10, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Email: mullman@corus.jnj.com
CC: Orlando, Matthew [JJCUSJ] Morland3@its.jnj.com

Re: Co-filing of shareholder resolution: COVID 19 Proposal

As of November 10, 2020, the Congregation of Benedictine Sisters held, and has held continuously for at least one year, 51 shares of Johnson & Johnson stock. These shares have been held with Morgan Stanley with DTC # 0015.

If you need further information, please contact us at 210.366.6660.

Heidi Siller

Heidi Siller
Registered Associate
The Quantitative Group at Graystone Consulting
A Business of Morgan Stanley



Benedictine Sisters of Virginia

Clothed in Faith with the Gospel as our Guide

November 11, 2020

Michael H. Ullmann

Vice President, General Counsel

Johnson & Johnson

One Johnson & Johnson Plaza

New Brunswick, New Jersey 08933

Email: mullman@corus.jnj.com

Dear Mr. Ullmann:

I am writing you on behalf of Benedictine Sisters of Virginia to co-file the stockholder resolution on COVID-19 Proposal. In brief, the proposal states: **RESOLVED**, that shareholders of Johnson & Johnson ("JNJ") ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen's receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Oxfam America. I submit it for inclusion in the 2021 proxy statement for consideration and action by the shareholders at the 2021 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. We are the beneficial owner, as defined in Rule 13d-3 of the Securities Exchange Act of 1934, of more than \$2,000 worth of Johnson & Johnson shares.

We have been a continuous shareholder of more than one year of \$2,000 in market value of Johnson & Johnson stock and will continue to hold at least \$2,000 of Johnson & Johnson stock through the next annual meeting. Verification of our ownership position will be sent by our custodian. A representative of the filers will attend the stockholders' meeting to move the resolution as required by SEC rules.

Benedictine Sisters of Virginia

Clothed in Faith with the Gospel as our Guide

We truly hope that the company will be willing to dialogue with the filers about this proposal. We consider Oxfam America the lead filer of this resolution. As such, Oxfam America, serving as the primary filer, is authorized to act on our behalf in all aspects of the resolution, including negotiation and deputize them to withdraw the resolution on our behalf if an agreement is reached. Please note that the contact person for this resolution/proposal will be Diana Kearney, of Oxfam America who may be reached by email: diana.kearney@oxfam.org.

As a co-filer, however, we respectfully request direct communication from the company and to be listed in the proxy.

Sincerely,

Sister Andrea Westkamp, OSB

Sister Andrea Westkamp, OSB

Treasurer

2021 Johnson & Johnson COVID-19 Proposal

RESOLVED that shareholders of Johnson & Johnson ("JNJ") ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen's receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

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JNJ stated publicly that it will distribute a COVID-19 vaccine on a "nonprofit" basis, but that commitment is limited to "emergency pandemic use."⁴ JNJ has not clarified what "nonprofit" means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

If JNJ's vaccine is approved, scaling up production beyond JNJ's goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen's agreements with BARDA have been criticized for limiting the government's intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

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¹⁰ See <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-16.pdf>, at 11.



Scott &
Stringfellow

November 11, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Email: mullman@corus.inj.com

Re: Co-filing of shareholder resolution: Independent Board Chair

As of November 11, 2020, Benedictine Sisters of VA, Inc. held, and has held continuously for at least one year, 2169 shares of Johnson and Johnson. These shares have been held with BB&T Scott & Stringfellow – DTC #0702.

If you need further information, please contact us at 804-787-8284.

Sincerely,

Steve Gow, CFA®
Vice President
Financial Advisor

Cc: Sister Andrea Westkamp, OSB



November 9, 2020

Johnson & Johnson, Inc.
Attn: Assistant General Counsel and Corporate Secretary, Mr. Matt Orlando
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
Email: MOrland3@ITS.JNJ.COM

Dear Mr. Orlando,

CommonSpirit Health is a nonprofit, Catholic health system dedicated to advancing health for all people. With a team of approximately 125,000 employees and 25,000 physicians and advanced practice clinicians, CommonSpirit Health operates 137 hospitals and more than 1000 care sites across 21 states.

As a religiously sponsored organization, CommonSpirit seeks to reflect its mission, vision and values in its investment decisions. As one of the nation's largest health care providers, we have seen the devastating impacts of COVID-19 on an extraordinary scale. It is in the best interest of all that any vaccine be both accessible and affordable, and we have specific concerns that any government funded research and development reflect a commitment to achieving these goals.

Through this letter we notify the company of our intention to co-file the enclosed resolution, the primary filer of which is Oxfam America, Inc. CommonSpirit is the beneficial owner of more than \$2,000 worth of stock in Johnson & Johnson, Inc. CommonSpirit has held these shares continuously for over twelve months and will continue to do so at least until after the next annual meeting of shareholders. A letter of verification of ownership is enclosed.

I am authorized to notify you of our intention to present the attached proposal for consideration and action by the stockholders at the next annual meeting. I submit this resolution for inclusion in the proxy statement, in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934.

Oxfam America as lead filer is authorized to negotiate on behalf of CommonSpirit Health any potential withdrawal of this proposal. Please direct any correspondence relating to this filing to Nicholas J. Lusiani, Senior Advisor, Private Sector Department, Oxfam America, Inc.

It is our tradition and preference as a religiously sponsored organization to participate in dialogue with companies and we appreciate the Company's commitment to this ongoing engagement. Thank you for

your attention to our concerns. We hope that submission of this proposal will lead to greater transparency regarding the issues our proposal raises.

Sincerely,

A handwritten signature in blue ink, appearing to read "Laura Krausa".

Laura Krausa, MNM

System Director Advocacy Programs

Attachments: Shareholder Resolution, Verification of Ownership

CC: Tina French, Assistant Corporate Secretary, tfrench1@its.jni.com; Nicholas J. Lusiani, Oxfam America, Inc.; Julie Wokaty, Interfaith Center on Corporate Responsibility

SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

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³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

⁴ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁵ See e.g., <https://www.nature.com/articles/d41586-020-02278-5>.

If JNJ's vaccine is approved, scaling up production beyond JNJ's goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen's agreements with BARDA have been criticized for limiting the government's intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ's 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ's] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

⁶ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁷ <https://www.wsj.com/articles/covid-19-vaccine-deployment-would-give-global-economy-a-lift-next-year-11601820001>.

⁸ See <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>.

⁹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>, at 4.

¹⁰ See <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-v16.pdf>, at 11.



November 9, 2020

Mr. Matt Orlando
Assistant General Counsel and Corporate Secretary
Johnson & Johnson, Inc.
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933

Re: CommonSpirit Health

Dear Matt,

This letter will certify that as of November 9, 2020, Northern Trust held for the beneficial interest of CommonSpirit Health, 38 shares of Johnson & Johnson, Inc.

We confirm that CommonSpirit Health, has beneficial ownership of at least \$2,000 in market value of the voting securities of Johnson & Johnson Inc, and that such beneficial ownership has existed continuously for at least one year, including a one year period preceding and including November 9, 2020, in accordance with rule 14a-8 of the Securities Exchange Act of 1934.

Further, it is CommonSpirit Health, intent to hold at least \$2,000 in market value through the next annual meeting.

Please be advised, Northern Trust is a DTC Participant, whose DTC number is 2669.

If you have any questions please feel free to give me a call.

Sincerely,

A handwritten signature in cursive script that reads 'Jennifer W. Beattie'.

Jennifer W. Beattie
Senior Vice President
The Northern Trust Company

CONGREGATION OF DIVINE PROVIDENCE

SAN ANTONIO, TEXAS

November 10, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Email: mullman@corus.jnj.com

Dear Mr. Ullmann:

I am writing you on behalf of the Congregation of Divine Providence to co-file the stockholder resolution on COVID-19 Proposal. In brief, the proposal states: **RESOLVED**, that shareholders of Johnson & Johnson ("JNJ") ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen's receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

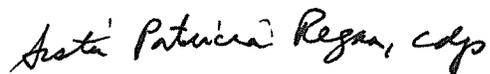
I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Oxfam America. I submit it for inclusion in the 2021 proxy statement for consideration and action by the shareholders at the 2021 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. We are the beneficial owner, as defined in Rule 13d-3 of the Securities Exchange Act of 1934, of \$2,000 worth of the shares.

We have been a continuous shareholder for one year of \$2,000 in market value of Johnson & Johnson stock and will continue to hold at least \$2,000 of Johnson & Johnson stock through the next annual meeting. Verification of our ownership position will be sent by our custodian. A representative of the filers will attend the stockholders' meeting to move the resolution as required by SEC rules.

We truly hope that the company will be willing to dialogue with the filers about this proposal. We consider Oxfam America the lead filer of this resolution. As such, Oxfam America, serving as the primary filer, is authorized to act on our behalf in all aspects of the resolution, including negotiation and deputize them to withdraw the resolution on our behalf if an agreement is reached. Please note that the contact person for this resolution/proposal will be Diana Kearney, of Oxfam America who may be reached by email: diana.kearney@oxfam.org.

As a co-filer, however, we respectfully request direct communication from the company and to be listed in the proxy.

Sincerely,


Sister Patricia Regan, CDP
General Treasurer

2021 Johnson & Johnson COVID-19 Proposal

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

SUPPORTING STATEMENT

Janssen has received substantial government funding for research and development related to COVID-19. In February 2020, Janssen entered into a “collaborative partnership” pursuant to which the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) provided \$456 million to develop a vaccine candidate for COVID-19,¹ and BARDA agreed to pay \$152 million for Janssen and a partner to screen compounds for efficacy in treating COVID-19.² BARDA committed \$1 billion to Janssen in August to fund expansion of vaccine manufacturing capability; the agreement entitles the federal government to 100 million doses.³

JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

If JNJ’s vaccine is approved, scaling up production beyond JNJ’s goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen’s agreements with BARDA have been criticized for limiting the government’s intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ’s 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ’s] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

¹ <https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine>.

² <https://www.reuters.com/article/health-coronavirus-usa-funding/factbox-u-s-pours-billions-into-development-of-coronavirus-vaccines-tests-idINL4N2D32T5>.

³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

⁴ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁵ See e.g. <https://www.nature.com/articles/d41586-020-02278-5>.

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⁷ <https://www.wsj.com/articles/covid-19-vaccine-deployment-would-give-global-economy-a-lift-next-year-11601820001>.

⁸ See <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>.

⁹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>, at 4.

¹⁰ See <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-v16.pdf>, at 11.

The Quantitative Group
755 E. Mulberry Ave
Suite 300
San Antonio, TX 78212
tel 210 277 4400
fax 210 735 1150
toll free 800 733 1150

Graystone
ConsultingSM

November 10, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Email: mullmann@corus.jnj.com

Re: Co-filling of shareholder resolution: COVIC-19 Proposal

As of November 10, 2020, Congregation of Divine Providence held and has held continuously for at least one year, 40 shares of Johnson & Johnson Common Stock. These shares have been held with Morgan Stanley DTC 0015. If you need further information, please contact Laurie Georgeff at (210) 366-6645.

Sincerely,



Laurie Georgeff
Institutional Consulting Associate



November 5, 2020

Matthew Orlando
Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dear Mr. Orlando:

Mercy Investment Services, Inc. ("Mercy"), as the investment program of the Sisters of Mercy of the Americas, has long been concerned not only with the financial returns of its investments, but also with their social and ethical implications. We believe that a demonstrated corporate responsibility in matters of the environment, and social and governance concerns fosters long-term business success. Mercy, a long-term investor, is currently the beneficial owner of shares of Johnson & Johnson.

Mercy is asking the Board of Directors to report to shareholders on whether and how JNJ subsidiary Janssen's receipt of public financial support for development and manufacture of vaccines and therapeutic for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

Mercy is co-filing the shareholder proposal with lead investor Oxfam America for inclusion in the 2021 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Mercy has been a shareholder continuously for more than one year holding at least \$2,000 in market value and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. A representative of the filers will attend the Annual Meeting to move the resolution as required by SEC rules. The verification of ownership by our custodian, a DTC participant, is enclosed with this letter. Oxfam America may withdraw the proposal on our behalf. We respectfully request direct communications from Johnson & Johnson and to have our supporting statement and organization name included in the proxy statement.

We look forward to having productive conversations with the company. Please direct your responses to me via my contact information below.

Best regards,

Lydia Kuykendal
Director of Shareholder Advocacy
317-910-8581
lkuykendal@mercyinvestments.org

SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

SUPPORTING STATEMENT

Janssen has received substantial government funding for research and development related to COVID-19. In February 2020, Janssen entered into a “collaborative partnership” pursuant to which the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) provided \$456 million to develop a vaccine candidate for COVID-19,¹ and BARDA agreed to pay \$152 million for Janssen and a partner to screen compounds for efficacy in treating COVID-19.² BARDA committed \$1 billion to Janssen in August to fund expansion of vaccine manufacturing capability; the agreement entitles the federal government to 100 million doses.³

JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

¹ <https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine>.

² <https://www.reuters.com/article/health-coronavirus-usa-funding/factbox-u-s-pours-billions-into-development-of-coronavirus-vaccines-tests-idINL4N2D32T5>.

³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

⁴ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁵ See e.g., <https://www.nature.com/articles/d41586-020-02278-5>.

If JNJ's vaccine is approved, scaling up production beyond JNJ's goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen's agreements with BARDA have been criticized for limiting the government's intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ's 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ's] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

⁶ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁷ <https://www.wsj.com/articles/covid-19-vaccine-deployment-would-give-global-economy-a-lift-next-year-11601820001>.

⁸ See <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>.

⁹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>, at 4.

¹⁰ See <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-v16.pdf>, at 11.



November 5, 2020

Matthew Orlando
Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Re: Mercy Investment Services Inc.

Dear Matthew,

This letter will certify that as of November 5, 2020, Northern Trust held for the beneficial interest of Mercy Investment Services Inc., 46 shares of Johnson & Johnson. We confirm that Mercy Investment Services Inc. has beneficial ownership of at least \$2,000 in market value of the voting securities of Johnson & Johnson, and that such beneficial ownership has existed continuously for at least one year including a one year period preceding and including November 5, 2020, in accordance with rule 14a-8 of the Securities Exchange Act of 1934. Further, it is Mercy Investment Services Inc., intent to hold at least \$2,000 in market value through the next annual meeting.

We also confirm that as of the filing date, November 5, 2020, Mercy Investment Services Inc., held 59,743.00 additional shares of Johnson & Johnson with a market value of \$8,349,681.68.

Please be advised, Northern Trust is a DTC Participant, whose DTC number is 2669.

If you have any questions please feel free to give me a call.

Sincerely,

Joe Wilimczyk
Officer
312 444 4146



Monasterio De San Benito
Rio Bamba 870
Colonia Liindavista
07300 Mexico, D.F. Mexico

November 10, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Email: mullman@corus.jnj.com

Dear Mr. Ullmann:

I am writing you on behalf of Monasterio De San Benito to co-file the stockholder resolution on COVID-19 Proposal. In brief, the proposal states: **RESOLVED**, that shareholders of Johnson & Johnson ("JNJ") ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen's receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Oxfam America. I submit it for inclusion in the 2021 proxy statement for consideration and action by the shareholders at the 2021 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. We are the beneficial owner, as defined in Rule 13d-3 of the Securities Exchange Act of 1934, of 70 shares of Johnson & Johnson or \$2,000 worth of the shares.

We have been a continuous shareholder for one year of \$2,000 in market value of Johnson & Johnson stock and will continue to hold at least \$2,000 of Johnson & Johnson stock through the next annual meeting. Verification of our ownership position will be sent by our custodian. A representative of the filers will attend the stockholders' meeting to move the resolution as required by SEC rules.

We truly hope that the company will be willing to dialogue with the filers about this proposal. We consider Oxfam America the lead filer of this resolution. As such, Oxfam America, serving as the primary filer, is authorized to act on our behalf in all aspects of the resolution, including negotiation and deputize them to withdraw the resolution on our behalf if an agreement is reached. Please note that the contact person for this resolution/proposal will be Diana Kearney, of Oxfam America who may be reached by email: diana.kearney@oxfam.org.

As a co-filer, however, we respectfully request direct communication from the company and to be listed in the proxy.

Sincerely,

Rose Marie Stallbaumer, OSB, Investment Representative

2021 Johnson & Johnson COVID-19 Proposal

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

SUPPORTING STATEMENT

Janssen has received substantial government funding for research and development related to COVID-19. In February 2020, Janssen entered into a “collaborative partnership” pursuant to which the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) provided \$456 million to develop a vaccine candidate for COVID-19,¹ and BARDA agreed to pay \$152 million for Janssen and a partner to screen compounds for efficacy in treating COVID-19.² BARDA committed \$1 billion to Janssen in August to fund expansion of vaccine manufacturing capability; the agreement entitles the federal government to 100 million doses.³

JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

If JNJ’s vaccine is approved, scaling up production beyond JNJ’s goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen’s agreements with BARDA have been criticized for limiting the government’s intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ’s 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ’s] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

¹ <https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine>.

² <https://www.reuters.com/article/health-coronavirus-usa-funding/factbox-u-s-pours-billions-into-development-of-coronavirus-vaccines-tests-idINL4N2D32T5>.

³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

⁴ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁵ See e.g. <https://www.nature.com/articles/d41586-020-02278-5>.

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⁸ See <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>.

⁹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>, at 4.

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Casey Truman
Registered Wealth Management Client Associate
Merrill
2959 N. Rock Rd. Ste. 200
Wichita, KS 67226
316.631.3522



November 10, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Email: mullman@corus.jnj.com

RE: Co-filing of shareholders resolution: COVID-19 Proposal

FAO: Benedictine Sisters of Monasterio De San Benito, Mexico City, TIN# 48-0548363

Dear Mr. Ullmann,

As of November 10, 2020, Benedictine Sisters of Monasterio De San Benito, Mexico City, held, and has held continuously for at least one year, 70 shares of Johnson & Johnson, Inc. common stock. These shares have been held with Merrill Lynch, DTC# 8862.

If you need further information please contact us at 316-631-3522.

Sincerely,

Casey Truman
Registered Wealth Management Client Associate

Cc: Benedictine Sisters of Mount St. Scholastica, Inc.

Merrill Lynch, Pierce, Fenner & Smith Incorporated (also referred to as "MLPF&S" or "Merrill") makes available certain investment products sponsored, managed, distributed or provided by companies that are affiliates of Bank of America Corporation ("BofA Corp."). MLPF&S is a registered broker-dealer, Member SIPC and a wholly owned subsidiary of BofA Corp.

Investment products:

Are Not FDIC Insured	Are Not Bank Guaranteed	May Lose Value
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November 6, 2020

Johnson & Johnson, Inc.
Matt Orlando, Assistant General Counsel &
Corporate Secretary
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933-0002

Dear Mr. Orlando,

In an effort to ensure widespread access to treatments and vaccines for COVID-19, PeaceHealth requests the Board of Johnson & Johnson to report on how the significant contribution from public entities to the COVID-19 products the Company seeks to commercialize will affect pricing and access.

Therefore, PeaceHealth is co-filing the enclosed resolution with Oxfam America, Inc. for inclusion in the 2021 proxy statement in accordance with rule 14a-8 of the general rules and regulations of the Securities and Exchange Act of 1934. A representative of the filers will attend the annual meeting to move the resolution as required by SEC Rules.

As of November 6, 2020 PeaceHealth held, and has held continuously for at least one year, 21.658 shares of Johnson & Johnson Corporation common stock. A letter verifying ownership in the Company is enclosed. We will continue to hold the required number of shares in Johnson & Johnson Corporation through the annual meeting in 2021.

For matters relating to this resolution, please contact our authorized representative, Diana Kearney, dianakearney@oxfam.org/ Please copy Judy Byron, OP on all communications: jbyron@ipjc.org/

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Seirer", with a long horizontal line extending to the right.

Jeff Seirer
PeaceHealth System VP Financial Integrity / Controller

Encl: Shareholder Resolution
Verification of Ownership

SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

SUPPORTING STATEMENT

Janssen has received substantial government funding for research and development related to COVID-19. In February 2020, Janssen entered into a “collaborative partnership” pursuant to which the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) provided \$456 million to develop a vaccine candidate for COVID-19,¹ and BARDA agreed to pay \$152 million for Janssen and a partner to screen compounds for efficacy in treating COVID-19.² BARDA committed \$1 billion to Janssen in August to fund expansion of vaccine manufacturing capability; the agreement entitles the federal government to 100 million doses.³

JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

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⁵ See e.g., <https://www.nature.com/articles/d41586-020-02278-5>.

If JNJ's vaccine is approved, scaling up production beyond JNJ's goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen's agreements with BARDA have been criticized for limiting the government's intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ's 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ's] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

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100 Vanguard Boulevard
Malvern, PA 19355

November 6, 2020

Matt Orlando, Assistant General Counsel & Corporate Secretary
Johnson & Johnson Corporation
1 Johnson and Johnson PLZ
New Brunswick, NJ 08933-0002

Mr. Orlando:

This letter is to verify that PeaceHealth owns 21.658 shares of Johnson & Johnson common stock. Furthermore, PeaceHealth has held these shares continuously since the acquisition date of 10/17/2017, up to and including the date of 11/06/2020. PeaceHealth will continue to hold at least the minimum number of shares required through the time of the company's next annual meeting.

This security is currently held by Vanguard who serves as custodian for PeaceHealth. The shares are registered in our nominee name at the Vanguard Group. Please note that the Vanguard Group is a DTC participant.

Sincerely,

Todd Feld

Todd Feld, Senior Relationship Manager
Vanguard Institutional NonProfit

PROVIDENCE TRUST

SAN ANTONIO, TEXAS

November 10, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Email: mullman@corus.jnj.com

Dear Mr. Ullmann:

I am writing you on behalf of Providence Trust to co-file the stockholder resolution on COVID-19 Proposal. In brief, the proposal states: **RESOLVED**, that shareholders of Johnson & Johnson ("JNJ") ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen's receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Oxfam America. I submit it for inclusion in the 2021 proxy statement for consideration and action by the shareholders at the 2021 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. We are the beneficial owner, as defined in Rule 13d-3 of the Securities Exchange Act of 1934, of \$2,000 worth of the shares.

We have been a continuous shareholder for one year of \$2,000 in market value of Johnson & Johnson stock and will continue to hold at least \$2,000 of Johnson & Johnson stock through the next annual meeting. Verification of our ownership position will be sent by our custodian. A representative of the filers will attend the stockholders' meeting to move the resolution as required by SEC rules.

We truly hope that the company will be willing to dialogue with the filers about this proposal. We consider Oxfam America the lead filer of this resolution. As such, Oxfam America, serving as the primary filer, is authorized to act on our behalf in all aspects of the resolution, including negotiation and deputize them to withdraw the resolution on our behalf if an agreement is reached. Please note that the contact person for this resolution/proposal will be Diana Kearney, of Oxfam America who may be reached by email: diana.kearney@oxfam.org.

As a co-filer, however, we respectfully request direct communication from the company and to be listed in the proxy.

Sincerely,



Sister Ramona Bezner, CDP
Trustee

2021 Johnson & Johnson COVID-19 Proposal

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

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JNJ stated publicly that it will distribute a COVID-19 vaccine on a “nonprofit” basis, but that commitment is limited to “emergency pandemic use.”⁴ JNJ has not clarified what “nonprofit” means when the government funds a significant portion of the research and development cost. If a COVID-19 vaccine must be readministered regularly to maintain herd immunity, as many experts predict,⁵ demand will outlast the pandemic, and the potential market will be vast.

If JNJ’s vaccine is approved, scaling up production beyond JNJ’s goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen’s agreements with BARDA have been criticized for limiting the government’s intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

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The Quantitative Group
755 E Mulberry Ave
Suite 300
San Antonio, TX 78212
tel 210 277 4400
fax 210 735 1150
toll free 800 733 1150

Graystone
ConsultingSM

November 10, 2020

Michael H. Ullmann
Vice President, General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Email: mullmann@corus.inj.com

Re: Co-filling of shareholder resolution: COVIC-19 Proposal

As of November 10, 2020, Providence Trust held and has held continuously for at least one year, 40 shares of Johnson & Johnson Common Stock. These shares have been held with Morgan Stanley DTC 0015. If you need further information, please contact Laurie Georgeff at (210) 366-6645.

Sincerely,



Laurie Georgeff
Institutional Consulting Associate



November 5, 2020

BY EMAIL AND DELIVERY

Johnson & Johnson, Inc.
Attn: Assistant General Counsel and Corporate Secretary, Mr. Matt Orlando
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
Email: MOOrland3@ITS.JNJ.COM

Re: Shareholder proposal for 2021 Annual Shareholder Meeting

Dear Mr. Orlando,

The Sisters of Charity of Saint Elizabeth hereby co-files a shareholder proposal submitted by lead filer Oxfam America, Inc. ("Oxfam America"), in accordance with SEC Rule 14a-8, to be included in the proxy statement of Johnson & Johnson, Inc. (the "Company") for its 2021 annual meeting of shareholders.

The Sisters of Charity of Saint Elizabeth has continuously held, for at least one year as of the date hereof, at least 500 shares of the Company's common stock to meet the requirements of Rule 14a-8 of the general rules and regulations of the Securities and Exchange Act of 1934, as amended. The Sisters of Charity of Saint Elizabeth intends to continue to hold such shares through the date of the Company's 2021 annual meeting of shareholders.

Oxfam America is the lead filer for this proposal and is authorized to negotiate on behalf of The Sisters of Charity of Saint Elizabeth any potential withdrawal of this proposal.

We welcome the opportunity to discuss this proposal with representatives of the Company. Please feel free to contact me with any questions.

Sincerely,

Sister Barbara Aires
Coordinator of Corporate Responsibility

(Enclosure)
SBA/lp



BAIRES@SCNJ.ORG

973.290.5402
973.290.5441
P.O. BOX 476
CONVENT STATION
NEW JERSEY
07961-0476

SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

SUPPORTING STATEMENT

Janssen has received substantial government funding for research and development related to COVID-19. In February 2020, Janssen entered into a “collaborative partnership” pursuant to which the U.S. Biomedical Advanced Research and Development Authority (“BARDA”) provided \$456 million to develop a vaccine candidate for COVID-19,¹ and BARDA agreed to pay \$152 million for Janssen and a partner to screen compounds for efficacy in treating COVID-19.² BARDA committed \$1 billion to Janssen in August to fund expansion of vaccine manufacturing capability; the agreement entitles the federal government to 100 million doses.³

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November 5th, 2020

Mr. Matt Orlando
Assistant General Counsel and Corporate Secretary
Johnson & Johnson, Inc
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933

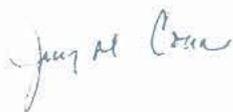
RE: Sisters of Charity of Saint Elizabeth a/c XXXXX

Dear Corporate Secretary,

This letter alone shall serve as proof of beneficial ownership of 555 shares of Johnson & Johnson common stock for the Sisters of Charity of Saint Elizabeth.

Please be advised that as of 11/5/2020, the Sisters of Charity of Saint Elizabeth have continuously held the requisite number of shares of common stock for at least one year, and intend to continue holding the requisite number of shares through the date of the next Annual Meeting of Shareholders.

Sincerely,



Jerry D. Coan | Vice President – Relationship Manager | Institutional Services Group
| 313-222-4562 | Fax: 313-222-7170 | jdcoan@comerica.com | 411 W. Lafayette Blvd. | MC 3462 |
Detroit, MI 48226



November 4, 2020

Johnson & Johnson, Inc.
Attn: Assistant General Counsel and Corporate Secretary, Mr. Matt Orlando
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933-0002

Re: Shareholder proposal for 2021 Annual Shareholder Meeting

Dear Mr. Orlando,

The Sisters of Providence, Mother Joseph Province hereby co-file a shareholder proposal submitted by lead filer Oxfam America, Inc. ("Oxfam America"), in accordance with SEC Rule 14a-8, to be included in the proxy statement of Johnson & Johnson, Inc. (the "Company") for its 2021 annual meeting of shareholders.

The Sisters of Providence, Mother Joseph Province has continuously held, for at least one year as of the date hereof, eight shares of the Company's common stock to meet the requirements of Rule 14a-8 of the general rules and regulations of the Securities and Exchange Act of 1934, as amended. The Sisters of Providence, Mother Joseph Province intends to continue to hold such shares through the date of the Company's 2021 annual meeting of shareholders.

Oxfam America is the lead filer for this proposal and is authorized to negotiate on behalf of the Sisters of Providence, Mother Joseph Province any potential withdrawal of this proposal.

We welcome the opportunity to discuss this proposal with representatives of the Company. Please copy me on all communications: David.Neisius@providence.org/

Sincerely,

A handwritten signature in black ink that reads 'David Neisius'.

David Neisius
Provincial Treasurer

Encl: Shareholder Resolution
Verification of Ownership



SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

RESOLVED that shareholders of Johnson & Johnson (“JNJ”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how JNJ subsidiary Janssen’s receipt of government financial support for development and manufacture of vaccines and therapeutics for COVID-19 is being, or will be, taken into account when engaging in conduct that affects access to such products, such as setting prices.

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Catherine M. Rowan
Director, Socially Responsible Investments
766 Brady Avenue, Apt. 635
Bronx, NY 10462
Phone: (718) 822-0820
Fax: (718) 504-4787
E-Mail Address: rowan@bestweb.net

November 5, 2020

Matthew Orlando
Worldwide Vice President, Corporate Governance & Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dear Mr. Orlando,

Mr. Trinity Health is the beneficial owner of over \$2,000 worth of shares of Johnson & Johnson. Trinity Health has held these shares continuously for over twelve months and will continue to do so at least until after the next annual meeting of shareholders. A letter of verification of ownership is enclosed.

I am authorized to notify you of our intention to present the attached proposal for consideration and action by the shareholders at the next annual meeting. I submit this proposal for inclusion in the proxy statement, in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934.

The enclosed proposal is the same one as being filed by Oxfam America, and the primary contact for the proposal is Mr. Nicholas J. Lusiani <Nicholas.Lusiani@Oxfam.org>. Trinity Health is co-filing. We designate Mr. Lusiani as lead filer to act on our behalf for all purposes in connection with the proposal.

We appreciate the ongoing shareholder dialogue we have with the Company, and we hope that submission of this proposal will lead to greater transparency regarding the concerns the proposal raises.

Sincerely,

Catherine Rowan

enc

SHAREHOLDER PROPOSAL REGARDING GOVERNMENT FINANCIAL SUPPORT AND ACCESS TO COVID-19 VACCINES AND THERAPEUTICS

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² <https://www.reuters.com/article/health-coronavirus-usa-funding/factbox-u-s-pours-billions-into-development-of-coronavirus-vaccines-tests-idINL4N2D32T5>.

³ <https://www.hhs.gov/about/news/2020/08/05/hhs-dod-collaborate-with-johnson-and-johnson-to-produce-millions-of-covid-19-investigational-vaccine-doses.html>.

⁴ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁵ See e.g., <https://www.nature.com/articles/d41586-020-02278-5>.

If JNJ's vaccine is approved, scaling up production beyond JNJ's goal of producing 1 billion doses per year⁶ will be essential to ensure universal and low-cost vaccine access, which is critical to maintain stability, reignite the global economy and investor returns,⁷ and prevent domestic outbreaks.⁸ Accordingly, JNJ will face enormous pressure to share intellectual property (including patents) over the COVID-19 vaccines or therapeutics to which public entities such as BARDA are contributing. Already, Janssen's agreements with BARDA have been criticized for limiting the government's intellectual property rights,⁹ which could place a chokehold on mass production commensurate with global need—increasing price, decreasing overall supply and preventing universal access.

JNJ's 2019 Transparency Report—pre-dating COVID-19—describes the factors it considers in pricing: balancing the value of a medicine, the “importance of preserving [JNJ's] ability to develop future groundbreaking cures and treatments,” and ensuring affordable access.¹⁰ Yet, JNJ does not at present disclose how public financial support factors into its approach to ensuring access over its COVID-19 products. This Proposal seeks to overcome this gap by asking JNJ to explain whether and how the significant contribution from public entities to the COVID-19 products JNJ seeks to commercialize affects, or will affect, its analysis of those factors and of actions, including pricing, that it could take to ensure access.

⁶ <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>.

⁷ <https://www.wsj.com/articles/covid-19-vaccine-deployment-would-give-global-economy-a-lift-next-year-11601820001>.

⁸ See <https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/>.

⁹ <https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>, at 4.

¹⁰ See <https://jnj-janssen.brightspotcdn.com/19/3f/55f6149249348ab7c64ba881c638/jsn-2019-us-transparency-report-v16.pdf>, at 11.



The Northern Trust Company
50 South LaSalle Street
Chicago, Illinois 60603

November 5, 2020

TO WHOM IT MAY CONCERN,

Please accept this letter as verification that as of November 5, 2020 Northern Trust as custodian held for the beneficial interest of Trinity Health 153,947 shares of Johnson & Johnson.

As of November 5, 2020 Trinity Health has held at least \$2,000 worth of Johnson & Johnson continuously for over one year. Trinity Health has informed us it intends to continue to hold these shares through the date of the company's next annual meeting.

This letter is to confirm that the aforementioned shares of stock are registered with Northern Trust, Participant Number 2669, at the Depository Trust Company.

Sincerely,

Ryan Stack
2nd Vice President
The Northern Trust Company
50 South La Salle Street
Chicago, Illinois 60603

EXHIBIT C

(see attached)



TRANSFORMING LIVES, ADVANCING HOPE

2019 JANSSEN U.S. TRANSPARENCY REPORT



NOTES ON THIS REPORT



INTRODUCTION

Notes on This Report

A Letter From
Our Leaders

2019 in Summary

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES



Notes on This Report. All information in this report refers to the U.S. operations of the Janssen Pharmaceutical Companies of Johnson & Johnson, unless noted otherwise. Financial and nonfinancial information covers the period between December 31, 2018 and December 29, 2019, except where noted. The methodologies used for analyses in this report may be different from those used by other organizations. This report is not audited and is not intended to address all our required disclosures.

Additional Resources. In this report, we refer to locations where you can find more information about specific Janssen U.S. and Johnson & Johnson programs,

disclosures, and patient resources. Financial performance information for our parent company and its subsidiaries, as well as its “Cautionary Note Regarding Forward-Looking Statements,” can be found in *Johnson & Johnson Annual Reports* at jnj.com/about-jnj/annual-reports. Information on corporate sustainability measures can be found at the *Johnson & Johnson Health for Humanity Report* at healthforhumanityreport.jnj.com.

Hyperlinks in this report connect you to additional information. This report and a one-page executive summary are also available at janssen.com/ustransparencyreport.



A LETTER FROM OUR LEADERS



INTRODUCTION

Notes on This Report

A Letter From Our Leaders

2019 in Summary

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

IN OUR WORK EVERY DAY, WE WITNESS INTELLECT, EMPATHY, and courage united in the service of patients. Our colleagues include researchers, pharmacists, medical doctors, policy analysts, commercial experts, and manufacturing engineers—professionals of all types who develop transformational medicines and work tirelessly to ensure they reach the people who need them.

We know our healthcare system has significant strengths. Thanks to an open and competitive marketplace, it offers an array of treatment options and generates groundbreaking discoveries that are typically available in the United States before anywhere else in the world. But all too frequently we're reminded that affordability remains a significant challenge for patients and their families. They want to know what they can expect to pay for their care, including their medicines, and what can be done to lower those costs.

In our fourth annual Janssen U.S. Transparency Report, we explain factors in our health system that influence the accessibility and affordability of medicines. As in years past, we offer information about our responsible business practices that put patients first:

- Since the beginning of 2016, the first year covered by this report, the compound net price decline of Janssen medicines was **-9.2%**¹
- We provided **\$24.5 billion** in discounts, rebates, and fees to government and private payers, as well as hospitals and others in the supply chain. In fact, for the first time, these discounts, rebates, and fees totaled **more than half the list price (51%)** of our medicines.²
- Globally, we invested **\$8.8 billion** in discovering and developing new medicines³—**91%** more than we spent on sales and marketing.⁴
- Over the last five years, we've spent **\$39.4 billion** on R&D,⁵ resulting in **7** new medicines⁶ and **38** new indications.⁷
- We helped **1.3 million** patients with access, affordability, and treatment support through Janssen CarePath.⁸
- We contributed practical policy solutions designed to bring down costs for patients and to make these costs more predictable, while supporting continued progress in the fight against disease.

Beyond providing a window into how we operate, we issue this Report because meaningful transparency is critical to the current discussion about healthcare. We aim to highlight what's at stake with the choices before us and show why it's important to preserve the parts of the U.S. system that patients count on—care when it's needed, innovative medicines, and progress in the fight against disease.



A LETTER FROM OUR LEADERS



INTRODUCTION

Notes on This Report

A Letter From Our Leaders

2019 in Summary

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

Historic advances in medicine—including cell and gene therapies that have the potential to cure rare and hard-to-treat diseases—promise to improve the lives of patients and increase the overall sustainability of healthcare in the U.S. Our Janssen therapies have made a significant impact. For example, one of our biologic therapies has been shown to reduce major bowel surgeries and cut hospitalizations for patients with Crohn’s disease. Our first-in-class cancer medicines can help extend the lives of patients with some of the most common and deadly types of cancer.⁹ Important as they are, these numbers don’t reflect the full impact such medicines can have: joy when health is regained; relief when the burdens of caregivers are lifted; pride when returning to work.

We want this Report to be useful to everyone with a stake in the future of our healthcare system—to policymakers, payers, providers, and most of all, patients. We hope the conversations it starts will bring us closer to a healthcare system that delivers greater access to care at a more manageable cost and, most important, better health for all.

Scott White

Company Group Chairman
North America Pharmaceuticals
Johnson & Johnson

Anastasia G. Daifotis, M.D.

Chief Scientific Officer
Janssen North America
Pharmaceuticals



2019 IN SUMMARY: TRANSFORMING LIVES FOR PATIENTS TODAY



INTRODUCTION

Notes on This Report

A Letter From
Our Leaders

2019 in Summary

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE
FOR PATIENTS
TOMORROW

REFERENCES

NET PRICES FOR OUR MEDICINES HAVE DECLINED



-9.2%

compound net price decline of Janssen medicines since the beginning of 2016,¹⁰ the first year covered by this report. In 2019, our average aggregate **net price decline was -1.2%**¹¹

\$24.5 billion

total amount Janssen paid in rebates, discounts, and fees in 2019¹²

51%

more than half the list price of our medicines went to intermediaries in the system¹³

NATIONWIDE, MEDICINE PRICES REMAIN FLAT, BUT PATIENTS ARE PAYING MORE

0.3%

Growth of net prices for brand medicines across the industry in 2018; less than the rate of inflation¹⁴

67%

increase in patient healthcare spending from 2008-2018¹⁵

1 in 4

American adults reported difficulty in affording prescription medicines in 2019¹⁶



WE'RE SUPPORTING PATIENTS TODAY AND WORKING TOWARD SUSTAINABLE SOLUTIONS FOR TOMORROW

1.3 million

patients helped with access, affordability, and treatment support through the Janssen CarePath program in 2019¹⁷



540,000

Commercially insured patients who reduced their out-of-pocket costs¹⁸ through the Janssen CarePath Savings Program in 2019*

*Included in the 1.3 million patients helped, above



2019 IN SUMMARY: ADVANCING HOPE FOR PATIENTS TOMORROW



INTRODUCTION

Notes on This Report

A Letter From
Our Leaders

2019 in Summary

TRANSFORMING
LIVES FOR
PATIENTS TODAY

ADVANCING HOPE
FOR PATIENTS
TOMORROW

REFERENCES

WE MAINTAINED OUR INVESTMENT IN DISCOVERING AND DEVELOPING NEW MEDICINES

\$8.8 billion
invested globally in pharmaceutical R&D¹⁹

91% more
invested in global R&D than in global sales and marketing²⁰



OUR SUSTAINED COMMITMENT TO R&D IS LEADING TO MEANINGFUL ADVANCES FOR PATIENTS

IN 2019:

2 new medicines and 9 new indications
approved by the U.S. Food & Drug Administration (FDA)^{*,21,22}



OVER THE PAST FIVE YEARS:

\$39.4 billion
invested in R&D²³

7 new medicines
approved by FDA²⁴

38 new indications
approved by FDA²⁵

7 FDA Breakthrough
Therapy Designations received^{26,27}

WE ARE HARD AT WORK DELIVERING THE NEXT GENERATION OF MEDICINES

140+
active collaborations
with universities,
biopharmaceutical
firms, academic medical
centers, and other
scientific organizations



80+
medicine
candidates in
development as
a result of our
investments
in R&D

120,000+
patients enrolled
worldwide in more
than 400 clinical
trials. We launched
more than 100 new
clinical trials in 2019

640+
start-up companies in
the Johnson & Johnson
Innovation—JLABS
incubator community,
58% of which are run by
first-time entrepreneurs²⁸

*New therapeutic uses for previously approved medicines





INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES



TRANSFORMING LIVES FOR PATIENTS TODAY

“Patients and families in the United States continue to be concerned about their ability to access and afford medicines. We share these concerns and are working toward solutions.”

— Scott White, Company Group Chairman, North America Pharmaceuticals, Johnson & Johnson

When people are sick, they should have affordable access to the medicines they need. But many in the U.S. do not.

Access to medicines is critical. Medicines have dramatically improved patient health²⁹ and reduced the need for surgeries, physician visits, hospital stays, long-term care, and other costly healthcare interventions.^{30,31,32} This brings down the total cost of treating patients, ultimately benefitting the entire U.S. healthcare system and our society as a whole.

In this section, we look at factors that affect medicines’ affordability, including how medicines are distributed and paid for, and how insurance benefits work.

We explain why patients do not often see the benefits of discounts and rebates we provide to insurers.

We also explain steps we’re taking to address access and affordability challenges, including appropriately providing financial assistance to eligible patients and working with policymakers to advance solutions that maintain what’s distinctive about American healthcare: access to innovative therapies, choice, and care that’s focused on the individual.

MEDICINES ARE MAKING A DIFFERENCE

Innovative medicines have fueled dramatic health gains in the U.S.

- Cancer death rates **decreased 27%** from 1991 to 2017³³
- Heart disease death rates **decreased 64%** since 1980³⁴
- **39 years:** Increase in the average lifespan for a person with HIV who takes current medicines³⁵

Earlier availability of these innovative medicines is a strength of the U.S. healthcare system

- Of new medicines launched worldwide between 2011-2018, **88%** were available in the U.S. vs. **46-59%** in the United Kingdom, France, and Canada³⁶
- Compared to patients in these same countries, cancer patients in the U.S. have **10-20% higher survival rates**^{37,38}



UNDERSTANDING THE PRICE OF MEDICINES

Empowering patients to make informed decisions about their healthcare starts with helping them understand more about the cost of their medicines.

HOW A LIST PRICE BECOMES A NET PRICE

The list price of a medicine is a starting point that is ultimately reduced to a net price by the substantial discounts, rebates, and fees pharmaceutical companies provide to payers and other intermediaries. These include government programs, insurance companies, and employers, as well as the pharmacy benefit managers (PBMs) who administer benefits on their behalf. Hospitals, clinics, physician offices, and others may also receive discounts and rebates. We also pay fees to pharmaceutical wholesalers to distribute our medicines. In 2019, we paid \$24.5 billion in rebates, discounts, and fees—more than half the list price of our medicines (51%).³⁹

We provide or pay these discounts and rebates to support broad access to our medicines, as outlined below:

- **Public and Private Payers.** To participate in public programs, we are required to give specific mandatory discounts to government insurers such as state Medicaid departments and the U.S. Department of Veterans Affairs. In addition, we provide discounts and rebates through negotiations with the private health insurance companies and PBMs who administer benefits for Medicaid and Medicare.

We also work with commercial health insurance companies and the PBMs that manage the purchase of medicines for individuals with private insurance

coverage. Private insurance companies determine which medicines will be included on their formulary (the list of medicines they cover) and the out-of-pocket amounts patients will pay for those medicines. Formulary determinations are based in part on pharmaceutical companies' negotiations with payers, which result in rebates from the pharmaceutical company to the payer.

- **Wholesalers and Distributors.** Pharmaceutical companies pay fees to wholesalers and distributors—companies that buy medicines in bulk and distribute them to pharmacies and healthcare providers.
- **Hospitals, Clinics, Physicians' Offices, and Other Dispensers of Medicines.** Pharmaceutical companies provide discounts on medicines to hospitals and clinics for inclusion on their formularies. In addition, we provide discounts and rebates to physicians' offices where certain medicines are administered. Under a federal program known as the 340B Drug Discount Program, we also are required to provide significant discounts on certain medicines purchased by specific categories of hospitals, clinics, and health centers that meet certain eligibility requirements set forth by the federal government.

Within the formularies of various payers, medicines are placed on tiers that correspond with patients' out-of-pocket costs. Because for many conditions there are multiple treatments available, payers create competition among pharmaceutical companies seeking to have their medicines placed on tiers with lower copays. We offer discounts and rebates to gain payer coverage and favorable formulary placement so our medicines are accessible and affordable. However, the amount a patient pays often does not reflect the discounts and rebates we give payers, as we explain in the next chapter. ●



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

THE PATH TO THE PATIENT

Many entities are involved in getting a medicine from the pharmaceutical company to the patient. Together, they make up the pharmaceutical supply chain. This chart depicts a typical route a medicine takes from drug manufacturer to patient. In 2018, about 46% of the money spent in the U.S. on brand name medicines across the pharmaceutical industry went to players in this supply chain, up from 33% in 2013.⁴⁰



HOW PATIENT COSTS ARE DETERMINED

A recent survey reported that one in four Americans finds it “very difficult” or “difficult” to afford their medicines.⁴¹ Why is that?

The amount insured patients pay out-of-pocket for their medicines is determined by how their health insurance is designed and how their pharmaceutical benefits are managed. Notably, on average, patients pay 12% of their prescription drug costs compared to 4% of their hospital care costs.⁴²

While many patients receive insurance through government programs or by purchasing it themselves, roughly half of all Americans receive insurance benefits from their employers.⁴³ Their employers choose plans with designated coverage levels, including copays, deductibles, coinsurance amounts, and out-of-pocket maximums for medicines.

One force driving up patients’ out-of-pocket spending is the use of high-deductible health plans, which are increasingly prevalent among employers and individuals. These plans offer lower monthly premiums but require more out-of-pocket costs, or a higher deductible, before coverage begins.⁴⁴ In 2019, the number of workers enrolled in high-deductible health plans increased to 30%, up from 4% in 2006.⁴⁵ For all people with employer-provided insurance, average deductibles more than quadrupled between 2006 and 2019.⁴⁶

accumulator adjustment programs. These programs prevent copay assistance—provided to patients by manufacturers, often in the form of savings cards—from applying toward patients’ out-of-pocket maximums or deductibles. This can result in additional and unexpected costs for patients, which make it harder for them to stay on their medications.⁴⁹

For specific illustrations of how copays, coinsurance, accumulator adjustment programs, and high-deductible healthcare plans can affect out-of-pocket costs for patients enrolled in plans with different benefit levels, please visit page 26 of our [2018 Janssen U.S. Transparency Report](#). ●

FAST FACT

39%

of large employers now offer only **high-deductible healthcare plans**, up from 7% in 2009.⁴⁷

34%

of insured adults find it **difficult to pay their deductible** before their insurance kicks in.⁴⁸



Other factors in healthcare benefit design can increase the amounts patients pay out-of-pocket. These include coinsurance, where insurers charge patients a percentage of the medicine’s list price instead of a fixed-dollar copay, and the addition of formulary tiers with higher cost sharing. Payers also can put in place



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

HOW UTILIZATION MANAGEMENT IMPACTS PATIENTS AND PROVIDERS



UTILIZATION MANAGEMENT TOOLS

Payers also employ various “utilization management tools” to ensure physicians adhere to their formularies. Aimed at steering patients to insurers’ preferred therapies, utilization management tools include:

- **Prior Authorization**, which requires physicians to obtain approval from an insurer before a patient can receive a prescribed medicine.^{50,51}
- **Step Therapy (also known as “fail first”)**, which requires patients to try medicines on an insurer’s preferred list of prescriptions before the insurer will cover the cost of another medicine.
- **New-to-Market Block**, where insurers delay coverage for newly approved medicines, sometimes for significant amounts of time.
- **Non-Medical Switching**, which happens when insurers eliminate coverage for a patient’s current medicine (sometimes within a plan year) requiring a clinically stable patient to switch from one branded medicine to another for non-medical reasons. Non-medical switching differs from a situation where a patient changes treatment for a medical reason.

Significantly, utilization management tools add to a physician’s administrative burden, taking time and attention from patient care.⁵² Across specialties, physicians report spending an average of 15 hours a week seeking authorizations from insurers.⁵³ ●

OUR POSITION ON NON-MEDICAL SWITCHING

We believe treatment decisions belong in the hands of patients and their healthcare professionals, which is why we are concerned about medically stable patients being switched to other therapies for non-medical reasons.

Because our first responsibility is to patients who use our medicines, we oppose non-medical switching even when it works to our advantage, as in cases where a Janssen medicine is the lowest-cost therapy on a payer’s formulary for a given condition. We do not proactively seek arrangements with payers that require patients who are clinically stable to switch to a different medicine.



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES



HOW COSTS AND OTHER ACCESS HURDLES AFFECT PATIENT HEALTH

Research shows that patients' health can suffer when they face obstacles to getting the medicines they need,⁵⁴ such as high out-of-pocket costs^{55,56} or barriers put up by insurers.

Patients with higher out-of-pocket costs are more likely to abandon their new prescriptions at the pharmacy.⁵⁷ Similarly, high out-of-pocket costs can contribute to medication "non-adherence," as has been shown in patients with rheumatoid arthritis⁵⁸ or breast cancer.⁵⁹

FAST FACT

69% of patients **did not fill a new prescription** when faced with out-of-pocket costs exceeding **\$250.**⁶⁰



Utilization management tools can cause delays in care and lead patients to report worse health outcomes.

In a survey carried out by the American Medical Association, nine out of ten physicians said the process of navigating prior authorization requirements may delay patients' access to necessary care.⁶¹ At the same time, studies have found

prior authorization requirements to be associated with worse health outcomes and increased healthcare costs in such areas as diabetes and mental health.^{62,63,64}

Non-medical switching also has impacts on patients. In a survey carried out by the Alliance for Patient Access (sponsored by Janssen Scientific Affairs, LLC), patients responded they experienced negative impacts on health outcomes and well-being because of non-medical switching. Three out of five reported complications and two out of five said they stopped taking their medication altogether. In another survey, 70% of patients said that when they were switched to different medications for non-medical reasons, they considered their new medications less effective.⁶⁵

ACCESS HURDLES THAT DELAY THERAPY CAN LIMIT THE LONG-TERM BENEFITS OF MEDICINES

Over the long term, medicines bring significant benefits to patients, the health system, and society. More than half of the improvements in patient outcomes since 1990 can be attributed to medicines, according to physicians surveyed.⁶⁶ When patients gained access to prescription drug coverage through the Medicare Part D benefit, it resulted in decreases in hospital admissions and inpatient charges.⁶⁷ More recently, novel treatments for hepatitis C have cured patients of what was once a chronic disease. These treatments are projected to save Medicaid an estimated \$12 billion from 2013-2022, despite initial concern about their cost.⁶⁸ For our medicines specifically, data shows they can improve long-term health outcomes, reducing costs to patients and to the health system. For more information, visit page 33 of our [2018 Janssen U.S. Transparency Report](#).

Beyond reducing costs to the healthcare system, medicines provide benefits to society more broadly. Patients taking one of our medicines to treat schizophrenia (a long-acting injectable) were significantly less likely to have an encounter with the criminal justice system in the 12-month period after starting the medicine than in the 12-month period before.⁶⁹ The results suggest that these medicines could reduce costs associated with the criminal justice system, including costs related to incarceration.⁷⁰

These benefits underscore the importance of access to medicines—the key factor in our responsible approach to pricing, which we discuss in the following section. ●



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

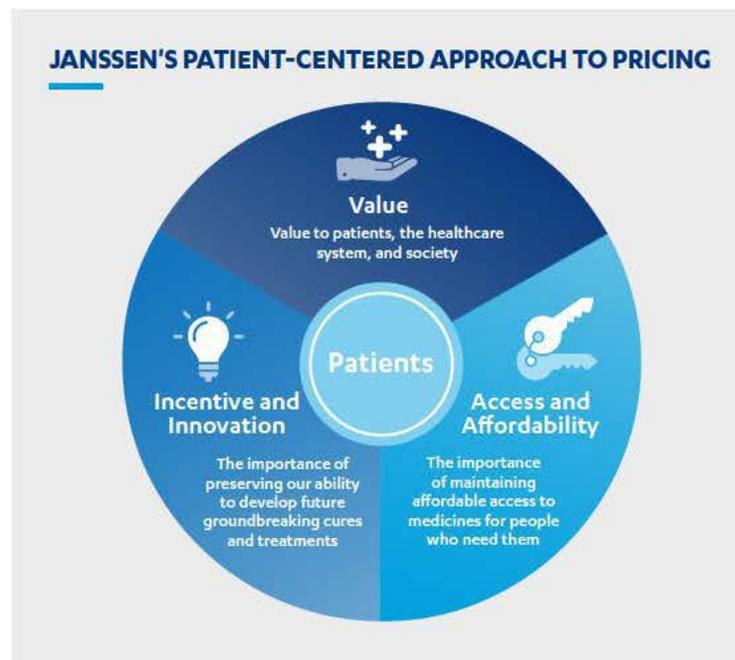
Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

OUR RESPONSIBLE APPROACH TO PRICING

At Janssen, our approach to pricing recognizes our dual responsibility to patients today and patients tomorrow. Patients today need access to our medicines. Patients tomorrow count on us to deliver cures and treatments for challenging diseases.



In setting an initial list price for a medicine, we balance:

- **Its value to patients, the healthcare system, and society.** What matters most is how the medicine will improve patient health. We also assess the medicine's potential to reduce a variety of costs—surgeries, hospital stays, or long-term care, for example—and the improvement the medicine represents over the existing standard of care. We consider the importance patients, their families, and their caregivers 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.

- **The importance of ensuring affordable access to medicines for people who need them.** We work closely with insurers, pharmacy benefit managers, governments, hospitals, physicians, and other providers of care so patients who are prescribed our medicines can get access to them.
- **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 necessary resources to invest in R&D to address serious, unmet medical needs.

Some observers propose a different approach. They argue that the price of medicines should be pegged to the costs of developing or manufacturing them. However, pricing a medicine based on its R&D or manufacturing costs alone would not take into account the full range of benefits a medicine provides. It would also leave out investments that we must make in drug candidates that fail in development. Pharmaceutical companies and the rest of the scientific community can learn from these failures to improve the research process.



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

OUR RESPONSIBLE APPROACH TO PRICING

OUR NET PRICES DECLINED IN 2019

After we set an initial list price for our medicines, it is substantially reduced by rebates, discounts, and fees, leading to a net price. In 2019, our average aggregate net price decline was -1.2%.⁷¹ The approximately \$24.5 billion in discounts, rebates, and fees we provided to payers, providers, and other intermediaries outweighed our single-digit list price increases.⁷² The total average amount provided off of our list price to health system intermediaries has grown by 44% since 2016, the first year we began disclosing approximate total discounts, rebates, and fees.⁷³

Although our net prices declined this year, our business has continued to grow and remains strong because of increased use of our medicines—growth that reflects their value to patients and healthcare providers. Our net price decline comes as the total rate of medical inflation in the U.S. rose approximately 4.6% in 2019.⁷⁴ ●

FAST FACT

Between 2016 and 2019, the **compound net price decline** of our medicines was **-9.2%**.⁷⁵



JANSSEN U.S. PRICING OVERVIEW

Year	List Price Change ⁷⁶	Net Price Change ⁷⁷
2019	5.1%	-1.2%
2018	6.3%	-6.8%
2017	8.1%	-4.6%
2016	8.5%	3.5%
2015	9.7%	5.2%



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

OUR PROGRAMS TO SUPPORT PATIENTS TODAY

Patients should have affordable access to medicines. We offer and support programs that can help.

As noted, the primary way we support patient access to our medicines is by negotiating with payers for preferred placement on their formularies. However, even with health insurance, some patients face high out-of-pocket costs for

prescription medicines, and finding financial assistance can be challenging. In compliance with relevant laws, we take additional steps to help patients obtain access to medicines. While we recognize these programs are not long-term solutions, they are one way we strive to meet the needs of the patients we serve and the healthcare professionals who care for them.

JANSSEN CAREPATH

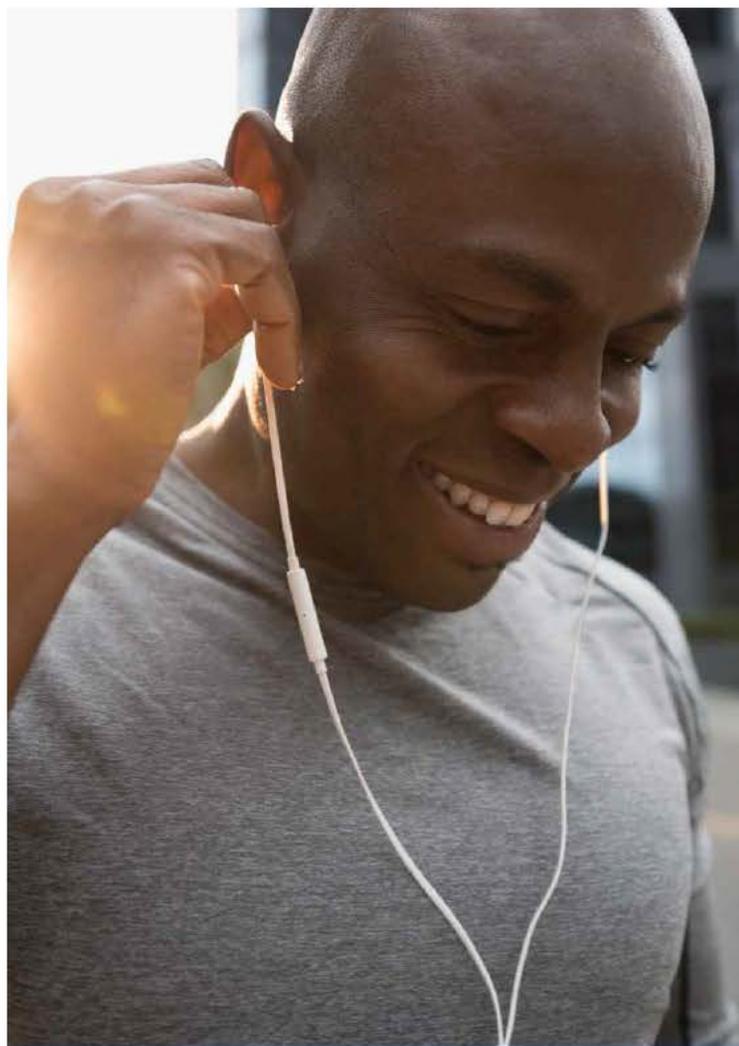
Janssen CarePath provides access, affordability, and treatment support resources to help patients get started on, and stay on, the Janssen medications their healthcare providers prescribe. Janssen CarePath Care Coordinators offer various forms of patient support: they answer questions about insurance coverage for Janssen medications and potential patient out-of-pocket costs; locate nearby treatment centers for certain medications; provide resources to help patients take their Janssen medications as prescribed; and if needed, they identify options that may help make the medications more affordable. These resources are available for patients who are prescribed Janssen medicines in the following therapeutic areas: cardiovascular and diabetes, dermatology, gastroenterology, infectious diseases, neuroscience, oncology, and rheumatology.

For commercially insured patients who meet the program requirements, we offer the Janssen CarePath Savings Program to help reduce patient out-of-pocket medication costs for prescribed Janssen medications. Such programs—sometimes referred to as “copay cards” or “copay coupons”—play a critical role in making out-of-pocket costs more manageable for patients by helping them gain access to the medicines prescribed by their healthcare providers.⁷⁸

Additionally, Janssen CarePath helps healthcare providers find access solutions for their patients 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 2019, we helped approximately 1.3 million patients through the Janssen CarePath program.⁷⁹ This includes approximately 540,000 commercially insured patients who reduced their out-of-pocket expenditures through the Janssen CarePath Savings Program.⁸⁰

To learn more, please visit [JanssenCarePath.com](https://www.JanssenCarePath.com) or call 1-877-CarePath (1-877-227-3728).



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

OUR PROGRAMS TO SUPPORT PATIENTS TODAY

INDEPENDENT PROGRAM AND FOUNDATION SUPPORT

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

- Janssen donates medicines and funding to the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF), an independent, nonprofit organization committed to helping eligible patients without insurance coverage receive prescription products donated by Johnson & Johnson operating companies.
- In 2019, we donated approximately \$1.2 billion⁸¹ in free products and financial support to the JJPAF, enabling the Foundation to provide medicines at no cost to approximately 82,000 patients.⁸² More information is available at jjpaf.org.
- We also make financial donations to independent charitable foundations that assist underinsured and financially needy patients with treatment-related expenses.
- In 2019, we donated approximately \$220 million to independent charitable foundations,⁸³ enabling them to assist an estimated 30,000 patients with medication-related copays for any physician-prescribed medicines that treat certain diseases covered by the foundations.⁸⁴

ADDITIONAL RESOURCES FOR PATIENTS

In 2019, we joined other leading pharmaceutical companies to create the Medicine Assistance Tool (MAT) program, connecting patients, caregivers, and providers with hundreds of different financial assistance programs that may help them afford their medicines. MAT also provides patients with more transparency about medicine costs, helping them to make more informed healthcare decisions. For more information, please visit mat.org.

While all of these programs provide meaningful support for patients today, we believe more sustainable solutions can be achieved through patient-centered policy reforms. ●



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES



ADVOCATING FOR PATIENT-CENTERED POLICY REFORMS



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

“We strive for a healthcare system that delivers affordable access for patients today and greater hope for patients tomorrow.”

—Scott White, Company Group Chairman, North America Pharmaceuticals, Johnson & Johnson

The U.S. healthcare system has many strengths. But as patients have made clear, the need for improvement is urgent.

At Janssen, we are committed to generating sustainable policy solutions that put patients first and build on the strengths of the U.S. healthcare system, which prioritizes treating patients as individuals, and fostering the development and rapid approval of new medicines.

OUR HEALTHCARE POLICY PRINCIPLES



Affordable Access. Policies should support broad patient access to appropriate, affordable, high-quality treatment options.



Choice. Policies should safeguard the physician-patient relationship and keep treatment decisions in the hands of patients and their healthcare professionals; clinically stable patients should not be switched to other therapies for non-medical reasons.



Patient Safety. Policies should promote patient safety by ensuring consistently rigorous clinical and manufacturing quality standards.



Sustainability. Policies should lower overall costs to the system while sustaining a biomedical research ecosystem that continues to deliver transformative medical advances to society.

We support reforms that reward value and promote competition in the U.S. healthcare system.

Ensuring every American has access to affordable healthcare, including the medicines they need, means changing how we pay for healthcare. Shifting to an approach that makes value, not volume, the priority means that everyone who plays a role in the healthcare system is held accountable for the results or outcomes they deliver, including pharmaceutical manufacturers like Janssen. This approach focuses on healthcare interventions—whether medicines, surgeries, in-office visits, or other forms of care—that deliver the best results at the lowest cost.

Competition is also key—it spurs innovation, provides choices at prices that reflect value, and keeps costs down. That’s why we believe in a level playing field for all companies, including manufacturers of generics and biosimilars. Roughly nine in ten prescriptions written in the U.S. are for generics, and the use of biosimilars continues to grow.⁸⁵ From 2009-2018, generics reduced U.S. health spending by \$2 trillion.⁸⁶ These savings can be used for other kinds of care, including innovative new treatments.

Some proposals to control the price of medicines may not lower patients’ costs and would lead to fewer new medicines being developed.

Over the last few years, several policy proposals have been put forward to reduce the costs of medicines for the health system, including:

- Importing medicines from countries outside the U.S.
- Forcing companies to tie the price of their medicines in the U.S. to that of other countries (known as international reference pricing)
- Capping the amount of inflation in drug prices year-over-year

These proposals may not actually reduce out-of-pocket costs for patients because they do not address key drivers of patient costs in our system. Patient costs are largely determined by their insurance benefit design and the degree to which fees and discounts are passed through the supply chain, which is often limited.



ADVOCATING FOR PATIENT-CENTERED POLICY REFORMS



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

Understanding the Price of Medicines

How Patient Costs Are Determined

How Utilization Management Impacts Patients and Providers

How Costs and Other Access Hurdles Affect Patient Health

Our Responsible Approach to Pricing

Our Programs to Support Patients Today

Advocating for Patient-Centered Policy Reforms

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

At the same time, these proposals could drastically reduce the incentives for innovation that benefit U.S. patients. In fact, recent analyses have found that under a proposal that includes reference pricing, between 50 and 100 fewer new medicines would be approved for patients over the next decade.^{87,88}

A better solution is to promote reforms that directly limit or lower patient out-of-pocket costs.

We support a cap on patient out-of-pocket costs, especially in Medicare Part D, and other proposals to increase the predictability of what patients pay month-to-month. More broadly, we believe patients should receive their fair share of the discounts and rebates that payers negotiate. Patient coinsurance and deductibles should be based on the net price the plan actually pays for the medicine, not its list price. And patients should not have to pay more in copays or coinsurance than their insurer pays for a given medicine.

Reforms must consider healthcare costs as a whole and the potential of medicines to manage those costs.

In the U.S., more than 85% of all healthcare spending goes to costs other than prescription medicines⁸⁹ and, as noted previously, medicines can reduce spending on hospitalization and other healthcare costs.^{90,91} In 2018, total retail prescription medicine spending grew 2.5% while overall healthcare expenditures increased 4.6%.⁹² More specifically, spending on hospital care and professional services grew by \$92.2 billion in 2018 compared to just \$8.3 billion in increased spending on outpatient prescription drugs.⁹³ As stakeholders seek ways to curb healthcare spending in the U.S., it is important to remember the limited role prescription medicines play in overall healthcare costs, especially given the tremendous value they bring.

We are listening, learning, and offering ideas.

We are committed to advancing the dialogue on healthcare reform. We have and will continue to share our perspective with state governments, Congress, and the Administration based on the beliefs we have outlined above. As we work toward practical solutions, it is important to remember we all share the same goal: building a more sustainable, affordable, and accessible healthcare system that improves the options for patients now—and in the future. ●

A CLOSER LOOK AT VALUE FRAMEWORKS

As healthcare decision makers' interest in value assessment has grown, so has our concern about the shortcomings of frameworks currently used to analyze the value of medicines. Typically, these frameworks fail to appropriately account for all the factors that make a medicine valuable, most notably to patients—improved quality of life, the ability to work and care for family, reduced burden on caregivers, and the chance to remain independent for a longer period of time.

Particularly concerning are value frameworks that use cost-effectiveness analyses and thresholds to determine whether or not patients should have access to medicines. Cost-effectiveness analyses attempt to quantify the level of health gained for each dollar spent on treatment. They are estimates that rest on numerous assumptions and rely on inputs from a wide variety of sources, some more credible than others. These estimates deem a medicine “valuable” if the ratio of dollars spent to health gained stays below a limit, or threshold. In practical terms, that threshold is arbitrary—and puts a monetary ceiling on the value of human health and life.⁹⁴

“Cost-effectiveness analyses generally use an input called the quality adjusted life year, or QALY. The QALY rates the value of human life relative to a subjective standard of perfect health, which is why its use may discriminate against populations such as the elderly, chronically ill, and disabled.⁹⁵ QALY-based frameworks place a lower value on treatments that extend and improve the lives of people who may never have perfect health—one of the main reasons they should not be used in valuing medicines.”^{96,97}

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





INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

ADVANCING HOPE FOR PATIENTS TOMORROW

“We issue this Report at a critical moment in U.S. healthcare. We need to ensure medical progress continues to give patients hope.”

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

At Janssen, we invest in research that transforms human health. We strive to make our research as efficient and productive as possible so that new treatments can reach the patients who need them. This requires that we employ highly creative scientists and physicians, and that we collaborate with the best researchers throughout the scientific community.

In the section below, we explain our approach to research and development (R&D) and discuss the medical advances enabled by our R&D investment, which

exceeds what we spend on sales and marketing. We detail how the research data we share enhances the efforts of the scientific community at large. We also express our support for the intellectual property framework that helps the R&D ecosystem function, clarify the role of government funding in research, and explain why and how we educate prescribers.

CUTTING-EDGE RESEARCH TO ADDRESS SIGNIFICANT PATIENT NEEDS

Diseases like cancer, cardiovascular disease, diabetes, and dementia continue to take a human and economic toll. In the U.S., such diseases:⁹⁸

- Claim **1 million lives** each year
- Affect **191 million people**, with **75 million** having more than one disease
- Will cost **\$42 trillion** between 2016 and 2030

Scientists across our industry are tackling these challenges head-on for a variety of diseases.

- More than **8,000 new medicines** are in development globally, including **4,500** in the U.S.⁹⁹
- **74% of the new medicines** in clinical development would be first-in-class innovations¹⁰⁰



OUR APPROACH TO RESEARCH AND DEVELOPMENT



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

At Janssen, our scientists are working to create a future where disease is a thing of the past.

Our research and development is centered on six therapeutic areas and a number of diseases within those areas, all of which have significant unmet need:

- **Cardiovascular & Metabolism:** Chronic kidney disease, type 2 diabetes, non-alcoholic steatohepatitis, thrombosis, and retinal diseases
- **Immunology:** Inflammatory bowel diseases, including Crohn's and ulcerative colitis, psoriatic arthritis, lupus, lupus nephritis, atopic dermatitis, and psoriasis
- **Infectious Diseases and Vaccines:** HIV, hepatitis B, Ebola, *E. coli*, and respiratory infections such as RSV, influenza, and COVID-19
- **Neuroscience:** Schizophrenia, major depressive disorder, multiple sclerosis, and Alzheimer's disease
- **Oncology:** Hematologic malignancies such as multiple myeloma and acute myeloid leukemia, and solid tumors such as prostate, lung, colon, and bladder cancer
- **Pulmonary Hypertension:** Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension

Across these diseases, we use our expertise in small molecules, monoclonal antibodies, cell and gene therapies, RNA therapeutics, and vaccines to develop transformational medical innovations.



R&D BY THE NUMBERS

2 new medicines and 9 new indications approved by the U.S. Food & Drug Administration (FDA) in 2019^{*,101,102}

\$8.8 billion invested globally in pharmaceutical R&D¹⁰³



91% more invested in global R&D than in global sales and marketing¹⁰⁴

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

140+ active collaborations with universities, biopharmaceutical firms, academic medical centers, and other scientific organizations

120,000+ patients enrolled worldwide in more than 400 clinical trials



640+ start-up companies in the Johnson & Johnson Innovation-JLABS incubator community

*New therapeutic uses for previously approved medicines

In 2019, we increased our global investment in R&D to \$8.8 billion, up from \$8.4 billion in 2018.¹⁰⁵ This investment represents a significant portion of Johnson & Johnson's overall 2019 R&D investment of \$11.4 billion, which is among the highest in the world in any industry.¹⁰⁶

Our R&D expenditures enable us to discover, test, and develop new medicines as well as demonstrate the efficacy, safety, and regulatory compliance of our medicines before approval. We also use our R&D resources to improve and monitor the safety of existing, FDA-approved products, and explore possible new indications in additional patient populations.



OUR APPROACH TO RESEARCH AND DEVELOPMENT

In 2019, we had two new medicines approved by the FDA,¹⁰⁷ along with nine expanded indications that allow new groups of patients to benefit from our medicines.¹⁰⁸

Our investment, along with the passion, ingenuity, and insight of our researchers, has enabled us to advance more than 80 medicine candidates. Seven of these have been granted Breakthrough Therapy Designations by the FDA in the past five years.^{109,110} Medicines with this designation show early clinical evidence of a substantial improvement over current therapies to treat serious conditions.¹¹¹

Over the last five years (2015-2019), we invested \$39.4 billion in R&D.¹¹² In that same period, we had a total of seven new medicines approved by the FDA¹¹³ and received 38 approvals for expanded indications or new product formulations.¹¹⁴

Our investment in global R&D (\$8.8 billion)¹¹⁵ significantly exceeds our spending in global sales and marketing (\$4.6 billion).¹¹⁶ In total we spent 91% more on R&D than we did on marketing and sales.¹¹⁷ We use global figures to make

this comparison because the R&D activities we undertake around the world collectively contribute to medicine development.

The Janssen sales and marketing figures in this report are even more specific than what is described in Johnson & Johnson's financial statements. Our financial statements combine sales and marketing expenses with other items in "Selling, Marketing, and Administrative Expenses" (SM&A). This SM&A figure accounts for much more than pharmaceutical sales and marketing expenses. It includes administrative and overhead activities that are not related to sales or marketing, such as operational expenses for insurance, accounting and product distribution. It is a global figure that pertains to all the businesses in the Johnson & Johnson Family of Companies, which include medical devices and consumer products in addition to pharmaceuticals. ●



MOBILIZING AGAINST THE COVID-19 CORONAVIRUS



Building on our experience and significant investment in vaccine research and development, we [launched a multipronged response](#) to address the global outbreak of a new form of coronavirus (also known as 2019-nCoV or COVID-19). We believe collaboration is key to combating this crisis, and that public-private partnerships and coordinated efforts among scientists, researchers, government, and academia will offer the most promising solutions. Our approach includes collaborations to develop a vaccine candidate against 2019-nCoV,^{118,119} and to screen a library of antiviral therapies to protect people from this serious and sometimes deadly disease.¹²⁰ We are expanding our global manufacturing capacity, including through the establishment of new U.S. vaccine manufacturing capabilities and scaling up capacity in other countries. The additional capacity will assist in the rapid production of a vaccine and will enable the supply of more than one billion doses of a safe and effective vaccine globally. We plan to begin production at risk, and are committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.¹²¹



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

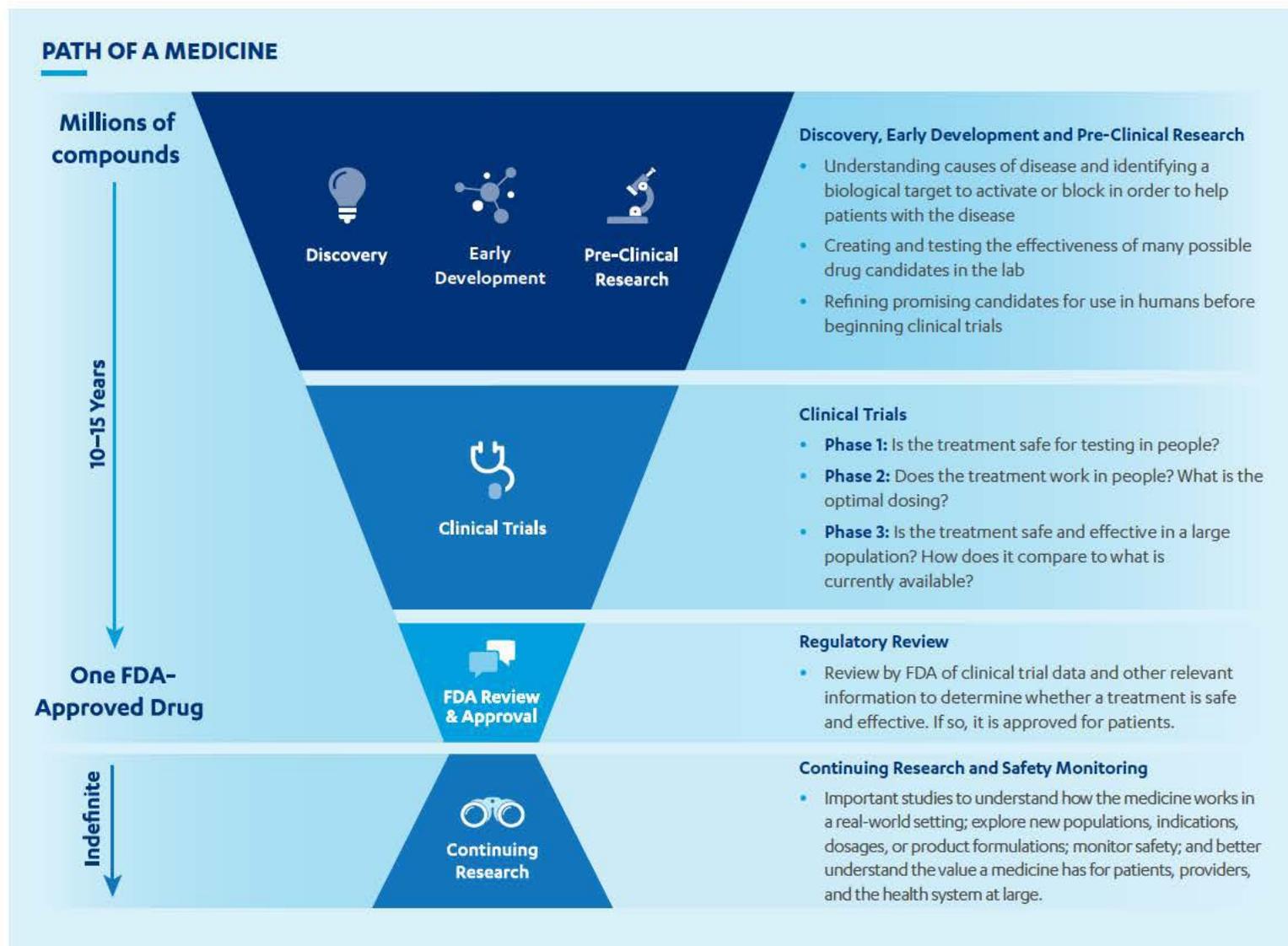
Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES



CONTINUALLY ENHANCING DISCOVERY AND DEVELOPMENT

Bringing a new medicine to patients includes several stages of research conducted over many years and comes with significant cost and risk of failure. Developing a medicine and then gaining approval from the FDA typically takes 10-15 years¹²² and can cost billions of dollars.¹²³



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES



CONTINUALLY ENHANCING DISCOVERY AND DEVELOPMENT

The diagram on the previous page illustrates the journey of a new medicine from laboratory to launch. But no diagram can capture the full complexity of developing a new medicine and having it approved by regulators.

The process begins with millions of molecules being screened and investigated. These are winnowed to a few candidates selected for development, which are refined, characterized, tested, and further culled in the course of research. In the end, new medicines are approved infrequently, likely after a decade or more of research and billions of dollars in investment.



FAST FACT

We currently have more than **120,000 patients** enrolled worldwide in more than **400 clinical trials**. In 2019, we launched more than **100 new clinical trials**.



SPEEDING THE SCIENCE

Janssen is continually working to improve the medicine development process so we can more efficiently and effectively follow leads, strengthen our clinical data, and increase the number of medicines that gain approval by regulatory agencies, including the FDA and its counterparts in other nations. We are:

Investing in data science. We are harnessing cutting-edge analytical tools, including machine learning, deep learning, natural language processing, and more to analyze new and expanded sources of data. These include clinical trial data, physician notes, patient-reported outcomes, lab results, images, and data from wearable devices. These technologies can help us better identify targets, improve the probability of success in advancing promising candidates, reduce research timelines, and evaluate our medicines more efficiently and effectively than ever before.

Taking a more integrated view. By studying biological pathways that underpin more than one disease, we aim to speed the development of new therapies for multiple conditions, compared to previous efforts that focused on one disease in isolation.

Improving clinical trials. Clinical trials are often the longest and most expensive element of the development sequence. Each trial is designed in compliance with regulatory policies and conducted by independent investigators to maintain the quality and integrity of the data. To ensure the safety of patient volunteers, we work with top scientific experts to design, execute, and report data from our trials. These trials take months to design, months to years to enroll, and years to execute. We are working to improve our clinical trials in the following ways:

- We consider patient perspectives early in the process. Patients, caregivers, and patient advocacy groups provide critical perspectives and often help us clarify our research priorities and goals by contributing insights that improve the design of our clinical trials. For more information about our approach to patient engagement, visit page 12 of our [2018 Janssen U.S. Transparency Report](#).



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES



CONTINUALLY ENHANCING DISCOVERY AND DEVELOPMENT



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

- We strive to make our clinical trial populations reflect the diversity of real-world patient populations. In 2019, we launched an effort to increase the diversity of clinical trial participants and build greater trust in the process. As an example, we enabled more members of under-represented populations to participate in one of our immunology clinical trials, by using machine learning and data science to address a longstanding challenge to recruitment—the choice of appropriate trial sites.
- We explore appropriate ways to supplement the clinical evidence generated by randomized controlled trials with real-world evidence. In 2019, we utilized data science and real-world data to streamline a clinical trial of one of our oncology medicines. ●

PIONEERING DIGITAL CLINICAL TRIALS

We are collaborating with Apple on the Heartline™ study to analyze the impact of wearable technology on the early detection and diagnosis of atrial fibrillation (Afib), a condition that can lead to stroke and other devastating health complications. To learn more about this study, visit heartline.com.



PRE-APPROVAL ACCESS PROGRAMS

The main pathway for gaining access to Janssen's investigational medicines is for a patient to enroll in a clinical trial. Pre-Approval Access (PAA) is the overarching term used for access to an investigational medicine outside of a clinical trial and prior to its approval by a health authority.

For patients with serious or life-threatening illnesses who cannot enroll in clinical trials, pre-approval access programs, such as "expanded access" programs and "named patient" programs for multiple patients, or "single-patient access" requests for individual patients, can be considered. Our policy for considering pre-approval access to investigational medicines is grounded in key ethical principles. Visit janssen.com/compassionate-use-pre-approval-access to learn more.

We typically consider making pre-approval access available when our clinical studies are complete, or when enough scientific evidence is available to inform careful review of requests prior to health authority approval. In 2019, Janssen provided access to 455 patients through PAA programs.¹²⁴

For more information, please visit janssen.com/compassionate-use-pre-approval-access. Healthcare providers may submit a request for access by calling 1-800-JANSSEN or email janssenmedinfo@its.jnj.com.



CONTRIBUTING TO A STRONGER R&D ECOSYSTEM

No single company has all the best ideas. Success in the discovery and development of new medicines and vaccines depends on collaborations between scientific organizations ranging from small startups to universities to large global companies.

We do our part to support science and accelerate the development of new medicines by:

- Making our clinical trial data more accessible
- Creating an infrastructure for other healthcare innovators to succeed
- Enabling and financing promising science

MAKING CLINICAL TRIAL DATA MORE ACCESSIBLE

Increasing the availability of our clinical trial results allows the scientific community to learn from efforts of other researchers and the patients who volunteer for clinical studies. This advances science and benefits public health in important ways.

Like others in our industry, we disclose summary 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 scientific journals. But we go beyond what's required.



In a first-of-its-kind agreement with Yale Medical School, we share pharmaceutical, medical 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 this clinical trial data in their own scientific or medical research to increase medical knowledge and improve public health.

Our leadership in data sharing has been recognized by external organizations like Bioethics International.¹²⁵ For more information about the YODA Project and to request access to data from Janssen's clinical trials, please visit yoda.yale.edu.

BY THE NUMBERS: YODA RESULTS¹²⁶

IN 2019:

32
Requests for data



10
Papers published using YODA data

SINCE PROGRAM INCEPTION IN 2014:

154
Requests for data



27
Papers published using YODA data

CREATING AN INFRASTRUCTURE FOR INNOVATORS TO SUCCEED

In 1953, Janssen itself was a startup, with our namesake, Dr. Paul Janssen, working out of a space provided by his father. Today we remain faithful to our roots and are passionate about helping the next generation of biomedical innovators.



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

CONTRIBUTING TO A STRONGER R&D ECOSYSTEM



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

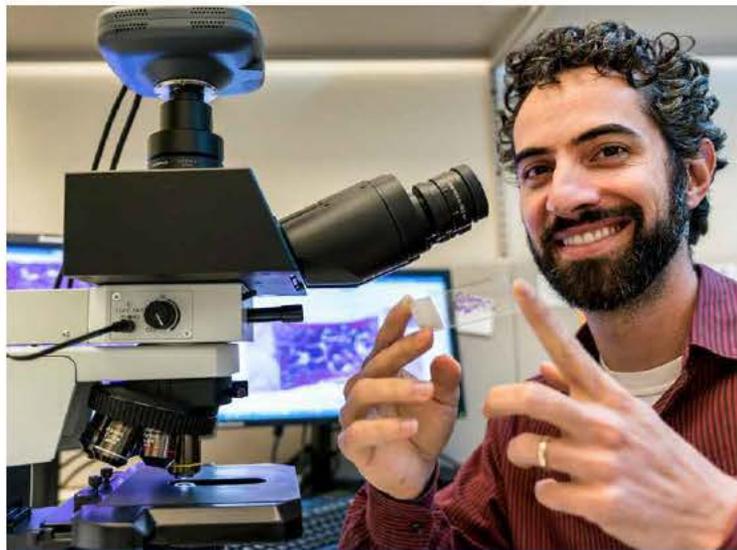
This is demonstrated through Johnson & Johnson Innovation – JLABS, our network of open innovation ecosystems. Through JLABS, we provide early-stage healthcare companies with access to the expertise, funding, services, and state-of-the-art equipment to get started and scale up. JLABS follows a “no-strings-attached” model, so entrepreneurs are free to develop their science while holding on to their intellectual property.

More than 640 companies are either current JLABS residents or alumni, 58% of which are first-time entrepreneurs. Collectively they have secured \$27.7 billion of investments in their companies through financing and strategic relationships.¹²⁷ To learn more, please visit [jlabs.jnjinnovation.com/JLABSNavigator#/.](https://jlabs.jnjinnovation.com/JLABSNavigator#/)

ENABLING AND FINANCING PROMISING SCIENCE

Our partnerships and collaborations span the research spectrum, from licensing new drug targets to full-scale development partnerships. These relationships may entail upfront and milestone payments, royalty agreements, and R&D expense sharing.

In some cases, we work with academic institutes and biotech companies on early-stage research. For example, we have an ongoing collaboration with researchers at the Broad Institute of MIT and Harvard to discover new targets and develop therapeutics for immune-mediated diseases using cutting-edge genetics and innovative screening tools.



On the other end of the spectrum, we also collaborate with the world’s largest private companies and government research organizations. In 2019, we joined with the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH), the HIV Vaccine Trials Network (HVTN), and the U.S. Army Medical Research and Development Command (USAMRDC) to launch the first large-scale Phase 3 clinical trial of our “mosaic-based” investigational vaccine aimed at preventing infections from multiple strains of HIV.¹²⁸ For more information about what a mosaic-based vaccine is, visit jnj.com/innovation/what-is-a-mosaic-hiv-vaccine. ●

FAST FACT

We have more than **140 active collaborations** and partnerships. We formed **53 new ones** in 2019.



ADVANCING PERSONALIZED CANCER CARE

Every year in the U.S., more than 30,000 patients are diagnosed with multiple myeloma, and more than 12,000 patients die from the disease. Through a collaboration with Legend Biotech USA, Inc., Janssen is advancing the development of a chimeric antigen receptor T cell (CAR-T) therapy, which harnesses the body’s own immune system to fight cancer. CAR-T therapy is a type of immunotherapy that involves extracting a patient’s white blood cells, genetically modifying them in a laboratory, and re-administering the modified cells to the patient. In 2019, Janssen [received U.S. FDA Breakthrough Therapy Designation](#) for JNJ-4528, an investigational CAR-T therapy.¹²⁹ Additionally, we are investing in state-of-the-art supply chain capabilities in support of our ongoing clinical efforts and potential future needs. We are committed to advancing this novel therapy through clinical development and bringing this treatment to patients who are still in need of effective therapies.



THE COMPLEMENTARY ROLES OF PUBLIC AND PRIVATELY FUNDED RESEARCH

We are sometimes asked: Does Janssen benefit from research funded by U.S. taxpayers?

Government funding is a critical part of the nation's R&D ecosystem. The NIH provides the most public biomedical research funding of any government agency in the world.¹³⁰ The bulk of the NIH's budget is disbursed as grants to academic researchers,¹³¹ while just 7.6% of NIH's 2019 grant funding went to domestic for-profit companies.¹³²

Generally, the NIH funds early-stage, basic research to understand the causes of a disease or the mechanisms underlying a biological process, such as what makes cancer cells divide.¹³³ Academic scientists, biotechnology companies,

and large pharmaceutical companies work to translate that basic research into drug or vaccine candidates for development and clinical testing. As previously noted, it takes many years and billions of dollars to carry out the applied research to develop a new medicine, which is why it is typically conducted by companies such as Janssen.^{134,135} Sometimes, after a product is initially approved, government funders may support research by academics or other scientists to explore further uses that may or may not result in FDA-approved indications of the product.

In total, the biopharmaceutical industry's R&D investments in 2018 were approximately \$102.1 billion, more than 2.5 times the NIH's \$35.4 billion spending on research.¹³⁶ Both sources of research funding are critical to advancing patient care, and both should be encouraged.



PUBLIC FUNDING AND JANSSEN RESEARCH

U.S. government officials have recently stressed the importance of collaboration between the public and private sectors, academia, and others when dealing with public health threats.^{137,138} All of the government funding we received to support our research over the last five years is for a limited number of projects that supplement our investments to address public health threats. These projects are typically part of broader collaborations with support from additional institutions, including other governments, nonprofit funders, and more. The U.S. government funding we received from 2015-2019, which amounted to less than one percent of our global R&D investment, supported the following:¹³⁹

- A vaccine candidate for the prevention of Ebola currently being tested or provided in the Democratic Republic of Congo, Rwanda, and other countries
- A vaccine candidate for the prevention of HIV currently being tested in at-risk populations in the U.S., Africa, South America, and Europe
- Vaccine and therapeutic candidates for the prevention and treatment of emerging infectious disease, including pandemic influenza
- A therapeutic to treat acute radiation exposure

Separately, in the rare cases where Janssen developed and successfully commercialized a new medicine by building on research discovered and patented by the government, we pay royalty and commercial milestone payments back to the government. These payments to the NIH totaled more than \$242 million over the last five years.¹⁴⁰ ●



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES



SUSTAINING THE ENGINE OF BIOMEDICAL INNOVATION



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

Innovation is a strength of American healthcare. However, some have questioned whether the intellectual property (IP) protections in the U.S. prevent patients from attaining affordable access to these innovations. A closer look suggests otherwise.



IP protections include both patents and, in the pharmaceutical industry specifically, data exclusivity. Patents provide innovators with a limited time period where inventions that are considered new, useful, and non-obvious cannot be copied. In the pharmaceutical industry specifically, data exclusivity provides companies that conduct tolerability, safety, and efficacy testing on their products a limited time where only they can use their clinical data for regulatory approval. The strong IP protections in the U.S. benefit patients in numerous ways:

- **Promoting Innovation.** Time-limited patent protection enables innovators to receive a fair return for the extensive resources, time, and effort it takes to develop their current and future products. The patent system does not guarantee commercial success, but simply provides some certainty that if meaningful advances are made, the innovator's work will not be immediately copied. The comparative strength of the U.S. IP system is a key reason more new medicines are developed in the U.S. than in any other nation.¹⁴¹

- **Supporting Transparency and Competition.** In exchange for the limited window of protection provided by patents, researchers must publicly disclose information about their discoveries which others can use to develop the next generation of treatments. Even while a medicine is under IP protection, competing companies may be able to bring even better treatments to patients. In fact, most first-in-class medicines face competition from another branded product either when they are first approved, or within the first three years after introduction.¹⁴²
- **Fostering Generic and Biosimilar Entry.** After data exclusivity ends, generic and biosimilar manufacturers can gain approval of copies or near-copies of medicines without having to repeat costly clinical trials. This is because they can rely on the clinical data provided by the company that developed the original medicine. Without a stream of innovative new medicines, there would be no additional generics or biosimilars. Today, nine in ten prescriptions are for generic medicines.¹⁴³

Because an open, competitive market has proven to be the best model to support the development of new treatments for patients, we continue to support strong, reliable, and enforceable IP protections. ●



BRINGING OUR APPROVED MEDICINES TO PATIENTS: SALES AND MARKETING

After we have FDA approval for an innovative medicine, we invest in providing accurate, up-to-date information to healthcare providers and patients so it can be used appropriately.

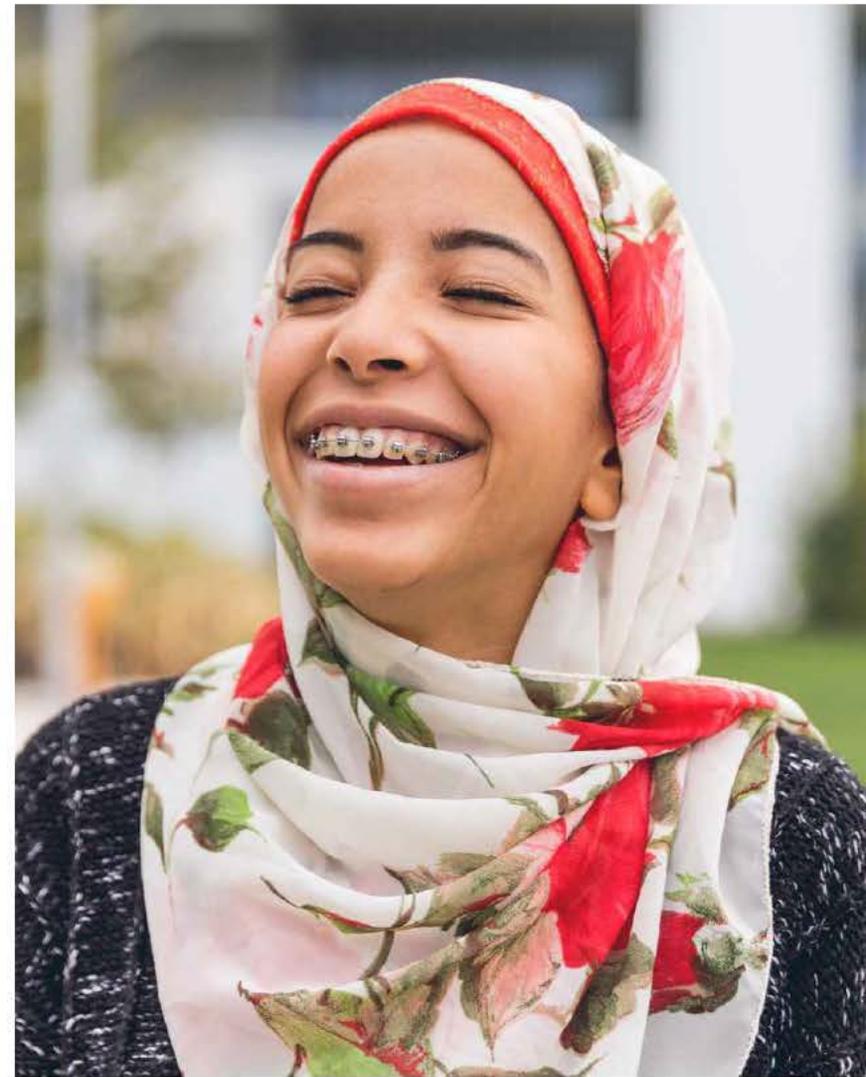
RESPONSIBLE COMMUNICATIONS ABOUT OUR MEDICINES

In 2019, we spent \$4.6 billion globally (\$2.7 billion in the U.S.) on pharmaceutical sales and marketing activities,¹⁴⁴ including communications with healthcare professionals about our medicines' approved uses, effectiveness, side effects, benefits, and risks. These expenditures also include patient education and direct-to-consumer communication.

Our sales and marketing activities adhere to industry ethics standards and codes of conduct, including the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code on Interactions with Healthcare Professionals and the [PhRMA Guiding Principles on Direct-to-Consumer \(DTC\) Advertisements about Prescription Medicines](#). We view these guidelines as a starting point and challenge ourselves to deliver even more for patients.

We ensure the information we share with patients and healthcare professionals is balanced, accurate, current, and credible. We work with healthcare providers on peer-to-peer education with the goal of advancing the health of patients by sharing clinical outcomes through transparent, compliant activities. Healthcare providers with real-world clinical experience in specific therapeutic areas are uniquely qualified to provide education and insights into new advancements regarding our medicines. This type of interaction can address potential treatment gaps, as it allows providers to discuss important medical information about the appropriate use of our products.

Beyond educating healthcare professionals and informing patients about our medicines, our responsible approach to sales and marketing helps generate the revenues we need to fund research into future treatments and cures.



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES



BRINGING OUR APPROVED MEDICINES TO PATIENTS: SALES AND MARKETING



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

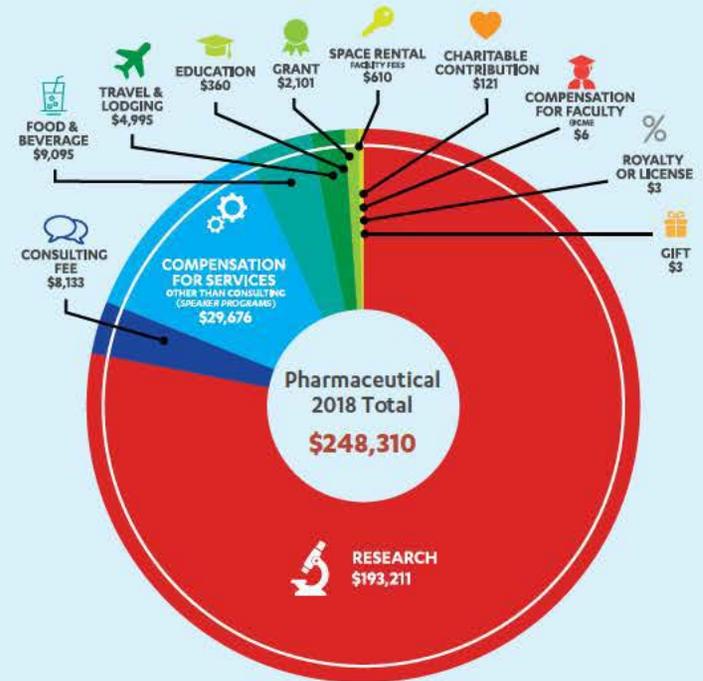
OPEN PAYMENTS: R&D ACCOUNTS FOR 77% OF OUR PAYMENTS TO PHYSICIANS

In compliance with Open Payments requirements, we report to the U.S. Centers for Medicare and Medicaid Services (CMS) the compensation or transfers of value that we provide as a part of our sales and marketing outreach to educate healthcare professionals about our medicines. These transfers of value include, but are not limited to, medical textbooks, scientific articles, meals, and travel expenses. This information is available through the CMS Open Payments database and we make this information available to the public on jnj.com. The great majority—77%—of our Open Payments disclosures in 2018, the latest reporting year, are research payments.¹⁴⁵ These include, but are not limited to, payments we make to healthcare providers and academic medical centers for conducting research during the multi-year medicine development process.

We anticipate that 2019 Open Payments data will be available through CMS on June 30, 2020.

RESEARCH	Clinical studies and research that provide valuable scientific and clinical information about the medicines and medical devices that improve patients' lives
CONSULTING FEE	Product development • Training • Development of educational materials and disease management programs • Unblinded market research
COMPENSATION FOR SERVICES OTHER THAN CONSULTING (SPEAKER PROGRAMS)	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 • Acquisition payments
FOOD & BEVERAGE	Meals, whether paid directly or reimbursed, may be provided in conjunction with: Consulting services • Training • Educational and other business discussions with physicians
TRAVEL & LODGING	Travel, whether paid directly or reimbursed, in conjunction with: Consulting services • Product training
EDUCATION	Medical textbooks • Scientific journal articles
GRANT	Sponsorship of an educational event, patient advocacy event, or publication • Sponsorship of fellowships for fellow and resident training • Certified independent educational activities (i.e., activities certified by a continuing medical education provider) • Non-certified medical education activities
SPACE RENTAL FACILITY FEES	Space Rental or Facility Fees (Teaching Hospital Only) • Booth or exhibit space rental • Facility rental for product training or clinical studies

Numbers contained in the chart below are shown in thousands.



2018 data excludes late data, dispute resolutions, and Actelion data.

CHARITABLE CONTRIBUTION	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
COMPENSATION FOR FACULTY @CME	Indirect payment by a third-party organization to speakers at an accredited educational program, funded by an educational grant from a J&J company
ROYALTY OR LICENSE	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
GIFT	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 appropriate category available



FIGHTING SICKNESS WITH SCIENCE: AN ALZHEIMER'S DISEASE STORY



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

Our Approach to Research and Development

Continually Enhancing Discovery and Development

Contributing to a Stronger R&D Ecosystem

The Complementary Roles of Public and Privately Funded Research

Sustaining the Engine of Biomedical Innovation

Bringing Our Approved Medicines to Patients: Sales and Marketing

Fighting Sickness with Science: An Alzheimer's Disease Story

REFERENCES

Alzheimer's disease is the sixth-leading cause of death in the U.S. and has no existing cure. That's not for lack of trying.

For more than two decades, researchers have seen a series of promising therapies fail in clinical trials. In fact, from 1998 to 2017, there have been more than 140 failed attempts to develop a treatment for Alzheimer's disease, a medical condition whose causes are notoriously difficult to isolate and address.¹⁴⁶ Without further advances, Alzheimer's disease will affect nearly 14 million Americans over the age of 65 by 2060,¹⁴⁷ by which time the total cost of care for people with Alzheimer's and other dementias could top \$1.1 trillion.*¹⁴⁸

Despite some of our own setbacks in this space, we continue our R&D commitment to Alzheimer's disease because the need for treatment remains so great.

To speed advances against Alzheimer's, we share important data and samples with researchers outside our organization. In 2019, Janssen, Shionogi & Co., and the Alzheimer's Drug Discovery Foundation's Diagnostics Accelerator announced an initiative to share data and samples with researchers around the world. Our goal is to find new biomarkers—the telltale signs of disease that can be detected through tests. Finding additional biomarkers would be a major step toward novel treatment options and could be especially valuable in intercepting Alzheimer's disease before it does irreparable damage to the patient's brain. There is much work to do here, but we are up to the task of conquering this major public health challenge in our lifetimes.



WHEN THE QUEST FOR A CURE IS PERSONAL

Gayle Wittenberg, Ph.D., a Neuroscience Data Scientist at Janssen Research & Development, LLC, whose father passed away from Alzheimer's disease in 2019, tells us why we need to continue our quest for a cure.

"As it stands today, there is no cure for Alzheimer's disease, and that's not a legacy that we want to pass on to subsequent generations. If my dad were here today, he would look at the challenges involved in finding a cure for Alzheimer's disease and he would remind us, 'you can do hard things.' When things don't always go the way you would like, you don't let that break you. You stand back and you say, okay universe, challenge accepted, and then you find joy in the creative problem solving that comes next."



Patients like Gayle's dad are why we strive to deliver the medicines that will transform tomorrow—and why we work to make medicines that are available today accessible to all who need them.

We live in a moment of incredible hope, on the verge of extraordinary progress that could change our lives and the lives of our children and grandchildren. At Janssen, we are committed to bringing that promise to life. ●

*In 2018 dollars



REFERENCES



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

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REFERENCES



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

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REFERENCES



INTRODUCTION

TRANSFORMING LIVES FOR PATIENTS TODAY

ADVANCING HOPE FOR PATIENTS TOMORROW

REFERENCES

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EXHIBIT D

(see attached)

Johnson & Johnson Joins Other Companies in Signing a Landmark Communiqué on Expanded Global Access for COVID-19

In signing the communiqué, Johnson & Johnson and 15 other life science companies are committing to prioritize the safety, science and accessibility of the potential vaccines, therapeutic medicines or diagnostic tools they are developing to help fight the pandemic.

By **Johnson & Johnson** September 30, 2020

C OVID-19 changed the world as we know it this year, and life science companies around the globe have been hard at work for months in the fight against the virus, banding together to launch the most expansive and ambitious pandemic research and development response effort in history.

Today, CEOs from 16 of those companies and Bill and Melinda Gates, co-chairs of the **Bill & Melinda Gates Foundation**, have signed a landmark Communiqué on Expanded Global Access commitment to ensure that people everywhere have access to the potential COVID-19 innovations under development at the companies—regardless of their income level. The agreement calls on governments, NGOs and other stakeholders to join the cause and help accelerate the end of the pandemic.



The 5 Stages of COVID-19 Vaccine Development: What You Need to Know About How a Clinical Trial Works

As part of its commitment today, Johnson & Johnson also plans to allocate up to 500 million vaccine doses to lower income countries with delivery beginning mid next year.

“Johnson & Johnson stands alongside our peers and the Bill & Melinda Gates Foundation in our unwavering commitment to equitable global access to the medicines and innovations being developed to fight the COVID-19 pandemic,” says Alex Gorsky



Alex Gorsky,
Chairman and CEO, Johnson & Johnson

, Chairman and CEO, Johnson & Johnson. “Since the beginning of our **COVID-19 response**, Johnson & Johnson has been committed to bringing forward a safe, effective and affordable vaccine on a not-for-profit basis for emergency pandemic use, while also focusing on making sure the vaccine candidate will be accessible globally. Decisive, collaborative action now will help us beat this pandemic and better prepare us for future virus outbreaks.”

Here are some highlights from the **Communiqué on Expanded Global Access**, announced this morning during the U.N. General Assembly—and what this historic pledge means for people across the globe.

I.

Johnson & Johnson has signed the commitment along with 15 other life science companies.



5 Latest Facts About Johnson & Johnson's Investigational COVID-19 Vaccine

Each of the signing companies—AstraZeneca; Bayer; bioMérieux; Boehringer Ingelheim; Bristol Myers Squibb; Eisai; Eli Lilly; Gilead; GSK; Johnson & Johnson; Merck & Co. (known as MSD outside the U.S. and Canada); Merck KGaA, Darmstadt, Germany; Novartis; Pfizer; Roche; and Sanofi—have agreed to follow a specific set of five principles outlined in the communiqué to help ensure global access to potential vaccines, therapeutics and diagnostics that could help accelerate the end of the pandemic.

2.

Each company has pledged to make their products affordable for lower-income countries.

While each company will have its own approach for ensuring that this goal is met, solutions could include donations, not-for-profit supply or equity-based tiered pricing based on a country's needs and capabilities.



The Impact of COVID-19 on a Company: 6 Questions for the Chief Financial Officer of Johnson & Johnson

Johnson & Johnson, for instance, stated at the beginning of its COVID-19 response that it was committed to bringing an affordable vaccine to the public on a **not-for-profit basis** for emergency pandemic use.

3.

The communiqué calls for more diverse representation at all levels of innovation.

In order to create potential COVID-19 diagnostics, therapeutics and vaccines that can meet the needs of populations around the world, the signing companies have agreed to expand the diversity of their clinical trials to include lower-income settings and address the specific product characteristics that might be needed for use in those settings.



Clinical Trials 2.0: 5 Ways Johnson & Johnson Is Helping Revamp—and Revolutionize—How They're Conducted

The signing companies are also calling on governments, NGOs and other companies to diversify the voices heard when it comes to critical decision-making as it pertains to COVID-19, with special emphasis on ensuring low-income and lower-middle-income countries are represented.

4.

This is not Johnson & Johnson's first partnership with the Bill & Melinda Gates Foundation.

Ten years ago, Johnson & Johnson joined other pharmaceutical companies and organizations, including the Bill & Melinda Gates Foundation, to endorse the [London Declaration on Neglected Tropical Diseases](#)—a landmark pledge to donate existing treatments and develop new tools to help combat such illnesses as dengue and leprosy.



How Johnson & Johnson Is Helping Tackle a Devastating Tropical Disease That Impacts Kids

At that time, Johnson & Johnson committed to giving 200 million doses of mebendazole—a medication that fights intestinal worm infections, which impact approximately 1.5 billion people worldwide—annually through 2020 via a donation program operated by the World Health Organization.

In 2019, the company [extended that commitment](#) another five years and pledged to donate an additional 1 billion doses of the medication for high-burden countries starting in 2021 and going through 2025.

5.

The agreement aims to build and maintain confidence in the innovations that the companies are developing.

Safety is of the highest priority, which is why the signing companies have agreed to adhere to the strictest scientific and ethical standards in their product development and manufacturing processes, as well as in the approval mechanisms for potential diagnostics, therapeutics and vaccines by ensuring robust safety and efficacy reviews.

Earlier this month, Johnson & Johnson also announced that, alongside eight other companies working on investigational COVID-19 vaccines, it was signing a [#WeStandWithScience](#) pledge committed to upholding the integrity of the scientific process as the companies work towards potential global regulatory filings and approvals of the first vaccines for COVID-19.



**Johnson & Johnson
Signs a Historic
Pledge to Uphold the
Integrity of the
Scientific Process in
Developing an
Investigational
COVID-19 Vaccine**



Th **dy**

Volunteers from diverse groups are needed to res **dy** agational vaccine. Please note that by clicking this link, you'll be leaving jnj.com and going to a third-party website not governed by the jnj.com privacy policy.
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♥ 178

- Caring & Giving
- Innovation
- Johnson & Johnson
- COVID-19
- Coronavirus
- Vaccines

EXHIBIT E

(see attached)

OUR COMPANY

Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use

Johnson & Johnson and BARDA Together Commit More than \$1 Billion to Novel Coronavirus Vaccine Research and Development; Company Expects to Initiate Phase 1 Human Clinical Studies of Vaccine Candidate at Latest by September 2020

Johnson & Johnson Will Establish New U.S. Vaccine Manufacturing Capabilities and Additional Production Capacity Outside the U.S. to Begin Production at Risk to Help Ensure Global Vaccine Supply

NEW BRUNSWICK, N.J., March 30, 2020 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced the selection of a lead COVID-19 vaccine candidate from constructs it has been working on since January 2020; the significant expansion of the existing partnership between the Janssen Pharmaceutical Companies of Johnson & Johnson and the Biomedical Advanced Research and Development Authority (BARDA); and the rapid scaling of the Company's manufacturing capacity with the goal of providing global supply of more than one billion doses of a vaccine. The Company expects to initiate human clinical studies of its lead vaccine candidate at the latest by September 2020 and anticipates the first batches of a COVID-19 vaccine could be available for emergency use authorization in early 2021, a substantially accelerated timeframe in comparison to the typical vaccine development process.

Through a landmark new partnership, BARDA, which is part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services, and Johnson & Johnson together have committed more than \$1 billion of investment to co-fund vaccine research, development, and clinical testing. Johnson & Johnson will use its validated vaccine platform and is allocating resources, including personnel and infrastructure globally, as needed, to focus on these efforts. Separately, BARDA and the Company have provided additional funding that will enable expansion of their ongoing work to identify potential antiviral treatment against the novel coronavirus.

As part of its commitment, Johnson & Johnson is also expanding the Company's global manufacturing capacity, including through the establishment of new U.S. vaccine manufacturing capabilities and scaling up capacity in other countries. The additional capacity will assist in the rapid production of a vaccine and will enable the supply of more than one billion doses of a safe and effective vaccine globally. The Company plans to begin production at risk imminently and is committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.

Ale Gorzky, Chairman and Chief Executive Officer, Johnson & Johnson, said, "The world is facing an urgent public health crisis and we are committed to doing our part to make a COVID-19 vaccine available and affordable globally as quickly as possible. As the world's largest healthcare company, we feel a deep responsibility to improve the health of people around the world every day. Johnson & Johnson is well positioned through our combination of scientific expertise, operational scale and financial strength to bring our resources in collaboration with others to accelerate the fight against this pandemic."

Paul Stoffel, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson, said, "We greatly value the U.S. government's confidence and support for our R&D efforts. Johnson & Johnson's global team of experts has ramped up our research and development processes to unprecedented levels, and our teams are working tirelessly alongside BARDA, scientific partners, and global health authorities. We are very pleased to have identified a lead vaccine candidate from the construct we have been working on since January. We are moving on an accelerated timeline toward Phase 1 human clinical trials at the latest by September 2020 and, supported by the global production capability that we are scaling up in parallel to this testing, we expect a vaccine could be ready for emergency use in early 2021."

Johnson & Johnson's Lead COVID-19 Vaccine Candidate

Johnson & Johnson began efforts in January 2020, as soon as the novel coronavirus (COVID-19) sequence became available, to research potential vaccine candidate. Research team at Janssen, in collaboration with Beth Israel Deaconess Medical Center, part of Harvard Medical School, constructed and tested multiple vaccine candidates using the Janssen AdVac® technology.

Through collaborations with scientists at multiple academic institutions, the vaccine constructs were then tested to identify those with the most promise in producing an immune response in preclinical testing.

Based on this work, Johnson & Johnson has identified a lead COVID-19 vaccine candidate (with two back-ups), which will progress into the first manufacturing steps. Under an accelerated timeline, the Company is aiming to initiate a Phase 1 clinical study in September 2020, with clinical data on safety and efficacy expected to be available by the end of the year. This could allow vaccine availability for emergency use in early 2021. For comparison, the typical vaccine development process involves a number of different research stages, spanning 5 to 7 years, before a candidate is even considered for approval.

For more than 20 years, Johnson & Johnson has invested billions of dollars in antivirals and vaccine capabilities. The COVID-19 vaccine program is leveraging Janssen's proven **AdVac®** and **PER.C6®** technologies that provide the ability to rapidly develop new vaccine candidates and upscale production of the optimal vaccine candidate. The same technology was used to develop and manufacture the Company's Ebola vaccine and construct our Zika, RSV, and HIV vaccine candidates which are in Phase 2 or Phase 3 clinical development stages.

Expanded Antiviral Research

In addition to the vaccine development efforts, BARDA and Johnson & Johnson have also expanded their partnership to accelerate Janssen's ongoing work in screening compound libraries, including compounds from other pharmaceutical companies. The Company's aim is to identify potential treatments against the novel coronavirus. Johnson & Johnson and BARDA are both providing funding as part of this partnership. These antiviral screening efforts are being conducted in partnership with the Rega Institute for Medical Research (KU Leuven/University of Leuven), in Belgium.

As announced in February 2020, the Company and BARDA have been working closely with global partners to screen Janssen's library of antiviral molecules to accelerate the discovery of potential COVID-19 treatments.

COVID-19 belongs to a group of viruses called coronaviruses that attack the respiratory system. There is currently no approved vaccine, treatment or cure for COVID-19.

For more information on Johnson & Johnson's multi-pronged approach to combatting the pandemic, visit: www.jnj.com/coronavirus.

###

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.jnj.com. Follow us at [@JNJNews](https://twitter.com/JNJNews).

About the Janssen Pharmaceutical Companies

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com. Follow us at [@JanssenGlobal](https://twitter.com/JanssenGlobal).

Notice to Investors Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of potential preventive and treatment regimens for COVID-19. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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EXHIBIT F

(see attached)

The Impact of COVID-19 on a Company: 6 Questions for the Chief Financial Officer of Johnson & Johnson

When you're the CFO of a company, you have a holistic view of how a pandemic can touch every aspect of a business, especially when it's a healthcare company. So we posed inquiring mind questions to Joe Wolk about what the past eight months have been like for him at the financial helm of the company—via a Zoom interview.



By **Liz Ozaist**, Global Content Lab Editor-in-Chief, Johnson & Johnson September 24, 2020

The year 1944 was historic for Johnson & Johnson. On September 24, under the leadership of **Robert Wood Johnson**, the company went public with a listing on the New York Stock Exchange and its initial public offering of stock (IPO).

The year 2020 has also been a historic one for Johnson & Johnson as it works to help address the current **COVID-19 pandemic**—an event that has proven to be unprecedented for people the world over.



Joe Wolk, Chief Financial Officer and Executive Vice President, Johnson & Johnson



The 5 Stages of COVID-19 Vaccine Development: What You Need to Know About How a Clinical Trial Works

It's also an event that has touched every aspect of the company, from scientists who have been clocking countless hours researching an investigational COVID-19 vaccine to manufacturing employees who have worked equally hard to ensure that supplies of products like Tylenol® are available to people who need them most.

To commemorate the anniversary of Johnson & Johnson's IPO, we connected with the company's Chief Financial Officer and Executive Vice President, Joe Wolk, to look beyond the numbers and discuss how the pandemic has impacted the company's three core

segments—and how he has leveraged his over-20-year tenure with Johnson & Johnson to help guide the company during this truly unique time in history.

Q: Scientists at the Janssen Pharmaceutical Companies of Johnson & Johnson are hard at work on an investigational COVID-19 vaccine. Should it be proven to be viable, the company has stated that it would provide the vaccine for emergency pandemic use on a not-for-profit basis. How exactly would this work?

A: Joe Wolk: That's a great question because companies traded on the New York Stock Exchange typically don't utilize not-for-profit business models. Essentially, in simplest terms, it means distributing the vaccine at a cost to payers that covers our costs, such as development, clinical trials required and manufacturing and distribution.

While this may seem straightforward, it can still be subject to many different interpretations. Given this, we are anchoring our not-for-profit pricing based on a formula established and utilized by the Bill & Melinda Gates Foundation (BMGF) for vaccine product pricing in lower-income countries.



She's a Scientist with One of the World's Most Important Jobs: Creating a Potential COVID-19 Vaccine

We feel it's important to be transparent about the costs that we considered, and given that the BMGF formula is widely accepted, we believe this is a relevant benchmark. Further, we are looking to have our calculations independently verified.

During the initial emergency pandemic use period, we felt it was important to do our part to remove barriers to access and that people not have to worry about the price of a potential vaccine. That said, responsible pricing is nothing new for Johnson & Johnson.

The net price for our medicines in the U.S. has decreased in each of the last four years across our entire pharmaceutical portfolio—and we'll continue to act responsibly in this regard. Our success is tied to innovation that addresses unmet medical needs, not price increases.

Q: This decision also speaks to the tenets outlined in Our Credo, the company's guiding mission statement.

A: Absolutely. It reminds me of the scenario that was in front of me when I was CFO for our pharmaceuticals group in North America and Ebola first emerged. We made the decision then to pursue research and development on a vaccine even though it wouldn't provide the financial returns typically associated with risk-based development—we knew we had a responsibility to help combat Ebola to benefit society.





5 Latest Facts About Johnson & Johnson's Ebola Vaccine

The situation today is not too different, and highlights the relevance of the fourth paragraph of **Our Credo**: It's critically important that we're not just getting by on financial performance, but that we are financially strong. That muscle provides us the latitude to live into the other three paragraphs of Our Credo more profoundly—enabling us to do things like invest above benchmark in innovation, ensure employees are fairly rewarded, and act in a way that has a positive impact on the community.

Our Credo (shown here at corporate headquarters in New Brunswick, New Jersey) has the word "must" in it 22 times. That's a very unequivocal word. "Must" cannot be interpreted as "if you feel like it" or "if the time is right." It's an obligation, a commitment, that creates a nice, healthy tension whereby we make responsible choices, weighing the interests of all stakeholders.

Q: Johnson & Johnson is uniquely positioned to persevere during this challenging time due in part to its broadly based portfolio. How has the pandemic affected the company's three core sectors—consumer health, medical devices and pharmaceuticals?

A: Even though our business segments are all linked through the common mission of healthcare and providing better solutions for those we serve, they've all been impacted somewhat differently as a result of the current pandemic.

Medical devices has seen the most pronounced impact. When you look at our portfolio, about two-thirds of our products are used in elective procedures, and we saw restrictions placed on those procedures across the globe early in the pandemic. That segment of the market is recovering nicely as more people have returned to hospitals and physicians to undergo these important medical procedures.

So, in summary, the valleys weren't as deep as we thought initially, and the recovery occurred quicker than we assumed. And we'll get better clarity going into the fourth quarter as summer is naturally a slower time for hospital visits and procedures. But I would say a recovery is well underway.



4 High-Tech Tools Johnson & Johnson Is Using to Get Products to You During the Pandemic

In consumer health, we saw a significant uptake in what was known as "pantry loading." It was a need for self care, where people were saying to themselves: *I'm going to be prepared in case I need these solutions at my disposal.*

For example, we saw a surge in demand for Tylenol—and the team did a great job to meet this elevated demand. Perhaps the most unique story relates to Listerine® sales, which were extremely strong in the first quarter. The theory one person offered was that people are wearing masks and realizing they've got bad breath. I can't speak to whether that's true or not, but it's not irrational!

Finally, our pharmaceutical segment continued to shine. Many of our lifesaving or life-enhancing therapies are for very severe disease states within **immunology**, **oncology**, **neuroscience** and infectious diseases. Given the often chronic nature of these ailments, those treatments continued to be maintained pretty well for patients.

Our business has been a tale of all cities in terms of ups and downs. But I do believe Johnson & Johnson is emerging stronger because of the breadth of our portfolio and our relentless drive towards innovation across all three segments during the pandemic.

“

The resiliency of Johnson & Johnson employees and our business, coupled with a spirit of learning and innovation to tackle a challenging situation and solve it in a way that improves a process or outcome for the long-term, has been inspiring to experience.

”

Q: Speaking of innovation, has the pandemic presented new ways of thinking about healthcare that have intrigued you in any way?

A: We've seen the emergence of and growth in telehealth visits on a large scale, which I think is here to stay.



People are finding they're getting more dedicated time with their doctors in this way—we have heard patients and physicians can have a solid conversation for 30 minutes without distractions.

Along the same lines, the pandemic has also presented a greater opportunity to harness technology as it relates to better preventive care by being able to self-monitor your health in a technologically enabled way, which could be a growth area for the broader industry.

Q: The company recently announced that it has entered into a definitive agreement to acquire Momenta Pharmaceuticals, Inc. The world is so focused on COVID-19, but it's important to continue to address other unmet healthcare needs. How would this acquisition complement Johnson & Johnson's existing portfolio?

A: It really speaks to an overarching principle of thinking long term in our management of the business—we've been able to find innovation early enough that we can now influence what we're going to treat and how expansive those treatments may be.



Johnson & Johnson's New Chief Financial Officer Answers 7 Popular Investor Questions

Momenta Pharmaceuticals provides another opportunity, complementing the expertise and capabilities we already have within our immunology team related to autoimmune diseases.

It also goes back to the fourth paragraph of Our Credo—we are financially strong and have the financial muscle, strength and creditworthiness to purchase a company that will play into our long-term success and our commitment to ensuring good health is within reach of everyone, everywhere.

Q: It goes without saying that we are all living through an unprecedented time, but how has this moment in time evolved your own approach and viewpoint on your work as CFO?

A: If you would have told me on January 1 of this year, "You're going to close your books for the first, second and likely third quarters with 99% of the team working remote," it would have made me a little nervous.



5 Latest Facts About Johnson & Johnson's Investigational COVID-19 Vaccine

But the resiliency of Johnson & Johnson employees and our business, coupled with a spirit of learning and innovation to tackle a challenging situation and solve it in a way that improves a process or outcome for the long term, has been inspiring to experience.

When you have a situation like this, our teams don't get mired in concerns of how they are going to get through this. Instead, they ask, "How are we going to lead through this?"



Johnson & Johnson Reports Second Quarter Earnings

Read the earnings press release, which includes financial details for the second quarter of 2020.

[Learn more](#)

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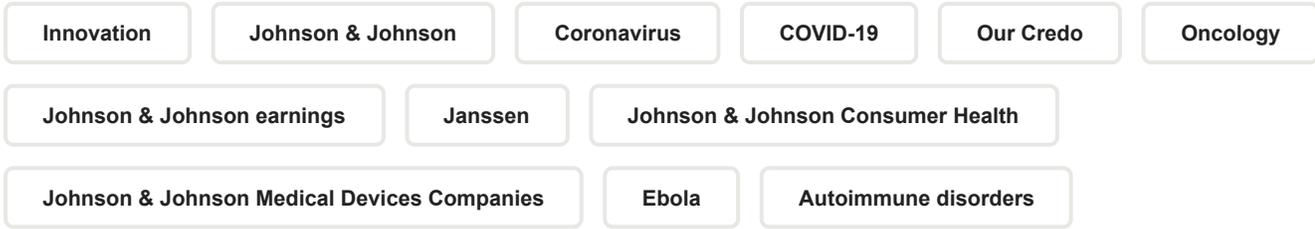


EXHIBIT G

(see attached)

Production Economics for Vaccines



CONTACT INFORMATION

It is the hope of the foundation that vaccine Production Economics (PE) assessments will be completed collaboratively with manufacturers through transparent dialog and data sharing. We find that this approach leads to the most accurate assessments and ultimately supports the best strategies for partnering to achieve healthy vaccine markets.

Do not hesitate to reach out to the foundation with any questions or comments on PE assessments. Please contact Robyn Iqbal or Tina Lorenson in Vaccine Delivery – Market Dynamics.

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Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation aspires to help all people lead healthy, productive lives. We are dedicated to discovering and disseminating innovative approaches to addressing extreme poverty and poor health in developing countries and improving the U.S. education system. Because our financial resources, while significant, represent a small fraction of what's needed to address these challenges, we work in partnership with governments, the private sector, and other donors and organizations to achieve the greatest possible impact.

For additional information on the Bill & Melinda Gates Foundation, please visit our website: www.gatesfoundation.org.

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Contents

OVERVIEW 2

Provides an introduction, background, overview of how to use this handbook, and the executive summary



OVERVIEW

DATA COLLECTION METHODOLOGIES 8

Discusses the foundation's approach to collecting data to assess Production Economics (PE) costs



DATA

DETERMINING PE COSTS 12

Offers an overview of the types of costs and the different cost categories appropriate for assessing PE



PE COSTS

ALLOCATION OF COSTS 25

Discusses how to properly allocate costs so the PE are specific to a vaccine and market



ALLOCATIONS

IMPACT OF ECONOMIC VARIABLES 30

Describes micro- and macroeconomic variables as well as other economic factors that have an impact on PE over time



IMPACT

GLOSSARY 34

Definitions of key terms



GLOSSARY

Overview



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

IN THIS SECTION

Introduction

Background

How to Use This handbook

Executive Summary

Introduction

The mission of the Bill & Melinda Gates Foundation (the foundation) is to help all people lead healthy, productive lives. Specifically, the Global Development Division at the foundation works to help the world's poorest people lift themselves out of hunger and poverty, while the Global Health Division aims to harness advances in science and technology to save lives. We work with partners to provide proven tools—including vaccines, drugs, and diagnostics—and to discover novel solutions that are both affordable and reliable. Equally important is innovation in how health interventions are delivered to those who need them most.

In collaboration with Gavi Alliance partners, the foundation develops vaccine market strategies to ensure affordable and sustainable access to vaccines in lower-income countries. When investments can support our market goals, the foundation has a variety of investment tools (e.g., grants, loans, guarantees, etc.) that can create mutually beneficial opportunities with manufacturers. When evaluating and structuring these investments, we find it critical to have a strong and reliable understanding of a manufacturer's **Production Economics** (PE). Core to understanding PE, is understanding a manufacturer's fully loaded cost base for a product, from the initial costs of discovery and development through manufacturing and final packaging, with allocations made as appropriate. Throughout this handbook we use the term PE to refer to this core component. Within this handbook we also use the term **Production Economics Cost of Goods Sold (PE COGS)**¹ to refer to all costs associated with the definition of PE above.

Use of a robust and comprehensive methodology to assess PE is core to a fair and sustainable market.

Use of a robust and comprehensive methodology to assess PE is core to a fair and sustainable market—for both countries and manufacturers. Specifically, it is important for:

- Ensuring access and affordability of vaccines and other health-related products in lower-income markets; and
- Assuring that the manufacturers serving these markets earn an appropriate return on investment that allows the production of such vaccines and other health-related products to be beneficial for the manufacturer and its stakeholders.

As an organization that values vaccines and the positive impact they have on global health, the foundation recognizes the importance of balancing these two goals and in being transparent in how we evaluate PE. As such, the foundation is sharing this handbook with manufacturers and other relevant partners. This handbook contains details on the standard methodology the foundation uses to evaluate the PE of a vaccine produced by a specific manufacturer in a particular market. **We recognize that manufacturers may internally account for these costs in different ways, and the intent of developing this methodology is for the foundation to have and use a consistent and standardized approach to PE in order to evaluate different investment opportunities in a more accurate and reliable way.**

¹ While COGS is a common accounting term with a narrow definition, please note we are defining PE COGS as the costs discussed in this handbook.



Background

This handbook is focused on PE for vaccines, and specifically for vaccines intended for global health.² Vaccines save millions of lives each year and are among the most cost-effective health interventions. That said, vaccines are often too expensive for the world's poorest countries, and supply shortages as well as downstream delivery obstacles pose challenges to access.

As a collaborator on the Global Vaccine Action Plan (GVAP), the foundation is committed to a framework that aims to prevent millions of deaths by 2020 through more equitable access to existing vaccines for people in all communities. In addition, as part of the broader vaccine community, the foundation supports the innovation needed to develop new vaccines and associated delivery technologies. As such, the foundation's Global Health Division invests heavily in vaccines to prevent infectious diseases (including improvements on current vaccines as well as new vaccines), related health interventions, and supporting technologies. The foundation focuses its investments on increasing vaccine access for the 73 Gavi eligible countries with the goal of creating equal access to new and underused vaccines for children living in the world's poorest countries.

When developing strategies to achieve healthy vaccine markets and considering specific investments, the foundation is mindful of economic considerations and tradeoffs involved in the development and commercialization of a vaccine. The foundation establishes an **intervention target product profile (iTTP)** for priority vaccines to define minimal and optimal parameters for vaccines, as this helps to guide product development investment decisions. PE is one of the important parameters defined in the iTTP, as it directly informs global access and affordability.

! We recognize that vaccine pricing must be sustainable for manufacturers, and therefore the price must also incorporate profit and risk, and that acceptable values for these elements will vary by manufacturer for numerous reasons. Furthermore, having a strong understanding of PE helps the foundation and manufacturers participate in a transparent conversation about pricing to ensure that an investment will be both fair and sustainable for the manufacturer and also have the intended global health impact. When a manufacturer is willing to collaborate and contribute to the foundation's understanding of PE, our shared understanding of PE will be deeper, and subsequent conversations around investments will be more informed.

Pricing discussions aim to ensure sustainability for a manufacturer and its ability to meet the intended global health impact.

² Note that the PE methodology and principles outlined in this handbook are specific to vaccines, but may also be extended to other biologics such as monoclonal antibodies.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

How to Use This Handbook

The intention of this handbook is for use in the following ways:

1. To gain familiarity with the foundation's approach to calculating PE COGS so differences in an individual manufacturer's approach can be identified and can inform discussions (note there is not an expectation that manufacturers conform to the foundation's approach for the manufacturer's own internal accounting purposes)
2. To guide PE COGS calculations by manufacturers
3. To provide guidance for partner organizations calculating PE COGS on the foundation's or a manufacturer's behalf

The methodology outlined in this handbook can be applied to commercialized vaccines as well as to vaccines in the earliest stages of development. In many instances, an organization—be it a manufacturer or public health organization—is concerned not with the overarching PE of a vaccine, but more specifically the PE of that vaccine related to specific countries or regions, such as the Gavi market.

Further, the foundation recognizes that there are, at times, significant costs that extend beyond the PE of the manufacturer (e.g., downstream delivery) that are part of the total systems costs of a given vaccine. While the foundation is simultaneously working to estimate and reduce these costs, these costs are outside the scope of this handbook, which focuses on costs specific to a given vaccine manufacturer.

Downstream delivery costs are not included in the foundation's approach to calculating PE COGS.

Organization of This Handbook

The remainder of this handbook outlines the principles and methodologies for assessing the PE for a vaccine; it is organized into the following sections:

- **Overview** provides an executive summary of the foundation's approach to PE;
- **Data Collection Methodologies** discusses the foundation's approach to collecting data to assess PE;
- **Determining Production Economics Costs** presents an overview of the types of costs and cost categories appropriate for assessing PE;
- **Allocation of Costs** details how to properly allocate costs so the PE is specific to a vaccine and market; and
- **Impact of Economic Variables** describes micro- and macroeconomic variables as well as other economic factors that have an impact on PE over time.

NAVIGATING THE HANDBOOK

The following elements will alert you to other resources or information that may be helpful while reviewing this handbook.

Bold blue terms are jump links to and from the glossary section.



The computer icon indicates information relevant to the workbook that can be found at:

https://docs.gatesfoundation.org/Documents/PE_Vaccines_Appendix_2016.xlsx



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Executive Summary

The foundation uses a standardized methodology to evaluate the PE of a particular vaccine in a particular market to ensure that all relevant cost categories are captured, and captured in a consistent way. Costs incurred throughout the product life cycle of a vaccine can be grouped into the following specific cost categories:

- **Product Development:** Costs incurred to discover, develop, and bring a vaccine to market (e.g., upfront R&D, clinical trials, regulatory approval including WHO Prequalification (WHO PQ), etc.);³
- **Facilities and Equipment:** Costs associated with fixed assets. Includes capitalized costs that depreciate over time (e.g., land, buildings, machinery, etc.) as well as ongoing costs of upkeep (e.g., repairs and maintenance, utilities, etc.);
- **Direct Labor:** Employee costs (e.g., wages, benefits) directly attributable to a specific vaccine;
- **Consumables:** Raw materials used as inputs in production of a specific vaccine;
- **Overhead:** Costs necessary for the manufacturer to incur in order to function, but not directly attributable to a specific vaccine. This handbook makes a distinction between two types of overhead: **Indirect Overhead** (e.g., plant management salaries, wages, training, etc.) for indirect expenses associated with plant management at each stage in the production process and **Corporate Overhead** (e.g., C-suite salaries, centralized back-office functions, insurance) for indirect expenses associated with the broader infrastructure of the manufacturer;

- **Commercialization:** Expenses incurred post regulatory approval associated with selling and marketing the product in the relevant market (e.g., advertising, marketing, distribution, etc.); and
- **Licensing:** Any income received (or expenses paid) for granting (or licensing) the right to use product-related intellectual property in order to produce the vaccine (e.g., technology). Any income received would be included as an offset to costs.

Along with costs incurred, these inputs impact costs—potentially reducing PE COGS—and should be included:

- **Third-Party Contributions:** All contributions (e.g., grants, loans, subsidies) from governments and other third-party (i.e., non-foundation) organizations are included to capture their impact on costs; and
- **Foundation Contributions:** All contributions (e.g., grants, loans) from the foundation are included as an impact to costs.

Third-party contributions such as grants, loans, and subsidies may reduce PE COGS.

³ The categorization between R&D, regulatory expenses, and marketing expenses can be a blurred line (e.g., clinical trials done to comply with regulatory organizations, local market registration that can be considered commercialization). As such, for the purposes of this handbook, we use the term Product Development to encompass all activities and associated costs incurred by a manufacturer to achieve commercial production of a vaccine (e.g., discovery, trials, PQ, local market registration). To the extent that a detailed breakout of these costs is available, it will be taken into account. Please note that there is also a separate Commercialization category; however it is intended only to include sales and marketing (to the extent it exists), as local market registration will fall under Product Development.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

These cost categories are designed to be general enough to cover all applicable costs. Depending on the level of detail available, each of these cost categories may represent the aggregation of a number of more detailed cost categories, or in the case of less detail, data may need to be segmented based on a reasonable allocation key in order to map to these cost categories. In either case, **it is important to confirm that costs are not double counted (i.e., by inclusion in more than one category).**

Further, the foundation’s data collection methodology as described within this handbook places an emphasis on data collection by production step, to the extent available. Collecting data and assessing the components by production step is driven by the foundation’s desire to more fully understand the drivers of PE. This understanding can shape the foundation’s investment construct to best support a manufacturer’s needs and can also help identify potential areas for cost reductions, which in turn can improve affordability and sustainability.

While the foundation recognizes that manufacturers may not keep costs in a format consistent with the production steps laid out in this handbook, to the extent possible, segmenting relevant cost categories by these four main commercial production steps allows for further insights to be made from the PE assessment.

The four commercial production steps are:

1. **Bulk:** Costs incurred in the production of the bulk product, including both upstream and downstream processes, but before any formulation, filling, and finishing occurs. For vaccine production,

bulk production is often the most complex and costly of the four steps, and typically includes a cell culture or fermentation stage followed by some combination of recovery, purification, and/or conjugation unit operations to arrive at a final bulk vaccine product;

2. **Formulation, Filling, and Finishing (Form/Fill/Finish):** Costs incurred during the production of final dosage form, including formulation (e.g., adjuvantation and lyophilization), aseptic filling, and finishing steps of the production process, including vial labeling before any secondary packaging;
3. **Secondary Packaging:** Costs incurred during packaging of the final dosage form, commonly referred to as secondary packaging. This will generally include activities such as putting finished vaccines into cartons and preparing them for shipment. This also includes all warehousing costs; and
4. **QA/QC:** Costs involved with quality control and quality assurance testing. These activities may occur at multiple points throughout the production process and therefore if possible, it is helpful to segment the related costs by the above production steps. To the extent that these costs are already embedded in the above production steps and cannot be broken out, it is important not to double count.

The diagram below displays the vaccine production process beginning with Product Development (as defined above) and moving into Commercial Production, which includes the four steps outlined previously. The fully loaded costs associated with a specific vaccine in a specific market may span both Product Development and Commercial Production.

DIAGRAM 1: VACCINE PRODUCTION PROCESS



Data Collection Methodologies



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

IN THIS SECTION

Data Collection Process
Inside-out vs. Outside-in
Data Collection Templates
Identifying and Capturing
Fully-Loaded Costs

Data Collection Process

The most accurate PE assessment will use the most reliable data available. Generally, this involves coordination with the manufacturer and review of available data (e.g., actuals, projections, analogs, etc.). When this information is not directly available, there are alternative means for collecting data to perform a PE assessment. Typically this involves relying on industry data (for the same or comparable vaccines), industry expert input, and/or institutional knowledge, as discussed in more detail below.

Inside-Out vs. Outside-In

While each PE assessment is unique to the facts and circumstances of the specific product and market (as well as the investment opportunity), there are generally three approaches for performing a PE assessment to understand the costs to produce a specific vaccine in a specific market:

1. **Inside-Out:** Data collection approach based on quantitative and qualitative manufacturer data and process information;
2. **Outside-In:** Data collection approach based on indirect sources of information such as conversations with third-party consultants/experts or applicable vaccine data from other sources (e.g., industry studies); and
3. **Hybrid:** A combination of the two above approaches generally comprised of using third-party sources to substantiate or augment manufacturer data and process information.

The selected approach is typically dictated by the availability and reliability of manufacturing/product-specific information. The Hybrid approach can be seen as a means to supplement an Inside-Out

approach, particularly in situations where the available manufacturer data and process information are based on early stage projections (e.g., estimates of costs at commercial scale based on pilot facility) or when product-specific projections are not available. In those cases, a Hybrid approach can account for missing or ambiguous information through the use of industry benchmarks (e.g., obtained from internal and/or external experts) or the manufacturer's experience with analog products.

When data and process information are not available, for whatever reason, using analog data can prove useful. Analog products can be later stage/commercialized products that have a similar production process as the product in question. It is also possible that different analogs can be used for each step in the production process, for example:

- The costs for a manufacturer that produces a four-valent HPV vaccine are known and a researcher wants to estimate the cost of a proposed nine-valent vaccine by the same manufacturer. The costs may be estimated by using the costs of the four-valent vaccine as a starting point and making adjustments based on known differences in the production process of the two vaccines (e.g., materials costs for additional antigens).
- A researcher wants to estimate the costs of a four-valent HPV vaccine produced by a different manufacturer. The costs may be estimated by starting with the known costs of producing the four-valent HPV vaccine and adjusting for differences in the manufacturer (e.g., production process, labor costs across geographies).



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Using one or more of the above, a hypothetical production process model can be developed to project costs for an early stage product taking into account both specific product and manufacturer attributes. Often, this model can serve as a starting point for capturing production costs. Adjustments based on industry knowledge and/or direct manufacturer data can then be made for differences in production process (by step), manufacturing location, scale, etc. One should also be sure to capture fully loaded costs, including indirect costs, which can be overlooked in an analog analysis.

Based on experience, the Inside-Out (and in some cases Hybrid) approach is our preferred approach as the foundation finds direct manufacturer input (and data) to be particularly helpful in any PE assessment. Analyses based on an Outside-In approach tend to be the most high-level and are therefore often less accurate, on a relative basis. The Outside-In approach is typically the method of last resort relied upon when direct data is unavailable.

Data Collection Templates

The foundation has prepared the attached Excel template to ease and standardize data collection. Instructions for completion are self-contained within the template. In general, the tabs within the Excel template align with each of the major cost categories discussed in this handbook (see links throughout).

- ! **The foundation recognizes that manufacturers may each have their own format for keeping data (e.g., formats can be dependent upon internal accounting). To the extent that data does not align with the Excel templates provided, the foundation is open to alternative forms of initial data sharing.** Ultimately, however, the foundation's intent is to leverage the data provided by the manufacturer to conduct a PE assessment using the methodology described herein.

No information provided by any one manufacturer will ever be shared with any other manufacturer or organization without explicit consent.

Please note that any manufacturer data is treated as highly confidential. No information provided by any one manufacturer will ever be shared with any other manufacturer or organization without explicit consent.

Identifying and Capturing Fully Loaded Costs

The data collection templates present costs on both an absolute cost basis and a per-dose cost basis. Capturing costs (or ultimately calculating costs) on a per-dose basis allows for comparisons between and among vaccines on a more consistent basis.

In order to calculate costs on a per-dose basis, it is important to determine the appropriate denominator, which may vary by stage. For example, the appropriate denominator for bulk production may be mass or volume, whereas for finished dosage form, it may be units or doses. Care should be given to identify the volume actually produced or expected to be produced based on operational capacity. In other words, volume should be based on **operational maximum capacity**, which takes into account planned downtime for repairs and maintenance as well as batch failures, whereas **theoretical maximum capacity** is the maximum capacity obtained if a facility operates during all operating hours and has no wastage or downtime.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Volume for this calculation is therefore not the volume demanded by the market, the volume ultimately sold into the market, nor the manufacturer's theoretical capacity. Instead, volume is calculated as the volume actually produced, which takes into account existing process capabilities, operational constraints (e.g., yields, equipment scale, single-product vs. multi-product operation, bottlenecks, changeover time, planned downtime, wastage, etc.), and appetite for risk.

Costs may also be expressed on a per-course basis in order to establish a consistent metric for total regimen costs across vaccines used to treat the same condition but require differing dosage regimens. A course is defined as the number of doses per regimen (e.g., there may be three doses per course) and can therefore easily be calculated by multiplying costs per dose by the number of doses per course.

! Both per-dose and per-course costs should be calculated after any allocations are made such that costs are for the specified vaccine in the specific market of interest. (See the Allocations of Costs section for more detail on allocations).

Volume is calculated as the volume actually produced, which takes into account existing operational constraints.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Determining PE Costs



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

IN THIS SECTION

Organization of Types of Costs

Costs by Production Step

Types of Costs

Organization of Types of Costs

For the purposes of this handbook, there are different types of costs that are included in a PE assessment. These are defined in this section and discussed in detail throughout the remainder of the handbook. Note that manufacturers may have different methods of organizing costs and that the methodologies discussed below serve only to illustrate the reliable and consistent approach employed by the foundation in a PE assessment.

Costs incurred throughout the product life cycle of a vaccine can be grouped into specific cost categories. The cost categories included in this handbook are:

- Product Development;
- Facilities and Equipment;
- Direct Labor;
- Consumables;
- Overhead;
- Commercialization; and
- Licensing Costs.

Potential offsets to those costs include:

- Third-Party Contributions; and
- Foundation Contributions.

To the extent possible (and relevant), each cost category, specifically Direct Labor, Consumables, and Facilities and Equipment, should be segmented by production step. Additionally, throughput, yield, scale of operation, and operational capacity should be defined for each production step. These production steps are:

- Bulk;
- Form/Fill/Finish;
- Packaging; and
- QA/QC.

Cost categories are organized or grouped into different **cost classifications**. These cost categories are:

- Fixed;
- Variable; and
- Semi-variable.

These cost classifications reference how a given cost category is impacted by changes in volume. (Additional discussion on the impact of scale is discussed in the Impact of Economic Variables section).

Costs can also be dichotomized into direct costs and indirect costs, which differentiate costs based on whether they are solely relevant to a specific product in a specific market or are general costs that affect multiple products and/or multiple markets. (Direct and Indirect Costs are discussed further in the Allocation of Costs section).

Characterization of costs is important not only for standardization, but to understand how costs may move and change over time and at different volumes.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Costs by Production Step

The foundation's data collection methodology as described within this handbook places an emphasis on data collection by production step, to the extent available. The desire to collect data and process information and to assess the components by production step is driven by the foundation's goal to fully understand the drivers of PE. Particularly when manufacturers have limited or no cost data for commercial manufacturing (as in the case of a development-stage vaccine), process information is especially helpful in estimating PE COGS for commercial scale production. This understanding can help shape an appropriate investment construct and can also help identify potential areas for reductions in cost, which in turn can increase affordability and sustainability.

While the foundation recognizes that manufacturers may not keep costs in a format consistent with the production steps laid out in this handbook, to the extent possible segmenting relevant cost categories by these four main production steps can allow for further insights to be made from the PE assessment.

The four primary product steps are as follows [\[see details noted previously\]](#):

- **Bulk**
- **Formulation, Filling, and Finishing (Form/Fill/Finish)**
- **Secondary Packaging**
- **QA/QC**

As described above, it is also helpful to capture process information, including a description of major unit operations, process equipment, scale, and overall and step yields. Certain documents commonly developed by manufacturers, such as **process flow diagrams**, bills of materials, product specifications, and equipment lists are useful for this purpose.

Segmenting relevant cost categories by the main production steps allows for further insights to be made.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Types of Costs:

Cost Classifications and Cost Categories

There are three broad types of costs into which the nature of the cost categories are classified: fixed, variable, and semi-variable.

- **Fixed costs** are costs that will not change as output increases or decreases and thus, by nature, will not be impacted in aggregate by changes in output. As such, per-dose fixed costs will decrease with an increase in output (up to a certain point) and vice versa, as the same total costs are being spread across a greater number of doses.
- **Variable costs** are costs that will increase directly with additional output. In other words, each additional unit produced will require additional variable costs.
- **Semi-variable costs** are costs that are correlated with output in aggregate, but not as directly as variable costs. The most common example of a semi-variable cost is direct labor, as labor costs will not increase with each additional unit of the vaccine produced in the same manner that consumables will, but the direct labor costs of production are still fairly sensitive to output.

Determining the nature of the costs included in each cost classification (i.e., fixed, variable, and semi-variable) is an important step in understanding how changes in volume will impact PE, and the impact that allocation methods will have on per-dose expenses (this point will be discussed in greater detail in the Allocation of Costs section). Note that certain cost categories (e.g., overhead) are comprised of a range of specific costs (e.g., IT systems, management) and may not fit into one cost classification. In addition, a specific cost category may have a different cost classification depending on the product and/or manufacturer.

The diagram below classifies each of the cost categories by the appropriate cost classification.

DIAGRAM 2: SAMPLE COST CATEGORIES GROUPED BY COST CLASSIFICATIONS



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Fixed Costs

PRODUCT DEVELOPMENT

► DEFINITION

Product development includes costs incurred by a manufacturer to discover, develop, and bring a vaccine to market. The two primary components of product development are **research and development (R&D)** and regulatory. Specifically, product development costs may include items such as:

- Discovery;
 - Clinical trials;
 - Animal studies, including preclinical toxicology
- CMC work, including analytical and process development, process validation, and formulation development
- R&D for national regulatory authorities (NRA);
- R&D for WHO PQ; and
- Regulatory expenses (e.g., filing fees).

Product development includes both general and product-specific items. Although all general product development costs will not be relevant to the specific product being analyzed, it is important to understand all costs a manufacturer bears and potentially make allocations of general costs as appropriate.

► GUIDELINES

To the extent that product development costs relate to multiple products and/or multiple markets, these costs should be allocated using the methods discussed in the Allocation of Costs section. For accounting purposes, product development costs are typically

expensed in the year they are incurred, rather than capitalized. However, to smooth out costs and ensure that all relevant investment costs are included (these are calculated at a particular point in time), product development costs directly related to the vaccine should be capitalized over a relevant period of time (referred to as the **useful life**) and be included through amortization. This treatment allows for product development expenses to be converted to an annual amount, which can in turn be divided by annual production volume to arrive at a per-dose cost. It is important to note that there is no standard amortization schedule, but the remaining patent life (or a reasonable proxy) of the vaccine or the remaining life of the vaccine before it is replaced by a competitor's product or new version of the same vaccine (e.g., Prevnar 13 vs. Prevnar 7) is often used as an estimate. In our experience, useful life typically ranges from 10 to 20 years. Performing sensitivities around the useful life, especially in the case that development expenses are significant, can be useful.

! To the extent all or a portion of product development costs were funded by charitable or other public sources, only costs incurred by the manufacturer will ultimately be included in the PE COGS. However, to have visibility to the full cost of product development, mechanically, total product development costs should be in this cost category and the funds provided by the charity or other public source should be included as an offsetting cost in the appropriate cost category (e.g., third-party contributions, foundation contributions). A separate template to capture product development costs can be provided by request.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

► EXAMPLE

The vaccine requires the manufacturer to employ technology and processes it does not have previous experience with, and therefore it must incur R&D costs before production can begin.

- These costs are specifically related to the vaccine and should be included in the cost base.
- If these costs relate to the vaccine, as well as other vaccines currently in production, the costs should be allocated among vaccines using an appropriate allocation key (see the Allocation of Costs section).
- If these costs were funded by a grant from the foundation, they should be included in R&D but offset in the foundation contributions cost category by a negative cost of equal magnitude.

! Note that including both the cost of the R&D and the grant will result in a net impact of zero. However, it is useful to show both for illustrative and comparative purposes.

FACILITIES AND EQUIPMENT

► DEFINITION

Facilities and equipment refers to the fixed assets held on the manufacturer's balance sheet and depreciated. For a vaccine manufacturer, this will include:

- Process equipment;
- Plant and critical utilities;
- Buildings;
- Land;
- Machinery and equipment;

- Furniture and fixtures;
- Office equipment; and
- Infrastructure (e.g., roads).

A manufacturer operating on a contract basis may not own the equipment and the associated expense may instead take the form of rent (typically an annual expense).

► GUIDELINES

The fully loaded cost base of a vaccine will be affected by facilities and equipment in two ways: depreciation expenses and ongoing costs of upkeep (e.g., repairs and maintenance, utilities).

► DEPRECIATION EXPENSES

Facilities and equipment expenditures are capitalized upfront, meaning that from an accounting standpoint, the costs associated with the purchases are spread over the useful life of the asset rather than being expensed entirely in the year when the purchase occurs. It is important to note that there is no standard depreciation schedule; rather, the depreciation schedule is based on factors such as the purchase price of the asset, the residual value (meaning the amount the asset could be sold for at the end of its useful life), and the expected useful life of the asset. Therefore, the depreciation schedule and useful life may differ for each of the relevant assets. Further, for inclusion in the fully loaded cost base, the appropriate depreciation schedule may differ from the accounting or tax treatment and differ within facilities and equipment. The useful life of a piece of equipment or facility is typically equal to an estimate of the duration that the equipment or facility will contribute to the business before it becomes obsolete and needs to be replaced. The useful life is typically shorter for a novel piece of equipment (e.g., a filling line) vs. a brick-and-mortar facility.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

When accounting for depreciation to determine PE COGS, it is advisable to start with the original cost of the asset, the useful life, and the depreciation schedule (e.g., straight line) to determine the annual depreciation figure in each relevant year. There may then be certain offsets to the depreciation amount to take into account: depreciation recovered on the asset during a prior use (e.g., depreciation associated with a facility that was recovered when the facility was in use previously for a different product), any grant or subsidy associated with procuring or building the asset, and any other adjustments that might be relevant, including allocations between products and/or markets as discussed in the Allocation of Costs section. To understand a comprehensive picture of an asset and its impact on Production Economics, it is helpful to detail these steps in the calculation.

► ONGOING COSTS OF UPKEEP

In addition to the capital outlay associated with building/purchasing facilities, equipment, and other assets, manufacturers incur annual operating expenses associated with the upkeep of these assets. Ongoing costs of upkeep, such as repairs and maintenance and utilities (e.g., electricity, water) should therefore also be included in this cost category. That said, these costs are annual costs and should not be capitalized.

For example, the total annual cost associated with one piece of equipment would be the annual depreciation expense plus any expenses involved with maintaining that equipment during that year.

► EXAMPLE

In order to supply a vaccine to the Gavi market, the manufacturer will build a new, dedicated \$10-million facility in 2016 that will begin operating on January 1, 2017 with a useful life of 20 years.

- For each year over the next 20 years (i.e., 2017 to 2037), a depreciation expense of \$500,000 (assuming straight-line depreciation) will be incurred and should be included in PE COGS.
- Separately, an annual expense will also be incurred and will include any costs associated with maintaining/repairing the asset over the course of a given year as well as other operational costs such as utilities.

Variable Costs

CONSUMABLES

► DEFINITION

Consumables are defined as materials used as inputs in production, including raw materials. For a vaccine, consumables include:

- Bulk consumables such as biological and chemical agents along with all raw materials and consumables used in the production of the bulk vaccine;
- Fill/Finish consumables such as vials, stoppers, and seals;
- Packaging consumables such as labels, including vaccine vial monitors (VVM), and secondary and tertiary cartons; and
- QC consumables such as inputs for testing kits.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

► GUIDELINES

Typically, consumables for each production step are related to both the manufacturing process design and the scale of operation, which should be clearly defined, particularly if different scales of operation are used in different sections of the production process. For capturing the manufacturing process design, as described above, the availability of a **process flow diagram** and **bill of materials** are particularly useful. This information should include all significant raw materials, process solutions, and process consumables (e.g., filters, chromatography resins, buffer bags) used in the manufacturing process for each production step. Process yields should also be described by unit operation or process section.

Consumables costs also include all shipping and freight costs involved with having consumables delivered, if these costs are borne by the manufacturer. Further, consumables costs will include all import taxes (such as value-added taxes).

Consumables costs should also include the cost of extra materials used up due to wastage (e.g., broken vials and overfill) or product failures. In other words, the PE assessment should account for expected normal loss rates.

Some consumables are 100 percent variable in that each additional dose produced requires additional raw material inputs. However, certain consumables are only semi-variable in that additional production will ultimately require additional raw material inputs—but this is not one for one. For example, a single disposable filter may be used to process an entire batch of a vaccine. Other consumables, such as chromatography resins, may be used for multiple batches of vaccine before their useful life is extinguished. As such, it is important to understand the variable nature of material consumables by providing information such as capacity and lifetime of the consumables where appropriate. Again, a bill of materials may be helpful for making these distinctions. Bulk antigen obtained from a

third party (as with all products obtained from third parties) should be included at cost to the manufacturer, without any additional markup.

► EXAMPLE

Due to overfill, breakage, and other types of wastage, consumables for a theoretical yield of 112 million doses are required to produce 100 million doses.

- Raw material costs per dose should be calculated based on the cost of materials necessary for 112 million doses, divided by the actual yield of 100 million doses.

Semi-Variable Costs

DIRECT LABOR

► DEFINITION

Direct labor costs are fully loaded and include all employee costs directly attributable to the production of the specific vaccine, such as:

- Wages (including overtime);
- Bonuses;
- Fringe benefits (e.g., healthcare, payroll taxes, etc.); and
- Product-specific training.

Costs will vary by product and manufacturer based on market labor rates, manufacturing labor intensity, worker skill-level required, and complexity of manufacturing processes.

Indirect labor costs are discussed below and in more detail in the Overhead subsection.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

► GUIDELINES

In accounting for direct labor costs, it is useful to distinguish between direct labor and indirect labor:

- **Direct labor:** Labor costs that can be easily attributed to a specific product in a specific market. For example, the employees working on a specific vaccine are a direct cost for that product.
- **Indirect labor:** Labor costs that benefit multiple products and/or markets, and thus can only be indirectly attributed to a specific product or market. For example, the costs of a manufacturer's plant management wages are indirect costs because they apply to all products and markets produced within a given facility.

An overview of staffing levels for all GMP-related functions (i.e., through an organization chart if appropriate) as well as specific data on labor expenses by production step are both particularly helpful for this part of the analysis. If specific data on labor expenses by production step is unavailable, allocation by the time spent or headcount related to each step can be applied to estimate a proportionate division of labor expense. Product specifications, which can help define QC testing requirements, are also helpful. As mentioned previously, indirect labor costs should be accounted for in the Overhead subsection. Within Overhead, indirect labor, if it relates to plant management may be included in Indirect Overhead, whereas if it relates to C-suite executives it may be included in Corporate Overhead.

► EXAMPLE

In the first year of production, the manufacturer expects to have 40 full-time employees engaged directly in the vaccine production on a single shift basis. But as demand increases, based on the manufacturer's experience with other similar products, the manufacturer expects to switch to a multi-shift operation with 65 full-time employees to double production.

- Total direct labor costs will increase as more employees are hired to execute the multi-shift operation;
- The manufacturer's direct labor costs on a per-dose basis should decline to reflect the reduction in labor necessary as experience is gained and capacity utilization increases.

Cost Categories Spanning More Than One Type of Cost

OVERHEAD

► DEFINITION

Overhead costs are indirect costs that are necessary for the manufacturer to function, but are not directly attributable to a specific product. Overhead may include such items as:

- Indirect labor;
- Management;
- IT systems;
- Insurance;
- Transportation;
- Security; and
- Other head-office or back-office expenses.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

For the purposes of this handbook, Overhead costs are split between **Indirect Overhead** and **Corporate Overhead**. While each of these two categories may include items from the above list, the distinction made is that Indirect Overhead is associated with all indirect expenses at a specific plant, whereas Corporate Overhead is associated with all indirect expenses incurred by the manufacturer outside of the specific plant that are required to support the broader operations of the manufacturer.

► GUIDELINES

Overhead costs typically apply to many or all products made by a manufacturer; as such, overhead should be properly allocated among all products to reflect actual overhead usage rate. The allocation of Indirect Overhead and Corporate Overhead may very well be different.

Further, different individual costs within the overhead cost category fall under different cost classifications. For example, the insurance costs would be semi-variable, whereas an internal IT system would be a fixed cost.

► EXAMPLE

A manufacturer spends \$5 million annually maintaining an IT system in a plant that is used to produce five vaccines. The manufacturer believes that the associated overhead expense can be allocated evenly between the vaccines.

- Each vaccine will be allocated \$1 million of Indirect Overhead annually.
- The \$1 million can be divided by the vaccine's annual production volume to find the per-dose impact of the overhead expense.

COMMERCIALIZATION

► DEFINITION

Commercialization costs are expenses incurred post-regulatory approval such as ongoing sales and marketing costs. Specific examples may include:

- Advertising;
- Marketing materials;
- Sales force; and
- Distribution.

► GUIDELINES

Commercialization costs are often particular to specific markets; as such, it is important to only account for costs relevant to the market where the vaccine is being sold. Commercialization expenses that span multiple products or markets (such as a global, companywide ad campaign) should be properly allocated between products and markets. Note that commercialization costs will typically be low for the Gavi market where procurement is through UNICEF and marketing is not necessary. **It is not appropriate to incorporate commercialization costs incurred exclusively for high-income markets into the cost base of the vaccine intended for the Gavi market.**

Manufacturers may not account for commercialization costs separately. Do not double count with costs captured in other categories, such as indirect labor involved with marketing or sales that may be captured within Overhead.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

► EXAMPLE

The manufacturer is negotiating an agreement to supply the vaccine through UNICEF's Supply Division for procurement by several countries, including India. Additionally, the manufacturer intends to market the vaccine in certain Western markets (e.g., the United States and Europe).

- Commercialization costs for India should be minimal given the procurement method. To the extent the manufacturer conducts any additional commercialization efforts in India, costs associated with these efforts should be included. That said, in most instances this is unlikely.
- Commercialization costs for the Western markets are relevant, but should be 100 percent allocated to the Western markets and have no impact on the PE COGS for the vaccine for the Indian market or other non-Western markets.

Other Cost Categories

LICENSING COSTS

► DEFINITION

Licensing costs include any income received (or expenses paid) for granting (or licensing) the right to use product-related intellectual property (e.g., technology) in order to develop, produce, and/or commercialize the vaccine.

► GUIDELINES

Payments to third parties should be considered costs to all applicable products and should be allocated to the extent the licensed intellectual property is used across different products

and/or markets. Income received from the out-licensing of intellectual property should likewise be allocated if necessary and counted as a negative cost.

Licensing expenses can be fixed, variable, or semi-variable, depending on the payment structure. For example, a one-time payment would be amortized and counted as a fixed cost, whereas a variable payment structure based on volume could be a variable or semi-variable cost. Licensing expenses can also take the form of a royalty, meaning that the licensee will be obligated to provide the licensor a percentage of the revenue earned using the licensed technology.

► EXAMPLE

The manufacturer spends \$100 million developing a process and amortizes that process over 10 years, thus incurring a charge of \$10 million in amortization annually. However, another manufacturer pays \$5 million annually for the right to use the process.

- The \$10 million amortization expense would count as a product development cost.
- The \$5 million of income would count as licensing income and a reduction to licensing costs.

THIRD-PARTY CONTRIBUTIONS

► DEFINITION

Third-party contributions include all contributions from governments and other third-party (i.e., non-foundation) organizations. Specifically, this category includes:



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

- Loans;
- Grants;
- Subsidies (e.g., government subsidies for land or other resources);
- Tax credits (e.g., for R&D and specific investments); and
- Other incentives (e.g., priority review vouchers).

Each of these items is generally an offset to PE COGS. However, third-party financing costs, which include debt payments (e.g., interest) related to specific financing obtained for the product analyzed have a cost component and should be included in PE COGS.

► GUIDELINES

Only those third-party contributions directly related to the incremental production of the vaccine being assessed should be counted. In other words, if a firm takes out debt as a way to fund its day-to-day operations, then this should not be considered to be part of the PE COGS. However, if a firm takes out a loan in order to fund capital expenditures to increase capacity, then the cost of that loan should be allocated to all products that benefit from the capital expenditure.

This section should also include all potential financing-related costs, such as the carrying costs associated with late payments and accounts receivable (e.g., from raw material manufacturers) including any ensuing financing costs as well as opportunity costs due to the time value of money borne by the manufacturer.

Since interest payments are generally fixed, financing costs are a fixed cost.

Tax credits received should be considered when quantifying the annual cost of those investments. In other words, if a manufacturer received a tax credit for building a new facility, thereby reducing its income tax payment, the cost of the facility included should

be computed as the actual cost of the facility less the tax credit. Similarly, direct government subsidies related to the product analyzed should also be taken into account. In some cases (e.g., subsidy for the purchase of land), they may need to be allocated across multiple products.

To the extent that tax credits or subsidies are related to a fixed asset, these are fixed costs (or rather, an offset to fixed costs).

A priority review voucher is a government incentive that allows a manufacturer to be able to bring the product to market relatively faster and may allow the manufacturer to generate product revenues sooner and potentially achieve a first-mover advantage. Thought should be given to if and how the benefit of the priority review voucher should be included as an offset to the costs of the product that generated the voucher.

► EXAMPLE

As a result of taking out a \$10-million loan to build its new facility, the manufacturer incurs a yearly interest expense of \$1 million.

- The initial cost of the facility would be added as a facilities and equipment cost and be counted annually through depreciation.
- The annual interest expense would be counted as a financing cost.
- The time value of money component associated with borrowing money (i.e., the benefit involved with receiving money now) should also be taken into account as an offset to the PE COGS.

India subsidizes product exports and China subsidizes electricity costs for some manufacturers.

- The full reductions in the form of the subsidy would be counted against (i.e., as negative expenses or contra expenses) the PE COGS and included in this cost category.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

FOUNDATION CONTRIBUTIONS

► DEFINITION

Foundation contributions are grants, loans, or other investments provided by the foundation to manufacturers. Foundation contributions can have the impact of reductions to costs from grants or interest expenses associated with foundation loans (plus a benefit associated with the time value of money component of the loan). The foundation is also able to provide more tailored and complex contributions to meet a manufacturer's business need. The impact of these more complex investments needs to be assessed on an individual basis.

► GUIDELINES

Foundation contributions should be accounted for in the same manner as third-party grants or third-party loans. These costs are accounted for in a separate cost category only for presentation purposes.

Foundation grants will often be directed to support a specific expenditure, such as clinical trials or construction of a new facility. If the entirety of a grant is provided upfront, the costs should be spread over the useful life of the underlying expenditure (e.g., useful life of the facility the grant is used to build). The foundation may also structure grants in other ways such as providing milestone payments linked to key development benchmarks; these situations should be reviewed on a case-by-case basis to determine whether the impact of these grants should be expensed annually (i.e., each payment affects the PE COGS of the year in which it occurs) or capitalized (e.g., summed up and spread over a useful life in a manner similar to that of an upfront grant). Typically, the grant should be treated in the same manner as the associated expense.

► EXAMPLE

The foundation provides a manufacturer with a grant to be used to perform clinical trials for a new vaccine.

- The cost of the clinical trials should be recorded as an R&D expense and amortized over an estimated useful life (e.g., length of a patent for the technology and estimated time until competitors enter market).

The annual impact of the grant should be smoothed over the same useful life and recorded as a foundation contribution offsetting the funded portion of the clinical trials.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Allocation of Costs



IN THIS SECTION

Introduction to Allocation of Costs

Allocation Keys

Overview of Common Allocation Keys



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

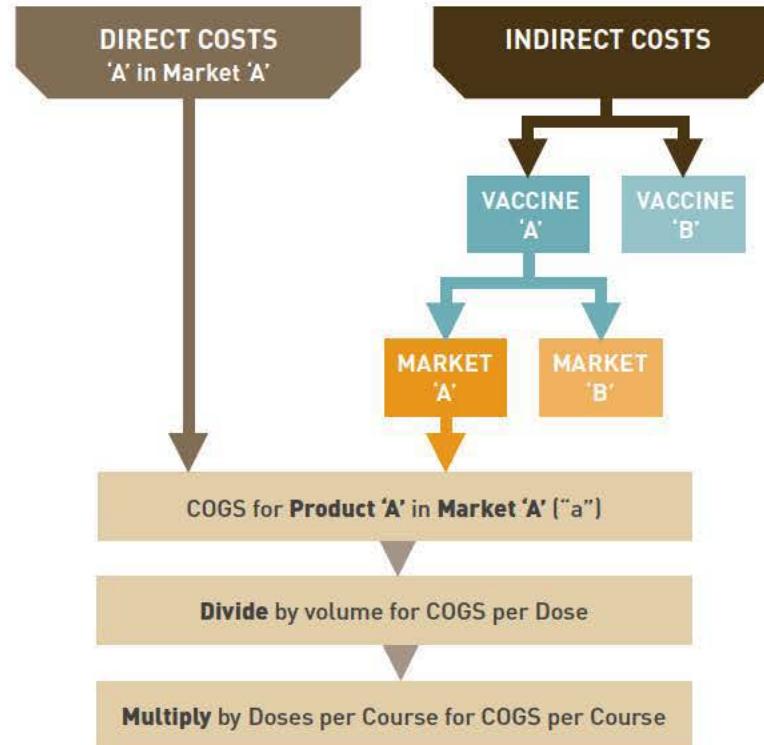
Introduction to Allocation of Costs

There are generally three reasons for allocating costs:

- To isolate the costs of resources used in the manufacture of a specific vaccine, where resources may be used to manufacture and commercialize multiple products;
- To isolate the costs of production and introduction (e.g., registration and related costs) for the vaccine specific to a particular geography when the product is sold in multiple markets; and
- To isolate production costs of a specific vaccine between production steps (i.e., bulk, form/fill/finish, packaging, QA/QC).

The diagram below illustrates how direct costs and the allocable portion of indirect costs build up for a specific product (Product 'A') in a specific market (Market 'A'), which can then be expressed on a per-dose or per-course basis. Note that in this example, indirect costs are allocated first by product and then by market; in certain instances, only one of the two will be necessary (e.g., if a manufacturer makes only one product but supplies it to multiple markets). This diagram does not include allocations by production step.

DIAGRAM 3: DIRECT COSTS AND ALLOCATION OF INDIRECT COSTS TO ASSESS PE FOR A VACCINE IN A SPECIFIC MARKET



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Allocation Keys

The metric used to allocate costs is called an **allocation key** and is based on an observable characteristic of the production or sale of the vaccine.

The aim should be to select an allocation key that balances **accuracy, simplicity, and equity**, with the greatest weight placed on accuracy.

The primary allocation keys used are generally volume and revenue. However, there are many other common allocation keys (some of which are described below). Any observable characteristic could be used as an allocation key provided that it leads to a reasonably accurate apportionment of costs.

When allocating costs, it is good practice to avoid using rules of thumb that are not based on the actual production of the vaccine, and should always ensure that the allocation method employed will not lead to over-allocation of costs if applied to all of the manufacturer's products. For example, if a company allocates 30 percent of overhead costs to each of its 10 vaccine products the result would be a total allocation of 300 percent of overhead costs instead of 100 percent.

Manufacturers should provide any available data on the metrics used for the allocation keys below.

METRIC	DEFINITION	EXAMPLE
ACCURACY	The allocation key should reliably reflect the cost drivers.	If the cost of form/fill/finish is primarily driven by the amount of time it takes to fill/finish a particular vaccine, and the time it takes to fill/finish two different vaccines is approximately equal on a per-dose basis, then allocation by volume would provide a reasonable estimate of the resources used by each vaccine.
SIMPLICITY	The allocation key should be easily and inexpensively obtained.	Production volume is often readily available, whereas actual time spent by employees on particular activities may be unavailable or require an additional, and perhaps costly, analysis.
EQUITY	The allocation key should take into consideration the ability to bear the cost.	A higher margin product earning a larger return should bear a greater proportion of investment costs and indirect costs associated with production. In this way, products sold in higher-income markets may have a higher cost than (nearly) identical products sold in lower-income markets.



Overview of Common Allocation Keys

Volume Allocation

► DEFINITION

A **volume allocation** key allocates costs to different products and markets based on the relative volume produced or sold.

► EXAMPLE

100 million doses of a vaccine are produced and sold in different markets.

- 90 million doses are sold in non-Gavi markets.
- 10 million doses are sold in Gavi markets.
- Based on volume allocation, 10 percent of costs would be allocated to production for Gavi markets (i.e., $10 / (10 + 90) = 10$ percent).

A fill/finish facility with a 25-million-dose capacity is shared between two vaccines.

- 5 million doses of vaccine A are sold by the facility.
- 20 million doses of vaccine B are sold by the facility.
- Based on a volume allocation, 20 percent of costs would be allocated to vaccine A (i.e., $5 / (20 + 5) = 20$ percent).

The volume allocation key implicitly assumes that the cost to produce a single dose does not vary across products or by region.

The optimal type of allocation utilized depends on the specific scenario.

The volume allocation may also apply to costs applied to different presentations of the same vaccine (e.g., if a manufacturer produces a vaccine in a 1-dose vial for some markets and a 5-dose vial for others); in these cases, costs that are shared may be allocated by volume while costs that are specific to one market are only allocated to that market.

Note that by using a volume allocation, the benefits of economies of scale created by producing more vaccines for either market are shared across both markets.

Volume sold and volume produced are both reasonable allocation keys, but do differ. For example:

- A manufacturer may intentionally overproduce to stockpile inventory for future sale; or
- A manufacturer may experience wasted batches due to a manufacturing error.

Consideration should be made as to whether volume sold or volume produced is most appropriate in each situation.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Revenue Allocation

► DEFINITION

A **revenue allocation** key allocates costs to different products and markets based on relative revenues.

► EXAMPLE

20 million doses of a vaccine are produced and sold in different markets.

- 10 million doses are sold in non-Gavi markets at \$9 per dose.
- 10 million doses are sold in Gavi markets at \$1 per dose.
- Based on revenue allocation, 10 percent of costs would be allocated to Gavi markets (i.e., $1 / (9 + 1) = 10$ percent).

By comparison, using a volume allocation, 50 percent of costs would be allocated to lower-income markets (i.e., $10 / (10 + 10) = 50$ percent).

Other Allocation Keys

Other allocation keys may be appropriate in apportioning costs to different products, markets, or production steps in certain circumstances.

Other examples of allocation keys that may be appropriate are:

- **Time** – Use of a bulk production facility is split between two vaccines. Every year the facility produces vaccine A for 13 weeks and vaccine B for 26 weeks, with the remaining 13 weeks necessary for transitioning the facility between vaccines. Based on a time allocation, 33 percent of costs would be allocated to vaccine A and 67 percent of costs to vaccine B;
- **Square footage** – If a building has production split between two suites, then it may be appropriate to allocate the indirect building costs based on the suites' relative square footage; and
- **Headcount** – Costs of employee benefits may be most appropriately allocated based on the number of employees engaged in a particular activity.



OVERVIEW



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PE COSTS



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GLOSSARY

Impact of Economic Variables



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GLOSSARY

IN THIS SECTION

Inflation Rates

Foreign Exchange Rates

Changes in Costs Due to
Volume Increases/Decreases

Economies and
Diseconomies of Scale

Capacity Constraints

Impact of Economic Variables

In order to forecast how costs may change over time, it is important to understand how costs may be affected by various economic variables, such as inflation rates, foreign exchange rates, changes in costs due to volume increases/decreases, economies and diseconomies of scale, and capacity constraints. For example, these variables are important to consider when:

- Projecting future costs of a specific vaccine (e.g., projecting 2016 costs for a PE assessment on a product that is expected to be launched in 2020, and as such the year under analysis is post-2020);
- Aggregating analog vaccines by production step to assess PE for a specific vaccine; and
- Making adjustments to financial projections of a specific vaccine to account for recent changes in scale, location, etc.

Inflation Rates

Inflation refers to the increase in prices over time, and consequently, the decrease in the purchasing power of money. For example, as prices of inputs related to the vaccine's production increase, underlying costs will increase.

Rates of inflation may differ between markets. For example, while inflation in the United States (and in U.S. dollars) is generally low (i.e., less than three percent per year), inflation in some markets exceeds 10 percent per year. Markets with developing economies, such as India, typically exhibit higher inflation rates than markets with mature economies, such as the United States.

In general, past inflation trends can serve as a useful predictor of future inflation. However, it is important to understand that inflation rates can be cyclical in nature, and it is therefore insufficient to simply extrapolate rates from the previous year. Utilizing multi-year averages is one means of smoothing the effect of business cycles on inflation. It is also important to consider recent trends and extraordinary events (e.g., recessionary and boom periods) when using historical inflation rates for forecasting purposes.

Foreign Exchange Rates

The costs of inputs (e.g., raw materials and wages) may be denominated in various currencies and/or not be the same as the currency in which the final product (i.e., the vaccine) is sold by the manufacturer. **Foreign exchange rates** between currencies fluctuate constantly, and understanding how currency movements affect a manufacturer's costs is crucial to projecting PE.

Similar to inflation, past exchange rates can be used as predictors for future trends, but due to the often cyclical nature of rates, an average over a multi-year period will serve as a more reasonable method of forecasting foreign exchange rates than a simple extrapolation based on a single-period rate.

Manufacturers that purchase input goods or services from foreign suppliers are exposed to the risk that fluctuations in exchange rates will decrease the purchasing power of their local currency and consequently increase effective costs. Some manufacturers mitigate risk by hedging against currency fluctuations, and any hedging costs should be included as part of the PE COGS under third-party contributions (e.g., financing costs).



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Foreign exchange rates will be influenced by inflation thus consideration should be made to avoid double counting as the impact of these economic variables should be looked at collectively.

It is important to keep in mind that foreign exchange rates will be influenced by inflation in the relevant countries; as such, consideration should be made to avoid double counting as the impact of these economic variables should be looked at collectively.

Changes in Costs Due to Volume Increases/Decreases

Cost curves are representations of changes in production costs as output increases or decreases. When a process-based model is built/available, it can assist in forecasting changes in PE COGS as a function of changes in scale, capacity, or utilization and to develop cost curves as a function of scale or capacity. **In assessing PE, cost curves can be used to:**

- **Help forecast changes in a manufacturer's costs based on changes in expected future output; and**
- **Compare costs at different volumes, which can inform decisions about optimal output.**

Since fixed costs are costs that will not change as output increases or decreases, they will not be impacted in aggregate by changes in output (until capacity constraints, described in detail below, are reached, requiring additional capital expenditure). As such, per-dose fixed costs will decrease with an increase in output, as the same total costs are being spread across a greater number of doses.

Variable costs will increase directly with additional output. Therefore, as output increases, the ratio of fixed costs versus variable costs as part of total costs will increasingly shift in favor of variable costs.

Semi-variable costs will also correlate with output, but not as strongly as variable costs do, as each incremental increase in volume will not trigger an equally incremental increase in aggregate semi-variable expenses.

Economies and Diseconomies of Scale

Economies of scale are cost advantages that manufacturers gain from increasing output. In other words, economies of scale will cause decreases in total costs per dose as production volume increases. The main sources of cost savings for manufacturers may include:

- Decreased raw materials costs due to bulk pricing discounts;
- Production efficiencies and experience (e.g., larger batches, less wastage, increase yield); and
- The ability to spread fixed costs over a greater number of products.

Diseconomies of scale are the converse of economies of scale and represent increases in variable costs per dose as production volume increases. Diseconomies of scale can be caused by factors including:

- Inefficiencies involved with running a larger, less focused operation; and
- Decreased operating precision leading to smaller yields.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Capacity Constraints

Capacity constraints are factors that cause breakpoints or hurdles in a cost curve, appearing as an inflection point when the fixed costs begin to increase with scale. Inflection points can be caused by the need for additional capital expenditures (increases in fixed costs) to produce additional volume. For example, a manufacturer's costs per dose may decrease with increases in output initially; however, after a certain point, additional output may require investments in new equipment and/or additional facility space, etc. When amortized and added to the per-dose cost, this can cause an increase in the per-dose cost.

Identifying the inflection points at which manufacturers will require additional capital expenditures is important, as they represent levels of output where the manufacturer will see incremental increases in the PE COGS on a per-dose basis. While the effects of economies or diseconomies of scale cause smooth changes in costs with increases in output, capacity constraints create steps where breakpoints in output cause increases in costs.



OVERVIEW



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Defined Terms

Allocation Key: Metric used to allocate costs (e.g., time, square footage, and headcount).

Bill of Materials: An itemized listing of all raw materials and consumables used in each production step. Grade of material used, supplier, and quantities required for a given production scale are typically included.

Bulk: Costs incurred in the production of the bulk product, including both upstream and downstream processes, but before any dosage form manufacturing occurs.

Capacity Constraints: Factors that cause breakpoints or hurdles in a cost curve, appearing as an inflection point when the fixed costs begin to increase with scale.

Commercialization: Expenses incurred post-regulatory approval such as ongoing sales and marketing costs (e.g., advertising, marketing, distribution, etc.).

Consumables: Raw materials used as inputs in production for a specific vaccine.

Cost Classifications: Cost categories grouped as fixed costs, variable costs, and semi-variable costs.

Cost Curves: Representations of changes in production costs as output increases or decreases.

Direct Labor: Fully loaded employee costs (e.g., wages, benefits) directly attributable to a specific vaccine.

Diseconomies of Scale: The converse of economies of scale, these represent increases in variable costs per dose as production volume increases.

Economies of Scale: Cost advantages that manufacturers gain from increasing output.

Facilities and Equipment: Costs associated with fixed assets. Includes capitalized costs that depreciate over time (e.g., land, buildings, machinery, etc.) as well as ongoing costs of upkeep (e.g., repairs and maintenance, utilities, etc.).

Fixed Costs: Costs that will not change as output increases or decreases and thus, by nature, will not be impacted in aggregate by changes in output. As such, per-dose fixed costs will decrease with an increase in output (up to a certain point) and vice versa, as the same total costs are being spread across a greater number of doses.

Formulation, Filling, and Finishing (Form/Fill/Finish): Costs incurred during the formulation (including adjuvantation and lyophilization), filling, and finishing steps of the production process, before any secondary packaging.

Foundation Contributions: All contributions (e.g., grants, loans) from the foundation.

Hybrid: A combination of two data collection approaches generally comprised of using third-party sources to substantiate or augment data received directly from the manufacturer.

Indirect Labor: Labor costs that benefit multiple products and/or markets, and thus can only be indirectly attributed to a specific product or market (included in Overhead).

Inflation: Refers to the increase in prices over time, and consequently, the decrease in the purchasing power of money.

Inside-Out: Data collection approach based on quantitative and qualitative data, and process information received directly from the manufacturer.

Intervention Target Product Profile (iTTP): A profile established by the foundation for priority vaccines to define minimal and optimal parameters for vaccines, and thereby help guide product development investments and decisions.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

Licensing: Any income received (or expenses paid) for granting (or licensing) the right to use product-related intellectual property in order to produce the vaccine (e.g., technology).

Operational Maximum Capacity: Maximum capacity achievable when taking into account planned downtime for repairs, maintenance and batch failures.

Outside-In: Data collection approach based on using indirect sources of information such as conversations with third-party consultants/experts or applicable vaccine data and process information from other sources (e.g., industry studies).

Overhead: Indirect costs necessary for the manufacturer to function, but not directly attributable to a specific vaccine, including indirect labor (e.g., management salaries, wages, training, etc.) and other operating expenses (e.g., insurance). This category can be broken into Indirect Overhead and Corporate Overhead.

Process Flow Diagram (PFD): A schematic representation of a manufacturing process, including information about process unit operations for a production step. PFDs typically include information about in-process solutions, major process equipment, critical control parameters and tests, and production scale and yields.

Production Economics (PE): A manufacturer's fully loaded cost base for a product, from the initial costs of discovery and development through manufacturing and final packaging, with allocations made as appropriate.

Production Economics Cost of Goods Sold (PE COGS): For the purposes of this handbook, PE COGS refers to all costs associated with the definition of PE above.

QA/QC: Costs involved with quality control and quality assurance testing.

Research and Development (R&D): Costs incurred to discover, develop, and bring a vaccine to market (e.g., upfront R&D, clinical trials, regulatory approval including WHO Prequalification (WHO PQ), etc.).

Revenue Allocation: Key allocates costs to different products and markets based on relative revenues.

Secondary Packaging: Costs incurred during the packaging step, commonly referred to as secondary packaging. This will generally include activities such as putting finished vaccines into cartons and preparing them for shipment. This also includes all warehousing costs.

Semi-Variable Costs: Costs that are correlated with output in aggregate, but not as directly as variable costs.

Theoretical Maximum Capacity: The maximum capacity achievable when the facility is operated during all normal operating hours and assuming no wastage.

Third-Party Contributions: All contributions (e.g., grants, loans, subsidies) from governments and other third-party (i.e., non-foundation) organizations.

Useful Life: An estimate for the amount of time a capitalized asset (e.g., investment in a facility) will be useful.

Variable Costs: Costs that will increase directly with additional output. In other words, each additional unit produced will require additional variable costs.

Volume Allocation: Key allocates costs to different products and markets based on the relative volume produced or sold.



OVERVIEW



DATA



PE COSTS



ALLOCATIONS



IMPACT



GLOSSARY

