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COVID-19 Vaccines: Global Health Issues

December 8, 2020

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R46633

CRS REPORT
Prepared for Members and
Committees of Congress

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SUMMARY

R46633

December 8, 2020

Sara M. Tharakan, Coordinator
Analyst in Global Health and International Development

Kavya Sekar
Analyst in Health Policy

Tiaji Salaam-Blyther
Specialist in Global Health

COVID-19 Vaccines: Global Health Issues

The Coronavirus Disease 2019 (COVID-19) pandemic has led to severe health and economic consequences across the globe, with country governments struggling to contain the spread of the disease through physical lockdown and quarantine measures, while working towards vaccines, to prevent further morbidity (illness) and mortality (death). As of December 8, 2020, COVID-19 cases had reached roughly 67 million, with over 1.5 million deaths globally. The successful deployment of a COVID-19 vaccine globally could curb spread of the virus by aiding in creating herd immunity; whereby a high proportion of individuals within a population are resistant to infection based on pre-existing immunity (through vaccination and/or previous infection). At least 200 experimental COVID-19 vaccine candidates are under development worldwide. As of November 30, 2020, several companies, including Pfizer and Moderna, had requested emergency use authorization from the Food and Drug Administration (FDA) for their vaccine candidates. Vaccine development is typically a long, complex, and difficult process that can take decades. However, given the urgency of controlling the COVID-19 pandemic, governments, philanthropies, international organizations, scientists, and manufacturers are expediting research and development (R&D) for COVID-19 vaccines and other medical countermeasures. The stated goal of many entities is making a vaccine widely available within two years. These accelerated efforts include performing different stages of vaccine trials simultaneously, testing multiple vaccine and therapeutic candidates in coordinated clinical trials, and ramping up production and distribution capacity for when a vaccine candidate receives regulatory approval.

Congress appropriates funds for multilateral and bilateral global immunization activities in the Department of State, Foreign Operations, and Related Programs, and Departments of Labor and Health and Human Services appropriations bills. These activities are implemented bilaterally by the U.S. Centers for Disease Control and Prevention (CDC) and the United States Agency for International Development (USAID), and used in support of multilateral vaccine campaigns for diseases like polio and measles, led by groups like the United Nations Children's Emergency Fund (UNICEF). The U.S. government is the second-largest contributor to global vaccination campaigns. During the COVID-19 pandemic, however, U.S. engagement with the international community has been seen as uneven. On the one hand, U.S. agencies such as the FDA are collaborating with international counterparts on COVID-19 vaccines development regulation. On the other hand, the U.S. government has not joined new multilateral and international efforts for COVID-19 vaccine development.

This report provides an overview of U.S. government and multilateral efforts to develop COVID-19 vaccines. It also describes how other related issues, such as domestic and medical product regulation, as well as humanitarian, foreign assistance, diplomatic, and international trade considerations, might affect the availability of an eventual COVID-19 vaccine. As Congress considers its role in advancing a COVID-19 vaccine, it may consider several issues, including

- global health funding options for COVID-19 vaccines,
- low- and middle-income countries' (LMICs) access to COVID-19 vaccines, and
- adapting vaccine platforms for future infectious disease outbreaks.

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Background

As of December 8, 2020, the COVID-19 pandemic has infected over 66 million people and killed more than 1.5 million worldwide.[1] Vaccine development is typically a long, complex, and difficult process that can take many years. Governments, researchers, philanthropies, and other organizations are expediting research and development (R&D) for COVID-19 vaccines (see **Figure 1**), with the goal of making them widely available within two years.[2] Given the urgency of the COVID-19 pandemic, hundreds of experimental COVID-19 vaccine candidates are under development worldwide.[3] More than 50 vaccines are in human clinical trials, and approximately 85 vaccines are in preclinical trials with animals.[4] Several companies, including Pfizer and Moderna, have applied to the FDA for emergency use authorization of their COVID-19 candidate vaccines.

Historically, the United States has been one of the leading country donors to global vaccination campaigns.[8] For example, in FY2018 and FY2019 appropriations for immunization campaigns implemented by the multilateral organization Gavi averaged $290 million annually, while funds for campaigns administered by the U.S. Centers for Disease Control and Prevention (CDC) averaged $226 million annually. USAID provides additional support for global vaccine efforts through health systems strengthening and other efforts. Global experts are considering how to use distribution networks established through these and other programs to distribute eventual COVID-19 vaccines in low-resource settings.

What Is a Vaccine?[5]

A vaccine is a biological preparation that contains small amounts of weak or dead disease-causing agents, known as antigens, which include viruses, bacteria, fractions of these agents, or the toxins they produce. Once an antigen is introduced into a person's body, the immune system "attacks" the antigen and creates antibodies and immune memory cells that prevent future infection from the same disease. Because the antigen in approved vaccines is weakened or dead, vaccines generally do not cause the illness they are designed to prevent (except in rare cases for certain vaccines).[6]

Along with the antigen, vaccines contain other ingredients such as preservatives, stabilizers, and adjuvants. Preservatives are intended to keep vaccines free from contamination. Stabilizers allow vaccines to be stored for a period of time and help stabilize antigens. Adjuvants help trigger the immune response, particularly for vaccines made with fractions of disease-causing agents.[7]

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[1] World Health Organization, *WHO Coronavirus Disease (COVID-19) Dashboard*, December 8, 2020.

[2] Under an accelerated timeline, vaccine development stages may proceed simultaneously. For more information, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Agata Dabrowska and Susan Thaul; CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*, by Suzanne M. Kirchhoff, Judith A. Johnson, and Susan Thaul; CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues, by Agata Dabrowska*; and CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Agata Dabrowska and Victoria R. Green.

[3] Ewen Callaway, "The Race for Coronavirus Vaccines: A Graphical Guide," *Nature*, April 28, 2020.

[4] "Coronavirus Vaccine Tracker," *The New York Times*, November 3, 2020.

[5] Kavya Sekar, Analyst in Health Policy, and Agata Dabrowska, Analyst in Health Policy, contributed to this section.

[6] CDC, *Common Questions About Vaccines*, May 14, 2019.

[7] Department of Health and Human Services (HHS), "Vaccine Ingredients," vaccines.gov, December 2017. CDC, "What's in Vaccines?" August 2019. Food and Drug Administration (FDA), "Common Ingredients in U.S. Licensed Vaccines."

[8] For more information on global vaccination campaigns, see CRS Report R45975, *Global Vaccination: Trends and U.S. Role*, by Sara M. Tharakan.

Debates about the U.S. government role in this process are ongoing. Efforts by the Trump Administration, for example, to withdraw from the World Health Organization (WHO) arguably could be impeding U.S. cooperation with vaccine development efforts coordinated by the organization.[9] On the other hand, the U.S. government is providing some support for COVID-19 vaccine development efforts conducted by other groups. In October 2020, for example, USAID announced a five-year $20 million contribution to the Coalition for Epidemic Preparedness and Innovation (CEPI) for development of vaccines to fight future infectious disease threats.[10] It is unclear how a Biden Administration would affect these issues, although Biden expressed opposition to WHO withdrawal during his campaign.[11]

The Vaccine Development Process[12]

A vaccine is a biological preparation used to provide protection against a disease (see **text box** above). Vaccines typically require three phases of clinical trials in progressively larger groups of human subjects.[13] Vaccines for infectious diseases are generally held to higher safety standards than other medical products because they are intended to prevent rather than treat disease, and because they are often administered to a large segment of the population. In the United States, the Food and Drug Administration (FDA) licenses (i.e., approves) vaccines for marketing based, in large part, on safety and effectiveness data from clinical trials. [14] The entire vaccine development process typically can take roughly 10 years and additional time to manufacture and distribute the vaccine at scale (**Figure 1**). Under certain emergency circumstances, such as a pandemic, , the FDA may issue an emergency use authorization (EUA) in lieu of licensure, allowing for the distribution and use of an unlicensed vaccine while safety and effectiveness data are still being generated.

The traditional vaccine development and approval process is similar globally. Many countries involved in drug development participate in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), which aims to harmonize regulatory standards for safety, efficacy, and quality of pharmaceutical products intended for human use.[15] However, countries are not required to abide by the international standards. Many countries are simultaneously pursuing independent vaccine development efforts while supporting

[9] For more information on the U.S. efforts to withdraw from WHO, see CRS Report R46575, *U.S. Withdrawal from the World Health Organization: Process and Implications*, coordinated by Tiaji Salaam-Blyther.

[10] Chris Galford, "USAID Offers $20M in aid to CEPI for infectious diseases vaccine development," *Homeland Preparedness News*, October 27, 2020. CEPI is a global public-private partnership launched in 2017 to accelerate development of, and increase equitable access to, vaccines for emerging infectious diseases.

[11] See https://twitter.com/JoeBiden/status/1280603719831359489, July 7, 2020.

[12] For more information, see CRS Report R46593, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines*, by Kavya Sekar and Agata Dabrowska.

[13] Phase 1 clinical trials assess safety and immunogenicity in a small number of volunteers. Phase 2 trials assess dosing and side effects and may enroll hundreds of volunteers. Phase 3 trials assess effectiveness and continue to monitor safety and typically enroll tens of thousands of volunteers. *Immunogenicity* refers to an immune response to a therapeutic that may affect product safety and effectiveness. One FDA guidance document specifically defines immunogenicity (for the purpose of the guidance) as "the propensity of a therapeutic protein product to generate immune responses to itself and to related proteins or to induce immunologically related adverse clinical events"; see *Immunogenicity Assessment for Therapeutic Protein Products*, August 2014.

[14] CRS Report R46593, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines*, by Kavya Sekar and Agata Dabrowska.

[15] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), "About ICH."

the COVID-19 Vaccines Global Access Facility (COVAX)—a multilateral effort led by the WHO to combat COVID-19 in low- and middle-income countries (LMICs). The United States government is not supporting COVAX, though U.S.-based nongovernmental organizations, including the Bill and Melinda Gates Foundation, are providing assistance.

U.S. COVID-19 Vaccine Development Efforts

Since Chinese scientists first shared the genetic code for the COVID-19 virus with the global scientific community, on January 11, 2020, U.S. researchers, including those at the National Institutes of Health (NIH), have sought to develop a COVID-19 vaccine.[16] Those efforts have been bolstered by Operation Warp Speed (OWS), the nation's major COVID-19 vaccine, therapeutic, and diagnostic development initiative.[17] The effort is coordinated by the Department of Health and Human Services (HHS) and the Department of Defense (DOD). As of October 29, 2020, eight investigational vaccines were supported within OWS's portfolio.[18] As of November 2020, at least $10 billion in contracts had been awarded for vaccines supported by OWS.[19] Some OWS-supported vaccine partners are also collaborating with multilateral organizations. For example, a COVID-19 vaccine initially developed by the NIH Vaccine Research Center[20] in partnership with the pharmaceutical company Moderna and CEPI is now in Phase 3 clinical trials.[21]

[16] For a complete chronology of the early days of the pandemic, see CRS Report R46354, *COVID-19 and China: A Chronology of Events (December 2019-January 2020)*, by Susan V. Lawrence.

[17] OWS is funded by both regular agency budget authority and funding that was provided in several coronavirus supplemental appropriations acts. For more information, see CRS Report R45715, *Federal Research and Development (R&D) Funding: FY2020*, coordinated by John F. Sargent Jr., and CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*, by Agata Dabrowska et al.

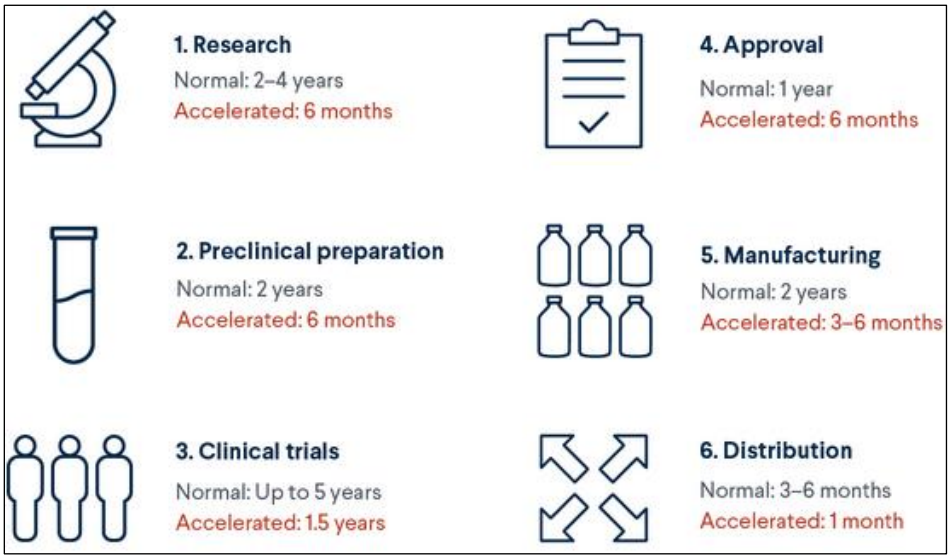
[18] Moncef Slaoui and Matthew Hepburn, "Developing Safe and Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach," *New England Journal of Medicine*, October 29, 2020.

[19] U.S. Government Accountability Office, *Biomedical Research: COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development*, GAO-21-52, October 2020, https://www.gao.gov/assets/720/710287.pdf.

[20] The Date and Betty Bumpers Vaccine Research Center is based in the National Institute of Allergy and Infectious Diseases, one of 27 NIH Institutes and Centers.

[21] "Coronavirus Vaccine Tracker," *The New York Times*, November 5, 2020. National Institutes of Health, "NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins," press release, March 16, 2020; and HHS, "Trump Administration Collaborates with Moderna to Produce 100 Million Doses of COVID-19 investigational vaccine," Press Release, August 11, 2020.

Figure 1. Overview: Normal vs. Accelerated Vaccine Development Process



Source: Claire Felter, *What Is The World Doing to Create a COVID-19 Vaccine?*, Council on Foreign Relations, May 18, 2020, updated May 20, 2020, the *New York Times*, and Johns Hopkins University.

It is unclear how much OWS resources would ultimately be used to support the distribution of COVID-19 vaccines in LMICs, though the Trump Administration reportedly plans to "freely disseminate information" to other countries, share manufacturing technologies, and possibly make extra doses for the world.[22] U.S. technical agencies are clearly engaged globally in other areas affecting COVID-19 vaccine development. The FDA, for example, has been working with the EMA and the International Coalition of Medicines Regulatory Authorities (ICMRA) on vaccine development matters.[23] On March 18, 2020, the FDA and the EMA jointly chaired a meeting of global regulators, through the ICMRA, to discuss regulatory strategies related to the development of COVID-19 candidate vaccines.[24] It is unclear whether participating countries will comply with agreements under ICMRA, however, as the body lacks an enforcement authority.

The FDA also reports that its existing international technical expert clusters that worked together prior to the pandemic have pivoted to focus on COVID-19. [25] According to FDA commissioners, the FDA's "expert group on vaccines has expanded into a multilateral forum to discuss regulatory issues related to the development of SARS-CoV-2 vaccines."[26] The FDA and the EMA also conduct inspections of each other's vaccine manufacturing facilities under a Mutual Recognition Agreement (MRA) developed in May 2014. The MRA allows drug inspectors to use information

[22] Ibid.

[23] The International Coalition of Medicines Regulatory Authorities (ICMRA) is a global coalition of heads of agency created, after calls to do so at the 2012 World Health Assembly, to address common issues around human medicine and safety.

[24] FDA, "FDA and EMA Collaborate to Facilitate SARS-CoV-2 Vaccine Development," press release, March 23, 2020.

[25] Since 2003, the FDA and the EMA have facilitated "technical expert clusters" of U.S. and EU regulatory authorities, along with relevant authorities from Japan, Canada, and Australia, among others.

[26] Anna Abram, Deputy Commissioner for Policy, Legislation, and International Affairs and Mark Abdoo, Associate Commissioner for Global Policy and Strategy, *Partnering with the European Union and Global Regulators on COVID-19*, FDA, June 25, 2020.

from inspections conducted within each other's borders.[27] Currently, the MRA covers routine surveillance inspections, but not preapproval or prelicensure inspections. The MRA does not provide for reciprocal licensure or marketing authorization of vaccines for human use. As a result, a COVID-19 candidate vaccine authorized for use in the EU would not be automatically FDA-licensed or authorized for use in the U.S. population.[28] Further, in the event that a vaccine is first made available in the United States under an EUA, the FDA is not required to inspect the manufacturing facility prior to authorization. Instead, the FDA is expected to rely on manufacturing process data submitted by the company developing the vaccine.

Other Countries' COVID-19 Vaccine Development Efforts

Companies, universities, and research institutes in China, Canada, France, Germany, India, Israel, Korea, Japan, Thailand, and the United Kingdom have COVID-19 vaccine candidates in various stages of clinical trials.[29] Many of these entities are collaborating with international counterparts to carry out clinical trials. For example, the German company BioNTech, U.S.-based Pfizer, and the Chinese company Fosun Pharma announced the launch of Phase 2/3 clinical trials of their BNT162b2 vaccine candidate in the United States, Brazil, and Germany.[30] China has four COVID-19 vaccine candidates in Phase 3 testing and has reportedly administered hundreds of thousands of doses of experimental vaccines to Chinese citizens under urgent use authorizations.[31] Chinese pharma company Sinopharm is reportedly providing emergency doses of two trial vaccines to the United Arab Emirates, and the company is reportedly running Phase 3 trials in Jordan, Bahrain, Egypt, Argentina, Brazil, Bangladesh, Indonesia, Morocco, Peru, Russia, and Saudi Arabia.[32]

On December 2, 2020 the UK's Medicines and Healthcare products Regulatory Agency (MHRA) granted temporary approval to the Pfizer/BioNTech COVID-19 candidate vaccine for use in the country, becoming the first country in the world to do so.[33] The UK National Health Service (NHS) announced that nursing home residents and staff would be prioritized for vaccination, which began on December 8, 2020.[34] According to press reports, some EU politicians and regulators have questioned the UK's relatively fast approval timeline for the COVID-19 vaccine, and cautioned against similar actions in European countries.[35]

Russia has rolled out the "Sputnik V" COVID-19 vaccine domestically, without conducting Phase 3 clinical trials. The Russian government is reportedly planning to supply India with 100 million

[27] 21 U.S.C. §384e. According to the FDA, "under the Food and Drug Administration Safety and Innovation Act, enacted in 2012, FDA has the authority to enter into agreements to recognize drug inspections conducted by foreign regulatory authorities if the FDA determined those authorities are capable of conducting inspections that met U.S. requirements." FDA, *Mutual Recognition Agreement*, May 8, 2020.

[28] Ibid.

[29] "Coronavirus Vaccine Tracker," *The New York Times*, November 5, 2020.

[30] Ibid.

[31] Ibid and Eva Dou and Isabelle Khurdshudyan, "China and Russia are ahead in the global coronavirus vaccine race, bending long-standing rules as they go," *The Washington Post*, September 18, 2020.

[32] Ibid.

[33] Medicines and Healthcare products Regulatory Agency and the National Health Service , "UK medicines regulator gives approval for first UK COVID-19 vaccine ," press release, December 2, 2020.

[34] Ibid and Ivana Kottasova and Emma Reynolds , "First Britons receive Covid-19 vaccine, a landmark moment in the pandemic," *CNN*, December 8, 2020.

[35] "EU criticises 'hasty' UK approval of COVID-19 vaccine," *Al Jazeera* , December 2, 2020. Ciara Nugent , "How the U.K. Approved Pfizer's COVID-19 Vaccine Faster Than the U.S. and Europe," *Time* , December 2, 2020.

doses of Sputnik V, and Argentina, Brazil, Mexico and Kazakhstan have reportedly agreed to purchase Sputnik V vaccine doses.[36]

WHO COVID-19 Vaccine Development Efforts

In April 2020, the Director-General of WHO, the President of France, the President of the European Commission, and the Bill and Melinda Gates Foundation launched the Access to COVID-19 Tools (ACT) Accelerator to accelerate the development, production, and distribution of COVID-19 diagnostics, therapeutics, and vaccines.[37] The vaccine arm of the ACT Accelerator, COVAX, aims to secure 2 billion doses of an eventual COVID-19 vaccine by 2021.[38] According to the WHO, implementing partners of the ACT Accelerator commit to

- promote equitable global access to COVID-19 tools;
- coordinate related activities;
- engage in "collective problem-solving, interconnectedness and inclusivity" so all countries can benefit from the platform's expertise;
- build on lessons learned from controlling past emerging infectious disease outbreaks; and
- be accountable to communities most affected by COVID-19.[39]

The WHO estimates the plan will cost $31.3 billion over 18 months. As of December 2, 2020, donors have contributed $5 billion toward the plan.[40] The ACT-Accelerator has four pillars:

- **Diagnostics.** Co-convened by the multilateral Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) and Foundation for Innovative New Diagnostics (FIND), collaborators are focused on bringing to market high-quality rapid tests, training 10,000 health care professionals across 50 countries, and establishing testing for 500 million people in low- and middle-income countries (LMICs) by mid-2021. The Global Fund estimates that it will cost $6 billion over one year to develop and secure access to diagnostic tests for LMICs.[41]
- **Therapeutics.** Co-led by the U.N. organization Unitaid and British philanthropic Wellcome Foundation, partners are working to develop, manufacture, and distribute 245 million COVID-19 treatments to LMICs by April 2021.[42] The ACT Accelerator Therapeutics Partnerships estimates that it will cost $11.6 billion over one year to accelerate development and evaluation of new and repurposed drugs.[43] Almost 5,500 patients in roughly 40 countries are participating in the WHO-coordinated Solidarity Trial, which has tested the efficacy of four drugs.[44]

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[36] Ibid.

[37] For more information on the ACT-Accelerator, see https://www.who.int/initiatives/act-accelerator.

[38] COVAX, *The COVAX Facility: Global Procurement for COVID-19 Vaccines*, August 6, 2020.

[39] Ibid.

[40] WHO, "Access to COVID-19 Tools Funding Commitment Tracker," News Release, December 2, 2020.

[41] The Global Fund, "Access to COVID-19 Tools Accelerator."

[42] For more information on the Solidarity Trial, see https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments, accessed on July 15, 2020.

[43] ACT Accelerator Therapeutics Partnership, *COVID-19 Therapeutics Investment Case*.

[44] The four drugs are remdesivir, a drug that showed efficacy in initial clinical trials for SARS and COVID-19 and has

- **Vaccines.** Coordinated by the WHO and NGOs CEPI and Gavi, collaborators are searching for an effective vaccine, supporting global manufacturing capacity, and prepurchasing 2 billion doses of COVID-19 vaccine, half of which is planned to go to LMICs by the end of 2021.[45] Gavi estimates it will cost $2 billion to purchase vaccine doses for LMICs once licensed.[46] As of December 2, 2020, over 150 candidate vaccines are being researched, including 13 that are in human clinical trials.[47]
- **Health systems.** Co-led by the World Bank and the Global Fund, collaborators are working to ensure that heath systems, especially in LMICs, are prepared to administer tools developed through the ACT Accelerator. The partners are leading efforts to build health system capacity, particularly in the areas of laboratory capacity, training for laboratory and health staff, management of protective equipment for health workers, contact tracing, and community engagement.[48]

COVAX partners have committed to provide sufficient doses of eventual COVID-19 vaccines to cover 20% of populations in needy countries.[49] Gavi reports that 92 LMICs will be eligible for access to COVID-19 vaccines through a COVAX advanced market commitment (AMC).[50] Although more than 150 countries and regional groups have voiced support for the ACT Accelerator, experts note the absence of the United States—a key COVID-19 vaccine developer—from the initiative.[51] Observers question how the U.S. absence might affect availability of an eventual COVID-19 vaccine, and note actions by several countries and groups who pledged support for COVAX to launch their own trials and enter into independent

since been approved by the FDA for treatment of COVID-19; lopinavir/ritonavir, a licensed HIV treatment; hydroxychloroquine, an anti-malarial drug; and interferon beta-1a, a multiple sclerosis treatment. The Solidarity Trial's International Steering Committee decided to discontinue trials on hydroxychloroquine and lopinavir/ritonavir after finding that the drugs were ineffective in slowing disease progression or improving survival of COVID-19 patients. *Remdesivir* (GS-5734) is authorized for use under an Emergency Use Authorization (EUA) only for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. The drug has not been approved by the U.S. Food and Drug Administration for any use, and its safety and efficacy for the treatment of COVID-19 has not been established. The drug has also been approved as a treatment for patients with severe COVID-19 in Japan, Taiwan, India, Singapore, the United Arab Emirates, and the European Union. The European Commission has granted conditional marketing authorization for Veklury, the branded version of the drug, for the treatment of COVID-19. For more information, see Gilead, "European Commission Grants Conditional Marketing Authorization for Gilead's Veklury® (remdesivir) for the treatment of COVID-19," Press Release, July 3, 2020. For more information, see WHO Solidarity Trial website, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments, accessed on July 15, 2020.

[45] For more information on WHO-coordinated vaccine R&D efforts, see https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/accelerating-a-safe-and-effective-covid-19-vaccine, accessed on July 14, 2020. CEPI is a global public-private partnership launched in 2017 to "accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks." For more information on CEPI, see https://cepi.net/.

[46] Gavi, *The Gavi COVAX AMC: An Investment Opportunity*, June 2020.

[47] Gavi, *The COVID-19 Vaccine Race*, December 2, 2020.

[48] WHO ACT Accelerator website, https://www.who.int/initiatives/act-accelerator, accessed on July 14, 2020.

[49] Ibid.

[50] The COVAX Advanced Market Commitment (AMC) aims to attract $2 billion from investors to be used to bolster the purchasing power of lower-income countries. See more at Gavi, *The Gavi COVAX AMC: An Investment Opportunity*, August 2020.

[51] WHO, "More Than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility," Press Release, July 15, 2020.

agreements with vaccine manufacturers. The European Commission (EC) and Africa Union have each launched their own COVID-19 trials, while asserting support for the ACT Accelerator.[52] Although the EC announced that it "is committed to the principle of universal, equitable and affordable access to vaccines, especially for the most vulnerable countries," it declared in June 2020 that it "will enter into agreements with individual vaccine producers on behalf of the Member States."

Other Multilateral COVID-19 Efforts

Global health experts are considering how to leverage supply chain networks established for routine vaccine campaigns to distribute an eventual COVID-19 vaccine. Key partners under consideration include the United Nations Children's Fund (UNICEF), one of the largest global procurers of vaccines,[53] and Gavi, a public-private partnership launched in 2000 to address declining momentum and funding for child immunization campaigns, of which the United States is a founding member.[54] Gavi is part of COVAX and reportedly is providing emergency funding to countries to procure diagnostic supplies and protective equipment for use against COVID-19.[55] At its June 2020 fundraising summit, Gavi raised over $8 billion, including the February 2020 commitment of $1.16 billion for FY2020-FY2023 from the U.S. government to Gavi's campaigns against vaccine preventable diseases.[56] The Group of 20 (G-20) health ministers are also reportedly developing a global response to the COVID-19 pandemic.[57]

Challenges

Health experts are discussing the following challenges facing the use of eventual COVID-19 vaccines post development:

International cooperation. Some observers warn that "vaccine nationalism," what they describe as an unwillingness to engage with international partners on COVID-19 vaccine development, may undermine U.S. national security," as "vaccine-preventable outbreaks in other countries would eventually make Americans less secure, risking a resurgence of COVID-19 in the country."[58] Others counter that the large COVID-19 outbreak in the United States justifies a concentration of U.S. resources on domestic efforts.[59]

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[52] For more information on EC clinical trials, see https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19#information-on-ongoing-clinical-trials-in-the-eu-section, accessed on July 15, 2020; for information on African Union trials, see https://africacdc.org/news-item/ african-union-commission-launches-consortium-for-covid-19-vaccine-clinical-trial/.

[53] UNICEF, *How UNICEF is helping*, May 2020.

[54] GAVI, Facts and Figures, 2019.

[55] Ibid.

[56] GAVI, *Global Vaccine Summit 2020*, May 19, 2020. Gavi, the Vaccine Alliance, *United States endorses Gavi with recommendation of US$ 1.16 billion, four-year commitment*, February 10, 2020.

[57] "G20 Health Ministers Start Virtual Meeting on Coronavirus," *Reuters*, April 19, 2020.

[58] Eric Friedman, Lawrence Gostin, Mathew Kavanagh, et al., "Joining COVAX Could Save American Lives," *Foreign Policy*, September 15, 2020.

[59] Perspectives from CFR Conference Call: After COVID-19: China's Role in the World and U.S.-China Relations, *After COVID-19: China's Role in the World and U.S.-China Relations*, April 16, 2020.

Public awareness and response. Some experts say that misinformation about COVID-19 is endangering public acceptance and use of an eventual COVID-19 vaccine in many countries.[60] Recent global polls indicate that COVID-19 vaccine acceptance rates may range from 42% (American citizens) to 90% (Chinese citizens).[61] According to experts, at least 60% to 75% of a given population would need to be vaccinated to create herd immunity.[62]

Vaccine manufacturing and related infrastructure. Mass vaccine manufacturing capacity is concentrated in a handful of countries (see **Figure 2**), which may present challenges for the availability of an eventual COVID-19 vaccine to LMICs. Experts note that the high cost of vaccine manufacturing—ranging from $50 million to $300 million per plant—and slow manufacturing processes—which can take 6 months to 29 months—may also affect global availability.[63] Novel vaccine approaches, like the nucleic acid-based (both mRNA and DNA) vaccines, are designed to allow for more streamlined and scalable vaccine production.[64]

[60] Md Saiful Islam, Tonmoy Sarkar, Sized Hossain Khan, et al., "COVID-19–Related Infodemic and Its Impact on Public Health: A Global Social Media Analysis," *The American Journal of Tropical Medicine and Hygiene*, August 10, 2020.

[61] Jeffrey Lazarus, Scott Ratzan, Adam Palayew, et al., "A global survey of potential acceptance of a COVID-19 vaccine," *Nature Medicine*, October 20, 2020. "YouGov Poll Coronavirus July 2020," *Yahoo! News*, July 30, 2020.

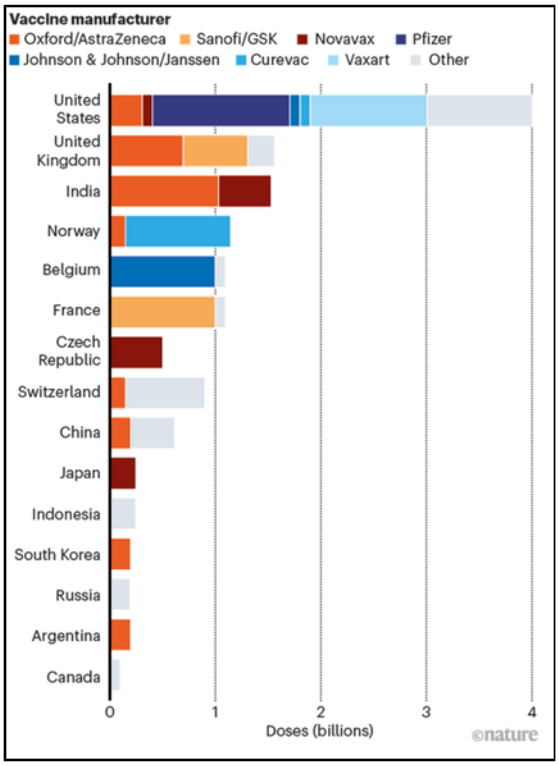
[62] Sarah M. Bartsch, Kelly J. O'Shea, Marie Ferguson, et al., "Vaccine Efficacy Needed for a COVID-19 Coronavirus Vaccine to Prevent or Stop an Epidemic as the Sole Intervention," *American Journal of Preventive Medicine*, July 15, 2020.

[63] R. Gordon Douglas and Vijay B. Samant, "Chapter 4: The Vaccine Industry," in *Plotkin's Vaccines*, 7th ed. (2017), pp. 41-50; and Philippe Juvin, "Complexity of Vaccine Manufacture and Supply," in *Adult Vaccinations: Changing the Immunization Paradigm*, ed. Jean-Pierre Michel and Stefania Maggi (2019), pp. 1-5.

[64] Nicolas A.C. Jackson, Kent E. Kester, Danilo Casimiro, et al., "The Promise of mRNA Vaccines: A Biotech and Industrial Perspective," *npj Vaccines*, vol. 5, no. 11 (February 4, 2020).

Vaccine prioritization and allocation. The supply of eventual COVID-19 vaccines will likely be limited initially, prompting various groups domestically and globally to consider prioritizing distribution of vaccines. In September 2020, the WHO announced a values framework for allocating and prioritizing COVID-19 vaccination, stating that COVID-19 vaccines must be a "global public good" and ensure equity in vaccine access and benefit, both within countries (e.g. for groups experiencing greater burdens of COVID-19) and between countries.[65] In its report on COVID-19 vaccine allocation, the National Academies of Sciences, Engineering and Medicine recommended that in addition to OWS efforts, the U.S. government should join COVAX and deploy 10% of the U.S. vaccine supply for global distribution, "to build global solidarity," and as insurance for the U.S. population in case OWS-backed candidate vaccines prove ineffective.[66]

Figure 2. Where Vaccines Will Be Produced



Source: Ewen Callaway, "The unequal scramble for coronavirus vaccines—by the numbers," *Nature*, August 24, 2020.

Selected Policy Issues

Since the beginning of the pandemic, many Members of Congress have demonstrated strong interest in COVID-19 vaccine development and dissemination, among other related issues. Several House and Senate committees have held hearings that focused on or included discussion of COVID-19 vaccine development.[67] The House Committee on Oversight and Reform created the Select Subcommittee on the Coronavirus Crisis, which has held hearings and released reports overseeing the Administration's response to the pandemic.[68] Many Members of Congress have also delivered floor speeches, given press statements, and held town halls and discussions on COVID-19

[65] World Health Organization Strategic Advisory Group of Experts on Immunization, *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*, September 14, 2020.

[66] The National Academies of Sciences, Engineering and Medicine, "Ensuring Equity in COVID-19 Vaccine Allocation Globally," in *Framework for Equitable Allocation of COVID-19 Vaccine* (National Academies Press, 2020).

[67] For example, on March 5, 2020, the House Science, Space and Technology Committee held a hearing on Understanding the Spread of Infectious Diseases. On July 2, 2020, the Subcommittee on Labor HHS Education and Related Agencies Appropriations held a hearing on Review of Operation Warp Speed: Researching, Manufacturing, and Distributing a Safe and Effective Coronavirus Vaccine. On July 21, 2020, the House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing on Developing a COVID-19 Vaccine. On September 9, 2020, the Senate HELP Committee held a hearing on the Role of Vaccines in Preventing Outbreaks.

[68] For more information on reports and oversight activities from the House Select Subcommittee on the Coronavirus Crisis, see https://coronavirus.house.gov/news.

vaccines.[69] During the 117th Congress, Members may consider the following issues related to COVID-19 vaccines.

Funding for COVID-19 Vaccines

A number of bills have been introduced in the 116th Congress to provide additional support for bilateral and multilateral COVID-19 pandemic responses.[70] For example, S. 3669, the COVID-19 International Response and Recovery Act of 2020, calls for continued support for multilateral COVID-19 responses and would direct the Administration to "increase funding for the United Nation's effort to combat COVID-19 in the world's poorest and most vulnerable countries." The 117th Congress might consider other issues, including

- whether to encourage Administration representatives to the multilateral development banks to use their voices and votes to generate global support for COVID-19 vaccine development and distribution efforts aimed at low-resource countries;[71]
- whether to encourage the Administration to work with the G7 and G20 to support a global COVID-19 vaccines distribution effort, particularly in LMICs, and U.S. government support for such efforts;[72]
- how to balance funding for bilateral and multilateral COVID-19 immunization campaigns; and
- whether to leverage existing U.S. global health programs for COVID-19 vaccine distribution in LMICs, for example by using improved health system capacity from the President's Emergency Plan for AIDS Relief, to aid in the deployment of COVID-19 vaccines.

LMICs Access to COVID-19 Vaccines

In the 116th Congress, Members have debated how to balance support for domestic and international COVID-19 vaccine development efforts. For example, S. 4546, the Abiding by the United States Commitment Acts of 2020, states that "the United States should participate in

[69] For example, see Representative Fred Keller, "Congressmen Fred Keller and John Joyce Hold Virtual Discussion on COVID-19," press release, October 30, 2020; Congressman Bradley Byrne, "Taking A Vaccine Seriously," press release, October 26, 2020; Senator Gary Peters, "New Peters Report Presses Trump Administration to Take Immediate Action to Ensure Trusted, Safe, Effective Coronavirus Vaccines," press release, October 23, 2020; Senator Maggie Hassan and Senator Lisa Murkowski, "The FDA and CDC Promised Transparency in the Vaccine Approval Process. Here's How Congress Can Hold Them to It," *Time Magazine*, October 23, 2020.

[70] For example, see Lois Frankel, "America's Global Leadership During COVID-19," extension of remarks, *Congressional Record*, vol. 166, part 80 (April 28, 2020), and Grace Meng, "America's Global Leadership During COVID-19," extension of remarks, *Congressional Record*, vol. 166, part 80 (April 28, 2020).

[71] For example, see S. 3829, the Global Health Security and Diplomacy Act of 2020, which would require the United States to enter into negotiations to establish a "Trust Fund for Global Health Security" within the World Bank to "advance research, development, and deployment of effective infectious disease tracking tools, diagnostics, therapeutics, and vaccines." The bill would also authorize U.S. contributions to CEPI and the appointment of a U.S. representative to the Investors Council of CEPI.

[72] At the G20 Leaders' Summit in Riyadh, Saudi Arabia, on November 21-22, 2020, leaders committed to "fully support ... the COVAX facility [of the ACT Accelerator]." For more information, see G20 Summit, *G20 Riyadh Summit Leaders Declaration*, November 22, 2020. As of November 30, 2020, the WHO, Gavi, and CEPI had indicated that COVAX still needs approximately $26 billion to fully fund its goals of vaccinating 20% populations in LMICs by the end of 2021.

global public-private efforts to develop, manufacture, and equitably distribute a vaccine for COVID-19, including in the COVID-19 Vaccines Global Access (COVAX) Facility."[73] Similarly, some members of the Senate Health, Education, Labor and Pensions (HELP) Committee released a $25 billion plan that would "require U.S. membership in and support for ... international efforts to develop vaccines, encourage COVID-19 vaccine developers to transfer their COVID-19 vaccine technology to other countries, and participate in the ACT Accelerator, CEPI, and other efforts."[74] Other Members have prioritized ensuring that U.S. COVID-19 vaccine needs are met before investing in international vaccine distribution efforts. For example, S. 4542, the America First Vaccine Act, would prohibit international distribution of a COVID-19 vaccine developed with federal funding until "the domestic need for the vaccine has been met."[75]

Adapting Vaccine Platforms for Future Disease Outbreaks

The U.S. government has long invested in vaccine and therapeutics research and development, including to prevent and prepare for future infectious disease outbreaks. Some investigational vaccines and existing therapies being tested for potential use in COVID-19 patients were created with U.S. government investment and research support through NIH and DOD, among others. As required by Public Health Service Act (PHSA) Section 2811, several agencies participate in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), an interagency coordination effort to annually assess and update a strategy and implementation plan for medical countermeasure preparedness for public health emergencies, such as infectious disease emergencies. Participating agencies include NIH, DOD, and the Biomedical Advanced Research and Development Authority (BARDA). The PHEMCE played major roles in vaccine development for the Ebola and Zika outbreaks.[76] According to testimony by former BARDA Director Rick Bright, the PHEMCE was largely disbanded in 2017, potentially affecting federal preparedness for COVID-19.[77]

Some experts have called for renewed and further investment in these types of research, arguing that such investments help to ensure the U.S. government is prepared for potential future infectious disease outbreaks. For example, in his testimony to the House Energy and Commerce Subcommittee hearing on COVID-19 Vaccine Manufacturers, Pfizer executive John Young said, "We should learn from this unprecedented global crisis and ensure that the world has vaccine platforms capable of rapid development and deployment to prevent the human and economic tragedy of COVID-19 from ever happening again."[78] Moderna President Stephen Hoge stated that Moderna is using mRNA technologies that are "flexible and quickly adaptable," building on research on vaccines for coronaviruses like SARs and MERs. He also stated, "we have been able

[73] S. 4546, the Abiding by United States Commitments Act of 2020.

[74] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *The Democratic COVID-19 Response: A Roadmap to Getting a Safe and Effective Vaccine to All*, prepared by Senator Patty Murray, Ranking Member, Senate Health, Education, Labor, and Pensions Committee, 116th Cong., 2nd sess., July 13, 2020.

[75] S. 4542.

[76] See Public Health Emergency Medical Countermeasures Enterprise, "PHEMCE Strategy and Implementation Plan," at https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx.

[77] U.S. Congress, House Committee on Energy and Commerce, *Hearing on Science and the New Coronavirus*, 116th Cong., 2nd sess., May 14, 2020.

[78] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *COVID-19 Vaccine Manufacturers*, Testimony of Pfizer Chief Business Officer John Young, 116th Cong., 2nd sess., July 21, 2020.

to research and develop mRNA-1273 so quickly because we leveraged our prior research on vaccines."[79]

Given the U.S. government's historical role in this type of foundational research, Congress may consider whether to provide oversight and strengthen agency requirements for medical countermeasure preparedness for future infectious disease outbreaks. The PHEMCE is already required by Congress to produce a multiyear budget for medical countermeasure development planning (PHSA Section 2811(b)(7)) based on an analysis of potential public health threats. In recent years, these budgets have focused more on preparing for bioterrorism events, antimicrobial resistance, and pandemic influenza than for emerging infectious diseases such as those caused by novel coronaviruses.[80] Congress may consider amendments to this requirement to ensure that the nation is adequately prepared to develop vaccines and other countermeasures for all types of public health threats.

Author Information

Sara M. Tharakan, Coordinator
Analyst in Global Health and International Development

Tiaji Salaam-Blyther
Specialist in Global Health

Kavya Sekar
Analyst in Health Policy

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[79] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *COVID-19 Vaccine Manufacturers*, Testimony of Moderna President Stephen Hoge, 116th Cong., 2nd sess., July 21, 2020.

[80] See "PHEMCE Multiyear Budget," https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/Pages/default.aspx.