



June 17, 2020

The Honorable Anna Eshoo
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Michael Burgess, M.D.
1139 Longworth House Office Building
Washington, DC 20515

Dear Chairwoman Eshoo, Ranking Member Burgess, M.D. and Members of the Committee:

I am writing on behalf of Johnson & Johnson (“J&J”) to thank you for holding a hearing on “Health Care Inequality: Confronting Racial and Ethnic Disparities in COVID-19 and the Health Care System.” We share your deep concern about the devastating impact of COVID-19 on diverse communities. We have a long history of working to address these disparities, including support for those on the front lines of care and ending preventable maternal mortality and morbidity, an issue that Energy & Commerce has long been focused on addressing.

One of the areas where racial disparities is evident is the under-representation of communities of color in clinical trials. J&J is proud to foster diversity and inclusion in research and has a longstanding commitment to leadership in this space. I am pleased to share information regarding our response to the COVID-19 pandemic and our commitment to diversity in clinical trials.

The values that guide all of our Company’s decisions are established in Our Credo. Since 1943, Our Credo has challenged us to put the needs and well-being of the people we serve first. These core values are embedded in our commitment to diversity and inclusion in clinical trials (“DICT”) and reflected in [Our Ethical Code for the Conduct of Research and Development](#).

Our Response to the Pandemic

J&J has a history of addressing global health crises and is working closely with partners worldwide to combat the current COVID-19 pandemic through a multi-pronged approach. To put our commitment into context, I would first like to outline J&J’s efforts to respond to the COVID-19 pandemic through potential prevention and treatment, and how we are putting the health of all patients at the heart of these efforts, including in clinical trials.

Vaccine Development

Since January, the Janssen Pharmaceutical Companies of Johnson & Johnson (“Janssen”) have been working with governments and health authorities to help end the COVID-19 pandemic through the accelerated development of a possible preventive vaccine candidate against SARS-CoV-2. Janssen is working to accelerate the development of its vaccine through collaboration between Janssen and the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health & Human Services, and other governments, health authorities and global partners.

In March, we announced that Janssen had identified a lead investigational COVID-19 vaccine candidate. Janssen has accelerated initiation of the Phase 1/2a first-in-human clinical trial of its investigational vaccine, which is now expected to begin in the second half of July. We are also in discussions with the National Institutes of Allergy and Infectious Diseases with the objective to start the Phase 3 clinical trials



ahead of the original schedule, pending outcome of Phase 1 studies and approval of regulators, with the anticipation that the first batches of a COVID-19 vaccine could be available for emergency use authorization (EUA) in 2021. We are prepared to rapidly scale the Company's manufacturing capacity with the goal of providing global supply of more than one billion doses of a vaccine. To date, J&J has signed two agreements for U.S. based manufacturing with Emergent BioSolutions and Catalent, Inc.

Our goal is to develop a vaccine that is capable of being manufactured globally to produce large quantities of product with the aim to manufacture one billion doses. We plan to begin production at risk imminently and are committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.

Therapeutics

In addition to our vaccine development efforts, J&J has also expanded our pre-existing partnership with BARDA to accelerate the ongoing work to screen compound libraries, including from other pharmaceutical companies, to identify potential treatments for COVID-19. By testing the antiviral activity of these compounds against COVID-19, we hope to identify an existing drug that could have the potential to be turned into a new treatment for the virus.

Caring for Health Care Workers, Employees and Current Patients

As we advance our vaccine and therapeutic research, we are also:

- Continuing to supply the critical medicines, devices, and products our customers and patients depend on.
- Taking precautions to support the safety and well-being of our employees, contractors, and the communities in which we live and work.
- Mobilizing to provide equipment, our products and financial donations to support organizations and health care workers on the front lines.

Support for COVID-19 Demographic Data

We recognize the need to demonstrate the outsized impact of COVID-19 on diverse communities through health disparity data. Earlier this month, we were pleased to join hundreds of stakeholder groups in signing a coalition letter to Congressional leadership in support of improved collection and reporting of demographic data on COVID-19 patients.

With this background information provided, the following is our approach to ensuring diversity and inclusion in our clinical trials.

Our Janssen Diversity in Clinical Trials Strategy

We have a Company-wide philosophy and approach to diversity and inclusion in research and development, and we have established a dedicated team within our pharmaceutical sector, Janssen, that is focused on advancing diverse and inclusive participation in our clinical trials.

With an emphasis on underserved and underrepresented populations, our Diversity in Clinical Trials strategy is comprised of three main focus areas:



1. *Culture*: Advance internal awareness on the need to successfully recruit underserved and underrepresented patients, and apply new tools to increase enrollment of diverse populations in our clinical trials;
2. *Access*: Increase underserved and underrepresented populations' access to participation in clinical trials through various internal and external initiatives that address barriers to enrollment; and
3. *Awareness & Trust*: Improve awareness and education about clinical trials in underrepresented populations, to facilitate greater trust and participation in clinical trials.

Reducing Barriers to Clinical Trials

There are several systemic obstacles to diverse representation in clinical trials, from mistrust of the medical establishment to a lack of easy and affordable transportation to clinical trial sites. With regard to our company-sponsored COVID-19 clinical trials, we are:

- Leveraging a special engagement strategy that includes a digital and community outreach plan to provide relevant educational information about clinical research to underserved and underrepresented communities, and to provide resources and links to find opportunities to participate in clinical research;
- Identifying and implementing opportunities to reduce operational barriers and patient burden;
- Applying lessons from other trial recruitment efforts that included a focus on underserved and underrepresented populations; and
- Educating African American, Asian American and Hispanic/Latinx communities across the United States about clinical trials and the importance of diverse participation.

Utilizing Diverse Clinical Trial Personnel

There are many considerations when we evaluate our potential trial sites ability to recruit and enroll diverse populations, including:

- Understanding the cultural competence level of a potential site and its access to and accessibility by diverse populations during our site selection process;
- Leveraging our Medical Science Liaisons' (MSL) networks to identify sites that have access to diverse patient populations that we could leverage for our clinical trials;
- Sponsoring a three-year educational grant for Clinical Research Pathways to provide funding to the Morehouse School of Medicine in Atlanta, Georgia, to encourage, support and grow community physicians into clinical researchers; and
- Amplifying the importance of diverse recruitment and enrollment within Janssen's network of strategic partner sites.

Ensuring Language Accessibility

We recognize that providing clinical trial information in English-language only is not conducive to successful enrollment of diverse participants. Moreover, the use of technical vernacular in clinical trial recruitment can lead to a comprehension gap that hampers participation. As such, we are:

- Ensuring our clinical trial recruitment and other study participant materials use simple language and translated into the languages needed for their patient populations; and



- Assessing additional language/translation needs at our various clinical trial sites.

Investing in Participant Recruitment by Partnering with Minority Health and Community Advocacy Organizations

To bring health to billions of people around the world, we at Johnson & Johnson recognize it is critically important that we invest in, and understand the needs, values and preferences of, the diverse patients and consumers we serve. To that end, we have developed long-standing, strategic partnerships with well-respected, national organizations such as the National Urban League and Unidos US. These partnerships help to accelerate J&J's commitment to:

- Advance a culture of inclusion;
- Develop a diverse workforce for the future; and
- Align diversity and inclusion efforts to our business strategy to drive innovation and enhance the quality and efficacy of products and therapies.

Through grassroots efforts, our African Ancestry Leadership Council and Hispanic Organization for Leadership and Achievement Employee Resource Groups collaborate annually with these organizations to:

- Connect directly with diverse patients and consumers to donate J&J products;
- Provide information on chronic conditions which disproportionately affect diverse communities; and
- Build awareness about the importance of clinical trial participation.

In addition to building general awareness, we are partnering with community and patient organizations to provide education and awareness about our clinical studies and how to participate. We are committed to this same outreach and partnership approach with our COVID-19 clinical trial plans. Since 2018, we have sponsored a community awareness campaign with the Center for Information and Study on Clinical Research Participation (CISCRP), called Journey to Better Health, to provide education and information about clinical research and the importance of diverse participation. We have pledged to continue support of this program through 2025.

Working in Partnership is Critical to our Shared Success

No single stakeholder alone can resolve the issues related to health and economic disparities magnified by COVID-19. That is why Johnson & Johnson has been working internally and externally with partners to use our resources in a broad range of ways to help communities most at risk for COVID-19.

We believe in elevating, amplifying, and accelerating actions that work locally within medical systems to share with community partners facts, best practices, and other relevant health content that can be sent quickly to the people who need it most and can share it widely within communities. For example, American Organization for Nursing Leadership (AONL) has launched [Leading Through Crisis: A Resource Compendium for Nurse Leaders](#), a free compendium comprised of brief online modules designed to equip nurse leaders with practical tips and effective strategies for addressing challenges unique to a crisis. Supported by an independent educational grant from the Johnson & Johnson Foundation / the [Johnson & Johnson Center for Health Worker Innovation](#), the compendium's resources are also

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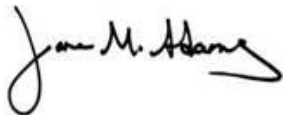
beneficial to nurses in clinical roles and other clinical leaders. The materials have been sent to AONL's 43,000 individual members as well as the 5,000 institutional members of the American Hospital Association.

Additionally, we are working with community health partners in a number of markets to support the addition of COVID-19 testing as part of the range of health services delivered through already-established mobile health care service units or "vans." Mobile Healthcare Service Centers (MHSCs) are an innovative and proven intervention that can successfully deliver cost-effective healthcare particularly related to preventive strategies and screening for disease. Among other functions, MHSCs permit rapid upscaling and delivery of COVID-19 testing among vulnerable populations.

From companies to academia, to regulators and to civil society organizations, we all must work together to address disparities in health care and ultimately secure broader societal benefit from medical innovation. We must move away from zip codes determining health outcomes. You can count on Johnson & Johnson to be a committed partner in this critical endeavor as we work to improve data and insights, increase education and awareness, and facilitate access to testing and health services.

Once again, we applaud your attention to this critical issue. If you have any questions, please e-mail Larry Camm at LCamm@its.jnj.com. Please let us know if you may need additional information and we look forward to serving as a resource.

Sincerely,



Jane M. Adams
Vice President, Federal Affairs