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The U.S. Government's Role in Domestic and Global COVID-19 Vaccine Supply and Distribution: Frequently Asked Questions

This In Focus answers frequently asked questions regarding domestic and global vaccine supply and distribution, and U.S. spending on Coronavirus Disease 2019 (COVID-19) vaccines. Unless otherwise stated, information is current as of January 10, 2022.

Domestic Vaccine Development, Purchasing, and Distribution

Which federal agencies funded the development and manufacturing of COVID-19 vaccines? Numerous federal entities supported COVID-19 vaccine development and manufacturing, including the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), the Department of Defense (DOD), and others, both within and separately from the Operation Warp Speed (OWS) initiative. See CRS In Focus IF11951, *Domestic Funding for COVID-19 Vaccines: An Overview* for more information. This product focuses on domestic BARDA efforts.

What agreements did the U.S. government enter into with vaccine manufacturers for COVID-19 vaccine development, manufacturing, and purchase? Sanofi Pasteur and GSK, ModernaTX Inc., Janssen Pharmaceuticals Inc., AstraZeneca, Novavax Inc., and Merck and IAVI entered into agreements with BARDA for the manufacturing and development of COVID-19 vaccines. In some cases, these agreements included provisions for advance purchase of completed vaccines that ensured the U.S. government would own a certain number of doses that resulted from federal investment. Pfizer Inc. accepted funding only for advance purchase of vaccines, not for development and manufacturing. Other subsequent awards were made solely for the purpose of purchasing doses from six manufacturers: Pfizer, Sanofi Pasteur and GSK, ModernaTX, Janssen Pharmaceuticals, AstraZeneca, and Novavax, Inc. Merck and IAVI received a base award for accelerating the development of a COVID-19 vaccine that did not include provision for purchase of doses.

How many COVID-19 vaccines has the U.S. government purchased for domestic use? Roughly 1.2 billion doses of COVID-19 vaccines have been purchased by the U.S. government for domestic use.

Per Pfizer, as of October 28, 2021, a total of 600 million Pfizer vaccine doses have been purchased for domestic use. (The original July 2020 agreement with BARDA and DOD included a provision for ownership of 100 million doses, with the option to purchase an additional 500 million doses. Based on public statements, additional doses purchased in 2020 and 2021 total 550 million, the majority of which were for adult/adolescent doses.) Per the Department of Health and Human Services (HHS), as of June 2021 (the most recent data available), a total of 500 million

ModernaTX vaccine doses had been purchased for domestic use. As of March 2021, a total of 100 million Janssen Pharmaceuticals, Inc., vaccine doses had been purchased for domestic use. These doses were purchased in August 2020. Additionally, the U.S. government has executed contracts with Sanofi Pasteur and GSK, AstraZeneca, and Novavax Inc. that included provisions for federal ownership of a certain number of doses (100 million, 300 million, and 100 million, respectively). These vaccines currently lack an Emergency Use Authorization (EUA) or Food and Drug Administration (FDA) approval. Originally, these vaccine doses were purchased with the intent for domestic use, but they currently have an unspecified planned usage.

How much money has BARDA awarded for COVID-19 vaccine development, manufacturing, and purchasing? BARDA, in partnership with DOD, has committed about \$29 billion for COVID-19 vaccine development, manufacturing, and purchasing among the seven aforementioned vaccine manufacturers. Per the BARDA COVID-19 Medical Countermeasure Portfolio website, awards include \$12 billion to Pfizer; \$2 billion to Sanofi Pasteur and GSK; \$9.6 billion to ModernaTX; \$2 billion to Janssen Pharmaceuticals; \$1.6 billion to AstraZeneca; \$1.6 billion to Novavax Inc; and \$38 million to Merck and IAVI.

How do state and local health departments order vaccines? What systems are used to track orders and distribution, and are data regarding distribution publicly available? The U.S. government continues to determine the maximum number of COVID-19 vaccine doses per manufacturer that each of the 64 state, local, and territorial health jurisdictions can order based on their population over age 18. Additionally, federal providers (e.g., VA, DOD, HHS) and participating nongovernment entities (e.g., pharmacy chains) can place orders based on their populations of need. These jurisdictions and providers can independently determine how many doses to order, up to this threshold amount, and place their order using the Vaccine Tracking System (VTrckS). VTrckS also allows the Centers for Disease Control and Prevention (CDC) to monitor vaccine allocations, distribution, and shipments. Roughly 639.7 million vaccine doses have been delivered domestically, of which 81.2% had been administered.

Is the U.S. government meeting its domestic vaccination goals? In December 2020, then President-elect Joseph R. Biden Jr. announced the intention of administering 100 million vaccines in his first 100 days in office; this goal was met within the first 58 days of his administration. In May 2021, the Biden Administration announced the goal of administering one dose to 70% of the eligible population by July 4, 2021; the 70% threshold was attained in August

2021. Currently, the Biden Administration is focused on vaccinating the unvaccinated and providing booster doses.

Global Vaccine Distribution and Funding

How much foreign assistance has Congress appropriated for COVID-19 vaccine distribution and related efforts? Congress has appropriated roughly \$17 billion for international COVID-19 response, including \$4 billion to Gavi, the Vaccine Alliance, for U.S. membership in the COVID-19 Vaccine Global Access Initiative (COVAX, the vaccines arm of the Access to COVID-19 Tools Accelerator [ACT-A], led by the World Health Organization [WHO] and others). U.S. government commitments for global vaccine readiness efforts total approximately \$1.3 billion. In addition, CDC has committed \$800 million for COVID-19 response and vaccine-related efforts. The remaining \$11 billion is being used for a variety of foreign assistance efforts to respond to the effects of the pandemic.

Is there a central strategy and/or coordinating mechanism governing U.S. government global vaccine distribution efforts? On December 6, 2021, the United States Agency for International Development (USAID) announced the U.S. Government's Initiative for Global Vaccine Access (Global VAX) to accelerate U.S. vaccine delivery. Focus areas include bolstering cold chain supply and logistics, service delivery, vaccine confidence and demand, local planning, and vaccine safety and effectiveness in low- and middle-income countries (LMICs). Global efforts build on U.S. commitments to COVAX. Global VAX activities will be implemented using \$400 million from P.L. 117-2, with a focus on safe vaccine delivery and storage, building in-country vaccine manufacturing capacity and knowledge sharing, and Rapid Response Surge Support (e.g., improving oxygen production and delivery), among other things.

How is the Biden Administration deciding how to allocate global COVID-19 vaccine dose donations? The U.S. government has promised to donate 1.2 billion vaccine doses globally. The White House stated 75% of donated doses will be shared through COVAX to maximize the number of vaccines available equitably for the largest number of countries and at-risk populations within countries. The remaining 25% will be shared directly with countries in need, those experiencing COVID-19 surges, and countries requesting immediate U.S. assistance.

Which countries have received COVID-19 vaccines from the United States? How many doses has the United States committed to donate and how many have been distributed? The U.S. government is the leading donor of COVID-19 vaccines globally, and according to the State Department, has shipped 365 million COVID-19 vaccines to 110 countries, including 103 million doses to sub-Saharan Africa; 89 million doses to East Asia and the Pacific; 60 million doses to Latin America and the Caribbean; 84 million doses to South and Central Asia; 24 million doses the Middle East and North Africa; and 4.1 million doses to Moldova, Ukraine, Kosovo, and Georgia.

What is the status of COVAX, ACT-A, and the Multilateral Leaders Task Force? COVAX has shipped 967 million COVID-19 vaccines to 144 participant countries and economies. Donors have committed \$300

million toward 2022 targets. WHO reports a funding gap of \$6.97 billion to reach ACT-A strategic plan targets, to achieve 70% vaccination coverage in LMICs by mid-2022. The Task Force on COVID-19 Vaccines, Therapeutics and Diagnostics for Developing Countries (the Task Force), established on May 31, 2021, by the International Monetary Fund (IMF), the World Bank Group, WHO, and the World Trade Organization (WTO), is working toward COVAX's targets, improving transparency and data sharing, and seeking \$50 billion in support of COVAX and ACT-A goals.

Where is the global community in meeting these targets? The pace of vaccination in low-income countries would reportedly need to increase to nearly 20 times current levels to achieve these targets. Globally, more than 7 billion shots have been administered, the majority in high-income countries. At least 50 countries are falling short of global vaccination targets; less than 25% of their populations are fully vaccinated (defined as the number of doses in a full regimen of a specific immunization scheme; for example, two doses of the Moderna or Pfizer vaccine). It remains to be seen how the emergence of new variants (such as Omicron), and the need for booster shots for more complete protection against severe disease (in many high-income countries a three-dose regimen is becoming the norm), will affect countries' ability to meet these targets.

Which other countries/entities are top donors to COVAX, and of those that have promised COVID-19 vaccine doses, how many have been delivered? Per the Task Force, other top vaccine donors to COVAX are the European Union (464 million promised, of which 57 million have been shipped), France (120 million promised; 19 million delivered), the United Kingdom (120 million promised; 8 million delivered), and Germany (175 million promised; 15 million delivered). The United States has promised 857 million doses to COVAX, of which 131 million have been delivered.

What contracts does COVAX have with vaccine manufacturers? COVAX has formalized contracts for over 4 billion doses with nine vaccine manufacturers (AstraZeneca, Clover Biopharmaceuticals, Janssen Pharmaceuticals Inc., ModernaTX Inc., Novavax Inc., Pfizer Inc., Sanofi Pasteur and GSK, Sinopharm, and Sinovac). COVAX Advanced Market Commitment doses are capped at \$3 per dose. These contracts are reportedly worth at least \$12 billion.

Are there enough COVID-19 vaccines for the world's population? What factors are hindering global vaccine access? Global COVID-19 vaccine production is at approximately 1.5 billion doses per month, meaning that hypothetically there is sufficient vaccine supply to achieve global vaccination targets. Global health experts identify equitable distribution as the key current issue. WHO has called on countries to donate resources for vaccine rollout in LMICs, and for wealthy nations to swap vaccine delivery schedules with countries in need, accelerate dose sharing, and fulfill donation commitments to COVAX.

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