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A shot at recovery

Measuring corporate commitments towards a free, fair, and accessible COVID-19 vaccine

Summary

The COVID-19 pandemic has devastated families and economies here in the US and around the world. Our collective hope rests in the hands of the taxpayer-funded researchers seeking an effective vaccine against the coronavirus. But development and approval of a safe and effective vaccine is just the first step. Equally important is making sure the vaccine is available and affordable to everyone.

More than \$10 billion of US taxpayer dollars have already been invested with pharma corporations such as Johnson & Johnson and Moderna to develop the COVID-19 vaccine, yet there's still no guarantee that everyone will even be able to afford it, or even that there will be enough to go around. While some companies have made important commitments to making the resulting vaccine accessible, Big Pharma as a whole remains ready to double down on their "business as usual" model—making billions from taxpayer-funded research, charging sky-high prices, and funneling profits to rich investors. To make things worse, rich countries, including the US, have already purchased more than half of the vaccines being developed.

Access to a life-saving vaccine should not depend on how much money you have or where you live. A safe and effective COVID-19 vaccine that is mass-produced and available to everyone—a people's vaccine—is a public health necessity, an economic priority, and a moral imperative.

Overview

The COVID-19 pandemic has been devastating, with more than a million lives lost and billions of people struggling to survive, pay their bills, and stay healthy – here at home and around the world. A safe and effective vaccine can be a way out of this nightmare, and researchers are racing to find it.

More than 100 groups have joined the mission to develop and produce a vaccine¹ and more than 209 vaccines are in development worldwide, 68 of which are in the US.² Five candidates,

currently being developed by Pfizer/BioNTech, Moderna, AstraZeneca/University of Oxford, Johnson & Johnson and Merck are considered the frontrunners. But development and approval of a safe and effective vaccine is just the first step. Equally important is making sure the vaccines are available and affordable to everyone.

The race toward a COVID-19 vaccine has been funded largely by taxpayer dollars. In fact, as of September 2020, more than \$10 billion of US taxpayers' money has been spent on this research, mostly through the Biomedical Advanced Research and Development Authority (BARDA) that is part of the US Department of Health and Human Services. But instead of commitments to making the resulting vaccines a global public good, Big Pharma is getting ready to double down on their "business as usual" model—making billions off of taxpayer-funded research, charging sky-high prices, and funneling profits to rich investors. This lack of transparency is fueling perceptions of crony capitalism and vaccine hesitancy. In the case of COVID-19, this could mean luxury for the few and disaster for the many.

To make things worse, we have also seen rich countries, starting with the United States, adopt a "me first" nationalistic approach that could prevent or delay the vaccine from reaching vulnerable people, especially those living in developing countries. Today's worldwide production capacity is estimated at anywhere between 2 billion and 12 billion vaccine doses by the end of 2021, if one includes the vaccines being produced in Russia and China.³ Some of these vaccine candidates will likely fail in late-stage clinical trials, and so the actual doses available to the public will be much less. The total production capacity of the four advanced vaccine candidates discussed in this brief is approximately 6 billion doses maximum in 2021. Of that, the United States has already secured 700 million doses of vaccine, with the option of purchasing 900 million more doses to capture approximately 1.6 billion doses in total.4 That means, in principle, that the United States—less than 4 percent of the world's population—may have already captured almost 5 doses per person. The perceived scarcity that emerges from this type of hoarding is driving a bidding war between countries for privileged early access to the vaccine. Last month, an Oxfam analysis of the publicly available deals for five of the leading vaccines estimated that wealthy nations representing just 13 percent of the world's population have already cornered more than half (51 percent) of the promised doses of COVID-19 vaccine candidates being developed by AstraZeneca/Oxford, Gamaleya/Sputnik, Moderna, Pfizer and Sinovac.

Equally worrying, especially in view of the likelihood of failure for some of the candidates, none of the vaccine developers will be able to produce the quantities of vaccine doses needed to meet global demand in the coming two years. Worse yet, neither the US government nor the pharmaceutical industry are taking the necessary steps now to ensure that there is maximum supply of a new vaccine commensurate with global need. Mass production requires not only investments in at-risk production but also a requirement that pharmaceutical companies share their intellectual property, know-how, and data as widely as possible so that there are multiple suppliers for new vaccines. Even if there are multiple suppliers, there will be insufficient supply for a global population. Getting rid of artificial supply barriers, such as monopoly control over production, will help many countries around the world protect the most vulnerable and at-risk populations and set us on the right path to defeating COVID-19. Every additional dose matters.

A People's Vaccine to Save Lives and Livelihoods

A COVID-19 vaccine must not only be safe and effective, it must also be universally accessible. Public health experts, more than 140 former and current heads of state and other world leaders, the UN Secretary General, and Nobel laureates all agree that this moment calls for a COVID-19 People's Vaccine.⁵ The People's Vaccine would be free of charge to the public, fairly distributed on the basis of need and risk, and produced at a mass scale.

To be free of charge to the public, the COVID-19 vaccine must be sold at a low enough price so that governments around the world can afford to purchase a vaccine for their people without going into debt. Toward that end, the price should be as close to the actual cost of production as possible. Further, the public must have full transparency into the actual cost of production, the contributions of governments, philanthropies, universities, and multilateral agencies towards the development of a vaccine, and the terms and conditions that companies and governments enter into over the vaccines.

To be fairly allocated based on need and risk not wealth, countries, including the US, must stop hoarding the initial supplies of vaccines, and must agree to plan to fairly distribute the vaccines within and, between countries to save as many lives as possible. Within countries, this will require prioritizing those who are bearing the biggest brunt of the disease burden, including frontline health and social-care workers, older people, and people at higher risk due to underlying health conditions. Likewise, vaccine supplies must be shared between countries to ensure those who truly need the vaccines first receive them, no matter where they live.

To be produced at a scale to meet global demand, we cannot let these life-saving vaccines fall victim to monopoly control over production. Intellectual property, deep technology transfer and know-how to make a COVID-19 vaccine must be shared openly with the world to quicken the pace of production and drive down costs. Corporations at a minimum should agree not to enforce patents and should license their technology with appropriate terms and conditions, publish data, and provide technical assistance to teach appropriate vaccine production, so that qualified manufacturers everywhere can help expand the world's supply and prevent artificial scarcity which will cost lives and livelihoods at home and abroad.

In this brief, we take a look at the leading vaccine candidates to better understand the companies' commitments to a free, fair and accessible COVID-19 vaccine: a people's vaccine. For perspective, we also place these commitments to an accessible COVID-19 vaccine in the context of the companies' other commitments to shareholder payouts and CEO compensation.

Two key lessons can be distilled from this evaluation. First, differences do emerge between companies partly because of civil society pressure, with AstraZeneca/Oxford in the best position to produce the most accessible vaccine. Second, while some companies' commitments go further than others, company goodwill alone will not lead us to a people's vaccine and out of the pandemic. Government coordination and proactive measures are paramount to ensuring a free, fair, and accessible COVID-19 vaccine. Given the fact that the US government remains the world's largest investor in the development and manufacturing of a new COVID-19 vaccine, this brief concludes with a number of recommendations for the US government to ensure these scientific breakthroughs benefit all people and bring this crisis to a rapid end.

TABLE 1: COMPARING MAJOR VACCINE DEVELOPERS COMMITMENTS TO DELIVER A PEOPLE'S VACCINE

	FREE		FAIRLY DISTRIBUTED		ACCESSIBLE
	Transparent	Lowest	Within	Between	Patent-free, with
	contracts	price	countries	countries	shared technology
					& know-how
Pfizer/BioNTech					
Moderna					
AstraZeneca/Oxford					
J&J					
Merck					

Each company was scored for their commitments to key elements of ensuring a free, fair and accessible COVID-19 vaccine—a People's Vaccine. Red implies no commitment (or active opposition), yellow implies partial commitment and green a close to full commitment, in comparison to other companies. Company commitments are described in detail below, as of October 10, 2020. Note that these are rough approximations based on limited information, and are only snapshots in time which will change with new developments.

AstraZeneca and Oxford University (AZD1222)

Research and development

AstraZeneca licensed its viral vector-based vaccine from the University of Oxford.⁶ Phase 1 trials for the vaccine began in late April.⁷ The AstraZeneca/Oxford partnership started Phase 3 trials since May in countries worldwide including the US, the UK, Brazil, South Africa and more.⁸ On September 8, AstraZeneca announced a pause on all trials to assess a patient illness to determine if it was related to the vaccine.⁹ Days later it was determined that the safety concern was unlikely related to the vaccine and by mid-September, most Phase 3 trials of the AstraZeneca/Oxford vaccine were restarted.¹⁰

Public funding

The company announced in May 2020 a partnership with the US government. US taxpayers (via BARDA) will contribute up to \$1.2 billion for the development and supply of the vaccine.¹¹ Additionally, CEPI and Gavi, the Vaccine Alliance announced a \$750 million agreement with the company to manufacture, procure and distribute the vaccine.¹²

Previously in 2018, CEPI gave Oxford \$18 million to develop vaccines for viruses, including older coronaviruses, such as MERS.¹³ Since then, CEPI funds have shifted to fund COVID-19 vaccine efforts at Oxford.¹⁴ The UK government has also contributed \$25 million to Oxford's COVID-19 vaccine development research and trials.¹⁵ Pre-clinical stage trials for Oxford's vaccine also utilized American taxpayer money, because the trials were partly run by the National Institute of Health.¹⁶

Transparency

Neither AstraZeneca nor Oxford University has yet committed to disclosing the terms and conditions of any contracts for development or procurement with public entities, nor to being transparent about the true cost of R&D and manufacturing of its vaccine candidate.

Pricing strategies

According to AstraZeneca, the company "has prioritized broad and equitable supply of a vaccine throughout the world at no profit during the pandemic." Oxford and AstraZeneca went on to announce that its vaccine will be available at a non-profit price for approximately \$3 globally throughout the pandemic. 18 The exact price will vary slightly depending on the complexity and volumes of the respective supply chains, according to the company. The pandemic price of AstraZeneca/Oxford's vaccine is thus the lowest of all other advanced vaccine candidates explored in this brief.

AstraZeneca, at least according to one contract signed between the company and a Brazilian manufacturer, retains the sole right (in good faith) to declare the end of the so-called 'pandemic period' as early as July 2021, at which point the company would no longer be obligated to market the vaccine at the lower pandemic price.19 Since this contract was signed, however, the company has committed to "to make the vaccine available to low- to middle-income countries at no profit in perpetuity."²⁰

Production levels

Oxford partnered with AstraZeneca to further develop and manufacture the vaccine at scale.²¹ The companies have deals with at least 25 manufacturers around the world, including a licensing agreement with an Indian manufacturer, to supply 1 billion doses for low and middle-income countries²² as well as an agreement with Argentina and Mexico to supply Latin America.²³ Altogether, the partnership's total targeted production level hits approximately 3 billion doses per year.²⁴ and intends to expand manufacturing further.

Sharing intellectual property, technologies and know-how

The intellectual property of this vaccine is owned by Oxford University. AstraZeneca/Oxford has agreed to sub-licensing deals in various countries, including India, Brazil and Argentina, which may include technology transfer for manufacturing, although the terms and conditions of such technology transfer are not disclosed. Yet, the partners have not yet made a broader, public commitment in support of sharing its COVID-19 vaccine knowledge, intellectual property, data and know-how to boost supply, reduce price and enhance equity. In fact, AstraZeneca's CEO, Pascal Soriot, has been vocally opposed, arguing that intellectual property is "a fundamental part of our industry and if you don't protect IP, then essentially, there is no incentive for anybody to innovate. What is important is for companies to volunteer to provide their products at no profit, like we're doing right now in case of a pandemic or crisis, when it's needed."²⁵

Fair distribution

As of mid-September, many nations have deals, with varying terms, with AstraZeneca. The UK has purchased 100 million doses, ²⁶ and the US has purchased 300 million doses. ²⁷ The European Commission purchased 300 million doses for EU member states, with a contingency for an additional 100 million doses if the vaccine is proven safe. ²⁸ Australia agreed to terms for 33.8 million doses that will be produced and supplied inside their own borders. ²⁹ Japan has purchased 120 million doses. ³⁰The companies have also made an initial agreement with Canada to supply 20 million doses, ³¹ and Hong Kong/Macau 10 million. ³²

Latin America, excluding Brazil, has agreed to purchase at least 150 million doses.³³ Brazil purchased 100 million doses.³⁴ An Indian manufacturer will supply one billion doses for India and low and middle-income countries.³⁵ China will receive 200 million doses.³⁶ A Russian manufacturer will manufacture and distribute the vaccine in Russia with export to Commonwealth of Independent States, Middle East and Balkans for at least 1 billion doses.³⁷ Finally, AstraZeneca/Oxford has also partnered with the ACT Accelerator COVAX Facility led by GAVI, CEPI and WHO to manufacture and procure 300 million doses for this mechanism.³⁸

These deals when rolled out would lead to rich countries controlling approximately 884 million doses now, or 984 million should the EU exercise its option (approximately 26% of the total supplied). LMICs meanwhile are estimated to be allocated 2.75 billion doses,³⁹ or approximately 74% of the total. Thus, AstraZeneca/Oxford has so far allocated the highest percentage of doses to LMICs.

As relates to the key question of which groups should be prioritized with the first supplies of vaccines, AstraZeneca/Oxford supports "evidence-based prioritization so that health care workers, high-risk individuals, and other priority groups identified by WHO and other health authorities are protected for the duration of the pandemic, regardless of the country they live in."

CEO pay (AstraZeneca)41

FY 2019: \$18,978,876 FY 2018: \$16,400,505

Political lobby spend on US federal government (AstraZeneca)⁴²

Q1 2020: \$1,560,000 Q2 2020: \$780,000

Recent shareholder payouts (AstraZeneca)⁴³

Q1 2020: \$2.4 billion in dividends

Q2 2020: 0

FY 2020 (full year expected): \$3.6 billion in dividends

FY 2019: \$3.6 billion in dividends

Johnson & Johnson (Ad26COVS1)

Research & development

Johnson & Johnson's vaccine utilizes viral vector technology. The company believes it can develop a vaccine requiring only one dose, but it will be testing a two-dose approach in its clinical trials.⁴⁴ The company initiated Phase 1/2a clinical studies in late August 2020 both in the US and Belgium.⁴⁵ Johnson & Johnson (JNJ) announced on September 23rd they had begun a multi-country Phase 3 trial⁴⁶, making them the fourth company to reach this milestone in the US. The first batch of vaccines may be available to the public in early 2021.⁴⁷

Public funding

BARDA has awarded JNJ \$456 million to be invested in development of the company's COVID-19 vaccine. Additionally, the US government announced another \$1 billion deal to expand manufacturing capacity. This brings the US taxpayer investment into this vaccine to almost \$1.5 billion. Notably, this funding does not reflect the hundreds of millions of taxpayer dollars the US government has given to the company in the past unrelated to COVID-19 vaccine research and development that may have indirectly contributed to the advancement of its coronavirus vaccine.

Transparency

JNJ has not committed to disclosing the terms and conditions of any contracts for development or procurement with public entities, nor to being transparent about the true cost of R&D and manufacturing of its vaccine candidate.

Pricing strategies

JNJ stated in public hearings that the vaccine should be free to the public, because it is useless if people cannot afford it.⁵¹ The company also stated that the vaccine development and production effort will be not-for-profit and will be accessible globally,⁵² stating in particular that the vaccine would cost \$10 per vaccine dose/regimen, during the course of the pandemic.⁵³ Without transparency on the true costs of development and manufacturing, however, it is impossible to verify how close to 'not-for-profit' the vaccine would be.

Production levels

JNJ is investing in expanding its manufacturing capabilities globally,⁵⁴ with plans to manufacture 600 to 900 million vaccine doses by the first quarter of 2021 and increase the number of available doses to 1 billion over the year.⁵⁵

Sharing intellectual property, technologies and know-how

JNJ has not made a public commitment in support of sharing its COVID-19 vaccine knowledge, technology, intellectual property, data and know-how to boost supply, reduce price and enhance equity.

Fair distribution between and within countries

The US ordered 100 million doses of the vaccine, paying \$1 billion for the supply through BARDA funds.⁵⁶ The UK has purchased 30 million doses.⁵⁷ The EU secured 200 million doses from JNJ with potential to expand to double that amount.⁵⁸ Canada also signed a deal for up to 38 million doses.⁵⁹ So far, JNJ does not seem to have agreed to any specific deals with LMICs, but JNJ's CEO Alex Gorsky committed on September 30, 2020 to allocate 500 million doses of its vaccine, if approved, to LMICs, with delivery starting in mid-2021.⁶⁰

At present, JNJ seems to have made supply deals exclusively with rich nations. 368 million doses are currently secured by rich nations, with 568 million (57%) available to high-income countries should the EU exercise its options. Should JNJ effectively allocate 500 million of the remaining doses to LMICs, poorer countries would then receive 50% of the company's total supply.

In regards to the distribution of the vaccine, the company's Chief Scientific Officer stated in an interview that the company will not decide who will get the vaccine, because "that's not up to [the company]."⁶¹ However, the company later publicly went on record to support "evidence-based prioritization so that health care workers, high-risk individuals, and other priority groups identified by WHO and other health authorities are protected for the duration of the pandemic, regardless of the country they live in."⁶² It has also said that it has created a strategy considering ethics-based risk and medical need, ⁶³ but details are not publicly disclosed.

CEO pay⁶⁴

FY2019: \$25,365,777 FY 2018: \$20,097,572

Recent investor payouts⁶⁵

Q1 2020: \$4.2 billion (\$2.5 billion in dividends; \$1.7 billion in stock buybacks) Q2 2020: \$3.4 billion (\$2.7 billion in dividends; \$706 million in stock buybacks)

FY 2020 (full year expected): \$14.6 billion (\$10.1 billion in dividends; \$4.5 billion in share

buybacks)

FY 2019: \$16.66 billion (\$9.9 billion in dividends; \$6.8 billion in share buybacks)

Political lobby spend on US federal government⁶⁶

Q1 2020: \$1,500,000 Q2 2020: \$1,760,000

Merck & Co

Research and development

As part of the company's response to the pandemic, Merck & Co is exploring two different vaccine candidates. The first, adapting the technology developed for its Ebola vaccine,

ERVEBO, is in collaboration with the non-profit scientific research organization IAVI.⁶⁷ It is likely that the vaccine will require only one dose and the company is testing both oral and intramuscular administration.⁶⁸ Additionally, Merck has acquired the Austrian biotech firm Themis, which is also developing a separate COVID-19 vaccine that utilizes a measles-vector technology developed at the non-profit Institut Pasteur with funding from CEPI.⁶⁹ Both of these vaccine candidates are in very early stages, compared to the other four vaccine candidates described above.

Public funding

To date, BARDA has awarded \$27 million to Merck for the development and production of a vaccine.⁷⁰ This public funding is in addition to the public funding that the company previously received to develop its Ebola vaccine, which is now contributing to the company's development of one of its coronavirus vaccine candidates.⁷¹

Transparency

Merck has not yet committed to disclosing the terms and conditions of any contracts for development or procurement with public entities. The company has said that it would be transparent in its pricing,⁷² but hasn't stated what that would entail concretely, for example disclosing the true cost of R&D and manufacturing of its vaccine candidate.

Pricing strategies

For one of its vaccine candidates, Merck has entered into a memorandum of understanding with Institut Pasteur and CEPI, ensuring that the vaccine will be developed, manufactured, and distributed on a global basis, with "pricing that makes the vaccine both available around the world and accessible to those who need it, including low-income, middle-income and high-income countries based on the medical need when the vaccine may become available." Yet, it has also stated in a Congressional hearing that the company does not envision selling its vaccines at cost.

Production levels

Although both of the vaccine candidates are in early stages, the company has already begun preparing for eventual large-scale vaccine production.⁷⁵ The company is in the process of identifying internal resources and contract manufacturers that can allow it to produce hundreds of millions of doses.⁷⁶

Sharing intellectual property, technologies and know-how

The company stated that it does not file patents in any low-income countries defined as such by the World Bank in its Country and Lending Group classifications, 77 although least-developed countries are not required to issue patents in any case until at least 2033. 78 The company has not however committed to sharing its COVID-19 vaccine knowledge, technology, intellectual property, data and know-how to boost supply, reduce price and enhance equity.

Fair distribution

Merck and IAVI have stated that they will collaborate to "make [the vaccine] accessible and affordable globally, if approved,"79 and Merck is actively involved in the ACT-Accelerator.80 Due to how early the company's vaccine candidates are in the process, however, with no supply deals agreed to date, the balance of supply between richer and poorer countries cannot be predicted.

As relates to the key question of which groups should be prioritized with the first supplies of vaccines, Merck supports "evidence-based prioritization so that health care workers, high-risk individuals, and other priority groups identified by WHO and other health authorities are protected for the duration of the pandemic, regardless of the country they live in."⁸¹

CEO pay⁸²

FY 2019: \$27,648,475 FY 2018: \$20,934,504

Recent investor payouts⁸³

Q1 2020: \$2.9 billion (\$1.6 billion in dividends; \$1.3 billion in stock buybacks)

Q2 2020: \$1.6 billion in dividends

FY 2020 (full year expected): \$9.7 billion (\$5.9 billion in dividends; \$3.7 billion in share

buybacks)

FY 2019: \$10.5 billion (\$5.7 billion in dividends; \$4.8 billion in share buybacks)

Political lobby spend in US⁸⁴

Q1 2020: \$2,170,000 Q2 2020: \$2,620,000

Moderna (mRNA-1273 vaccine)

Research and development

Moderna is one of the front-runners for the COVID-19 vaccine development with its mRNA-based vaccine, and has garnered the FDA's fast-track tag.⁸⁵ Two doses are to be injected intramuscularly and administered 28 days apart during clinical trials.⁸⁶ In May 2020, the company released positive interim results for Phase 1 of its clinical trial that started in March 2020,⁸⁷ and is now involved in Phase 3 trials, with the company considering emergency authorization for its vaccine for use on high risk patients.⁸⁸

Public funding

Moderna is so far set to receive \$955 million from the US federal government to develop and manufacture its vaccine candidate (\$483 million in first contract with BARDA⁸⁹ and an additional \$472 million in a second contract).⁹⁰ In addition, the company has received commitments from the US government to provide over \$1 billion for purchase of the vaccine, bringing the total

public contribution to Moderna, if certain milestones are met, to up to \$2.48 billion in taxpayers' money. 91 Besides the significant public investment, Moderna raised approximately \$1.34 billion from private investors to invest in its technology. 92

This public funding does not reflect the more than \$100 million the US government has invested in the company to develop the Zika vaccine, which helped the company refine and further develop the mRNA technology that is being used for the coronavirus vaccine. ⁹³ Additionally, Moderna's COVID-19 vaccine was co-developed with the US National Institutes of Health, a taxpayer-funded research institution. ⁹⁴ The Coalition for Epidemic Preparedness Innovations (CEPI) has also provided funding for the company's vaccine, but the exact amount awarded is unknown. ⁹⁵

Transparency

Moderna has not yet committed to disclosing the terms and conditions of any contracts for development or procurement with public entities, nor to being transparent about the true cost of R&D and manufacturing of its vaccine candidate.

Pricing strategies

While the CEO of Moderna, Stéphane Bancel, stated, "There is no world I think where we would contemplate to price this higher than other respiratory virus vaccines," the company has said it intends to make a profit from its vaccine. The company has sold its vaccines to the US government at prices that range from \$12-16.50 per dose, or \$24-33 per two-dose regimen. Prices in other countries have not yet been disclosed, but could range from between \$32 to \$37 per dose, or \$64-74 per two-dose regimen. The company considers this "pandemic pricing", so this price could conceivably increase once the pandemic is officially over.

The price of Moderna's vaccine paid for by the US government is the second-highest price of the other advanced vaccine candidates described in this brief. The price per unit also does not include the additional costs that countries—especially poorer countries—may have to incur to build additional cold chain capacity at -20°C for transportation and one-week storage of the mRNA vaccine between 2°C and 8°C, 100 as well as the need for careful management of the vaccine at the point of care to avoid vaccine wastage.

Sharing intellectual property, technologies and know-how

On October 9, Moderna made a public commitment, during the pandemic, to forgo enforcing its COVID-19 related patents against those making vaccines intended to combat the pandemic. It also confirmed that it is willing to license the intellectual property for COVID-19 vaccines to others for the post-pandemic period. While this was a step forward, the company has not committed to license their intellectual property (including patents) to the World Health Organization's COVID-19 Technology Access Pool for worldwide use, nor to share its manufacturing know-how and provide deep technology transfer to additional manufacturers.

Production levels

The limited size of its staff and in-house capabilities, especially in comparison with its vaccine competitors, may be a major obstacle to producing at the scale required capabilities. ¹⁰³ By the end of 2020, the company anticipates being able to produce up to 20 million doses of the

vaccine.¹⁰⁴ The first batches of the vaccine will be created by contract development and manufacturing organizations,¹⁰⁵¹⁰⁶ with an expected capacity by the end of 2021 of between 500 million and 1 billion doses per year at manufacturing sites in the US, Spain and Switzerland.¹⁰⁷

Fair distribution

To date, Moderna has sold the options for all its supply to rich nations. The US has agreed to a \$1.5 billion deal for 100 million doses with an option to purchase up to an additional 400 million. The EU and Moderna have concluded "advanced" talks landing on 80 million doses now, potentially 80 million more later. Canada has purchased 20 million doses, with an option of purchasing up to 56 million doses. Switzerland has purchased 4.5 million doses for itself, and Japan began discussions with Moderna to supply 40 million doses. Moderna has not entered into any agreements LMICs or COVAX to supply poorer countries, nor is there any public information about whether they plan to set aside any of their supply for this purpose.

With total production estimates capped at a maximum of 1 billion doses in 2021, 22% of Moderna's supply is already guaranteed to go to this small group of rich countries. If the USG and the EU both agree to exercise their respective 400 million and 80 million dose supply options, a full 760.5 million of the 1 billion dose total (76%) would be captured by just a small group of rich countries, with the US by itself cornering 50% of total supply in 2021.

As relates to the key question of which groups should be prioritized with the first supplies of vaccines, Moderna has made no public commitments.

CEO Pay¹¹³

FY 2019: \$8,948,207 FY 2018: \$58,608,484

Political lobby spend in US¹¹⁴

Q1 2020: \$10,000 Q2 2020: \$70,000

Pfizer and BioNTech (BNT-162)

Research and development

Pfizer and BioNTech are jointly developing a COVID-19 vaccine, ¹¹⁵ based on BioNTech's proprietary mRNA technology. In clinical trials, five variants of the vaccine are being tested, each including mRNA with instructions to make a distinct piece or the full length of the coronavirus's spike protein. ¹¹⁶ Pfizer and BioNTech started Phase 1/2 in Germany in April¹¹⁷ and in the US back in May. ¹¹⁸ In July, the companies announced the start of a global (except for China) Phase 2/3 safety and efficacy clinical study to evaluate the lead mRNA candidate BNT162b2 from their mRNA-based vaccine program. ¹¹⁹ Early Phase 3 data presented at an investor event indicated that BNT162b2 was well tolerated with mild to moderate fever, with no severe systematic events reported. ¹²⁰ In mid-September, Pfizer and BioNTech also announced expanding the enrolment of their Phase 3 COVID-19 vaccine trial from 30,000 to up to 44,000

participants allowing for the enrolment of new populations of patients. ¹²¹ The companies received the Fast Track designation from the U.S. Food and Drug Administration (FDA) for BNT162¹²² and the European Medicines Agency (EMA) accepted a rolling review process for BNT162b2's preclinical and clinical data. ¹²³ If these trials have successful results, the companies are projecting that the vaccine candidate could be available before the end of 2020. ¹²⁴

Public funding

Pfizer has stated that it would not rely on government funding, saying that it could move faster on its own. Pfizer has announced it was willing to spend \$1 billion in 2020 to develop and manufacture the vaccine before seeing positive results, but the company has not publicly disclosed (or committed to disclose) the true cost of the R&D and manufacturing, nor other details on whether or how precisely it may spend this budget. Furthermore, Pfizer has already signed a contract with the federal government, in which the US agreed to spend nearly \$2 billion to secure 100 million doses of the company's vaccine. The European Union also struck a 200 million dose deal with Pfizer at an undisclosed per dose price.

Additionally, BioNTech—the owner of the intellectual property for BNT-162—received a \$117 million (€100m) debt financing agreement with the European Investment Bank, a publicly owned international financial institution whose shareholders are the EU member states, for the development of its vaccine. Finally, BioNTech also received a \$439 million (€375m) grant from the German Federal Ministry of Education and Research to support scale-up of manufacturing and development process. Page 128

Transparency

Pfizer and BioNTech have not yet committed to disclosing the terms and conditions of any contracts for development or procurement with public entities, nor to being transparent about the true cost of R&D and manufacturing of its vaccine candidate.

Pricing strategies

Albert Bourla, CEO of Pfizer stated, "If we were to implement free, open-market principles in pricing the product, we could go to huge prices and sell everything we can manufacture. But it would be unethical, I think. We will not do it, because that's really taking advantage of a situation, and people will not forget if you do that." 129

However, he also stated that the vaccine is a "huge commercial opportunity," ¹³⁰ and that the company will not take a not-for-profit approach to the COVID-19 vaccine, as other companies have. ¹³¹

In the US, the companies have priced the vaccine at \$19.50 per a dose, or approximately \$40 per two-dose regimen, for its 100 million dose order. Pricing is based on a number of factors, according to the company's communication with investors, including volume purchased, advanced purchase time, equity and value from health savings. While price points for other countries are unknown, Pfizer told investors that that \$19.50 is a good benchmark for pricing for other industrialized countries that order the same volume of the vaccine.

Pfizer/BioNTech's vaccine has, so far, the highest publicly disclosed price of the vaccine candidates explored in this brief. An industry financial analyst estimates that cost of goods sold for each dose is in the single digits, suggesting that Pfizer could make a 60-80% profit margin on its deal with the US.¹³⁵ The price per unit also does not include the potentially very high expenses of the new and costly ultra-cold chain facilities needed to transport and distribute the mRNA vaccine,¹³⁶ a financial burden most likely falling on governments on top of the cost of the vaccine itself.

Production levels

Pfizer plans to outsource production of its current drug portfolio to its current 200 contractors to make way for its COVID-19 vaccine manufacturing operations.¹³⁷ Pfizer has designated three US sites (Kalamazoo, Michigan, Andover, Massachusetts, and St. Louis, Missouri) and one Belgian site (Puurs, Belgium) for its vaccine rollout.¹³⁸ BioNTech is producing the mRNA for the COVID-19 vaccine candidates for clinical trials in house at two of its existing facilities. In addition, BioNTech plans to acquire a GMP certified manufacturing facility in Marburg, Germany, with a production capacity of up to 750 million doses per year, once fully operational. The company plans to be able to produce up to 250 million doses of BNT162b2 in the first half of 2021.¹³⁹ Together, the companies are anticipating the ability to manufacture up to 100 million doses by end of 2020 and potentially 1.3 billion doses in 2021.¹⁴⁰

Sharing intellectual property, technologies and know-how

The German biotech company BioNTech owns the intellectual property for BNT-162.¹⁴¹ Neither Pfizer nor BioNTech has made a public commitment in support of sharing its COVID-19 vaccine knowledge, technology, intellectual property, data and know-how to boost supply, reduce price and enhance equity.

Fair distribution

In July 2020, the UK pre-ordered 30 million doses of the vaccine. Later that month, the US announced it would spend nearly \$2 billion to secure 100 million doses of the companies' vaccine, with the option of buying 500 million more doses in the future. Canada has "pre-ordered" at least 20 million vaccine doses to be delivered over the course of 2021. He Following these deals, Japan also secured 120 million doses. Exploratory talks with the European Union also were concluded to supply 200 million doses, with the option to purchase 100 million more. He Ffizer/BioNTech have also entered into agreements with the governments of Qatar for an undisclosed amount of doses. He Foru, Chile and Costa Rica have each also secured individual deals with the companies, for 9.9 million, He 10.1 million He 3 million doses, 150 respectively.

Alongside these bilateral deals, Pfizer and BioNTech have provided an expression of interest for possible supply to the COVAX Facility, 151 which aims to provide low- and middle-income countries (LMICs) access to COVID-19 candidate vaccines. And while the companies have said that they are setting aside doses for LMICs, it is unclear how many doses will be available for poorer countries.

If these deals discussed above materialize, only 23 million doses (2% of total supply) would be available at present to LMICs. Meanwhile, 36% (470 million doses) of Pfizer/BioNTech's 1.3

billion dose capacity (36%) would be guaranteed for rich countries. If the USG and the EU both agree to exercise their 500 million and 100 million dose respective options, a full 1.07 billion of the 1.3 billion dose (82%) would be captured by a handful of rich countries, with the US (only 4% of the world's population) by itself cornering 46% of total supply of this vaccine in 2021.

As relates to the key question of which groups should be prioritized with the first supplies of vaccines, Pfizer has signed a communique supporting "evidence-based prioritization so that health care workers, high-risk individuals, and other priority groups identified by WHO and other health authorities are protected for the duration of the pandemic, regardless of the country they live in." ¹⁵²

CEO pay (Pfizer)¹⁵³

FY 2019: \$17,928,963 FY 2018: \$9,854,557

Recent investor payouts (Pfizer)¹⁵⁴

Q1 2020: \$2.1 billion in dividends Q2 2020: \$2.1 billion in dividends

FY 2020 (full year expected): \$8.21 billion (\$8.21 billion in dividends; \$0 in share buybacks)

FY 2019: \$16.9 billion (\$8 billion in dividends; \$8.9 billion in share buybacks)

Political lobby spend in US federal government (Pfizer)¹⁵⁵

Q1 2020: \$4,090,000 Q2 2020: \$2,470,000

Recommendations

Access to COVID-19 vaccines and treatments will determine who lives and who dies. A people's vaccine is not just the right thing to do, it is also the fastest way to jumpstart our economy and prevent economic devastation facing families and small businesses. We cannot reopen our economy until we have an effective vaccine and enough people receive it. Who gets these life-saving goods—and when—will also determine how long this global health and economic crisis will continue to uproot our lives. That's why we are calling on Pharma and the US government to back a People's Vaccine.

We urge pharmaceutical corporations developing COVID-19 vaccines to:

Become fully transparent about all public subsidies and tax incentives received, the true costs of producing treatments and vaccines, and all lobbying activities here and around the world.

Contribute to making COVID-19 vaccines free of charge to the public by setting the price of vaccines as close to the true cost of manufacturing as possible.

Forgo monopoly control over all COVID-19 vaccines to allow for worldwide, low-cost production to meet the unprecedented demand. This will require sharing of intellectual property, data, know-how and to engage in deep technology transfer where appropriate.

Commit to support fair global and domestic distribution based on need, not price or nationality.

Contribute their fair share of tax to support public health systems—by publicly committing to pay tax on profits where economic activity takes place, stop shifting profits to low-tax jurisdictions, and committing to begin reporting to the Global Reporting Initiative's new Tax Standard.

We urge the President of the United States of America to:

Push for full transparency over US funding for development and purchase of COVID-19 vaccines, including by publishing contracts (and all of the terms and conditions of agreements signed) with companies and manufacturers so that the public can know what access terms have been negotiated, as well as determining the contributions to R&D provided for by the US government.

Guarantee that COVID-19 vaccines are made available free of charge to everyone, everywhere, with priority toward those most in need and/or at-risk. To make this fiscally responsible for the US and other governments, this will require including meaningful affordability conditions in government contracts with drug companies.

Immediately engage with world leaders to negotiate a fair global and equitable rapid manufacturing and distribution plan for the vaccines and all COVID-19 products and technologies that guarantees transparent 'at true cost-prices' and supplies according to need. The US should align itself, as much as possible, with the WHO's equitable allocation framework, and ensure sharing of new vaccines with - at a minimum - at risk populations and front-line workers around the world. 156

Commit to take all possible steps to expand supply of a vaccine (vaccines developed by the US through its government funding as well as vaccines under development elsewhere) by sharing medical technology with the public and the world through the licensing of patents and data and providing technical assistance so that vaccines can be widely manufactured (including at-risk manufacturing) and therefore available through a robust and affordable supply. This should be done through the existing global COVID-19 Technology Access Pool (C-TAP), so that COVID-19 vaccine licenses are freely available to all countries. Both BARDA and the NIH can attach technology-transfer and reasonable-pricing conditions to contracts, while government agencies can also overcome patent barriers and authorize competition through the government use of patents. Furthermore, the US government can license such technologies and related knowledge to qualified manufacturers, to partner governments, to the World Health Organization and other entities, to both advance research and expand supply of a new vaccine.

Should the private sector be unable to produce at scale, as is the case today, **invoke the Defense Production Act and the All-Hazards Preparedness Act to ensure mass manufacturing of the vaccines**. The US can activate several existing manufacturing facilities for this purpose and build more, much as other governments, such as the United Kingdom and Canada, have done in recent months.

We urge the US Congress to:

Pass the Make Medications Affordable by Preventing Pandemic Price gouging (MMAPPP) Act, co-lead by Reps. Rooney (R-FL) and Schakowsky (D-IL) in the House, and supported by Sen. Smith (D-MI)¹⁵⁷ and Sen. Harris (D-CA) in the Senate, which requires non-exclusive

licenses for all taxpayer-funded COVID-19 vaccines and treatments, affordable pricing controls, and enhanced transparency around total expenditures on a COVID-19 vaccines and treatments.

Pass the Taxpayer Research and Coronavirus Knowledge (TRACK) Act,¹⁵⁸ introduced Sen. Braun (R-IN) and Sen, Merkley (D-OR), which creates a database of federal biomedical investment information for COVID-19.

Pass the COVID-19 Emergency Manufacturing Act, ¹⁵⁹ sponsored by Sen. Warren and Rep. Schakowsky, which promotes public manufacture of PPE, prescription drugs, and other needed medical supplies.

Company engagement

Oxfam reached out to all the companies named in this briefing to ensure accuracy and fairness of the research findings. Pfizer, BioNTech, Moderna, AstraZeneca, the University of Oxford, and Merck & Co each responded with constructive feedback that has been incorporated into this analysis.

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