YALE INSTITUTE FOR GLOBAL HEALTH

A Discussion On Immediate Covid-19 Vaccine Global Scale Up

June 30 And July 1, 2021

Organized by the Yale Institute for Global Health (YIGH), Global Health Justice Partnership (GHJP), PrEP4All, Public Citizen, AVAC, ICAP at Columbia University and Resolve to Save Lives

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Summary of proceedings

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Note on text: All ‘$’ figures are dollar amounts.
1. INTRODUCTION: PURPOSE OF THE MEETING

Access to effective COVID-19 vaccines has been largely limited to higher-income countries, and current trends and plans for global vaccine distribution and use will do far too little to address the global gaps and have impact on the pandemic. These inequities are a concern on many levels, not the least of which is that delayed vaccination and continuous spread increases the risk of mutations, challenging the efficacy of existing tools. The health and well-being of billions of people in much of the world with limited and insufficient vaccine access remain at heightened risk from SARS-CoV-2, the virus that causes COVID-19, as do their livelihoods and future prospects due to the widespread social and economic impacts of the pandemic. The health, security and economies of the richer world also will remain threatened as long as the pandemic rages elsewhere.

The core premise of the two-day virtual meeting on June 30–July 1, 2021 was that making vaccines available to everyone worldwide as quickly as possible is the only way to minimize the worst short- and longer-term effects of this pandemic. The ethical and public health imperatives are even stronger now that a far more transmissible virus variant is spreading and others that may have equally or even more virulent features are likely to emerge. The consequences of failing to act rapidly and forcefully to close gaps in vaccine access could include millions of additional deaths and deeper and longer-lasting social and economic distress – all of which is avoidable, since the development of effective vaccines means that proven tools are available to blunt such impacts.

The event organized by the Yale Institute for Global Health (YIGH) along with several partners focused on identifying strategies and approaches to forestall these possibilities. It brought together individuals from academia, civil society, multilateral agencies, and philanthropic institutions from the United States (US) and other countries to consider how to jumpstart rapid production of vaccines to ensure that enough doses are available to dramatically increase protection from COVID-19 around the world to reach 50%–70% of the world’s population by the end of 2021.

By virtue of the country’s size, wealth, influence and technological and scientific expertise and experience – as well as its demonstrated appetite and ability over the past 18 months to invest massively in developing vaccine candidates – the US government was identified by the meeting’s organizers as the linchpin to address this urgency, which requires rapidly scaling up production and distribution of vaccines around the world. Much of the discussion centered on a proposal that was presented at the beginning of the meeting: that the most effective and efficient pathway to achieve this goal was to concentrate initially on messenger ribonucleic acid (mRNA) vaccines – specifically, the two that are already in widespread use, made by Moderna and Pfizer-BioNTech – and to have the US
government play a direct, leading role in accelerating scale-up of further production of these vaccines.

This approach framed much of the input during a series of presentations and panel and plenary discussions as participants considered how this could be achieved, what steps were needed to make it a reality, and what other options might be worth considering, including complementary approaches and actions that could be useful for the current health crisis and in the future from a global perspective.

This report provides a summary of some of the main issues and topics discussed. Annexes to this report include a list of participants, the meeting’s agenda, and the text of an advocacy statement to the US government that several participants began drafting during the proceedings. (The statement is not formally associated with the meeting. It was drafted separately by some attendees and was not discussed with an effort to reach agreement or consensus among all who participated in the two-day discussion.)

The meeting was conducted under the Chatham House Rule. Therefore, no specific participants’ names are associated with any of the observations, comments or other input that this report is based on.

2. WHY WE NEED TO ACT: THE CURRENT DEADLY AND INEQUITABLE SITUATION

The COVID-19 pandemic, the biggest global health threat in a century, has already killed 4 million people worldwide. The carnage shows little sign of abating. Some 16,000 people are dying every day, based on recent estimates of one death to COVID-19 every 5.4 seconds. The growing predominance of the more contagious Delta variant has turbocharged new infections and hospitalizations in countries from India to Uganda, and could set back efforts to keep the virus in check in places that had fared relatively well recently or since the pandemic began. Future variants could be even worse.

Vaccines offer the best hope to mute the negative personal and public health impacts in every country. The rapid development, testing and use of several vaccine products with demonstrated safety and effectiveness in mitigating the severity of SARS-CoV-2 infection is a remarkable scientific and policy achievement. But vaccine access has been inequitable, concentrated mostly in higher-income countries that purchased billions of doses in advance.

The multilateral COVAX facility, which was set up with the aim to boost vaccine supply and guarantee fair and equitable access to lower- and middle-income countries (LMICs), has yet to delivered on its original promise. Its targets were not
sufficiently ambitious, and it has not been able to meet its goals due to limited funding, insufficient vaccine supply and logistical challenges; as of mid-July 2021, it had shipped only 138 million doses so far, to 136 countries. Partly as a result, in late June between 0–2 doses had been administered per 100 people in much of Africa compared with, for example, 95 and 110 doses per 100 people in the US and the United Kingdom, respectively. Of the nearly 3 billion vaccine doses administered globally so far, fewer than 2% were in Africa, which translates into only about 60 million doses for a population of 1.2 billion people and 55 member states.

In response to growing pressure to address these inequities, the Group of 7 (G7) countries in June announced donations totaling 1 billion vaccine doses. However, upon closer examination of the actual commitments, only about 733 million doses were promised, and the timeline for meeting these commitments is as much as a year away. The scale and pace fail to reflect the realities, including World Health Organization (WHO) estimates that 11 billion doses will be needed to stamp out the pandemic.

Other factors contributing to the gaps in access and the “deliberate global architecture of unfairness” – in the words of Strive Masiyiwa, Special Envoy to the African Union for COVID response, at a conference on June 23\(^2\) – include overly optimistic projections by vaccine makers that are likely to delay richer countries’ ability to meet their commitments even if they intend to keep them. Some companies (e.g., AstraZeneca and Johnson & Johnson) have struggled with production problems, while others have faced domestic and political pressure forcing limitations on exportation of vaccines – e.g., the Serum Institute announcing that it would not send any of its doses outside of India until the end of 2021 at the earliest, after agreeing to provide 50% of all COVAX doses. Also, high-income countries with excess capacity or clout with producers could decide at some point that their priority instead is to ensure access to booster shots to those already vaccinated and/or to provide vaccination to much lower age ranges, further jeopardizing global commitments.

Meanwhile, a significant share of the vaccines that have been made available in many LMICs have been noted to have less efficacy, which reinforces the perception that richer countries are ‘dumping’ poorer-quality products. Concerns about the quality of Russian- and Chinese-made vaccines have risen with the release of some evidence that appears to show they are less effective and worrying reports of increases in case rates in countries highly dependent on these vaccines.

A related concern is that despite having only a small number of vaccines available, some countries are diverging from recommended stratified strategies for

\(^2\) Strive Masiyiwa did not attend the June 30–July 1, 2021 meeting. His quote was referenced by a participant.
vaccination: mortality-prioritized followed by age-stratified and then mass vaccination. Such challenges to efficient implementation and roll out at a country level are reducing the potential protective impact by failing to prioritize the most vulnerable.

Taken together, these trends and challenges suggest that it will be many years before effective global vaccination coverage will finally occur. The equity gaps and associated health, social and economic consequences will continue to grow, killing and harming millions of people and their communities unnecessarily, without stronger moral and policy leadership by the world’s powers – and especially the United States.

3. PROPOSED PRIORITY PRODUCTS: THE TWO CURRENTLY PRODUCED mRNA VACCINES

Given the need to prioritize speed, efficiency and effectiveness, mRNA vaccines were presented at the meeting as the best product option for initial rapid global scale-up. The main reasons are simple: They have the highest reported efficacy and can be manufactured with speed and at scale. Real-world experience in places including the US and Israel indicate that both the Moderna and Pfizer-BioNTech vaccines have proven to be extremely safe and effective, both in terms of preventing symptomatic COVID-19 disease and SARS-CoV-2 infection. Reported side effects are few and rare, and they seem to be effective against emerging variants.

Experience from both companies (e.g., at BioNTech’s plant in Marburg, Germany and Moderna contractor Lonza’s facilities) also shows that mRNA products can be scaled up rapidly. BioNTech, for example, was able to retool a facility, train staff and begin producing its vaccine within six months. One reason is that the nearly or entirely cell-free production process for antigen coding vaccines is faster, simpler and more robust: A batch can be completed in a couple of days, compared with months for cell-based vaccine products. A smaller footprint is required as well, including in terms of the size of the facilities – which builds in extra flexibility and speed.

Rapidly increasing production of mRNA vaccines would also increase understanding of the platform and the expertise needed to consider how it might be used to fight existing and future health problems. In addition to the potential benefits in mitigating the impact of other diseases, such as tuberculosis, dengue fever, HIV, Lassa fever and malaria, among others, this would help address the oft-heard argument that one should not build manufacturing capacity that risks remaining idle once a crisis has passed.
The cost-benefit analysis is as stark as the lives’ saved one. According to one modeling exercise mentioned by a meeting participant, a global manufacturing program would cost an estimated $25.9 billion. That would cover the cost of producing about 8 billion doses of either the Pfizer-BioNTech or Moderna products, including the capital expenditures to build infrastructure, the purchase of raw materials, labor and distribution costs, etc. In comparison, the estimated economic costs of inaction, should countries continue to pursue an uncoordinated approach to vaccine distribution, could be global gross domestic product (GDP) losses in 2021 alone of as much as $9.2 trillion.

Other mRNA vaccines for COVID-19 are in development or might be developed in the future, including some that may have equal or perhaps even greater efficacy or safety profiles than the Moderna and Pfizer-BioNTech products. Eventually some of these other candidates might be added to the mix of options for use globally. But, scaling up quickly in the short term can only be done with the two vaccines already being produced and used, and therefore they were the only two products discussed at the meeting.

Challenges noted to prioritizing and scaling up with mRNA products

Several possible constraints to scaling up quickly with mRNA vaccines and having them distributed and used efficiently have been noted since they were introduced. The following were among those raised during the meeting:

- **Access to some components could be a bottleneck**, including lipid nanoparticle (LNP) and capping reagents. Only a few small companies supply these ingredients, and investments in additional manufacturing capacity would be needed. On the positive side, the existing supply chains for the two mRNA products are working relatively well and other key players, including LNP makers, have been ramping up production.

- Although hundreds of scientists have been working and publishing on mRNA for over a decade, mRNA is a new technology. Thus, **there are relatively few experts** – and those with the expertise are mostly already engaged in existing production. This could limit the ability to establish new facilities quickly and to ensure quality control.

- The fragility of mRNA molecules means that both existing vaccines must be kept at extremely low temperatures. The **cold chain processes and systems needed** to distribute and store the products are expensive and require an infrastructure baseline that includes constant electricity to power refrigeration. These standards are not yet met in some parts of the world, but experience with the Ebola virus vaccine does provide an example of bringing this standard to rural and low-resource locations. There is some flexibility based on subsequent analysis, which for example has indicated that both products retain effectiveness over one-month storage at...
standard refrigeration temperatures (2-8°C), pre-puncture. However, the critical ‘last mile’ of distribution and use could still be difficult to ensure in some places due to cold chain issues.

- Countries might have **difficulties absorbing the vaccines** provided to them as part of a massive global scale-up initiative of mRNA products and other products. Such problems could set back support for and commitment to the overall initiative and cast doubt on its urgency. Identifying potential weaknesses and ensuring targeted logistical and technical support from multilateral partners is likely to be needed from the very beginning to minimize absorption limitations.

It was observed that a global assessment of what the limitations are and how they might be overcome should be a priority step in any approach involving the greatly expanded use of mRNA vaccines worldwide.

**4. SUGGESTED ACTIONS AND PROPOSALS**

*D Discussions coalesced around two main approaches for moving forward to rapidly increase production, centralized and distributive,* both of which were seen to have merits. A centralized approach could include building or retrofitting one or a small number of large facilities in the US or the European Union (EU) to produce mRNA vaccines. This could be financed and implemented by public entities in either (or both) places, including the US government, and private-sector firms. One way to manage the complexity of regulatory issues could be to license Lonza to manufacture more of the Moderna product. This approach, which would avoid tech transfer, was presented as the quickest way to get production ramped up on a large scale.

A distributive approach would include having mRNA vaccines equivalent to the Moderna or Pfizer-BioNTech products being made in more than one location, with particular attention to manufacturing in LMICs. In most scenarios, the originator or its contracting companies (e.g., Lonza) might not be directly involved in production, but ideally could be engaged to ease complexities of the tech transfer process. (This is critical, since the know-how would be obtained through tech transfer.) Intellectual property (IP) considerations might also need to be addressed, although there do not appear to be patent blockages to produce mRNA vaccines in most LMICs. The hub model discussed in Box 1 below is an example of a distributive approach.

One key factor noted by meeting participants is that facilities capable of making mRNA vaccines exist outside of those currently manufacturing them, including sites in India and other LMICs where capacity could be found for repurposing. Making quality products therefore should be feasible once all the key factors are in
place, including installed equipment, raw materials and consumable, and experts who know how to run processes and do quality control.

Several different and sometimes complementary actions were discussed at the meeting that could facilitate more rapid production under either or both a centralized and distributive approach.

- **Lifting IP protections**, even if just for the duration of the pandemic. This would need to be done for all aspects and components of mRNA vaccine production by one or both of the two companies, including for products made by suppliers (e.g., for LNP production).

- **Technology (or ‘tech’) transfer** is an essential priority for any solutions that include companies other than Moderna and Pfizer-BioNTech producing themselves. According to projections from some meeting participants, it could take 3-6 months from the moment an originator company starts sharing to when production could begin. That optimistic scenario would depend on tech transfer being done in an organized manner, including with the cooperation from and coordination with the originator from the very beginning. Other important considerations regarding tech transfer include:
  - The speed and efficiency of the tech transfer solution will also depend on how often it will be done, and where. For example, bilateral tech transfer would require fewer clinical trials for review and approval, but originator companies might experience strains and delays due to the extra work needed to conduct multiple transfers at the same time. A second scenario of a multilateral tech transfer could reduce some of this strain as tech transfer would only take place once. A critical piece of this type of transfer is that more validation might be needed to ensure that the products made at the participating sites perform as intended.
  - Also as noted at the meeting, one of the biggest barriers to tech transfer is the capacity of recipients to use it. For example, what Lonza was able to do in six months could take a year or longer for many other companies, especially if infrastructure and workforce resources are not readily available.
  - In general, it was acknowledged that tech transfer for mRNA vaccines is likely to be more ‘efficient’ if only done to higher-income countries with the most developed business, expertise and regulatory environments. Yet from a medium-term and longer perspective in particular, tech transfer to LMICs would more broadly disperse global know-how and capacity, reduce single points of failure, decrease dependencies on manufacturers located in high-income countries and their governments’ influence based on domestic and political priorities, and also possibly lead to lower costs.
• The **existing supply chains** built by the two companies are working relatively well and other key players, including LNP makers, have been ramping up production. Relying on the two companies’ existing supply chains thus might be an efficient option in the short term to get products quickly into arms.

**Box 1. WHO consortium proposal: mRNA tech transfer hub in South Africa**

In April 2021, WHO announced that it was seeking to expand the **capacity of LMICs to produce COVID-19 vaccines and scale up manufacturing via the establishment of tech transfer hubs**. This approach is based on a **hub and spoke model that would** transfer a comprehensive technology package and provide appropriate training to interested manufacturers in LMICs. As of early July 2021, an expression of interest generated 28 offers to either provide technology for mRNA vaccines or to host a technology hub (or both). Of those, the vast majority (25) were from LMIC respondents that could receive the technology to produce mRNA vaccines.

In June, WHO and its COVAX partners announced plans for a first hub to be established in South Africa. Partners include local and regional companies and research institutions as well as the Africa Centres for Disease Control and Prevention (ACDC) and the Medicines Patent Pool (MPP).

The goal is to facilitate tech transfer to a wide range of potential manufacturers in different countries by bringing together representatives of all sectors needed to get a product out the door, including IP holders, inventors, developers, researchers and other experts. Participating companies would learn the process and leave with a full understanding of all essential components after several weeks. Regulatory experts would provide GMP (good manufacturing practice) training and develop clinical protocols and pathways to approval, with the South African partner company Biovac ensuring the regulatory pathway in South Africa and eventually manufacturing there itself.

WHO and its partner reportedly have initiated discussions with a number of originator companies, including Moderna and Pfizer-BioNTech. The timeline as to when production of usable vaccines could start is difficult to determine this early on, as it will depend on a number of factors such as cooperation and participation of originator companies in tech transfer and where other the other companies are in development of their versions. **One projection made at the meeting was that with a listed originator, full finish could be achieved in 12**

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Three weeks after the meeting, Biovac signed a letter of intent with Pfizer and BioNTech to produce their vaccine for distribution in the African Union. This ‘fill and finish’ arrangement would include tech transfer and support for facilities’ upgrade as needed.
months and production in 24 months. An extra year would likely need to be added for candidates in Phase 3 clinical trials and another year on top of that for those at Phase 2.

Although the hub will not likely contribute to mRNA vaccine scale-up in the shorter term, it could have substantial benefits in the longer-term fight against COVID-19 as well as responses to other diseases, as noted elsewhere in this report. Yearly COVID vaccinations might be needed eventually, and the mRNA technology could have practical uses in other health areas that have yet to be identified.

Concerns about suggested actions and approaches

Some concerns were noted about each potential action and approach over the course of the meeting. Regarding the distributive approach, they include:

- **Neither Moderna nor Pfizer-BioNTech has publicly indicated any interest** in taking the steps needed to promote or accelerate the scale-up of their products outside of their direct control. This was evident when neither company participated in nor was mentioned when WHO announced the establishment of a new mRNA vaccine technology transfer hub in South Africa in June 2021. (That hub is discussed in Box 1 of this report.)

- **Regulatory challenges** could be significant and time-consuming, especially if production of mRNA vaccines takes place outside of the US and EU. The process of ensuring equal efficacy to the originator product(s) could be complex from a regulatory standpoint for any company anywhere that makes versions of the Moderna and Pfizer-BioNTech vaccines.

- The relatively **lengthy timeframe** required to increase production through the distributive approach could not address shorter-term needs in this increasingly urgent global health crisis.

Regarding the centralized approach, several concerns focused on the potential downsides of having everything be done in one country (the US) or just the US and EU. That scenario was described as risking the further concentration of power in a handful of countries and companies, such as Moderna and/or Pfizer-BioNTech, and possibly preventing the development or emergence of higher-quality mRNA vaccine candidates in the longer term. Such concentration fails to address power structures that created scarcity for LMICs in the first place, ensure greater global interdependence, or reduce the impact of ‘vaccine nationalism’ now or prevent it in the future.

Regarding donations, key concerns emphasized at the meeting were those regarding the size and reliability of supply. Donations could never come close to meeting the huge need or demand in the short or longer term. The approach also
relies to a significant extent on the ‘good will’ of the companies and governments that have already purchased the vaccines for the original purpose of distributing them domestically. There is little to stop them from reneging on donation pledges or to incentivize them to produce and donate more. For these reasons, meeting participants agreed that the approach should be seen as complementary to more extensive, sustainable actions in other areas.

Consensus: immediate, concurrent initiation of both the centralized and distributive approaches

Over the course of discussions at the meeting, it was generally agreed that the centralized and distributive approaches need not be oppositional, and that both should be initiated immediately and in parallel. This might include, for example, building a ‘new Lonza’ plant near an existing one and setting up contractual and logistical procedures to get the greatly increased product lines into global availability. And at the same time, laying the groundwork for production at sites in LMICs, including by facilitating tech transfer and supporting other critical capacity enhancements.

Although the distributive approach cannot achieve rapid mRNA vaccine production increases in the urgently needed shorter term, moving forward now in a distributive manner was seen as vital because of the future benefits beyond COVID in the long term, including when the next pandemic arrives. In this view, the time to act to ensure the capacity and conditions for distributive manufacturing is now, while the brief window of political will might still be open. Otherwise this essential priority will remain unaddressed.

The US government's strong engagement and leadership was invoked as important in both centralized and distributive approaches, whether it actually leads the new manufacturing directly or removes obstacles for other stakeholders to rapidly produce domestically or abroad.

5. What the USG could or should do: tools, strategies and actions

The US government (USG) has several tools it could use to promote or compel rapid global scale-up of and access to mRNA vaccines. They include:

- The USG has some leverage over the originator companies, and especially Moderna, due to its financial and scientific involvement. USG has been a key funder of the Moderna product, having contributed an estimated $6 billion to its development. Scientists at the National Institutes of Health (NIH) played a leading role in developing the core spike molecule at the heart of Moderna’s mRNA vaccine. Most of the details of the contractual arrangements are largely redacted and thus not publicly known, but USG could negotiate aggressively with Moderna for patent licensing terms that
would speed vaccinations to the developing world by requiring the company to cooperate in a plan to dramatically increase production and reduce prices.

- The *Defense Production Act (DPA)* gives USG the right to allocate materials directly. This federal law could potentially be used to mandate that originator companies accept or go into contracts that remove barriers to mRNA vaccine production by other parties, including by essentially forcing tech transfer. Using the DPA would likely be quicker and easier if done for production within the US, for example to create an mRNA vaccine manufacturing hub that would be focused on global access. But Congress has amended the sweeping law to allow it to be used to provide critical infrastructure abroad, which suggests that USG could mandate that Pfizer or Moderna collaborate with a South African company, for example.

- Financing is another tool. USG has already spent billions on vaccine development and an additional *$10 billion for the production of vaccines* was included in the American Rescue Plan Act passed in March 2021. Government funding therefore is available for domestic manufacturing capacity.

**Suggested actions for USG response**

Capitalizing on the above listed tools available to USG was linked directly or indirectly to several suggestions and observations from meeting participants regarding potential actions to be taken by USG to ensure as rapid as possible production scale up of mRNA vaccines for global access. These include the following:

- **Provide funding to companies or consortiums directly**, and with as wide a remit as possible. Cash is what is most needed to begin retrofitting facilities to produce mRNA vaccines in the US and other countries, including in LMICs such as India and Bangladesh. Targeted efforts should be made to get some of the funds to ‘non-traditional’ actors, including companies that have demonstrated the ability and interest to retrofit quickly.

- **Use the Defense Production Act** to renegotiate contracts and force tech transfer. Companies would be paid a royalty in return.

- **Use convening power to bring originator companies to the table** and motivate them to make tech transfer arrangements and take other steps aimed at rapid scale-up. This power could likely get results with both existing mRNA products, but the leverage is especially strong with Moderna given the funding and NIH support it received. Using its convening power in this way could be one of the main steps toward establishing viable hubs such as the one WHO is supporting in South Africa.
• **Offer incentives** to the companies, financially or otherwise. One example could be helping to ensure advance purchasing commitments from the United Nations Children's Fund (UNICEF), Gavi and other big actors in global immunization. This might help to address some companies’ concerns about the financial feasibility of investing in new vaccine production without any guarantees of eventual market or profit.

• **Playing hardball** could be a winning tactic. USG could essentially threaten to make or support the production of other versions of the Moderna vaccine unless the company licenses its technology and/or allows it to be made with reduced licensing fees. One model could be to leverage expertise in government, academia and other sources – e.g., at NIH, the Massachusetts Institute of Technology (MIT) or the University of Pennsylvania – to do tech transfer to produce generic versions without the cooperation of the companies.

• **Make available expertise and vaccine production capacity within the government** to support manufacturing scale-up where it is done. This could include staff at NIH, the Biomedical Advanced Research and Development Authority (BARDA), the Global Immunization Division at the Centers for Disease Control and Prevention (CDC), etc.

• **Help and support advocacy groups** both in and outside the US to find manufacturers other than Moderna and Pfizer-BioNTech that can produce mRNA vaccines.

• **Commission a rapid assessment** to help identify both the criteria needed to competently and quickly produce mRNA vaccines and the facilities currently in the best position to do it. This mapping exercise ideally should be done globally and could be especially valuable for a distributive manufacturing approach.

6. MAKING THE CASE TO USG: POSSIBLE ADVOCACY APPROACHES

A critical challenge that overlayed all discussions at the meeting was how to turn ideas into concrete decisions, policies and actions, especially by USG. The main obstacle is a political one. Even taking into account donations announced at the G7 meeting and in a few other instances, such as during the devastating April 2021 COVID-19 wave in India, the Biden administration has done little to substantively advance vaccine access outside of the US borders. And it has shown minimal interest in leading a massive ‘Marshall Plan’ or PEPFAR-like⁴ response to COVID-19 that would include rapidly scaling up vaccine manufacturing, centralized or decentralized.

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⁴ PEPFAR = US President’s Plan for AIDS Relief, launched in 2003, which has focused on increasing and sustaining access to HIV medicines and prevention tools in LMICs.
Meeting participants suggested several advocacy approaches that might galvanize greater attention, leadership vision and action from key government agencies and officials. There was consensus on the value of presenting a concrete list of prioritized options that could lead to the same result: the immediate and rapid scale-up of the manufacturing and global use of effective mRNA vaccines.

For example, the main overarching ‘credible options’ to be articulated might include public production of mRNA or other vaccines in the US and/or EU; support for private production of mRNA vaccines in the US, EU or elsewhere; and support for mRNA vaccine hubs (including WHO’s supported hub in South Africa, among others). A strong message should be sent that given the urgency of the crisis and the tools USG has at its disposal, it could immediately invest in and drive several solutions at the same time and therefore contribute to short-, medium- and long-term needs related to the current pandemic and future ones.

The following is a list of wide-ranging suggestions from the meeting about points to be made and stressed in efforts to provoke stronger USG action and leadership to take action in one or multiple ways.

- **The lack of global vaccine access is a public catastrophe that needs an ambitious public solution.** Governments are the only actors that can force a massive, rapid scale-up of production and ensure access everywhere.

- **New viral variants are a continued threat to the US public.** Mitigating the sickness and death caused by them in the future, especially for unvaccinated US residents, should be seen as a national defense and health interest. Increased rates of global vaccination can help to reduce the spread and severity of existing and emerging new variants. Increased mRNA vaccine production capacity would also be critical if booster shots are seen as necessary against variants.

- **Production can be ramped up relatively quickly,** as seen by experience in facilities being retrofitted and manufacturing beginning in six months or less.

- **The costs would be relatively small,** especially compared with the huge and growing toll of the global pandemic overall. One estimate is that constructing a hub in the US, for example, would cost about $2 billion. Several times that amount of money has already been allocated for vaccine production and it could be spent domestically or abroad.

- **Moderna and Pfizer-BioNTech are not exclusively capable.** The message sent or implied by the two companies that only they can produce quality mRNA vaccines is false. Other companies in both higher-income and lower-income countries can make them if they have access to the relevant know-how. Production capacity and ability already exist in many LMICs, including India.
• **Tech transfer to LMICs is a perceptive and far-sighted strategy** looking beyond the COVID-19 pandemic as well, including to ensure that the vaccines and other tools to confront future pandemics can be quickly developed, produced, and distributed worldwide. It should be considered an integral component of USG’s commitment to pandemic preparedness.

The following is a list of suggested **advocacy approaches to get the messages and ideas across** successfully and to generate action by USG.

- **Use both internal and external strategies**, including by continuing direct outreach to the administration while also generating media attention and public support that could prove influential.

- **Support the Nullifying Opportunities for Variants to Infect and Decimate (NOVID) Act in Congress**, which has many of the same goals and priorities of the meeting participants – including to vaccinate at least 60% of the world's vulnerable population. Substantial funding would be made available for COVID-19 vaccine manufacturing as part of a ‘whole of government’ response to reduce the crisis’ global impact more extensively and rapidly.

- **Escalate direct action**, including through the use of targeted bad press and good press. ACT-Up-style actions could also have an impact in highlighting the urgency and getting more attention from policy makers and the public.

- **Develop, sign on to and help publicize advocacy initiatives** such as a soon-to-be-launched Médecins Sans Frontières (MSF) digital campaign that will outline the issues and highlight some proposed actions, such as the administration needing to share more doses and accelerate mRNA vaccine production.

- **Identify allies and build a broader coalition**. One step could be to gather support from and show that the public health establishment (e.g., Rockefeller, Public Citizen, etc.) and professional organizations such as the Association of Schools and Programs of Public Health (ASPPH), the American Public Health Association (APHA), the Consortium of Universities for Global Health (CUGH), and the Infectious Disease Society of America are behind the efforts.

- **Expand civil society support**, including in LMICs. This might require finding ways to explain the situation and needs better, with particular attention on the importance and benefits of the sharing of IP and knowledge and the role of tech transfer.

- **Build on but reframe the COVID-19 vaccine patent waiver success**. USG’s waiver decision is definitely a ‘win’, but on its own it is not especially useful because it does not compel any action. Yet, many activists in the US and abroad continue to focus on waiver issues and have not been highlighting
affirmative steps such as public vaccine production or tech transfer. Redirecting activists' attention and resources, while also acknowledging the waiver success and putting it in context, could help to bolster overall advocacy work at global and national levels.
ANNEX 1. LIST OF PARTICIPANTS

Individuals participating in all or part of the June 30–July 1, 2021 vaccine global scale-up discussion are listed below in alphabetical order. The meeting was conducted under the Chatham House Rule. Therefore, no specific participants’ names are associated with specific observations or comments or other input that this report is based on. The report is intended to reflect a summary of the event and not a consensus of all participants and organizers.

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<tr>
<th>Name</th>
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<td>Alain Alsalhani</td>
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<td>Marine Buissonnière</td>
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<td>Larry Corey</td>
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<td>Wafaa El-Sadr</td>
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<td>Martin Friede</td>
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<td>Zoltán Kis</td>
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<td>Suhaib Siddiqi</td>
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<td>Els Torreele</td>
<td>Institute for Innovation and Public Purpose, University College London</td>
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<td>Christian Urrutia</td>
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ANNEX 2. AGENDA

A Discussion on Immediate COVID-19 Vaccine Global Scale Up
June 30th and July 1st, 2021

It is estimated that less than one percent of COVID-19 vaccines administered were in lower income countries. Currently, the COVAX Facility, a global initiative for COVID-19 vaccine distribution, estimates it can provide only 27% coverage for low and middle income country populations in 2021. This is an ethical and global health security challenge for the United States and world, as no country is safe until the vaccine is effectively dispersed worldwide. Our objective is to increase production capacity of mRNA vaccines such that enough doses are available to reach 50 to 70 percent of the world population regardless of resources or geography by the end of 2021.

To address this inequity, the Yale Institute for Global Health (YIGH), Global Health Justice Partnership (GHJP), Prep4ALL, Public Citizen, AVAC, ICAP at Columbia University and Resolve to Save Lives will host an in-depth policy discussion where our goal is to develop detailed recommendations for how the U.S. Government can accelerate scale-up of COVID-19 vaccine access for all nations. In the next six months, we believe it is possible to create an end-to-end solution for getting vaccines to a significant portion of the global population. To galvanize these policy recommendations, the event will engage stakeholders from academia; civil society; IP and tech transfer; manufacturing and pharmaceutical industries; philanthropists; and, multilateral agencies. Funding for this event is generously provided by the Whitney and Betty MacMillan Center for International and Area Studies at Yale.

DAY ONE AGENDA: June 30th, 2021

8:00 – 9:00 Presentation: Landscape, Problem, and Objective
This session will set the problem and context for both days of the workshop. After 30 minutes of presentation the discussion will focus on refining the problem statement and objective of our advocacy.
- **Moderator:** Gregg Gonsalves (GHJP)
- **Presenters:** Saad Omer (YIGH), Marine Buissonniere (Resolve to Save Lives), Zain Rizvi (Public Citizen) and James Krellenstein (Prep4All)

9:00 – 9:50 Manufacturing Capacity for mRNA Panel
This session will be a panel discussion on the key components needed to ensure rapid manufacture of mRNA vaccines at a global scale.
- **Moderator:** James Krellenstein
- **Panelists:** Zoltán Kis, Suhaib Siddiqi
- **Question Prompt:** What are the specific and most impactful policies that need to be in place to ensure rapid manufacture of mRNA vaccines on a global scale?

**9:50 – 10:00 Break**

**10:00 – 11:15 Manufacturing Policy Recommendation Working Session**

Through a facilitated discussion, the goal of this session is to identify and outline policy recommendations for the U.S. to facilitate rapid manufacture of mRNA vaccines at a global scale.

- **Facilitator:** Roxana Bonnell
- **YIGH Fellow:** Rachel Lobe-Costonis

**11:15 – 11:30 Summary of Day One**

**DAY TWO AGENDA: July 1st, 2021**

**8:00 – 8:55 Technology Transfer Panel**

This session will be a panel discussion on the key components needed to enable technology transfer for the scale up of mRNA vaccines.

- **Moderator:** Marine Buissonniere
- **Panelists:** Martin Friede, Marie-Paule Kieny, and Amy Kapczynski
- **Question Prompt:** What are specific policies that need to be in place for the U.S. to enable technology transfer for the rapid scale up of mRNA vaccines?

**8:55 – 9:00 Break**

**9:00 – 10:30 Technology Transfer Recommendation Working Session**

Through a facilitated discussion, the goal of this session is to identify and outline policy recommendations for the U.S. to enable tech transfer to facilitate the rapid manufacture of mRNA vaccines at a global scale.

- **Facilitator:** Els Torreele
- **YIGH Fellow:** Joeseph Williams

**10:30 – 11:00 Summary, Wrap Up, and Next Steps**
ANNEX 3. ADVOCACY SIGN-ON LETTER TO PRESIDENT BIDEN

Listed below is the text of an advocacy statement that several participants began drafting during the meeting, and which was finalized shortly thereafter. Addressed to President Biden, it was constructed as a sign-on letter that both meeting participants and other individuals can add their names to.

NOTE: The advocacy statement is not formally associated with the June 30–July 1, 2021 meeting. It was drafted separately by some attendees and was not discussed with an effort to achieve agreement or consensus among all who participated in the two-day discussion.

July 20, 2021

President Joseph R. Biden
1600 Pennsylvania Avenue NW
Washington, D.C. 20500

Dear President Biden,

Despite significant progress in the United States (US), the coronavirus pandemic continues to threaten lives and security across the globe. Without urgent and immediate scale up of vaccine production and distribution, millions more will be infected and die. The emergence of the Delta variant is resulting in a surge in increasing infection rates in Africa, Latin America and Asia, where vaccines are least available. This highlights the risk of newer, emerging variants, some of which may turn out to be resistant to current vaccines, which will threaten the progress made to date on the pandemic in the US and elsewhere. The time is now for ambitious leadership to vaccinate the world.

The need to be on a “wartime footing” to secure the world against this pandemic viral threat is paramount. Any global COVID vaccination program must be structured to address multiple interlinked priorities. First, the manufacturing capacity of mRNA vaccines in the US must be rapidly scaled up to reach approximately 4 billion people by the end of 2021. The US government has the capacity and the authority to act now and expand current manufacturing facility capacity as well as to develop mRNA vaccine manufacturing facilities, particularly as funding for this effort is already allocated by Congress. Second, it is equally important at the same time to use technology transfer and financing support to allow for further scale up of vaccine manufacturing capacity in all regions of the world. The latter will address the anticipated need for continued COVID-19 vaccination efforts, as well as prepare for the next potential pandemic.

Specifically, the US government should:
• **Commit to establishing 8 billion doses per year of mRNA vaccine capacity within six months using existing federal resources. A plan for this should be announced within one month.**

While multiple types of vaccines have been shown to be safe and effective and will have an important role to play in global vaccination efforts; to date, mRNA vaccines have proven to be faster and more reliable to produce than other vaccine technologies and are more effective against current variants. The U.S. investment in the development of mRNA vaccines, along with its co-ownership of the patents of this new technology, make mRNA vaccines the best first choice for the US role in global scale up. Based on past experience, newly retrofitted US owned facilities can be on-line to produce large numbers of doses within six months. Initial federal funding already allocated by Congress — at least US$10 billion — is likely sufficient for this task.

• **Simultaneously, the US government should develop and implement training and technology transfer for the development and manufacture of mRNA and other vaccines in hubs around the world. Such training and tech transfer can begin immediately in the U.S.-based facilities, at the proposed WHO-supported hub in South Africa, at facilities in India that can be quickly retrofitted for mRNA production capacity or at other locations (e.g., in South Korea). The US government should also compel originators to transfer technology and, in collaboration with other governments, provide financing for vaccine manufacturing around the world.**

The United States should explore all legal options to compel mRNA manufacturing originators to share technology and voluntarily license their technology to contract manufacturers around the world, including mRNA manufacturing hubs. Funding, along with international partners, should also be allocated to scale up manufacturing hubs around the world. In addition, training at USG owned facilities could be used to seed the manufacturing hubs. We cannot pursue one strategy alone and need to operate on multiple fronts and creating new capacity in the US and abroad at the same time is the most sustainable way forward.

• **Begin immediate export of vaccine doses — within one week — to COVAX or through other international distribution mechanisms — of at least 10 million doses per week.**

The United States currently has over 55 million doses of mRNA vaccines in
storage\(^5\), while only vaccinating approximately 900,000 people per day\(^6\). At this rate, it would take over two months to administer just the vaccine doses currently stored. Despite this, mRNA vaccine manufacturers are delivering over 17 million new doses each week to jurisdictions across the US\(^7\). Ten million excess doses could be immediately donated each week, while ensuring that the nation's mRNA vaccine dose stockpile remains constant in size.

We urge you to act now. Announcing within the next 30 days an ambitious global vaccine manufacturing program is the only way to control this pandemic, protect the precious gains made to date, and build vaccine infrastructure for the future.

\(^6\) https://covid.cdc.gov/covid-data-tracker/#vaccinations
\(^7\) Kaiser Family Foundation. Weekly COVID-19 Vaccine Allocations