

# \$25 Billion to Make Vaccines for the World The U.S. Government Must Ramp up Vaccine Production and End the Global Pandemic

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- The United States can help the world produce billions of vaccine doses for just over \$3 per dose. A \$25 billion investment in vaccine production by the U.S. government would produce enough vaccine for low- and middle-income countries in one year.
- Scaling-up production in the United States and in regional manufacturing centers around the world could shave years from the global pandemic.
- With \$25 billion in designated funding, BARDA (the Biomedical Advanced Research and Development Authority) has the experience to quickly implement a worldwide vaccine manufacturing program. It can build on its prior pandemic flu vaccine program. According to the World Health Organization, 19 manufacturers from more than a dozen countries in Africa, Asia, and Latin America have expressed interest in ramping up mRNA vaccine production.<sup>1</sup>
- This proposal aims to leverage the investment the United States already has made in COVID-19 vaccines, including the ownership rights the U.S. government has in the National Institutes of Health-Moderna vaccine. It would also ensure fair compensation to vaccine corporations.
- The proposal would assign authority to BARDA to determine exactly which vaccines should be mass-produced. It would also charge BARDA with determining where to best locate production facilities, which may include retrofitting and adding production lines to existing manufacturing facilities, with a starting presumption that in addition to what vaccine makers can produce on their own the agency would combine contract manufacturing in the United States on behalf of the U.S. government with licensing, technology transfer and investment in regional manufacturing centers around the world.
- In shortening the pandemic by years, this proposal would pay for itself many times over. It would save hundreds of thousands of lives in poorer countries. It would shorten the period of pandemic mitigation measures which are costing trillions in lost economic output. It would reduce the risk of new, vaccine-resistant variants emerging and traveling to the United States. And it would provide enhanced vaccine manufacturing capacity for the United States, making it possible to produce booster shots for coronavirus vaccines, if needed, on a much faster timetable than currently possible.
- The proposal would also reestablish U.S. scientific, technology, humanitarian and foreign policy leadership.

# **Maximizing Vaccine Production**

The U.S. government can maximize vaccine production by sharing vaccine manufacturing technology and building or retrofitting manufacturing facilities both in the U.S. and in regional centers across the world. While this cannot be done overnight, it can help start production in six months and shorten the pandemic, particularly for low- and middle-income countries which otherwise may wait several years for enough doses to successfully vaccinate their populations.

The FDA has authorized use of two mRNA vaccines: NIH-Moderna and Pfizer-BioNTech. Because mRNA vaccines are developed using synthetic processes instead of living cells, production facilities can be smaller, cheaper and faster to establish. mRNA facilities can also be quickly repurposed to tackle new variants and even new viruses. However, the cost of materials to produce mRNA doses is currently higher than for other kinds of vaccines.

#### \$3 Per Dose

# Repurposing and Building Manufacturing Facilities

Based on computational process modelling conducted by Imperial College engineers, Public Citizen estimates 55 production lines are needed to produce eight billion doses of the NIH-Moderna vaccine in one year. The total capital investment would be \$3.2 billion.

# **Producing Doses**

Producing eight billion doses of NIH-Moderna vaccine "drug substance" would cost \$17.5 billion. (Raw material costs are a major component and could be reduced by allowing multiple suppliers. ) Fill and finish to make the final "drug product" would cost \$2.2 billion if existing capacity were redeployed. A 5 percent profit margin would add \$1 billion.

# Technology Transfer

The government can negotiate with Moderna to share the mRNA vaccine technology with other manufacturers. The National Institutes of Health (NIH) and Moderna jointly invented the vaccine. The federal government helped run the clinical trials and paid Moderna to figure out how to scale-up production. Indeed, the public funded the vaccine's entire development. Moderna also does not have permission to use a key patented government technology incorporated in the vaccine. Scholars at New York University estimate that the government could demand over a billion dollars in compensation from Moderna based on its 2021 U.S. sales projections alone.

The government can leverage its rights and, to facilitate rapid technology transfer, provide an upfront \$1.5 billion payment to Moderna. In line with international practice on technology sharing, if Moderna can also be paid a four percent royalty rate on post-pandemic sales. An additional \$500 million can cover costs for a federal rapid-response program to provide technical assistance to manufacturers and the World Health Organization's technology hub, the COVID-19 Technology Access Pool. iii

Table 1: Producing Eight Billion Doses of Coronavirus Vaccine (NIH-Moderna)

| Туре                     | Activities                                    | USG Investment                  |
|--------------------------|---|---------------------------------|
| <b>Building Capacity</b> | - 55 production lines to produce 10,175       | \$3.2 billion                   |
| (Capital Expenditures)   | batches                                       |                                 |
| <b>Producing Doses</b>   | - Raw materials, single-use equipment, vials, | \$17.5 billion (drug substance) |
| (Operating               | reasonable profit                             | \$2.2 billion (drug product)    |
| Expenditures)            | - Labor costs for 4,620 employees             | \$1 billion (reasonable profit) |
| Technology Transfer      | - Technical assistance                        | \$2 billion                     |
|                          | - Compensation to originator corporation for  |                                 |
|                          | sharing intellectual property and know-how    |                                 |
| Total                    |   | \$25.9 billion                  |

World Health Organization, 6th Access to COVID-19 Tools (ACT) Accelerator Facilitation Council meeting <a href="https://www.who.int/news-room/events/detail/2021/05/12/default-calendar/6th-access-to-covid-19-tools-(act)-accelerator-facilitation-council-meeting">https://www.who.int/news-room/events/detail/2021/05/12/default-calendar/6th-access-to-covid-19-tools-(act)-accelerator-facilitation-council-meeting</a> (at 45:51)

Zoltan Kis et al., Rapid development and deployment of high-volume vaccines for pandemic response, 29 Journal of Advanced Manufacturing and Processing 2020.

iii LMIC population is 5 billion, excluding China. We assume 80 percent vaccination is required for herd immunity.

<sup>&</sup>lt;sup>IV</sup> An industry expert noted privately that removing IP barriers could lead to a 40 percent reduction in the price of some raw materials.

v Axios, The NIH claims joint ownership of Moderna's coronavirus vaccine (June 25, 2020), Moderna skirts disclosures of coronavirus vaccine costs (August 5, 2020).

vi WHO, Remuneration guidelines for non-voluntary use of a patent on medical technologies, https://apps.who.int/iris/handle/10665/69199

vii WHO, COVID-19 technology access pool, <a href="http://tinyurl.com/yejmlgne">http://tinyurl.com/yejmlgne</a>.