HUMAN RIGHTS WATCH

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April 12, 2021

Albert Bourla
Chief Executive Officer
Pfizer Inc.
via email: [redacted]

Re: Human Rights Due Diligence Surrounding the BioNTech-Pfizer Vaccine

Dear Dr. Bourla,

I am writing on behalf of Human Rights Watch, an international nongovernmental organization working on a range of human rights issues globally, including corporate accountability. We have been working on issues related to business and human rights for over two decades.

Human Rights Watch has been documenting the devastating human rights impacts of the Covid-19 pandemic. Among other things, we have advocated for rights-based approaches to Covid-19 vaccine research, development, manufacture, and distribution, to maximize the availability and affordability of vaccines.

As part of our research on Covid-19 vaccines, we are contacting companies producing Covid-19 vaccines, starting with those that have received World Health Organization (WHO) Emergency Use Listing. Companies like yours have an important role to play in maximizing vaccine availability and affordability.

We are writing to learn more about Pfizer's human rights due diligence, including policies and practices surrounding its Covid-19 vaccine. We were also part of a large group of civil society organizations and individuals that wrote to your company in December 2020.

All companies, including pharmaceutical companies, have a responsibility to respect human rights standards and principles and conduct effective human rights due diligence in accordance with the UN Guiding Principles on Business and Human Rights (UNGPs). Pharmaceutical companies also have responsibilities as outlined in the 2008 Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines issued by the UN Special Rapporteur on the Right to Health. These are explained in more

detail in Human Rights Watch's February question-and-answer document: Universal and Equitable Access to Covid-19 Vaccines, Testing, Treatments: Companies' Human Rights Responsibilities.

As part of our work and in the interests of thorough and objective reporting, we would like to learn more about Pfizer's human rights policies, practices, and due diligence processes, especially those relevant to its Covid-19 vaccine, and steps it has taken to make its vaccine widely available and affordable. In the Annex, we have provided a summary of information we have reviewed using publicly available sources, followed by a set of questions requesting additional information about (A) Overall policies and human rights approach to human rights due diligence; (B) Global allocation and delivery; (C) Supply; (D) Technology transfers; (E) Affordable pricing strategy; (F) Indemnification; (G) Contracts to supply vaccines; (H) Licensing agreements; and (I) TRIPS waiver, TRIPS flexibility, and patents.

We request a written response to the questions and any other relevant information by **April 26, 2021** via email to my colleague, [redacted] All responses received by April 26 may be reflected in our publications.

We thank you for your consideration. Please do not hesitate to contact us for any clarifications, to provide the information requested, or to coordinate a conference call with us.

Best regards,

[redacted]

Arvind Ganesan
Director, Business and Human Rights Division
Human Rights Watch

CC:
Caroline Roan, Chief Sustainability Officer and Vice President, Global Health and Patient Access
Angela Hwang, Group President, Pfizer Biopharmaceuticals Group
Germain Morin, Vice President, Global Supply Chain, Rare Disease and Vaccine

Annex: Summary of Information Reviewed and Questions Regarding Covid-19-Specific Human Rights Due Diligence

A. Overall Policies and Approach to Human Rights Due Diligence

Summary of Information Reviewed

We have reviewed Pfizer's August 2020 Human Rights Policy Statement, its latest available Sustainability Report, as well as the September 2020 joint statement with other companies and the Bill and Melinda Gates Foundation.

Questions

1. Policies

Does the company have a specific equitable access policy which applies to its business operations related to Covid-19 vaccines, including manufacturing, marketing, and distribution? Please provide more information, including copies of any written policies and how all policies are embedded across the company's operations.

2. Human rights due diligence processes

What steps has the company taken to conduct Covid-19 specific human rights risk assessments? Please outline all the *risks identified*, the *prevention, mitigation, and remedial measures* the company undertook, and the *indicators being used to track and assess the progress* of the company's prevention and mitigation strategy. Please provide information concerning the following risks:

a. Barriers to availability of the vaccine because of insufficient diffusion and sharing of technological know-how required to scale up manufacturing.
b. Barriers to availability of the vaccine because of intellectual property (IP) rights risks that can curb scale-up of manufacturing and distribution.
c. Barriers to affordability of the vaccine.
d. Barriers to accessibility of the vaccine.

3. Consultation with stakeholders and potentially affected groups

Please describe the methodology used by the company to conduct such risk assessments regarding its Covid-19 vaccine supply and affordable pricing strategy, including a list of "potentially affected groups" or "at-risk" populations and stakeholders that the company has consulted.

B. Global Allocation and Deliveries

Summary of Information Reviewed

In November 2020, the nongovernmental organization, Global Justice Now, estimated that of the initial 1.3 billion doses of Pfizer's vaccine, 82 percent (that is approximately 1.06 billion doses) were prebooked by high-income governments, notably, the EU, the UK, and the US. Subsequently, in February 2021, Pfizer stated that 36 percent of the two billion doses it plans to produce in 2021 will be directed towards low- and middle-income countries. The Knowledge Network on Innovation and Access to Medicines, a project of the Global Health Centre at the Graduate Institute in Geneva, reported that a vast majority of BioNTech/Pfizer's vaccine deals are with high-income countries (updated on April 1).

Questions

1. Please provide the total number of doses that the company has committed to supplying to date, and a breakdown of volume commitments across different categories—high-income, upper-middle-, lower-middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others. Please identify if this target is based on a five dose or six dose vial and if the company is considering access to dead weight syringes in its assessment of which markets would be able to extract six doses.
2. What factors does the company consider in decisions about how it sequences distribution of vaccines to different countries?
3. Does the company plan to publish a list of all national authorities, intergovernmental organizations, COVAX Facility, and other entities it supplies, building on the good practice set by the COVAX Interim Distribution Forecast and UNICEF's price transparency database? If yes, by when?

C. Supply

Summary of Information Reviewed

We understand that the company's Covid-19 vaccine production will increase from 1.3 billion to two billion doses by the end of 2021. We have reviewed announcements by Sanofi and Novartis of agreements with BioNTech, Pfizer's business partner, to expand vaccine manufacturing. We further understand that Pfizer's vaccine production is carried out by 25 different suppliers across 19 different countries, and 70 percent of the production is in Europe. We are also aware that since January 2021 the European Commission introduced rules that can restrict export of Covid-19 vaccines from EU Member States. We note the *Reuters* news report where Pfizer stated that it will not expand manufacturing during the "pandemic supply phase" beyond North America and Europe.

Questions

1. Please provide information about the company's global manufacturing capacity for its Covid-19 vaccine, its manufacturing plans and objectives, and steps the company has taken to scale up manufacturing capacity for the vaccine between 2020 and 2023?
2. How does Pfizer define the "pandemic supply phase" and how will the company determine when the pandemic phase is over?
3. What steps is the company taking to diversify its manufacturing to mitigate against the risk of export restrictions?

D. Technology Transfers

1. We understand that Pfizer has not yet joined the Covid-19 Technology Access Pool. Please detail the reasons for this decision and whether any steps are underway to join.
2. What steps is the company taking to conduct technology transfers related to its Covid-19 vaccine to contribute to building the manufacturing capacity of low- and middle-income countries?
3. Does the company restrict commercialization rights where it conducts technology transfers, especially the ability to export?

E. Affordable Pricing Strategy

Summary of Information Reviewed

Based on publicly available information, we have gathered the following information for pricing per dose: the African Union—US$6.75; the Dominican Republic and the European Commission—$14.50; the US—$19.50; and Israel—$30.00. At this writing, we have not been able to find the "not for profit" price at which vaccines were sold to the COVAX Facility. Pfizer recently estimated a net profit of 25 percent (or US$ 3.75 billion) on its Covid-19 revenue from vaccines while Pfizer executives said that the company envisions more opportunities from a demand and pricing perspective, drawing a distinction between the pandemic and endemic phases. Though we understand there is differentiated pricing, we are not clear on the steps Pfizer is taking to make the vaccine affordable and accessible.

Questions

1. Please provide information about Pfizer's affordable pricing strategy for its Covid-19 vaccines, including information about the criteria factored into determining affordable prices throughout the world. In particular, please provide details on how Pfizer's affordability strategy may differ in the pandemic and endemic phases.

2. Companies like AstraZeneca and Johnson & Johnson have committed to non-profit pricing for their Covid-19 vaccines. Does Pfizer plan to make a similar commitment beyond its pledge to COVAX and what is the non-profit price it is offering the COVAX Facility?
3. Johnson & Johnson committed to a third-party audit and verification of its non-profit pricing. Does Pfizer plan to make a similar commitment?
4. We note news reports that the company withdrew its application to manufacture in India, among other reasons, seeking pricing freedom. Please detail the reasons Pfizer withdrew its application in India and what policies it opposed.
5. How much government and nongovernment (philanthropic) funding has supported the development of the BioNTech/Pfizer vaccine (including the different stages of innovation) and how much money has Pfizer received through advance market commitments?
6. What is the estimated private investment in vaccine development, manufacture, and distribution?

F. Indemnification

Summary of Information Reviewed

We understand from a *Bureau of Investigative Journalism* report that Pfizer may have sought extensive indemnification and asset guarantees from governments such as Argentina and Brazil, as well as a third, unnamed Latin American country as conditions of vaccine procurement. The report states that government officials from Argentina and the unnamed country said that Pfizer's demands "went beyond those of other vaccine companies, and beyond those of COVAX." *CNN Brasil* reported that in March 2021, the Brazilian government agreed to deposit funds in a foreign account to serve as a guarantee of payment and take full responsibility for adverse events.

The NGO Knowledge Ecology International, which reviewed an agreement between the Dominican Republic and Pfizer, stated that Pfizer's indemnity clause "includes, for instance, failures to keep the vaccines at the recommended temperatures during transportation to the country."

Questions

1. Please provide details on the indemnification requirements Pfizer has sought from countries and the conditions that the company has made a precondition for countries to receive Pfizer's vaccines through the COVAX Facility.

2. Has Pfizer requested that governments provide any assets as collateral for the vaccine? If so, please list the governments that have made those commitments and the assets pledged.

G. Contracts to supply vaccines to national authorities/intergovernmental organizations/COVAX Facility

Summary of Information Reviewed

Contract transparency is key to providing the public a way to monitor government spending and is a bulwark against conflicts of interest and corruption. Many governments have procurement rules that obligate them to publish public contracts, and many have specifically committed to publishing Covid-19-related contracts as part of their emergency loan agreements with the International Monetary Fund. The World Bank's rules also require governments to publish contract awards it finances, including related to Covid-19.

The agreement between Pfizer and the Dominican Republic's government reveals that some parts of the agreements, including underlying orders, are seen as an "exception to an obligation to disclose set forth in article 17 of the Law No. 200-04 on Free Access to Public Information," and carries a clause that says "MISPAS [Dominican Republic government] represents, warrants and guarantees that it is under no obligation to publish or publicly disclose this document, or the terms and conditions herein, or to make any sort of publication or disclosure regarding this Binding Term Sheet or the terms contained herein either online, before any entity, or through any form of mass communication."

Questions

1. Does the company plan to publish its contracts related to the supply of its vaccines? If yes, by when will the company publish such a database on its website?
2. What measures does the company take to enable government compliance with Freedom of Information or Right to Information Laws or other good practices around government disclosure of contracts?
3. To whom should civil society and other interested parties direct queries regarding contracts and make requests for exemption to NDAs?

H. Licensing agreements

Questions

1. What measures is Pfizer taking to adopt good practices set by the Medicines Patent Pool to voluntarily publish licensing agreements related to Covid-19 vaccines?

2. Please provide a summary of all licenses issued with regard to Covid-19 vaccine manufacturing and outline the terms of the license and the license period. Please elaborate why the company has/has not agreed to voluntary, open, nonexclusive and global licenses.

I. TRIPS Waiver, TRIPS Flexibilities, and Patents

Summary of Information Reviewed

The Director-General of the WHO has publicly supported the proposal before the World Trade Organization (WTO) that would temporarily waive some IP rights under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) until "widespread vaccination is in place globally." However, Pfizer along with other companies and the Pharmaceutical Research and Manufacturers of America (PhRMA) wrote to President Biden in early March 2021 urging the US administration to continue "to oppose the TRIPS IP waiver." Numerous industry groups that Pfizer is a member of, including the Intellectual Property Owners Association (on whose board Pfizer sits) and PhRMA, have written to the US government advocating for action against countries exercising TRIPS flexibilities and to continue opposing the TRIPS waiver proposal. PhRMA refers to legitimate government exercise of TRIPS flexibilities as "compulsory licensing threats" and describes pricing controls to make life-saving healthcare affordable as a "non-tariff" trade barrier.

Questions

1. Please detail whether Pfizer will support the TRIPS waiver proposal in light of so many other relevant stakeholders', including the WHO's, views in support of the waiver.
2. How will the company respond to a government's use of public health safeguards and flexibilities included in the WTO TRIPS Agreement and reaffirmed by the Doha Declaration to discharge their human rights obligations to life and health?
3. What steps is the company taking to build on good practice of other companies like Moderna, to publicly disclose information about all relevant patents and patent filings (owned and licensed) for different underlying technologies used to produce, store, and distribute the Covid-19 vaccine?
4. Does the company intend to refrain from enforcing its patents (similar to public announcements made by Moderna and CureVac)? Please detail any such commitments.

Arvin Ganesan
Director, Business and Human Rights Division
Human Rights Watch

Dear Mr. Ganesan,

Thank you for reaching out to Pfizer. We welcome the discussion of human rights and agree on its utmost importance to the healthcare sector. We are grateful for this opportunity to share our thinking in this area.

Pfizer's purpose – *Breakthroughs that change patients' lives* – fuels everything we do and reflects both our passion for science and our commitment to patients. We are thrilled our COVID-19 vaccine has the potential to change more lives than any other breakthrough from the past century.

As you, we are extremely concerned about the toll that COVID-19 is taking on the lives and well-being of people all over the world; this is why we have put all the power of our Company behind the objective of contributing to ending this pandemic.

We knew that no one company, vaccine or treatment would be enough and that we would need to harness the potential of the full biotechnology ecosystem. That is why, in March last year, we committed to sharing our scientific tools and insights, development expertise, and manufacturing capacity in our 5-Point Plan. We also stood in solidarity with industry leaders and pledged to protect scientific integrity, building on our rich history in vaccine research and development. Pfizer made a public pledge—along with eight other vaccine makers—to help protect the time-tested scientific processes and regulatory protocols that have helped guide the safe delivery of medicines and vaccines to address patients' unmet needs.

One year later, there is increasing hope that the world will defeat the COVID-19 pandemic thanks to the outcomes of these unprecedented mobilization and collaborations, including the one we launched with our partner BioNTech that enabled development of the Pfizer/BioNTech COVID-19 vaccine.

Our COVID-19 efforts did not happen in isolation. Over the past four years, Pfizer has been engaged in a review of the UN Guiding Principles on Business and Human Rights and what they mean for our business. After assessing with internal and external stakeholders, we concluded that we needed to firmly state that the right to health is the most salient human rights issue for Pfizer and that more work was needed to demonstrate the steps the company is taking to bring a human rights-based approach to our work. This resulted in revising our human rights policy statement, which builds upon our purpose, *breakthroughs that change patients' lives*.

Consistent with that statement, our COVID-19 response is guided by our responsibility to respect *the right to health*. In addition, *equity* is one of the four core values that define our company and culture.

Since the beginning of the pandemic, our paramount consideration has been equitable and affordable access to COVID-19 vaccines for people around the world. We opted for a multi-pronged approach to enable this access, with the most vulnerable in mind:

Not-for-profit pricing for LMICs

We chose to charge governments a price that allow them to distribute our vaccine to their citizens for free. And recognizing that equity doesn't mean we give everyone the same, but rather we give more for those in higher need, we set a lower price for middle-income than high-income countries, and we are providing the vaccine to low-income and lower-middle-income countries at a not-for-profit price.

As of April 22, Pfizer-BioNTech doses allocated through COVAX have reached countries in every region of the world, including Rwanda, South Korea, Colombia, Peru, Cabo Verde, Tunisia, West Bank and the Gaza Strip, Moldova, El Salvador, Mongolia, the Maldives, Bosnia and Herzegovina, Georgia and the Ukraine. Shipments will continue to a diverse range of countries in every region of the world as part of the up to 40 million doses we have committed to COVAX in 2021 and in alignment with the COVAX mission to provide equal access to a broad portfolio of COVID-19 vaccines for all countries. We continue to engage with COVAX in discussions on how to get more doses to more people.

Capacity and resources to strengthen vaccine access for LMICs

On December 31, 2020, the Pfizer-BioNTech vaccine was granted the *first* World Health Organization (WHO) Emergency Use Listing of a COVID-19 Vaccine. This is an important step for enabling vaccine access for low and lower-middle income countries.

Beyond the supply of vaccines, we are taking steps to partner with global health stakeholders to provide expertise and resources that can help them strengthen healthcare systems where greater support may be needed to deploy COVID-19 vaccines.

We also know that medicines and vaccines are just one element in supporting the achievement of the right to health, specially by the most vulnerable people. Instability in healthcare systems or infrastructure are a major challenge to battling the pandemic.

In addition to vaccine supply, we are providing our expertise and resources for novel approaches that can help governments to strengthen their healthcare systems where greater support may be needed:

- We are partnering with global health stakeholders to analyze supply chain capabilities in low-income countries in order to understand where private sector could lend expertise and support the delivery of any COVID-19 vaccine - including dry ice

supply, transportation and best practice sharing.

- We are in conversations with UN agencies, governments and International Non-governmental Organizations' who work with refugee and other vulnerable populations, to understand how these groups will receive access to vaccines and where Pfizer can support these efforts, including preparations with health systems strengthening guidance, advocacy, delivery and supply.

Continued innovation to enable access

We continue to study the safety and efficacy of the vaccine. Specifically, we continue advancing the science and knowledge about the impact of our COVID-19 vaccine in specific populations, such as pregnant women and children. We have obtained approval for new storage options to help address distribution challenges, and we are delivering on our commitment to advance our research program for a COVID-19 Antiviral treatment, which is in development.

And beyond efforts around our COVID-19 vaccine, since the beginning of the pandemic we have been working with governments and international non-governmental organizations to provide relief and support where it is needed through donations of much needed medications and by working to support front line health workers in vulnerable communities.

As the above suggests, we see an equitable and rights-based approach to the vaccine as a paramount consideration and have taken several steps to meet this objective. At the same time, we are committed to continuous improvement and therefore welcome feedback and suggestions from our stakeholders, and further engagement with you on this topic. After reviewing your questions, we re-commit to place greater emphasis on clearly categorizing and communicating our efforts from a human rights lens.

In what follows, we have addressed some of your specific questions. We agree with your focus on transparency. Although there are a few places where legitimate business and legal constraints restrict what we can say, we have endeavored to be as transparent as possible in our responses.

Sincerely,

[redacted]

Albert Bourla

Responses to your questions regarding COVID-19-Specific Human Rights Due Diligence

Equitable Access Policies

Pfizer is committed to conducting business in an ethical and responsible manner. This includes respecting internationally recognized human rights throughout our operations.

In line with the UN Guiding Principles on Business and Human Rights, Pfizer's human rights policy focuses on addressing risks that could have the most severe impact on people: our patients, our colleagues, the workers of our business partners, and the communities in which we operate. Our responsibility to respect human rights extends throughout our operations, from lab to patient, including our diverse global supply chain of numerous local, third-party vendors.

As a biopharmaceutical company, the right to health is our most salient human rights risk. Pfizer's commitment to the right to health is reflected in our purpose: *breakthroughs that change patients' lives.*

Equity is one the four Company values underlying how we live our purpose. Both our commitment to human rights and our focus on Equity are embedded into our Code of Practice, which all colleagues and officers of Pfizer and its subsidiaries are responsible for living and holding each other accountable for.

Consistent with this, our approach to equitable access applies to all our products including Pfizer/BioNTech's COVID-19 Vaccine.

Here are some additional insights about how access is Governed at Pfizer:

In 2019, Pfizer began a purpose-driven transformation, launching its Purpose Blueprint – the roadmap that will guide our company for the foreseeable future and help deliver on our purpose: *Breakthroughs that change patients' lives.*

At the highest level, Pfizer's global Access to Medicine strategy is grounded in our purpose and integrated into the corporate Purpose Blueprint through its five "Bold Moves". Bold Move 3 "Transform our go-to-market model" specifically addresses the patient affordability challenge by exploring new, flexible payment approaches, including value-based agreements, and being bold in how we expand access to our medicines.

Since 2018, Pfizer has sought to deepen the alignment of our Access to Medicines (ATM) and corporate strategies across our portfolio of medicines and vaccines to address ongoing and emerging patient needs around the world. To improve the execution of our ATM strategy and more fully integrate it into the company's corporate strategy, Pfizer evolved its organizational structure, reorienting to create three distinct product access organizations – Patient Health & Impact; Global Health Partnerships; and Global Health and Social Impact. Each focuses on different segments of the patient income pyramid (as defined by the World Bank) to develop commercially viable models and access approaches at the business unit level and philanthropic efforts to provide sustainable, long-term access.

Additionally, in 2018, Pfizer established the Global Health Committee (GHC), a formal governance structure comprised of 12 senior executives across the enterprise, that assumes responsibility for Pfizer's ATM and global public health strategies above the individual business unit level. It is charged with developing and executing an integrated global ATM strategy in LIC and LMICs, including commercial activities and creative access models. It meets quarterly to review Pfizer's access efforts across the company, coordinate implementation across the commercial organization, and Pfizer Foundation's efforts to drive access to quality healthcare. It also leads coordination of standardized metrics and public reporting. Leadership from each of the three product access organizations are also part of Pfizer's GHC.

Pfizer is systematically developing commercially viable models at the business unit level to provide sustainable, long-term access at multiple socio-economic levels, including patients least able to pay for medicines.

We believe that our access to medicines and global public health strategies enhance Pfizer's long-term value to patients, society and our investors by opening new opportunities in new markets and population segments, giving us a foundation to expand our operations, and reaching patients beyond the limit of our traditional supply chain.

Approach to due diligence:

Human rights risks associated with Pfizer/BioNTech's COVID-19 vaccine are no different to those of other Pfizer products; the pandemic situation, however, has exacerbated them. The right to health remains the most salient risk, with availability, accessibility and affordability standing as key areas of focus.

We knew that minority populations and those in hard to reach locations, or lacking access to basic health services, would be those whose 'right to health' would be most severely impacted.

And because of the pandemic nature of the crisis, we have primarily engaged with Government officials and supranational organizations (such as WHO) to evolve our approach to access to our COVID-19 vaccine.

Our comprehensive approach to access and pricing has been described above (and in section "Affordable Pricing Strategy" below).

We believe the IP system is an essential facilitator to the availability of the vaccine and not an impediment or risk and remains a critical enabler of the future research that will be necessary to end the pandemic. The incentives provided by the IP system enabled Pfizer to build over many years the expertise and infrastructure that allowed us to quickly mobilize and devote the resources, technical knowledge and know-how required to combat the pandemic—and in doing so also facilitated the advancement of cutting edge technologies, such as mRNA vaccines. The IP system provided the infrastructure that enabled an unprecedented number of collaborations between biopharmaceutical innovators and governments, universities and other research partners to speed up progress and eventually find solutions to help end the pandemic.

On December 31, 2020, the Pfizer-BioNTech vaccine was granted the *first* World Health Organization (WHO) Emergency Use Listing of a COVID-19 Vaccine, which is an important step for enabling vaccine access for low and lower-middle income countries.

Early on we engaged with COVAX. As of April 22, Pfizer-BioNTech doses allocated through COVAX have reached countries in every region of the world, including Rwanda, South Korea, Colombia, Peru, Cabo Verde, Tunisia, West Bank and the Gaza Strip, Moldova, El Salvador, Mongolia, the Maldives, Bosnia and Herzegovina, Georgia and the Ukraine. Shipments will continue to a diverse range of countries in every region of the world as part of the up to 40 million doses we have committed to COVAX in 2021 and in alignment with the COVAX mission to provide equal access to a broad portfolio of COVID-19 vaccines for all countries. We continue to engage with COVAX in discussions on how to get more doses to more people.

There are other key barriers to access and availability, and we have also strived to address them:

- Diversity in clinical research
  From the start, we committed to decreasing health disparities in underrepresented populations

through our clinical trials. In our landmark trial, we selected investigative sites in diverse communities in the U.S. and globally that were disproportionately affected by COVID-19, to help ensure that individuals in communities that have been most impacted had the opportunity to participate. In our landmark Phase 3 study, approximately 42% of overall and 30% of U.S. participants came from diverse backgrounds. We shared with our investigative sites the importance of recruiting individuals who fully represent the racial and ethnic diversity of their communities, and we engaged patient advocacy partners and community groups to raise awareness about the importance of participation and representation. In all of our newly initiated trials, we remain committed to enrolling diverse participant populations.

- Distribution and safety of vaccines
  The Pfizer-BioNTech COVID-19 vaccine is an mRNA-based vaccine that requires ultra-cold chain capable shipping and storage, which we recognize could present infrastructure challenges in some countries. This is why we began working with our distribution partners from the very beginning, simultaneous to our vaccine development efforts, to design a thermal shipping solution that will help to mitigate the barriers that might exist for some countries to effectively administer the vaccine.

  We have developed detailed logistical plans and tools to support effective vaccine transport, storage and continuous temperature monitoring. Our distribution is built on a flexible just-in-time system which will ship the frozen vials to the point of vaccination. We have specially designed, temperature-controlled shippers utilizing dry ice to maintain recommended temperature conditions up to 10 days unopened. Also, stability data have demonstrated that once removed from the shipper or an ultra-low temperature freezer, as instructed, the undiluted vaccine can be stored for up to 5 days at 2 °C to 8 °C, or up to 2 hours at temperatures up to 30 °C, prior to use.

  The intent is to utilize Pfizer-strategic transportation partners to ship by air to major hubs within a country/region and by ground transport to dosing locations.

  Building on our 4 year partnership with Zipline, the world's largest drone delivery service, Pfizer is providing its funding and technical expertise to Zipline engineers to begin building a delivery solution that can safely and effectively distribute all COVID-19 vaccines in the countries where it operates. The objective is for the new end-to-end, cold chain distribution capability will leverage Zipline's drone delivery network to safely deliver refrigerated, frozen and ultra-low COVID-19 vaccines and medical products.

  This work is part of a larger partnership with Zipline started in 2019 to use the power of its technology to strengthen systems and expand access to care within hard-to-reach populations.

- Humanitarian settings
  COVID-19 is having a direct impact on under-resourced health systems and communities that have already suffered from war and humanitarian disasters. To help support the needs of these communities, The Pfizer Foundation is supporting the International Rescue Committee's (IRC) work to help prevent the spread of COVID-19 through a comprehensive strategy of infection prevention and control, fever testing and contact tracing, and community engagement and education.

  In addition, the Pfizer Foundation is also working with the IRC in collaboration with the Jordanian Ministry of Health, to launch an innovative health delivery model to provide essential primary health services to refugees in Jordan.

  We are in conversations with UN agencies, governments and International Non-Governmental Organizations who work with refugee and other vulnerable populations, to understand how these

groups will receive access to vaccines and where Pfizer can support these efforts, including guidance on health systems strengthening, advocacy, delivery and supply.

Global Allocation and Deliveries

Everyone has the right to access a COVID-19 vaccine. Whether you live in a high-income country or a low-income country, Pfizer is committed to working towards equitable access that will give all people access to a vaccine.

Since countries vary in terms of the strength of their economies, the stability of their healthcare systems and the infrastructure available to protect and care for their people. We must look at the needs of each country and tailor our approach to each one -- working together with governments and partners to support equitable access for those in need. This is our imperative as we strive to address the needs of the most vulnerable populations.

Manufacturing and distribution of our COVID-19 vaccine have progressed well. Not only did we achieve our 100M dose commitments for 2020, but to date, over 350M doses have been supplied globally to more than 80 countries and territories. We are currently in talks with around 125 countries and supranational organizations on the supply of our COVID-19 vaccine (including COVAX).

As this pandemic rages on, we know that there is a dire need to vaccinate more people, particularly front line healthcare workers and those at higher risk, as quickly as possible. So, we are expanding and enhancing our manufacturing capabilities to increase the number of doses we're able to produce globally by the end of 2021. As a result of these efforts, we recently raised our original estimate (1.3 billion doses), and we now believe that, based on current projections, Pfizer's and BioNTech's combined manufacturing network has the potential to supply 2.5 billion doses in 2021 (based on 6-dose vials).

To help this effort globally, Pfizer and BioNTech teams have been working in close contact with country authorities to improve the availability of low dead volume equipment ("LDV Equipment") necessary to extract the sixth dose of Vaccine from each vial.

As of April 22, Pfizer-BioNTech doses allocated through COVAX have reached countries in every region of the world, including Rwanda, South Korea, Colombia, Peru, Cabo Verde, Tunisia, West Bank and the Gaza Strip, Moldova, El Salvador, Mongolia, the Maldives, Bosnia and Herzegovina, Georgia and the Ukraine. Shipments will continue to a diverse range of countries in every region of the world as part of the up to 40 million doses we have committed to COVAX in 2021 and in alignment with its mission to provide equal access to a broad portfolio of COVID-19 vaccines for all countries. We continue to engage with COVAX in discussions on how to get more doses to more people.

Supply

Tackling a pandemic is a global effort, which depends on global supply chains, as well as an environment that is conducive to innovation.

While driven by the intention to protect the local population, export restrictions measures risk doing more harm than good, both for the availability of medicines and undermining global cooperation on solutions. Export restrictions – be they for vaccines, ICU medicines or other critical goods - have an immediate impact on globally integrated supply chains that ensure quality, safety, innovation, and distribution across the health sector. By driving mismatches between supply and demand, they increase the risk of shortages, disrupt distribution channels, and hinder the conduct of clinical trials.

The Pfizer-BioNTech vaccine contains 280 different components, manufactured in 86 different sites across 19 different countries. If any one of these 280 different components, is not provided, we cannot manufacture or release the vaccine.

Given the complex back and forth of manufacturing, the impact of export restrictions can go beyond the distribution of vaccines. For instance, our manufacturing site in Puurs cannot function without exports of samples to the U.S. for batch testing, a critical component of good manufacturing practices to assure quality. In 2020, we invested more than $650 million at risk in capital to advance our COVID-19 vaccine program and ordered more than $300 million in raw material, including specialized lipids, freezers and specialized transportation shippers.

Pfizer's COVID-19 vaccine research, development and manufacturing costs are entirely self-funded. To date, Pfizer has already invested billions of dollars in the development of the vaccine and Pfizer anticipates incurring additional development and manufacturing costs.

Over 350M doses have been supplied globally to more than 80 countries and territories. We are expanding and enhancing our manufacturing capabilities to increase the number of doses we're able to produce globally by the end of 2021. As a result of these efforts, we recently raised our original estimate (1.3 billion doses), and we now believe that we can potentially deliver more than 2.5 billion doses in total by the end of 2021. This increase in productivity is based on the updated 6-dose label, continuous process improvements to our existing production lines – in essence more doses from the current lines, expanding the supply of raw material from existing suppliers and bringing on new suppliers.

These changes include starting up new formulation suites to triple formulation capacity and adding additional fill finished lines. We have also doubled our batch sizes in order to minimize time between batches and increased the yield per batch – we know that every dose counts. We are reducing cycle times at every step and deploying faster laboratory test methods to reduce release times.

These improvements are now reflected in our updated timelines. When we began to supply the vaccine our average timeline from start to vial-ready was approximately 110 days. By employing the learnings and efficiencies mentioned, we have continued to reduce our timelines, and we are now approaching an average of 60 days from start to vial-ready -- an almost 50% improvement. To add perspective on our scale up: every month the volumes in our site in Puurs, Belgium, will increase such that by June, we will be producing 100M doses a month. To compare, we used to make 200M doses of vaccine per year.

It is important to remember that we operate under pandemic supply conditions with limited inventory. We also depend on a vast network of suppliers for materials. Any reduction in availability of these necessary materials, including reductions caused by new manufacturers attempting to manufacture a similar vaccine, could prevent us from meeting our supply goals.

So, in short, our efforts to reach our 2021 target quantities include expanding our manufacturing capabilities, increasing our supplier base for key materials and contract manufacturing options to our supply chain. This includes support from numerous companies providing manufacturing support, including Baxter, Delpharm, Sanofi, Novartis &Thermo Fisher. At this point we are favoring global contract manufacturers with broad regulatory approvals and significant available capacity over local contract manufacturers in individual markets.

Localizing vaccines require a significant lengthy process as well as commitment of technical resources that would divert Pfizer from focusing its efforts and resources in a way that maximizes the overall supply and better support the global needs.

We monitor WHO's definition of Public Health Emergency of International Concern (PHEIC) and track the deliberations of the IHR Committee in what regards any changes to PHEIC status.

Pfizer is a proven, reliable multinational vaccine producer, supplying vaccines to more than 165 countries. Before the Pfizer-BioNTech COVID-19 vaccine was developed, Pfizer manufactured more than 200 million doses of Pfizer vaccines annually. Additionally, Pfizer is one of the largest sterile injectables suppliers in the world, producing more than 1 billion sterile units per year. Our track record gives us confidence in our ability to continue to innovate, manufacture and distribute large quantities of a high-quality COVID-19 vaccine, leveraging multiple sites in the US and Europe.

Technology transfers & Licensing

Pfizer welcomes voluntary initiatives that add to the pool of resources and options available to promote equitable access to COVID-19 therapies and vaccines and we remain committed to constructive dialogue with all parties.

We have a deep sense of responsibility to help ensure the vaccine is made available and we have gone to enormous efforts, including manufacturing at risk, to put us in the best possible position as we seek to serve populations all over the world.

The development, manufacturing, distribution and storage of complex innovative products, including the mRNA technology, requires globally-optimized supply chains and we are actively focused on production arrangements to support a robust and reliable supply chain. We have signed supply agreements with the COVAX Facility and countries in all regions across the globe and are in discussions with governments all over the world to work towards equitable supply of the vaccine.

With many working to develop cell-based assays, viral screening, serological assays, and translational models to test potential therapies and vaccines, Pfizer is committed to making the vital tools we develop available on an open source platform to the broader scientific community and to sharing the data and learnings gained with other companies in real time to rapidly advance therapies and vaccines to patients.

Pfizer will continue to consider all viable options and mechanisms as needed to ensure that the vaccine and any potential therapies to help address the pandemic are accessible to those who need it**.**

Affordable Pricing Strategy

Pfizer's goal from the outset has always been to bring a safe, effective and affordable vaccine to combat this pandemic as soon as possible.

We have established pricing principles for our potential COVID vaccine which are consistent with Pfizer's commitment to the right to health, our values and our mission to bring *breakthroughs that change patients' lives*. These are extraordinary times, and our pricing reflects that. During the pandemic, we priced our vaccine consistent with the urgent global health emergency we are facing to help ensure widespread vaccination for all countries that supply our vaccine. Our pricing enables governments to offer the vaccine at little to no out-of-pocket costs for their populations.

Volume of doses ordered, advance commitments, and equity considerations are key drivers in our government contract pricing. We have a tiered pricing approach that enables poorer countries to pay less, and we also take into account advance commitments and the number of doses contracted.

In all agreements, we will deploy the same pricing approach for high, middle, and low-income countries with *low and lower-middle income countries paying a not-for-profit price.* High and middle-income countries will pay more than low-income countries, but at a value that is significantly discounted from our normal benchmarks during the pandemic.

Pfizer cannot comment on the purported commitments of other companies. Pfizer believes it has and will continue to engage in transparent and appropriate pricing consistent with Pfizer's commitment to the right to health, our values and our mission to bring breakthroughs that change patients' lives.

At country level, we support Governments in their efforts to ensure at-risk and most vulnerable populations are prioritized for vaccine roll out, as per international guidance and local regulations or recommendations. Currently we are in talks with more than 125 countries and supranational organizations on the supply of our COVID-19 vaccine. We have allocated doses for supply to low- and lower-middle-income countries at a not-for-profit price.

The Pfizer-BioNTech COVID-19 vaccine development program and manufacturing costs have been entirely self-funded. To date, Pfizer has already invested $2 billion in the development of the Vaccine. We have invested at risk and are prepared to continue to bear the costs of development and manufacturing in an effort to advance a solution to this pandemic.

In 2020, we invested more than $650million at risk in capital to advance our COVID-19 vaccine program and ordered more than $300 million in raw material, including specialized lipids, freezers and specialized transportation shippers.

The funds received by Pfizer through advance purchase agreement are payments for vaccine that governments are acquiring for their people. Characterization of these payments as government support of the development and production of the vaccine is incorrect.

India

In pursuance of the Emergency Use Authorization of its COVID-19 vaccine, Pfizer participated in the Subject Expert Committee meeting of the Drug Regulatory Authority of India on February 3. Based on the deliberations at the meeting and our understanding of additional information that the regulator may need, the company has decided to withdraw its application at this time. Pfizer will continue to engage with the authority and resubmit its approval request with additional information as it becomes available in the near future. Pfizer remains committed to making its vaccine available for use by the Government in India and to pursuing the requisite pathway for emergency use authorization that enables the availability of this vaccine for any future deployment.

Indemnification

The speed and scale of the pandemic response creates a risk of unprecedented liability exposure for all persons involved in the development, production and use of the vaccine, including doctors, pharmacies, NGOs and manufacturers. Therefore, Pfizer believes that appropriate liability protections are critical for all those working at unprecedented speed to develop and distribute the vaccine.

This unprecedented crisis has required pharmaceutical companies around the world to work to develop vaccines on an expedited basis and rapidly scale up production to provide for distribution to billions of people. Governments around the world understandably want access to Pfizer's vaccine as quickly as possible, but these circumstances create unusual and unprecedented risks to vaccine manufacturers of

substantial legal claims across the globe. This is why Pfizer seeks indemnity and liability protection in all agreements, including through the COVAX Facility, consistent with applicable local laws.

Many governments around the world do not have the legal or legislative protections in place for vaccine manufacturers that are already in effect in the U.S. Thus, in supply contracts with all governments around the world, Pfizer asks that the government indemnify Pfizer, BioNTech, their contractors and suppliers, and others involved in the development or manufacture of the vaccine against claims by third parties alleging an injury relating to the vaccine, in order to achieve a similar level of protection as afforded by the U.S. PREP Act.

To ensure the indemnity is enforceable against the governments, the governments have agreed to waive sovereign immunity from claims (this is not equivalent to posting assets as collateral). Notwithstanding any waiver of sovereign immunity, Pfizer has no intention of interfering with any country's diplomatic, military, or culturally-significant assets.

An agreement that governments will indemnify against legal claims, that is enforceable through a waiver of sovereign immunity, is a fair and equitable balancing of risks where Pfizer, in response to the governments' needs, has worked quickly and under unprecedented circumstances to produce a vaccine that can be supplied at significant scale to global populations in record time.

Contracts

We are proud of the transparency we have demonstrated throughout the vaccine development process and in engagements with governments. It started with our commitment to openly sharing the details of our clinical trial program and publishing data at the earliest opportunity in peer reviewed journals. We have throughout the process worked to provide as much information as we are able as to when we expect to meet manufacturing targets, sharing this critical information with the public to help governments and individuals manage expectations and logistics.

We have worked with governments around the world to balance our efforts to be transparent with local laws, and the need to keep certain details of our contracts confidential, as is customary in commercial transactions, so as not to prejudice the parties or ongoing negotiations around the world.

Freedom of Information or Right of Information Laws provide a mechanism for interested parties to seek certain information from governments, and Pfizer cooperates with governments when they receive such inquiries, consistent with those countries' laws.

TRIPS waiver, TRIPS Flexibilities and Patents

The pandemic has highlighted the extraordinary value that a vibrant private sector can deliver to society. It took not only unprecedented courage and dedication, but also significant investments, at-risk, to bring diagnostics, treatments and now finally vaccines to tackle COVID-19.

We believe the IP system is an essential facilitator to the availability of the vaccine and not an impediment or risk, and remains a critical enabler of the future research that will be necessary to end the pandemic. The incentives provided by the intellectual property system enabled Pfizer to build the expertise and infrastructure that allowed us to quickly mobilize and devote the resources, technical knowledge and know-how required to combat the pandemic—and it also facilitated the advancement of cutting-edge technologies such as mRNA vaccines. It has enabled an unprecedented number of collaborations between biopharmaceutical innovators and governments, universities and other research partners to speed up progress on finding solutions to end the pandemic, as demonstrated by our partnership with

BioNTech, who we entered into a collaboration agreement effective March 17, 2020. Under the agreement, the IP directed to the mRNA COVID-19 vaccine is primarily owned by BioNTech.

The TRIPS Agreement, which sets down minimum standards for many forms of intellectual property rights, is critical to lock in the IP protections that will be needed to incentivize innovation and facilitate partnerships, especially as we seek to find solutions for special populations (e.g., children) and overcome new variants of the virus. Not only would waiving those commitments send the wrong message to future innovators in the next pandemic, it could make it harder to resolve the current one, particularly if companies begin to buy up scarce inputs in the hopes of manufacturing a vaccine using technology developed by others. Greater demand pressures on inputs from new market entrants will make it harder, not easier, to manufacture vaccines in the near term.

As indicated in our Environmental, Social & Governance Report, responsible use of our intellectual property (IP) enables us to engage in collaborations and partnerships that have the potential to speed up progress on the most pressing unmet medical needs, including COVID-19. We are proud of our long-standing commitment to keeping patients and societal benefit at the center of our IP practice.

Today we, along with 25 members of the biopharmaceutical industry, launched the "IP Principles for Advancing Cures and Therapies" (IP PACT)--a groundbreaking, unified declaration of 10 key intellectual property principles that guide our companies' approach to IP—with patients as our North Star.

Pfizer shares the goal of facilitating access to medicines for patients and we support implementation of the Doha Declaration, which recognizes countries' right to protect public health, while also acknowledging that IP protection is important for the development of new medicines. We understand that the limited, narrow use of a compulsory license to address a national health emergency may be appropriate under certain circumstances and if all other options have been exhausted. We remain committed to working directly with governments and other stakeholders, including to ensure the vaccine and any potential treatment or vaccine developed by Pfizer to address COVID-19 is accessible and affordable for those who need them.

Recognizing the unique level of economic development and social challenges of Least Developed Countries, as defined by the United Nations Committee for Development Policy. Pfizer has a general policy of patent non-enforcement in LDCs.

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May 14, 2021

Albert Bourla
Chief Executive Officer
Pfizer Inc.
via email: [redacted]

HUMAN RIGHTS WATCH
HRW.org

Re: Follow-up letter to Pfizer regarding its human rights policies and practices surrounding the BioNTech/Pfizer Covid-19 vaccine

Dear Dr. Bourla,

Thank you for your response dated April 26 about Pfizer's approach to fulfilling its human rights responsibilities.

We write to share a set of urgent key recommendations to your company to maximize the availability and affordability of Covid-19 vaccines and increase transparency. Our recommendations are outlined in **Annex I** to this letter. These recommendations assume heightened importance given the ongoing public health crisis the world faces and the urgency of ensuring of lifesaving vaccines reach as much of the world as swiftly as possible. The huge surge in Covid-19 cases in India once again shows that until widespread vaccination is achieved globally, people's health and lives will continue to be at risk and economies will struggle to recover.

We are concerned about the public health impacts of Pfizer's stated approach to intellectual property (IP), pricing, and transparency. Pfizer has not publicly disclosed, or disclosed to Human Rights Watch, enough information to show that it is meeting the company's commitment to an "equitable and rights-based approach to the vaccine." The pandemic is a test for companies like Pfizer to put these principles into practice.

We believe the company should undertake robust human rights due diligence, assessing specifically for risks related to adequate supply, manufacturing capacity, the IP landscape, and affordable pricing. Conducting and disclosing that due diligence would help build public confidence in Pfizer's efforts to combat the pandemic by showing how those risks are mitigated.

We also write to request additional information for our reporting to clarify Pfizer's position on several issues. Our list of additional questions can be found in **Annex II** to this letter. Our recommendations and questions are based on our analysis of the human rights responsibilities of companies researching, developing, and manufacturing Covid-19 vaccines.

We request a written response to this letter by **May 28, 2021**, via email to my colleague, [redacted]. All responses received by May 28 may be reflected in our reporting.

We thank you for your consideration. Please do not hesitate to contact us for any clarifications, to provide the information requested, or to coordinate a conference call with us.

Best regards,

[redacted]

Arvind Ganesan
Director, Business and Human Rights Division
Human Rights Watch

CC:
Caroline Roan, Chief Sustainability Officer and Vice President, Global Health and Patient Access
Angela Hwang, Group President, Pfizer Biopharmaceuticals Group
Germain Morin, Vice President, Global Supply Chain, Rare Disease and Vaccine

Annex I: Urgent Key Recommendations to Pfizer

Take the following steps to meet the company's human rights responsibilities to maximize vaccine availability and affordability

- Join the Covid-19 Technology Access Pool (C-TAP) and provide open, non-exclusive licenses for all forms of IP underlying the company's Covid-19 vaccine.
    - Commit not to enforce any underlying patents until widespread vaccination is in place globally.
- Participate in the newly created World Health Organization (WHO) Covid-19 mRNA Vaccine Technology Transfer Hub to expand the capacity of low- and middle-income countries to produce Covid-19 vaccines and scale up manufacturing.
- Until widespread vaccination is in place globally, prioritize the health and human rights of people, especially those in low- and middle-income countries, and take the following measures:
    - Commit to non-profit pricing until widespread vaccination is in place globally;
    - Commit to no price increases in vaccine pricing after the pandemic phase until widespread vaccination is in place globally; and
    - Commit to third-party audits of non-profit pricing similar to J&J's commitment and publish results.
- Support India and South Africa's proposal at the World Trade Organization to waive certain IP rules under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) until widespread vaccination is in place globally. At a minimum, refrain from advocating against the TRIPS waiver and the use of TRIPS flexibilities.

Increase transparency to "know and show" how the company respects its human rights responsibilities

- Immediately publish and periodically update the total number of doses that the company has committed to supplying to countries around the world, including a breakdown of volume commitments across different categories—high-income, upper-middle-, lower-middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others;
- Build on good practices set by the COVAX Interim Distribution List and the UNICEF Pricing Database, and publish an index of all parties that Pfizer supplies, listing name of the entity, month/year when supply was delivered, and procurement price;
- Publish all Covid-19 procurement contracts with government agencies by July 1, 2021. Do not request exemptions to freedom of information laws or other financing rules, and withdraw any pending or current requests for exemptions;
    - Create an easily accessible process for any parties, including civil society, to request NDA exemptions in line with Guideline 8 of the Human Rights Guidelines

for Pharmaceutical Companies. Publish information about the process including company contact information and timelines;

- Follow good practices set by the Medicines Patent Pool and publish licensing terms for all licenses governing Covid-19 vaccines by July 1, 2021.
- Publicly disclose information about all relevant patents and patent filings (owned and licensed) for different underlying technologies used to produce, store, and distribute the Covid-19 vaccine, building on good practice by other companies like Moderna.

Annex II: Additional Questions regarding Pfizer's Approach

1. Will the company join the Covid-19 Technology Access Pool and provide open, non-exclusive licenses?
2. Will the company participate in the WHO Covid-19 mRNA Vaccine Technology Transfer Hub?
3. What is the company's timeline and process to review and approve technology transfer requests from manufacturers for the BioNTech/Pfizer Covid-19 vaccine?
4. Please provide a list of all technology transfer requests received by the company, indicating the month/year when the request was made, and final decision.
5. Will the company commit to non-profit pricing, drop any distinctions between pandemic, epidemic, and endemic pricing, and commit to no price escalations until widespread vaccinations are in place globally?
6. Until widespread vaccinations are in place globally, what measures will the company take to refrain from using any public funds received from any government authority or through COVAX to support stock buybacks, executive bonuses, dividends, and other practices that disproportionately benefit shareholders?
7. Will the company publish an index of all parties that Pfizer supplies, listing name of the entity, month/year when supply was delivered, and procurement price?
8. Will the company commit to a third-party audit of all non-profit prices it offers and publish the results?
9. To whom in the company can external parties direct requests for ND exemption?
10. Will the company commit to immediately publishing and periodically updating the total number of doses that the company has committed to supplying, and a breakdown of volume commitments across different categories—high-income, upper-middle-, lower-middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others?
11. Will the company publish its Covid-19 procurement contracts with government agencies by July 1, 2021?
12. Will the company follow good practices set by the Medicines Patent Pool and publish licensing terms for all licenses governing Covid-19 vaccines by July 1, 2021?

Arvin Ganesan
Director, Business and Human Rights Division
Human Rights Watch

Dear Mr. Ganesan,

Thank you for your follow up letter. We know there is a lot of interest in every aspect of our work in relation to our COVID-19 vaccine and are grateful for all feedback. We have reviewed with attention your recommendations and questions.

I would like to reiterate that Pfizer's purpose – *Breakthroughs that change patients' lives* – is the driver of everything we do. Equity, among our four Company values[1], determines how we deliver on our purpose and, in consequence, profoundly guides the ways in which we work to fulfill our responsibility to respect human rights.

Our multi-pronged approach to enable global equitable and affordable access to COVID-19 vaccines is the result of an assessment that had the most vulnerable in mind:

- We chose to charge a price that was set based on the income level of each country which allowed Governments to distribute our vaccine to their citizens for free;
- We partnered with global health stakeholders to help strengthen healthcare systems where greater support may be needed to deploy COVID-19 vaccines; and,
- We continue investing in innovation to enable access, advancing research into the needs of specific populations and of the evolution of the disease.

As the pandemic continues to ravage, our priority remains the same: *fair and equitable distribution of our COVID-19 vaccine.* To do this, we continue supporting Governments in their efforts to fulfil their duty to protect their people by ensuring there is enough supply of vaccines for everyone. We have announced that we will provide to the world more than 2.5 billion doses in 2021. In fact, our internal target is 3 billion doses, and by extrapolation, 4 billion doses in 2022. These doses are not for the rich or poor, not for the north or south. These are doses for ALL.

Although today most of the approximately 450 million doses we have shipped have gone to high income countries for a variety of reasons (including the time of their regulatory approvals and operational readiness), we actively took action, including me personally reaching out to Heads of State, to address the risk this imbalance represented to people in lower income countries. In many cases, Governments had decided to prioritize vaccines from other manufacturers whose supply forecasts have, unfortunately, not been met. Pfizer also engaged with

[1] The four values that guide Pfizer's culture are Equity, Joy, Excellence and Courage.

COVAX since the early phase of the pandemic. Thanks to these efforts, we now expect the supply balance to weigh in favor of middle- and low-income countries in the second half of 2021, and to have virtually enough supply for all in 2022.

At the G20-Global Health Summit last week we pledged to provide 2 billion doses of our COVID-19 vaccine to middle- and low-income countries over the next 18 months. We expect to provide 1 billion of these doses to low- and middle-income countries this year. And we pledged to deliver another 1 billion doses to these countries in 2022. Upon finalization of all agreements, we expect 40% of our planned supply to go to low- and middle -income countries.

As of May 10, Pfizer-BioNTech doses allocated through COVAX have reached countries in every region of the world, including Rwanda, South Korea, Colombia, Peru, Cabo Verde, Tunisia, West Bank and the Gaza Strip, Moldova, El Salvador, Mongolia, the Maldives, Bosnia and Herzegovina, Georgia, the Ukraine, Bolivia and the Philippines.

In the next round of COVAX allocations, Pfizer/BioNTech doses have been allocated to nearly 50 diverse countries and territories through June 2021, and we continue to engage with COVAX in discussions on how to get more doses to more people.

We are committed to positive health outcomes for people everywhere and continue working to continuously improve wherever we can. For example, when we saw the situation in India turned into an urgent emergency we decided to act.

India

Our colleagues at distribution centers in the United States, Europe and Asia have been hard at work rushing shipments of critical Pfizer medicines used to support hospitals and patients dealing with the impact of coronavirus; these medicines have been identified by the Government of India as a key part of their COVID-19 treatment protocol.

We are donating enough of these medicines to ensure that every COVID-19 patient in every public hospital across India can have access to them for 90 days free of charge. This includes steroid medications to reduce inflammation, anticoagulants to help prevent blood clotting and antibiotics that treat secondary bacterial infections. These donated medicines, valued at up to $70 million, have already been made available, and we are working closely with the government and our NGO partners to get them to where they are needed most.

This effort, in combination with Pfizer Foundation funding that supports humanitarian organizations providing essential and life-saving equipment to India, such as ventilators, oxygen concentrators and consumables, is our most comprehensive humanitarian relief response ever.

We are currently discussing with the Indian government an expedited approval pathway to make our Pfizer-BioNTech vaccine available for use in the country. We will continue to work to meet the public health

need and to collaborate with the Government of India to establish a path forward for our vaccine.

Intellectual property, pricing and access

I would like to emphasize that our approach to intellectual property remains aligned with our commitment to human rights and with our purpose - *Breakthroughs that change patients' lives*. We believe it also aligns fully with our responsibilities towards stakeholders *and* shareholders to deliver on our purpose.

Today the key restriction to vaccine manufacturing is the scarcity of highly specialized raw materials needed for production. The proposals to waive intellectual property threatens to disrupt this flow of raw materials. It will unleash a scramble for the critical inputs manufacturers require in order to make a safe and effective vaccine. So it is not a suitable measure to bring more vaccines to people in need today.

Our decision to implement a tier pricing approach reflects our vision about Equity. Equity doesn't mean we give everyone the same. Equity means we give more to those that need more, the most vulnerable. We continue committed to provide our COVID-19 vaccine to low-income and lower-middle-income countries at a not-for-profit price.

I have shared all these views publicly, and in the answers to your additional questions below you will find more details.

To conclude, we recognize and are concerned by the complex evolution of the pandemic and how it continues to have severe impacts on individuals, families and communities. We continue to regularly evaluate the risks it poses to people, particularly in the most vulnerable geographies, and among the most vulnerable groups of society. No single organization or Company can solve the equity challenge alone. We are committed to continue evolving and improving our response to this pandemic where we can. For this, we welcome the opportunity to engage with all stakeholders and to listen to external perspectives, such as yours. We value the opportunity to reflect on what we have already achieved, and our lessons learned, and will be continuing this conversation internally in line with our commitment to continuous improvement.

We remain fully focused on getting high-quality, safe and effective vaccines to patients all over the world as quickly as possible and to helping end this deadly pandemic.

Sincerely,

[redacted]

Albert Bourla

Answers to additional questions

1. *Will the company join the Covid-19 Technology Access Pool and provide open, non- exclusive licenses?*

We knew that no one company, vaccine or treatment would be enough to combat this pandemic and that we need to harness the potential of the full biotechnology ecosystem. That is why, in March of last year, we committed to sharing our scientific tools and insights, development expertise, and manufacturing capacity in our 5-Point Plan. We also stood in solidarity with industry leaders and pledged to protect scientific integrity, building on our rich history in vaccine research and development. One year later, there is increasing hope that the world will defeat the COVID-19 pandemic thanks to the outcomes of these unprecedented mobilization and collaborations, including the one we launched with our collaboration partner BioNTech that enabled the development of the Pfizer-BioNTech COVID-19 vaccine.

As mentioned in our April 26 letter, Pfizer welcomes voluntary initiatives that add to the pool of resources and options available to promote equitable access to COVID-19 therapies and vaccines and we remain committed to constructive dialogue with all parties. We will continue to consider all reasonable options and mechanisms as needed to ensure that the vaccine and any potential therapies to help address the pandemic are accessible to those who need it.

We are committed to helping ensure the vaccine is made available and we have gone to enormous efforts, including manufacturing at-risk before our clinical trial program was even completed, to put us in the best possible position as we seek to serve populations all over the world. COVID-19 vaccines are complex biologic products, and their manufacturing requires specialized experience, expertise, and equipment. It is not as simple as sharing a “recipe.” With only two mRNA vaccines in use globally, for the first time ever, only a few facilities in the world are able to perform the critical steps needed to manufacture mRNA vaccines and the inputs to produce those vaccines at a large scale. These challenges, in addition to tackling major logistical and healthcare delivery hurdles, are the true barriers to global vaccine distribution.

There is enormous collaboration to overcome these obstacles already taking place. Manufacturers with the appropriate expertise, technical capabilities, and facilities have entered into partnerships and licensing agreements to speed up the production and distribution of vaccines. For example, Thermo-Fisher, Sanofi, and Novartis are supporting the Pfizer-BioNTech efforts to increase the supply of our COVID-19 vaccine, which includes, expanding our manufacturing facilities and adding more suppliers and contract manufacturers to our supply chain.

2. *Will the company participate in the WHO Covid-19 mRNA Vaccine Technology Transfer Hub?*

The development, manufacturing, distribution and storage of complex innovative products, including the mRNA technology, requires globally-optimized supply chains and we are actively focused on production arrangements to support a robust and reliable global supply chain. We are one of the few companies that still develop and manufacture vaccines on a large scale. For biologics, sterile injectables and vaccines, we have approximately 17,000 colleagues in 23 manufacturing facilities in 11 countries. Pfizer is also one of the largest producers of generic sterile injectable products for the US market. We do the vast majority of our sterile filling internally for our branded and generics business, but we do use a great network of outside suppliers that do more specialized sterile filling for us.

Early on, we determined that the best way to quickly and safely manufacture this vaccine would be to activate our extensive manufacturing network in Europe and the United States, including thousands of highly skilled workers, to prepare to produce the COVID-19 vaccine for those most in need around the world. At this point we are favoring global contract manufacturers with broad regulatory approvals and

significant available capacity over local contract manufacturers in individual markets. Localizing vaccines requires a significant lengthy process as well as commitment of technical and personnel resources, resources that could have to be pulled away from our production of the vaccine; therefore Pfizer is focusing our efforts and resources in a way that maximizes our overall supply so we can better support the global needs.

We have undertaken significant efforts to scale up capacity and enhance efficiency. For example, we have added suppliers as well as contract manufacturers, made process improvements to our existing production lines, and we are also making continuous improvements in our sites. We also expanded the supply of raw material from existing suppliers and brought on new suppliers. We doubled our batch sizes in order to minimize time between batches and increased the yield per batch. Our efforts to date have paid off: we have increased projected 2021 global production from 1.3 billion doses, to more than 2 billion doses.

3. *What is the company's timeline and process to review and approve technology transfer requests from manufacturers for the BioNTech/Pfizer Covid-19 vaccine?*

As referenced above, we determined that the best way to quickly and safely manufacture the Pfizer-BioNTech COVID-19 vaccine would be to activate our extensive manufacturing network in Europe and the United States. For immediate supply needs, we are favoring global contract manufacturers with broad regulatory approvals and significant available capacity over local contract manufacturers in individual markets. We do however continue to work on a mid-to long term supply strategy and capacity expansion. Any new additions to our existing network of external supply partners undergo a well-established and stringent supplier qualification process. Timing required to onboard new contract manufacturer organizations (CMOs) is highly dependent on their individual capabilities, infrastructure and technical know-how. To ensure consistent quality and maintain public trust, it is essential that any new supplier meets the appropriate Pfizer quality requirements/standards.

4. *Please provide a list of all technology transfer requests received by the company, indicating the month/year when the request was made, and final decision.*

Since the launch of our COVID-19 Vaccine, we have been approached by several CMOs outside of our current network with offers to provide extra manufacturing capacity. As we rapidly build our supply capabilities for the vaccine within our existing network, we believe that using our established and qualified supplier network is the most effective way of maximising high-quality output in the shortest time. Planning for the future, Pfizer continues to evaluate new manufacturing partners with appropriate manufacturing expertise, technical capabilities, trained personnel, qualified facilities and scientific expertise.

5. *Will the company commit to non-profit pricing, drop any distinctions between pandemic, epidemic, and endemic pricing, and commit to no price escalations until widespread vaccinations are in place globally?*

As stated in our 26 April letter, we have established pricing principles for our potential COVID vaccine which are consistent with Pfizer's commitment to the right to health, our values and our mission to bring breakthroughs that change patients' lives. These are extraordinary times, and our pricing reflects that. During the pandemic, we priced our vaccine consistent with the urgent global health emergency we are facing to help ensure widespread vaccination for all countries that supply our vaccine. Our pricing enables governments to offer the vaccine at little to no out-of-pocket costs for their populations.

Volume of doses ordered, advance commitments, and equity considerations are key drivers in our government contract pricing. We have a tiered pricing approach that enables poorer countries to pay less, taking these considerations into account.

In all agreements, we will deploy the same pricing approach for high, middle, and low-income countries with low and lower-middle income countries paying a not-for-profit price. High and middle-income countries will pay more than low-income countries, but at a value that is significantly discounted from our normal benchmarks during the pandemic.

6. *Until widespread vaccinations are in place globally, what measures will the company take to refrain from using any public funds received from any government authority or through COVAX to support stock buybacks, executive bonuses, dividends, and other practices that disproportionately benefit shareholders?*

First, we would like to share that Pfizer is an early signatory of the Business' Roundtable Statement of the Purpose of a Corporation. In the statement we affirmed that each of our *stakeholders* is essential and committed to deliver value to *all* of them. This of course applies across all our business activities, including our pandemic response.

As indicated in our 26 April letter, Pfizer's COVID-19 vaccine development and manufacturing costs have been entirely self-funded. We made the early decision to begin clinical work and large-scale manufacturing at our own risk to ensure that product would be available immediately if our clinical trials prove successful, and an Emergency Use Authorization granted. In 2020, we invested more than $650million at risk in capital to advance our COVID-19 vaccine program and ordered more than $300 million in raw material, including specialized lipids, freezers and specialized transportation shippers. Recently, we decided to devote additional $600 million spending on COVID-19 research and development that will bring our total spend for R&D in 2021 to more than $10 billion.

The agreements Pfizer has entered with Governments are for supply of vaccine to their people, not for vaccine development. If Pfizer was unable to supply and approved vaccine, it wouldn't be entitled to any payment. We have invested from our own resources/flow of revenues at risk and are prepared to continue to bear the costs of development and manufacturing to advance a solution to this pandemic.

7. *Will the company publish an index of all parties that Pfizer supplies, listing name of the entity, month/year when supply was delivered, and procurement price?*

So far, we have shipped a total of approximately 450 million doses to more than 90 countries and territories in all regions of the world.

As of May 10, Pfizer-BioNTech doses allocated through COVAX have reached countries in every region of the world, including Rwanda, South Korea, Colombia, Peru, Cabo Verde, Tunisia, West Bank and the Gaza Strip, Moldova, El Salvador, Mongolia, the Maldives, Bosnia and Herzegovina, Georgia, the Ukraine, Bolivia and the Philippines.

In the next round of COVAX allocations, Pfizer/BioNTech doses have been allocated to nearly 50 diverse countries and territories around the world through June 2021, and we continue to engage with COVAX in discussions on how to get more doses to more people.

Certain details of our contracts, such as pricing, need to keep confidential as is customary in commercial transactions, so as not to prejudice the parties or ongoing negotiations around the world.

8. *Will the company commit to a third-party audit of all non-profit prices it offers and publish the results?*

Pfizer believes it has and will continue to engage in transparent and appropriate pricing consistent with Pfizer's commitment to the right to health, our values and our mission to bring breakthroughs that change patients' lives.

9. *To whom in the company can external parties direct requests for NDA exemption?*

Freedom of Information or Right of Information Laws provide a mechanism for interested parties to seek certain information from governments, and Pfizer cooperates with governments when they receive such inquiries, consistent with those countries' laws.

10. *Will the company commit to immediately publishing and periodically updating the total number of doses that the company has committed to supplying, and a breakdown of volume commitments across different categories—high-income, upper-middle-, lower- middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others?*

Based on current projections, Pfizer's and BioNTech's combined manufacturing network has confirmed supply of 2.5 billion doses in 2021, but our aim is to produce 3 billion doses this year. We have concluded agreements to supply 116 countries to date. Upon finalization of all agreements, we expect that approximately 40% of our doses, more than 1 billion, will go to middle- and low-income countries in 2021. Pfizer has committed 2 billion doses – 1 billion in 2021 and 1 billion in 2022 to go to low-and middle-income countries.

As of May 10, Pfizer-BioNTech doses allocated through COVAX have reached countries in every region of the world, including Rwanda, South Korea, Colombia, Perú, Cabo Verde, Tunisia, West Bank and the Gaza Strip, Moldova, El Salvador, Mongolia, the Maldives, Bosnia and Herzegovina, Georgia, the Ukraine, Bolivia and the Philippines.

In the next round of COVAX allocations, Pfizer/BioNTech doses have been allocated to nearly 50 diverse countries and territories around the world through June 2021, and we continue to engage with COVAX in discussions on how to get more doses to more people.

Last week we pledged to provide 2 billion doses of our COVID-19 vaccine to middle- and low-income countries over the next 18 months. We expect to provide 1 billion of these doses to low- and middle-income countries this year. And we pledged to deliver another 1 billion doses to these countries in 2022.

11. *Will the company publish its Covid-19 procurement contracts with government agencies by July 1, 2021?*

As mentioned in our 26 April letter, we have worked with governments around the world to balance our efforts to be transparent with local laws, and the need to keep certain details of our contracts confidential, as is customary in commercial transactions, so as not to prejudice the parties or ongoing negotiations around the world.

Freedom of Information or Right of Information Laws provide a mechanism for interested parties to seek certain information from governments, and Pfizer cooperates with governments when they receive such inquiries, consistent with those countries' laws.

12. *Will the company follow good practices set by the Medicines Patent Pool and publish licensing terms for all licenses governing Covid-19 vaccines by July 1, 2021?*

As mentioned in our 26 April letter, we are proud of the transparency we have demonstrated throughout the vaccine development process and in engagements with governments. It started with our commitment to openly sharing the details of our clinical trial program and publishing data at the earliest opportunity in peer reviewed journals. We have throughout the process worked to provide as much information as we are able

as to when we expect to meet manufacturing targets, sharing this critical information with the public to help governments and individuals manage expectations and logistics.

We have worked with governments around the world to balance our efforts to be transparent with local laws, and the need to keep certain details of our contracts confidential, as is customary in commercial transactions, so as not to prejudice the parties or ongoing negotiations around the world.

Freedom of Information or Right of Information Laws provide a mechanism for interested parties to seek certain information from governments, and Pfizer cooperates with governments when they receive such inquiries, consistent with those countries' laws.

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HUMAN RIGHTS WATCH

HRW.org

June 10, 2021

Stéphane Bancel
Chief Executive Officer
Moderna, Inc.
200 Technology Square
Cambridge, MA 02139
via email: [redacted]

Re: Human Rights Due Diligence Surrounding the Covid-19 Vaccine

Dear Mr. Bancel,

We are writing on behalf of Human Rights Watch, an international nongovernmental organization working on a range of human rights issues globally, including corporate accountability. We have been working on issues related to business and human rights for over two decades.

Human Rights Watch has been documenting the devastating human rights impacts of the Covid-19 pandemic. Among other things, we have advocated for rights-based approaches to Covid-19 vaccine research, development, manufacture, and distribution, to maximize the availability and affordability of vaccines.

As part of our research on Covid-19 vaccines, we are contacting companies producing Covid-19 vaccines, starting with those that have received World Health Organization (WHO) Emergency Use Listing. Companies like yours have an important role to play in maximizing vaccine availability and affordability.

We are writing to learn more about Moderna's human rights due diligence, including policies and practices surrounding its Covid-19 vaccine. We were also part of a large group of civil society organizations and individuals that wrote to your company in December 2020.

All companies, including pharmaceutical companies, have a responsibility to respect human rights standards and principles and conduct effective human rights due diligence in accordance with the UN Guiding Principles on Business and Human Rights (UNGPs). Pharmaceutical companies also have responsibilities as outlined in the 2008 Human Rights Guidelines for

Pharmaceutical Companies in relation to Access to Medicines issued by the UN Special Rapporteur on the Right to Health. These are explained in more detail in Human Rights Watch's February question-and-answer document: Universal and Equitable Access to Covid-19 Vaccines, Testing, Treatments: Companies' Human Rights Responsibilities.

As part of our work and in the interest of thorough and objective reporting, we would like to learn more about Moderna's human rights policies, practices, and due diligence processes, especially those relevant to its Covid-19 vaccine, and steps it has taken to make its vaccine widely available and affordable. In the Annex, we have provided a summary of information we have reviewed using publicly available sources, followed by a set of questions requesting additional information about (A) Overall policies and human rights approach to human rights due diligence; (B) Global allocation and delivery; (C) Supply; (D) Technology transfers; (E) Affordable pricing strategy; (F) Indemnification; (G) Contracts to supply vaccines; (H) Licensing agreements; and (I) TRIPS waiver, TRIPS flexibility, and intellectual property.

We request a written response to the questions and any other relevant information by **June 24, 2021**, via email to my colleague, [redacted]. All responses received by June 24 may be reflected in our publications.

We thank you for your consideration. Please do not hesitate to contact us for any clarifications, to provide the information requested, or to coordinate a conference call with us.

Best regards,

[redacted]

Arvind Ganesan
Director, Business and Human Rights Division
Human Rights Watch

CC:
Stephen Hoge, President: [redacted]
Lavina Talukdar, Senior Vice President and Head of Investor Relations:
[redacted]

Annex: Summary of Information Reviewed and Questions Regarding Covid-19-Specific Human Rights Due Diligence

A. Overall Policies and Approach to Human Rights Due Diligence

Summary of Information Reviewed

We have reviewed Moderna's December 2020 "Commitment to Vaccines and Therapeutics Access"; October 2020 "Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic," Code of Business Conduct and Ethics and Corporate Governance Guidelines (both adopted in September 2018 and updated in December 2020); November 2020 Human Rights policy, as well as other materials on Moderna's website, including those published as part of its NewsRoom, blog posts, and its CSR Whitepaper.

Questions

1. Policies

Does the company have a specific equitable access policy which applies to its business operations related to Covid-19 vaccines, including manufacturing, marketing, and distribution? Please provide more information, including copies of any written policies and how all policies are embedded across the company's operations.

2. Human rights due diligence processes

What steps has the company taken to conduct Covid-19 specific human rights risk assessments? Please outline all the *risks identified*, the *prevention, mitigation, and remedial measures* the company undertook, and the *indicators being used to track and assess the progress* of the company's prevention and mitigation strategy. Please provide information concerning the following risks:

a. Barriers to availability of the vaccine because of insufficient diffusion and sharing of technological know-how required to scale up manufacturing.
b. Barriers to availability of the vaccine because of intellectual property (IP) rights risks that can curb scale-up of manufacturing and distribution.
c. Barriers to affordability of the vaccine.
d. Barriers to accessibility of the vaccine.

3. Consultation with stakeholders and potentially affected groups

Please describe the methodology used by the company to conduct such risk assessments regarding its Covid-19 vaccine supply and affordable pricing strategy, including a list of

"potentially affected groups" or "at-risk" populations and stakeholders that the company has consulted.

B. Global Allocation and Deliveries

Summary of Information Reviewed

In February 2021, news reports estimated that a vast majority of Moderna's vaccines were supplied to predominantly high-income countries, including the US, EU, Japan, Canada, Australia, South Korea, Switzerland, and the UK, and at least one middle-income country, the Philippines. We understand that in May 2021 Moderna agreed to supply the COVAX Facility with up to 500 million doses of its Covid-19 vaccine. According to the Coalition for Epidemic Preparedness and Innovations (CEPI), which also provided some funding to Moderna, the company has "agreed to CEPI's equitable access principles meaning that appropriate products are first available to populations when and where they are needed and at prices that are affordable to the populations at risk, especially low- and middle- income countries or to public sector entities that procure on their behalf."

Questions

1. Please provide the total number of doses that the company has committed to supplying to date, and a breakdown of volume commitments across different categories—high-income, upper-middle-, lower-middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others.
2. What factors does the company consider in decisions about how it sequences distribution of vaccines to different countries?
3. Does the company plan to publish a list of all national authorities, intergovernmental organizations, COVAX Facility, and other entities it supplies, building on the good practice set by the COVAX Interim Distribution Forecast and UNICEF's price transparency database? If yes, by when?
4. What steps has the company taken to implement CEPI's equitable access principles, especially with regards to supplying low- and middle-income countries? Has the company received any communication from CEPI on its compliance, or lack thereof, with the equitable access principles?

C. Supply

Summary of Information Reviewed

We understand that Moderna's vaccine production is currently carried out mostly in the US and Europe through partnership agreements with Lonza (Switzerland), Catalent (US), ROVI (Spain),

and Sanofi (US); outside US/Europe, Moderna has a partnership with Samsung (South Korea). We note that Moderna expects to produce 3 billion doses of Covid-19 vaccines in 2022, and revised its 2021 manufacturing forecast to between 800 million and 1 billion vaccine doses. We are also aware that since January 2021 the European Commission introduced rules that can restrict export of Covid-19 vaccines from EU Member States. We also understand that Moderna draws a distinction between the pandemic and endemic supply phases.

Questions

1. Please provide information about the company's global manufacturing capacity for its Covid-19 vaccine, its manufacturing plans and objectives, and steps the company has taken to scale up manufacturing capacity for the vaccine between 2020 and 2023?
2. How does Moderna define the "pandemic phase" and how will the company determine when the pandemic phase is over?
3. What steps is the company taking to diversify its manufacturing to mitigate against the risk of export restrictions?

D. Technology Transfers

Vaccine manufacturers from other regions, including India and Bangladesh, have reportedly approached Moderna with proposals to explore manufacturing collaborations. We further understand that Moderna was able to build the capacity of contract manufacturers in Germany and Switzerland in less than six months. Experts on IP and access to medicines have argued that manufacturing of Moderna's Covid-19 vaccine could be dramatically expanded if the company transferred technology and shared know-how more widely.

Questions

1. We understand that Moderna has not yet joined the Covid-19 Technology Access Pool. Please detail the reasons for this decision and whether any steps are underway to join.
2. We understand that Moderna has yet to join the WHO Covid-19 mRNA Vaccines Technology Transfer Hub. Please detail the reasons for this decision and whether any steps are underway to join.
3. What steps is the company taking to conduct technology transfers related to its Covid-19 vaccine to contribute to building the manufacturing capacity of low- and middle-income countries?
4. Does the company restrict commercialization rights where it conducts technology transfers, especially the ability to export?
5. What is the company's timeline and process to review and approve licensing/technology transfer requests from manufacturers for its Covid-19 vaccine?

6. Have you received any direct requests to license or transfer technology for vaccine production? If so, please provide a list of all licensing/technology transfer requests received by the company, indicating the month/year when the request was made, and final decision.

E. Affordable Pricing Strategy

Summary of Information Reviewed

We understand that Moderna's vaccine is significantly funded by public money from the US government. Moderna saw its first ever quarterly profits from Covid-19 vaccine sales and projected a full year forecast of $19.2 billion. Unlike Pfizer, AstraZeneca, or Johnson & Johnson, we understand that Moderna has yet to make any commitment to supply any part of its vaccines at non-profit rates. Based on publicly available information on the UNICEF Covid-19 Dashboard, we gathered the following information for Moderna's vaccine pricing per dose: $15 to the US; $18 to the European Commission; and $32 to $37 for other high-income countries. We understand that according to Moderna's Commitment to Vaccines and Therapeutics Access, there is differentiated pricing, including Moderna's commitment to providing "Gavi eligible countries" with "Moderna's lowest prices" and to an "annual third party audit of this commitment." We would like more clarity on the steps Moderna is taking to make the vaccine affordable and accessible.

Questions

1. Please provide information about Moderna's affordable pricing strategy for its Covid-19 vaccines, including information about the criteria factored into determining affordable prices throughout the world. In particular, please provide details on how Moderna's affordability strategy may differ in the pandemic and endemic phases.
2. Companies like AstraZeneca and Johnson & Johnson have committed to non-profit pricing for their Covid-19 vaccines. Does Moderna plan to make a similar commitment?
3. How does Moderna's affordable pricing strategy apply to its licensee-manufacturers?
4. Johnson & Johnson committed to a third-party audit and verification of its non-profit pricing. We note Moderna committed to an annual third party audit of its own "lowest price" commitment. Please provide information regarding the third-party auditor, methodology, timeframe, and scope of the third-party audit. When will results be made publicly available?
5. How much government and nongovernment (philanthropic) funding has supported the development of the company's vaccine (including the different stages of innovation) and how much money has Moderna received through advance market commitments?

6. What is the estimated private investment in vaccine development, manufacture, and distribution?
7. Until widespread vaccination is in place globally, what measures will the company take to refrain from using all public funds received from any government authority or through COVAX to support stock buybacks, executive bonuses, dividends and other practices that disproportionately benefit shareholders?

F. Indemnification

Questions

1. Please provide details on the indemnification requirements Moderna has sought from government authorities, and the conditions that the company may make as a precondition for countries to receive its vaccines through the COVAX Facility.
2. Has Moderna requested that governments provide any assets as collateral for the vaccine? If so, please list the governments that have made those commitments and the assets pledged.

G. Contracts to supply vaccines to national authorities/intergovernmental organizations/COVAX Facility

Summary of Information Reviewed

Contract transparency is key to providing the public a way to monitor government spending and is a bulwark against conflicts of interest and corruption. Many governments have procurement rules that obligate them to publish public contracts, and many have specifically committed to publishing Covid-19-related contracts as part of their emergency loan agreements with the International Monetary Fund. The World Bank's rules also require governments to publish contract awards it finances, including related to Covid-19.

We note that Knowledge Ecology International reports that Moderna has disclosed at least two of its contracts with US government authorities, as part of its SEC filings.

Questions

1. Does the company plan to publish all its contracts related to the supply of its vaccines? If yes, by when will the company publish such a database on its website?
2. What measures does the company take to enable government compliance with Freedom of Information or Right to Information Laws or other good practices around government disclosure of contracts?

3. To whom should civil society and other interested parties direct queries regarding contracts and make requests for exemption to NDAs?

H. Licensing agreements

Summary of Information Reviewed

We understand that Moderna has voluntary licensing agreements in place with several manufacturers, as described above. We are interested to learn about the company's efforts to make information about these and other agreements publicly available. We note that Dr. Tedros Adhanom Ghebreyesus, director-general of the WHO, recently commented that voluntary licensing agreements "tend to be exclusive and nontransparent, compromising equitable access." We note that Moderna has published at least one of its licensing agreements as part of its SEC filing.

Questions

1. What measures is Moderna taking to adopt good practices set by the Medicines Patent Pool to voluntarily publish licensing agreements related to Covid-19vaccines?
2. How many licensing agreements in total has Moderna negotiated for its Covid-19 vaccine to date? Please provide a summary of all licenses issued with regard to Covid-19 vaccine manufacturing and outline the terms of the license and the license period. Please elaborate why the company has/has not agreed to voluntary, open, nonexclusive and global licenses.

I. TRIPS Waiver, TRIPS Flexibilities, and Patents

Summary of Information Reviewed

We note that Moderna has committed not to enforce its "Covid-19 related patents" "while the pandemic continues" and to allow licensing of those patents following the end of a "pandemic" phase, and has also begun disclosing some of them. The director-general of the WHO and more than 100 governments, including the US and New Zealand, have supported the proposal before the World Trade Organization (WTO) that would temporarily waive some IP rights under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) until "widespread vaccination is in place globally." Trade groups that Moderna is a member of, such as the Biotechnology Innovation Organization, have reportedly lobbied against the TRIPS waiver.

Questions

1. Please detail whether Moderna will support the TRIPS waiver proposal in light of so many other relevant stakeholders', including the WHO's and US government's, views in support of the waiver.
2. How will the company respond to a government's use of public health safeguards and flexibilities included in the WTO TRIPS Agreement and reaffirmed by the Doha Declaration to discharge their human rights obligations to life and health?
3. Can the company clarify how many patents related to Covid-19 it owns or has filed, and which among them it plans not to enforce, and where similar commitments are outstanding?
4. What steps is the company taking to build on its good practice and disclose information about all relevant patents and patent filings (owned and licensed) for different underlying technologies used to produce, store, and distribute its Covid-19 vaccine?

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June 29, 2021

Arvind Ganesan
Director, Business and Human Rights Division
Human Rights Watch
350 Fifth Avenue, 34 Floor
New York, NY 10118

Dear Mr. Ganesan

I am writing on behalf of Mr. Stephane Bancel, CEO Moderna, in response to your letter of June 10, 2021.

Background

Moderna was only founded a decade ago, and our COVID-19 vaccine is our first commercial product. Since our founding, our mission has been to improve patients' lives by creating a new generation of transformative medicines based on messenger RNA ("mRNA").

For our first decade, Moderna focused on research and development. We designed our strategy and operations to unlock the potential of mRNA over a long term horizon. We raised billions of dollars in capital and built and invested in our technology platform, which creates mRNA sequences that cells recognize as if they were produced in the body. We have announced twenty-four therapeutic and vaccine development programs to date. These programs span a wide range of conditions, including infectious diseases, immuno-oncology, rare diseases, autoimmune diseases, and cardiovasculardiseases.

This decade of research taught us valuable lessons about designing mRNA medicines, including vaccines. We learned how to manufacture and formulate mRNA that can be safely injected into people and induce an appropriate immune response. We also gained experience producing over 100 batches of mRNA for use in human clinical trials.

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When COVID-19 emerged, Moderna was able to develop our vaccine quickly because we leveraged our prior research, experience, and mRNA platform. We progressed from genetic sequencing to a vaccine ready for human testing in just 63 days. After clinical trials, on December 18, 2020, the U.S. Food & Drug Administration authorized the emergency use of our COVID-19 vaccine. This was the first time any Moderna product has been authorized for use outside of clinical testing.

Producing a vial of our vaccine is a multiple-stage process. First, we have to create large batches of the drug substance: mRNA encapsulated in a lipid nanoparticle. This first stage is itself a multistep process that requires the availability of raw materials and consumable supplies. The second and third major stages of the production process are filling vials with the drug substance, and then inspecting, testing, and packaging the filled vials for delivery. At any given time, millions of doses of our vaccine will be at different stages of this process.

The pace and volume of our production process has increased exponentially since we began making our vaccine, for several reasons. First, over time, the buildup of the product and other necessary supplies at each stage generally allows subsequent stages to operate more efficiently. Second, the pace also increases as the process gets refined and the highly skilled and experienced personnel operating that process gain greater familiarity with it. Third, as discussed below, we have been able to gradually onboard additional partners to expand our capacity.

Obviously, greater scale and speed cannot come at the expense of safety and quality. Ensuring both requires careful planning and specialized knowledge sharing between Moderna and its contract partners. As such, conducting technology transfers and ramping up new production lines requires significant time from a limited pool of experienced personnel with the requisite expertise.

Notwithstanding these challenges, to date, Moderna has produced and shipped well over 200 million doses of our vaccine, and we currently forecast producing between 800 million to 1 billion doses in 2021.

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Expanding Global Vaccine Access

As we have said in recent public statements—both during our Annual Meeting of Shareholders and during our first quarter earnings call—we do not believe that a waiver of the protections under the World Trade Organization ("WTO") Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") or the contribution of our intellectual property to the World Health Organization's ("WHO") COVID-19 Technology Access Pool ("C-TAP") are effective ways of rapidly expanding access to COVID-19 vaccines. We have undertaken several measures that we believe *will* meaningfully increase access to vaccines as quickly as possible, as further described below.

Supplying Up To 500 Million Doses To COVAX

On May 3, 2021, we announced that we have entered an agreement to supply up to 500 million doses of our vaccine to COVAX, including an initial 34 million doses to be delivered in the fourth quarter of 2021.[1] The agreement covers the 92 Gavi COVAX Advance Market Commitment low- and middle-income countries, and gives Gavi, the Vaccine Alliance, the option to procure 466 million additional doses in 2022. This agreement came just days after the WHO issued an Emergency Use Listing for Moderna's vaccine, a prerequisite to reaching agreement to supply COVAX. All doses are offered at Moderna's lowest tiered price.

Forming Partnerships to Increase Manufacturing Capacity

Moderna has entered into voluntary licensing arrangements to manufacture its vaccine and expand supply around the world. In the United States, Moderna's vaccine is produced both at its own Norwood, Massachusetts facility and at a facility in Portsmouth, New Hampshire operated by our contract manufacturing partner, Lonza Ltd. Moderna has also formed partnerships for the "fill-finish" stages of the process in the United States. That work is done by partners Catalent (in Bloomington, Indiana), Baxter BioPharma Solutions (in Bloomington,

[1] Moderna, Press Release: *Moderna Announces Supply Agreement with Gavi for up to 500 Million Doses of COVID-19 Vaccine Moderna for COVAX To Help End COVID-19 Pandemic in Lowest Income Countries* (May 3, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-gavi-500-million-doses-covid.

Indiana), Sanofi (in Ridgefield, New Jersey), and Thermo Fisher (in Greenville, North Carolina).

Moderna has also entered into partnerships to produce, fill, and finish its vaccine outside the United States. For nearly a year, Moderna has worked with Lonza to produce our vaccine at Lonza's facilities in Switzerland and The Netherlands. We recently partnered with Laboratorios Farmacéuticos Rovi in Spain for both the manufacturing and fill-finish process. We have also partnered with Recipharm in France for the fill-finish process.

We are committed to pursuing additional partnerships around the world to expedite production and delivery of our vaccine and we are continuing to seek out such agreements such as our agreement with Samsung Biologics in South Korea.

Making a Voluntary Pledge on Intellectual Property

Finally, on October 6, 2020—over seven months ago—Moderna voluntarily pledged not to enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.[2] Our statement noted that Moderna is a pioneer in the development of mRNA vaccines and therapeutics and that, with the support of our investors, we have invested billions of dollars into research and development to make mRNA medicines a reality. We recognized, as a company committed to innovation, that intellectual property rights play an important role in encouraging investment in research. We noted that our portfolio of intellectual property is an important asset that will protect and enhance our ability to continue to invest in innovative medicines.

Notwithstanding that, we explained that Moderna "feel[s] a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible." We pledged that "while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic." We also stated that "to eliminate any perceived IP barriers to vaccine development during the

[2] Moderna, Press Release: *Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic* (October 8, 2020), https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19.

pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period."

Barriers to Vaccine Access

With respect to mRNA vaccines, our view is that the complexity of the manufacturing process and the need to maintain rigorous safety and quality standards impose real constraints on the rate at which we can increase global supply. These practical constraints require cooperative, collaborative partnerships to overcome. As a result, it takes time and requires human expertise to ramp up new manufacturing lines.

There are additional barriers. Limits on raw materials and consumables, along with other supply chain issues, constrain the pace of production. Logistical challenges—such as the lack of cold storage and transportation and infrastructure problems—pose significant challenges to widespread distribution. Finally, local regulatory requirements and trade hurdles (including tariffs, export restrictions, customs procedures) serve as additional barriers to the effort to quickly vaccinate the global population.

Additional Intellectual Property and Technology Transfer Issues

As described above, Moderna has taken major steps to ensure that intellectual property rights are not a barrier to expanding global vaccine access. We have entered into voluntary licensing arrangements, conducted technology transfers, and formed manufacturing partnerships to expand production of our vaccine. We are committed to seeking additional partnerships. We have also voluntarily pledged not to enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic, and we have said that we are willing to license our intellectual property for COVID-19 vaccines to others for the post-pandemic period.

As discussed above, technology transfers require significant time from a limited pool of experienced personnel with the requisite expertise. We are focused on transferring technology to chosen partners around the world—partners that we are confident can produce our vaccine with the utmost commitment to safety and quality. We are prioritizing bringing these manufacturing capabilities and production lines online as quickly as possible. Trying to engage in additional

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technology transfers could put at risk the delivery of our current and upcoming production lines and could have negative efficiency, safety, and quality consequences.

With respect to a TRIPS waiver, we do not believe that waiving TRIPS protections will help increase the global supply of mRNA vaccines in 2021 or 2022. We are not aware of idle mRNA manufacturing capacity. Nor are we aware of companies who have developed manufacturing, purification, and medical processes that would allow them to rapidly run clinical trials and then produce a meaningful supply of mRNA vaccine. As a result, we are focused on the efforts described above to expand global vaccine access, as well as the development of vaccine boosters targeting emerging variants. From a policy perspective, we also believe that weakening intellectual property protections could impede future innovation by making it harder to fund research and development into high-risk, high-reward innovations over a long term horizon.

Sincerely,

[redacted]

John Lepore
SVP, Government Engagement

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HUMAN RIGHTS WATCH

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July 30, 2021

John Lepore
SVP, Government Engagement
Moderna, Inc.
200 Technology Square
Cambridge, MA 02139
via email: [redacted]

Re: Follow-up letter to Moderna regarding Human Rights Due Diligence Surrounding the Covid-19 Vaccine

Dear Mr. Lepore,

Thank you for your response dated June 29 about Moderna's approach to fulfilling its human rights responsibilities.

We are writing to seek additional information, especially about Moderna's commitment to a third-party audit as well as its commitment to not enforce its patents.

We are also writing to share a set of urgent key recommendations to your company to maximize the availability and affordability of Covid-19 vaccines and increase transparency. Our recommendations are outlined in Annex I to this letter. These recommendations assume heightened importance given the ongoing public health crisis the world faces and the urgency of ensuring lifesaving vaccines reach as much of the world as swiftly as possible. The huge surge in Covid-19 infections because of the Delta variant, which was first detected in India, once again shows that until widespread vaccination is achieved globally, people's health and lives will continue to be at risk and economies will struggle to recover.

We are concerned about the public health impacts of Moderna's stated approach to intellectual property (IP), pricing, and transparency. Moderna has not publicly disclosed, or disclosed to Human Rights Watch, enough information to show that it is fulfilling its human rights responsibilities.

We believe the company should undertake robust human rights due diligence in consultation with a wide range of stakeholders including independent health groups, rights groups, humanitarian organizations, and patient rights

advocates, assessing specifically for risks related to adequate supply, manufacturing capacity, the IP landscape, and affordable pricing. Conducting and disclosing that due diligence on an ongoing basis would help build public confidence in Moderna's efforts to combat the pandemic by showing how those risks are mitigated.

We are especially concerned that Moderna's commitments to predominantly supply high income governments coupled with its restrictive licensing practices are significantly limiting the availability and affordability of its Covid-19 vaccine. We note Moderna's assertion that the "pace and volume of our production process has increased exponentially since we began making our vaccine," but are concerned that the company's manufacturing remains located almost exclusively in Europe and North America. We urge the company to use open, non-exclusive licensing to help build manufacturing capacity in low- and middle-income countries and increase global supply of Covid-19 vaccines amid dire shortages.

We also write to request additional information for our reporting to clarify Moderna's position on several issues. Our list of additional questions can be found in Annex II to this letter.

Our recommendations and questions are based on our analysis of the human rights responsibilities of companies researching, developing, and manufacturing Covid-19 vaccines. We request a written response to this letter by August 13, 2021, via email to my colleague, [redacted] All responses received by August 13 may be reflected in our reporting.

Best regards,

[redacted]

Arvind Ganesan
Director, Business and Human Rights Division
Human Rights Watch

CC:
Stephen Hoge, President: [redacted]
Lavina Talukdar, Senior Vice President and Head of Investor Relations: [redacted]

Annex I: Urgent Key Recommendations to Moderna

Take the following steps to meet the company's human rights responsibilities to maximize vaccine availability and affordability.

- Join the Covid-19 Technology Access Pool (C-TAP) and provide open, nonexclusive licenses for all forms of IP underlying the company's Covid-19 vaccine.
    - Extend the company's existing commitment not to enforce any underlying patents **until widespread vaccination is in place globally**.

- Until widespread vaccination is in place globally, prioritize the health and human rights of people, especially those in low- and middle-income countries, and take the following measures:
    - Commit to non-profit pricing for all countries until widespread vaccination is in place globally;
    - Commit to no price increases in vaccine pricing after the pandemic phase until widespread vaccination is in place globally; and
    - Fulfill commitment to conduct a third-party audit of pricing and commit to publish results.

- Support India and South Africa's proposal at the World Trade Organization to waive certain IP rules under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) until widespread vaccination is in place globally. At a minimum, refrain from advocating against the TRIPS waiver and the use of TRIPS flexibilities.

Increase transparency to "know and show" how the company respects its human rights responsibilities.

- Immediately publish and periodically update the total number of doses that the company has committed to supplying to countries around the world, including a breakdown of volume commitments across different categories—high-income, upper-middle-, lower-middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others;
- Build on good practices set by the COVAX Interim Distribution List and the UNICEF Pricing Database and publish an Index of all parties that Moderna supplies, listing name of the entity; month/year when supply was delivered; and procurement price.
- Publish all Covid-19 procurement contracts with government agencies by September1, 2021. Do not request exemptions to freedom of information laws or other financing rules, and withdraw any pending or current requests for exemptions;
    - Create an easily accessible process for any parties, including civil society, to request NDA exemptions in line with Guideline 8 of the Human Rights Guidelines for Pharmaceutical Companies. Publish information about the process including company contact information and timelines.

- Follow good practices set by the Medicines Patent Pool and publish licensing termsfor all licenses governing Covid-19 vaccines by September 1, 2021.
- Expand public disclosure of information about all relevant patents and patent filings (owned and licensed) for different underlying technologies used to produce, store, and distribute the Covid-19 vaccine.

Annex II: Additional Questions regarding Moderna's Approach

1. As stated in our June 10 letter, we understand Moderna committed to an annual third-party audit of its own "lowest price" commitment. Please provide information regarding the third-party auditor, methodology, timeframe, and scope of the third-party audit. When will results be made publicly available?
2. We note that Moderna has agreed to supply doses to COVAX at its "lowest tiered price." Can the company clarify whether its lowest tiered price is a non-profit price? Does the price apply to the 34 million doses being supplied in the fourth quarter of 2021 as well as the additional optional doses that may be supplied in2022?
3. Will the company adopt non-profit pricing for all countries/buyers and commit to no price escalations until widespread vaccination is in place globally, dropping any distinctions between pandemic, epidemic, and endemic pricing? How will it incorporate non-profit pricing commitments into agreements with business partners, such as Catalent, Lonza, ROVI, and others?
4. Can the company clarify how many patents related to Covid-19 it owns or has filed, and which among them it plans not to enforce, and where similar commitments are outstanding?
5. How does Moderna define the "pandemic phase" and how will the company determine when the pandemic phase is over?
6. Moderna's June 29 response to HRW states: "We raised billions of dollars in capital and built and invested in our technology platform, which creates mRNA sequences that cells recognize as if they were produced in the body." Could the company provide a breakdown of all public funding underlying the various layers of technological innovations that have resulted in the development of the Covid-19 vaccines and also outline what private funding it received?
7. Moderna's June 29 response states: "[C]onducting technology transfers and ramping up new production lines requires significant time from a limited pool of experienced personnel with the requisite expertise." The letter also states that the company's approach is to transfer technology to "partners that we are confident can produce our vaccine with the utmost commitment to safety and quality." The company also states that it has several manufacturing partners in the US and Europe, and is "committed to pursuing additional partnerships around the world to expedite production and delivery of our vaccine and we are continuing to seek out such agreements such as our

agreement with Samsung Biologics in South Korea." Please provide additional information on the company's plans to scale-up production, specifically:

   a. How many licensing agreements in total has Moderna negotiated for its Covid-19 vaccine to date? Please provide a summary of all agreements made with regard to Covid-19 vaccine production and outline the terms.
   b. What is the company's plan to expand licensing beyond existing partners, particularly in low- and middle-income countries, to expand and diversify manufacturing and mitigate the risk of export restrictions?
   c. What is the company's timeline and process to review and approve licensing requests from manufacturers for its vaccine?
   d. The company states: "We are not aware of idle mRNA manufacturing capacity. Nor are we aware of companies who have developed manufacturing, purification, and medical processes that would allow them to rapidly run clinical trials and then produce a meaningful supply of mRNA vaccine." We understand from news reports that vaccine manufacturers from India and Bangladesh approached the company, saying they had the capacity. Please provide a list of all licensing requests received by the company, indicating the month/year when the request was made, and final decision.

8. Will the company join C-TAP and provide open, nonexclusive licenses?
9. Will the company join the WHO Covid-19 mRNA Technology Transfer Hub?
10. Please provide further information on which stakeholder groups the company consulted to inform its human rights due diligence around its Covid-19 vaccine, including rights groups, health groups, humanitarian organizations, IP rights experts, and others.
11. Until widespread vaccination is in place globally, what measures will the company take to refrain from using all public funds received from any government authority or through COVAX to support stock buybacks, executive bonuses, dividends and other practices that disproportionately benefit shareholders?
12. Will the company publish an Index of all parties that it supplies, listing name of the entity; month/year when supply was delivered; and procurement price?
13. To whom in the company can external parties direct requests for NDA exemption?
14. Will the company commit to immediately publishing and periodically updating the total number of doses that the company has committed to supplying, and a breakdown of volume commitments across different categories—high-income, upper-middle-, lower-middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others?
15. Will the company publish its Covid-19 procurement contracts with government agencies by September 1, 2021?
16. Will the company follow good practices set by the Medicines Patent Pool and publish licensing terms for all licenses governing Covid-19 vaccines by September 1, 2021?

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HUMAN RIGHTS WATCH

HRW.org

June 10, 2021

Alex Gorsky
Chairman, Board of Directors and Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
T: [redacted]
Via email: [redacted]

Re: Human Rights Due Diligence Surrounding the Johnson & Johnson Covid-19 Vaccine

Dear Mr. Gorsky,

I am writing on behalf of Human Rights Watch, an international nongovernmental organization working on a range of human rights issues globally, including corporate accountability. We have been working on issues related to business and human rights for over two decades.

Human Rights Watch has been documenting the devastating human rights impacts of the Covid-19 pandemic. Among other things, we have advocated for rights-based approaches to Covid-19 vaccine research, development, manufacture, and distribution, to maximize the availability and affordability of vaccines.

As part of our research on Covid-19 vaccines, we are contacting companies producing Covid-19 vaccines, starting with those that have received World Health Organization (WHO) Emergency Use Listing. Companies like yours have an important role to play in maximizing vaccine availability and affordability.

We are writing to learn more about Johnson & Johnson's human rights due diligence, including policies and practices surrounding its Covid-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson. We were also part of a large group of civil society organizations and individuals that wrote to your company in December 2020.

All companies, including pharmaceutical companies, have a responsibility to respect human rights standards and principles and conduct effective human rights due diligence in accordance with the UN Guiding Principles on Business and Human Rights (UNGPs). Pharmaceutical companies also have responsibilities as outlined in the 2008 Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines issued by the UN Special Rapporteur on the right to health. These are explained in more detail in Human Rights Watch's February question-and-answer document:

Universal and Equitable Access to Covid-19 Vaccines, Testing, Treatments: Companies' Human Rights Responsibilities.

As part of our work and in the interest of thorough and objective reporting, we would like to learn more about Johnson & Johnson's human rights policies, practices, and due diligence processes, especially those relevant to its Covid-19 vaccine, and steps it has taken to make its vaccine widely available and affordable. In the Annex, we have provided a summary of information we have reviewed using publicly available sources, followed by a set of questions requesting additional information about (A) Johnson & Johnson's overall policies and approach to human rights due diligence; (B) global allocation and delivery; (C) supply; (D) technology transfers; (E) affordable pricing strategy; (F) indemnification; (G) contracts to supply vaccines; (H) licensing agreements; and (I) the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and intellectual property (IP).

We request a written response to the questions and any other relevant information by **June 24, 2021** via email to my colleague, [redacted]. All responses received by June 24 may be reflected in our publications.

We thank you for your consideration. Please do not hesitate to contact us for any clarifications, to provide the information requested, or to coordinate a conference call with us.

Best regards,

[redacted]

Arvind Ganesan
Director, Business and Human Rights Division
Human Rights Watch

CC:
Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals: [redacted]
Kathy Wengel, Executive Vice President and Chief Global Supply Chain Officer: [redacted]
Michael Sneed, Executive Vice President, Global Corporate Affairs & Chief Communications Officer: [redacted]

Annex: Summary of Information Reviewed and Questions Regarding Covid-19-Specific Human Rights Due Diligence

A. Overall Policies and Approach to Human Rights Due Diligence

Summary of Information Reviewed

We have reviewed Johnson & Johnson's Credo, 2019 Health for Humanity Report, Position on Human Rights, Position on Supporting the United Nations Sustainable Development Goals, the 2020 Janssen US Transparency Report, the Janssen Access and Pricing Principles, various press releases and statements on the company's website, as well as the September 2020 joint statement with other companies and the Bill and Melinda Gates Foundation.

We note Johnson & Johnson's stated commitment to "ensuring equitable global access to its single-shot COVID-19 vaccine candidate on a not-for-profit basis for emergency pandemic use."

We also note Johnson & Johnson's statement "that human rights due diligence is a continuous process," and that it has "policies, processes, training and monitoring systems in place" to advance the company's commitment to respect human rights. Additionally, we note Johnson & Johnson's commitment to provide "effective resolution where we have caused or contributed to adverse human rights impacts."

We have reviewed Johnson & Johnson's Position on Stakeholder Engagement and note the company's stated aim "to engage inclusively with stakeholders representing different stakeholder groups at global, regional and local levels," focusing on "groups that are most extensively affected by our business."

Questions

1. Policies

Does the company have a specific equitable access policy that applies to its business operations related to Covid-19 vaccines, including manufacturing, marketing, and distribution? Please provide more information, including copies of any written policies and how all policies are embedded across the company's operations.

2. Human rights due diligence processes

What steps has the company taken to conduct Covid-19 specific human rights risk assessments? Please outline all the *risks identified*, the *prevention, mitigation, and remedial measures* the company undertook, and the *indicators being used to track and assess the progress* of the company's prevention and mitigation strategy. Please provide information concerning the following risks:

a. Barriers to availability of the vaccine because of insufficient diffusion and sharing of technological know-how required to scale up manufacturing.

b. Barriers to availability of the vaccine because of IP rights risks that can curb scale-up of manufacturing and distribution.
c. Barriers to affordability of the vaccine.
d. Barriers to accessibility of the vaccine.

3. Consultation with stakeholders and potentially affected groups
Please describe the methodology used by the company to conduct risk assessments regarding its Covid-19 vaccine supply and affordable pricing strategy, including a list of "potentially affected groups" or "at-risk" populations and stakeholders that the company has consulted.

B. Global Allocation and Deliveries

Summary of Information Reviewed
We understand that Johnson & Johnson has already made agreements to supply doses of its vaccine to the COVAX Facility, and to countries belonging to different income groups.

Questions
1. Please provide the total number of doses that the company has committed to supplying to date, and a breakdown of volume commitments across different categories—high- income, upper-middle-, lower-middle-, and low-income governments; COVAX Facility; humanitarian organizations, and others.
2. What factors does the company consider in decisions about how it sequences distribution of vaccines to different countries?
3. Does the company plan to publish a list of all national authorities, intergovernmental organizations, COVAX Facility, and other entities it supplies, building on the good practice set by the COVAX Interim Distribution Forecast and UNICEF's price transparency database? If yes, by when?

C. Supply

Summary of Information Reviewed
We understand that Johnson & Johnson aims to deliver more than one billion doses of its Covid-19 vaccine by the end of 2021. We further understand that Johnson & Johnson has "a global manufacturing and supply network" for its Covid-19 vaccine involving partners in different countries. Most of these are in Europe (includes Sanofi in France; IDT Biologika and Vibalogics in Germany; and Reig Jofre in Spain), and the US (includes Emergent BioSolutions, Merck, and Catalent). Two manufacturers are outside Europe and US: Biological E. in India and Aspen Pharmacare in South Africa. We note media reports that the "entire production" of vaccine doses in India by Biological E. would be "handed over directly" to Johnson & Johnson.

We have followed the production challenges that Johnson & Johnson has faced to date and note Johnson & Johnson's statement that its ability to meet its production target for the

European Union by the end of June is "in doubt" alongside media reporting that it has delivered less than 10 percent of its target to date. Experts have urged Johnson & Johnson to share vaccine technology widely with manufacturers around the world to help quickly ramp up and diversify global production, arguing the supply challenges the company has faced are exacerbated by its more restrictive licensing practices, and the small number of manufacturing agreements it has made as compared to other developers producing viral vector vaccines using similar technology like AstraZeneca and the Russian Direct Investment Fund (RDIF). We note reporting that Johnson & Johnson declined a request from Biolyse Pharma, a Canadian company, for a license to manufacture the Johnson & Johnson vaccine.

We are also aware that the US prioritized domestic producers, practically creating export restrictions on raw materials for vaccine production elsewhere, and the European Commission and India have introduced rules that restrict export of Covid-19 vaccines.

Questions

1. Please provide information about the company's global manufacturing capacity for its Covid-19 vaccine, its manufacturing plans and objectives, and steps the company has taken to scale up manufacturing capacity for the vaccine between 2020 and 2023?
2. What steps is the company taking to diversify its manufacturing to mitigate against the risk of export restrictions and other production disruptions?
3. Please outline the timeline and process within Johnson & Johnson to review licensing requests from manufacturers to product the company's Covid-19 vaccine and grant approval of voluntary licenses to manufacture.
4. Have you received any direct requests to license or transfer technology for vaccine production? If so, please provide a list of all licensing/technology transfer requests made to Johnson & Johnson, indicating the month and year when the request was made, final decisions made by Johnson & Johnsons and communicated to the requesting company, where permission was refused, and reasons for doing so.

D. Technology Transfers

Summary of Information Reviewed

We understand from the UNICEF's Covid-19 Vaccine Market Dashboard that Johnson & Johnson has nine manufacturing agreements in place to produce doses of its vaccine. We are interested to learn about Johnson & Johnson's efforts to share IP and technology more broadly with potential vaccine producers in low- and middle-income countries, in line with the World Health Organization's Solidarity Call to Action urging the pooling of knowledge, IP, and data for technologies needed for the Covid-19 response.

Questions

1. We understand that Johnson & Johnson has not yet joined the Covid-19 Technology Access Pool. Please detail the reasons for this decision and whether any steps are underway to join.

2. What steps is the company taking to conduct technology transfers related to its Covid-19 vaccine to contribute to building the manufacturing capacity of low- and middle-income countries?
3. Does the company restrict commercialization rights where it conducts technology transfers, especially the ability to export?

E. Affordable Pricing Strategy

Summary of Information Reviewed

The 2020 Janssen US Transparency Report states that the company is "on track to deliver one billion [Covid-19 vaccine] doses in 2021 at a not-for-profit price for emergency pandemic use." We note that Johnson & Johnson states that "not-for-profit pricing of the Company's COVID-19 vaccine will last for the duration of the emergency pandemic use period and will be determined using the Company's not-for-profit framework, which is consistent with the Bill and Melinda Gates Foundation's cost methodology for vaccines, accounting fairly for the costs, investment and effort required to develop and distribute novel vaccines, excluding any profit." We have reviewed the Bill & Melinda Gates Foundation's handbook on Production Economics for Vaccines, which describes a methodology the foundation uses for calculating production costs for vaccines. The handbook states 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." The handbook specifies that when "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 costing calculation.

We understand that Johnson & Johnson received an estimated US$1 billion in funding from the US government for development of its Covid-19 vaccine. We note the company's disclosure that research, development, and delivery of its vaccine "were funded in part with federal funds from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201700018C, and in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS)."

We further note the company's commitment to price its products "responsibly" to make them "more accessible and affordable in low-resource settings." We reviewed testimony by Janssen's head of clinical development and medical affairs before the Oversight & Investigation Subcommittee of the US House of Representatives Energy & Commerce Committee, which stated the company was "pursuing external validation of our not-for-profit calculation approach and external audit/certification of not-for-profit price."

We have reviewed the Janssen Access and Pricing Principles, which state that the company works with governments, insurers, and other stakeholders to negotiate the prices of medicines "based on their local value." Based on information from the UNICEF Covid-19

Vaccine Market Dashboard and other publicly available materials, we have gathered that pricing per dose for Johnson & Johnson's vaccine ranges from US$8.50 in a deal with the European Commission, to $10 in deals with the African Union and the US. However, we note that Janssen's head of clinical development and medical affairs stated that the company is "committed to one price globally, regardless of country or income tier," and that pricing "will be determined based on one cost structure, with all appropriate costs included." Access to medicines experts have raised concerns that Johnson & Johnson's prices are not affordable for many low- and middle-income countries. We note reporting that Johnson & Johnson executives suggested that the company may increase prices for its Covid-19 vaccine after the pandemic period.

We could not locate a detailed description of how the "not-for-profit" commitment is being contractually implemented in different geographies, nor a description of how long the company's "not-for-profit" commitment would remain in effect, and how pricing would be determined afterward.

We also reviewed a resolution filed by Johnson & Johnson shareholders in December 2020 requesting disclosure of additional information about government funding for, and pricing of, Johnson & Johnson's Covid-19 vaccines and therapeutics. We note reporting that Johnson & Johnson requested that the Securities and Exchange Commission (SEC) rule that it could withhold the proposal from shareholders.

Questions

1. Please provide information about Johnson & Johnson's affordable pricing strategy for its Covid-19 vaccine, including information about the criteria factored into determining affordable prices throughout the world. Does the company use differentiated or tiered pricing for its Covid-19 vaccine?
2. Please provide details on the company's "not-for-profit" commitment, including specific information on how it is using the Bill & Melinda Gates Foundation's costing methodology. Has Johnson & Johnson completed a "Production Economics assessment" as described in the foundation's handbook? If so, please provide a copy of the assessment results accounting for all costs incurred by the company for the life cycle of its Covid-19 vaccine, as well as third-party and foundation contributions that have offset these costs. Please also explain how this costing framework is being used to determine the company's "not-for-profit" price.
3. How long will the "not-for-profit" price remain in effect? How many doses will be supplied at the non-for profit price? How will an end point to "emergency pandemic use" would be determined?
4. How is the "not-for-profit" price incorporated into existing contracts and agreements? How does Johnson & Johnson's "not-for-profit" commitment apply to its licensee-manufacturers?
5. Please provide details about the company's pricing strategy in the post-pandemic period.
6. We welcome Johnson & Johnson's commitment to a third-party audit and verification of its not-for-profit pricing. Please provide information regarding the third-party

auditor, methodology, timeframe, and scope of the third-party audit. When will results be made publicly available?

7. How much government and nongovernment (philanthropic) funding has supported the development of the Johnson & Johnson vaccine (including the different stages of innovation) and how much money has Johnson & Johnson received through advance market commitments?
8. What is the estimated private investment in vaccine development, manufacture, and distribution?
9. Until widespread vaccination is in place globally, what measures will the company take to refrain from using all public funds received from any government authority or through COVAX to support stock buybacks, executive bonuses, dividends and other practices that disproportionately benefit shareholders?

F. Indemnification

Questions

1. Please provide details on the indemnification requirements AstraZeneca has sought from countries and any conditions that the company has made a precondition for countries to receive Johnson & Johnson's vaccines through the COVAX Facility or other agreements.
2. Has Johnson & Johnson requested that governments provide any assets as collateral for the vaccine? If so, please list the governments that have made those commitments and the assets pledged.

G. Contracts to Supply Vaccines to NationalAuthorities/Intergovernmental Organizations/COVAX Facility

Summary of Information Reviewed

Contract transparency is key to providing the public a way to monitor government spending and is a bulwark against conflicts of interest and corruption. Many governments have procurement rules that obligate them to publish public contracts, and many have specifically committed to publishing Covid-19-related contracts as part of their emergency loan agreements with the International Monetary Fund. The World Bank's rules also require governments to publish contract awards the Bank finances, including those related to Covid-19.

We note the US government's November 2020 publication of its Operation Warp Speed contract with Janssen Pharmaceuticals. We have also reviewed a heavily redacted copy of the contract between Johnson & Johnson and HHS, which was obtained by the nongovernmental organization Knowledge Ecology International through a Freedom of Information Act request.

Questions

1. Does the company plan to publish all its contracts related to the supply of its vaccines? If yes, by when will the company publish such a database on its website?
2. What measures does the company take to enable government compliance with Freedom of Information or Right to Information Laws or other good practices around government disclosure of contracts?
3. To whom should civil society and other interested parties direct queries regarding contracts and make requests for exemption to nondisclosure agreements?

H. Licensing agreements

Summary of Information Reviewed

We understand that Johnson & Johnson has voluntary licensing agreements in place with several manufacturers, as described above. We are interested to learn about the company's efforts to make information about these and other agreements publicly available. We note that Dr. Tedros Adhanom Ghebreyesus, director-general of the WHO, recently commented that voluntary licensing agreements "tend to be exclusive and nontransparent, compromising equitable access."

Questions

1. What measures is Johnson & Johnson taking to adopt good practices set by the Medicines Patent Pool to voluntarily publish licensing agreements related to Covid-19 vaccines?
2. How many licensing agreements in total has Johnson & Johnson negotiated for its Covid-19 vaccine to date? Please provide a summary of all licenses issued with regard to Covid-19 vaccine manufacturing and outline the terms of the license and the license period, including any fees or royalties. Please elaborate why the company has/has not agreed to voluntary, open, nonexclusive and global licenses.

I. TRIPS Waiver, TRIPS Flexibilities, and Intellectual Property

Summary of Information Reviewed

We have reviewed Johnson & Johnson's Position on Intellectual Property. The director-general of the WHO, and more than 100 governments, including the US and New Zealand, have publicly supported the proposal before the World Trade Organization (WTO) that would temporarily waive some IP rights under the TRIPS Agreement until "widespread vaccination is in place globally." However, Johnson & Johnson along with other companies and the Pharmaceutical Research and Manufacturers of America (PhRMA) wrote to President Biden in early March 2021 urging the US administration to continue "to oppose the TRIPS IP waiver." Numerous industry groups that Johnson & Johnson is a member of, including PhRMA, have written to the US government advocating for action against countries exercising TRIPS flexibilities and to continue opposing the TRIPS waiver proposal. PhRMA refers to legitimate government exercise of TRIPS flexibilities as "compulsory licensing threats" and describes pricing controls to make life-saving healthcare affordable as a "non-tariff" trade barrier. We note recent reporting on PhRMA's aggressive lobbying against the waiver proposal.

Questions

1. Does Johnson & Johnson support the TRIPS waiver proposal in light of so many other relevant stakeholders', including the WHO's and US government's, views in support of the waiver?
2. We note Johnson & Johnson's stated support for the TRIPS Agreement and the Doha Declaration, "that provide for the use of compulsory licenses in certain limited circumstances." How will Johnson & Johnson respond to a government's use of public health safeguards and flexibilities included in the WTO TRIPS Agreement and reaffirmed by the Doha Declaration to discharge their human rights obligations to life and health (for example, the Bolivian government's use)?
3. We note Johnson & Johnson's statement that in certain circumstances, it has pursued "royalty-free and non-exclusive license arrangements" and pledged "not to enforce certain patents" to address the needs of developing countries. Does the company intend to refrain from enforcing its patents (similar to public announcements made by Moderna and CureVac)? Please detail any relevant patents and related commitments.
4. What steps is the company taking to build on good practice of other companies, like Moderna, to publicly disclose information about all relevant patents and patent filings (owned and licensed) for different underlying technologies used to produce, store, and distribute the Covid-19 vaccine?