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Domestic Funding for COVID-19 Vaccines: An Overview

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To date, the U.S. Food and Drug Administration (FDA) has authorized for emergency use three Coronavirus Disease 2019 (COVID-19) vaccines; additional vaccines may become available within months. Federal efforts to develop, manufacture, regulate, purchase, and distribute vaccines have involved a number of agencies. Under the Trump Administration, such efforts were largely organized under Operation Warp Speed (OWS) led by the Department of Health and Human Services (HHS) and the Department of Defense (DOD). Coordinated interagency efforts continue under the Biden Administration.

Many aspects of federal domestic vaccine efforts have thus far been funded by appropriations in COVID-19 relief acts, especially funding to U.S. Public Health Service (PHS) agencies and accounts. The following provides an overview of appropriations for selected domestic COVID-19 vaccine related activities. (With the exception of the mandatory funding provided by the American Rescue Plan Act of 2021 (ARPA), all funding amounts discussed below are classified as discretionary.) The following is meant to inform a general understanding of available funding, but may not capture every federal account that can be used for vaccine-related activities. In general, many of the HHS appropriations are available for multiple years or until expended, and some of the funding is transferrable between accounts by the HHS Secretary. This product does not address financing for vaccine administration, global vaccination funding, or related allocations and spending.

Research and Development, Regulation, Manufacture, and Purchase

COVID-19 vaccine research and development (R&D), regulation, manufacture, and purchase have been largely supported by a collaboration among several federal agencies, including the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), FDA, DOD, and others (formerly OWS). Six vaccines were chosen for coordinated federal support under OWS. Some vaccine R&D has been supported by NIH, BARDA, and DOD separately from the OWS efforts.

For R&D, funding has been provided to accounts at NIH, DOD, and the Public Health and Social Services Emergency Fund (PHSSEF; parent account for BARDA) for COVID-19 related R&D, including vaccine R&D. In addition, over $50 billion in PHSSEF funding has been made available until September 24, 2024 for a broad set of medical countermeasures and surge capacity purposes, including for the

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development, manufacture, and purchase of vaccines and related supplies. Separately, FDA has received broad supplemental appropriations for its regulatory and other activities.

ARPA (P.L. 117-2) further provides appropriations that can be used for activities under this heading (all ARPA funds are mandatory appropriations):

- Section 2303 provides $6.05 billion to HHS, available until expended, for research, development, manufacturing, production, and the purchase of vaccines, therapeutics, and ancillary medical products and supplies—available for COVID-19 (or SARS-CoV-2), its variants, and any disease with potential for creating a pandemic.
- Section 2304 provides $500 million to FDA, available until expended, for a broad set of activities, including for its review of the performance, safety, and effectiveness of vaccines; inspection of vaccine manufacturing facilities; and oversight of the vaccine supply chain.
- Section 3101 provides $10 billion, available until September 30, 2025, for activities under the Defense Production Act with respect to medical supplies and equipment for the pandemic, including for vaccines and related supplies. Funds can support the purchase, production, and distribution of such supplies. After September 30, 2022, funds can be used to meet critical public health needs with respect to any pathogen that the President has determined has the potential for creating a public health emergency.

Domestic Vaccination Programs

The Centers for Disease Control and Prevention (CDC), in collaboration with other agencies, has led efforts with state, local, tribal, and territorial (SLTT) jurisdictions to plan and implement a nationwide vaccination program. Agencies with health care programs (e.g., Indian Health Service, IHS) have separately managed vaccination programs among employees and covered populations. The Biden Administration has expanded the role of additional agencies (e.g., the Federal Emergency Management Agency, FEMA) in vaccination programs, though CDC remains in a leading role.

Earlier in the pandemic, before vaccines were available, CDC had received broad supplemental appropriations for its pandemic-related activities in March 2020, and used some of this funding for vaccination program grants and planning. The Consolidated Appropriations Act, 2021 enacted in December, 2020 (P.L. 116-260) made available $8.75 billion to CDC specifically for vaccination-related activities, available until September 30, 2024. Of this total, at least $4.5 billion was designated for SLTT grants (or cooperative agreements), of which $210 million must be transferred to IHS and a separate amount of not less than $300 million was designated for "high-risk and underserved populations, including racial and ethnic minority populations and rural communities." Funding from the Disaster Relief Fund has also been used to support FEMA's vaccination efforts, including by reimbursing certain costs for SLTT programs and supplying direct assistance (e.g., supplies, personnel) to vaccination sites. With the expanded role of federally qualified health centers in the vaccination program, prior related appropriations may also be relevant.

ARPA (P.L. 117-2) further provides appropriations that can be used for activities under this heading (all ARPA funds are mandatory appropriations). There are many provisions with implications for vaccination programs, though the following are particularly relevant:

- Section 2301 provides $7.5 billion to CDC, available until expended, for activities to plan, promote, distribute, administer, monitor, and track COVID-19 vaccines. Funds may be awarded as SLTT grants, and the HHS Secretary is directed to award supplemental funding to eligible awardees that received grants under Consolidated Appropriations, 2021 (P.L. 116-260) based on an alternative formula allocation as specified.

- Section 2302 provides $1 billion for vaccine confidence activities at CDC, available until expended. Funds are to be used for providing further information and education about vaccines and improving vaccination rates, including through activities in Public Health Service Act Section 313 (amended by Section 311 in Division BB of Consolidated Appropriations, Act 2021, P.L. 116-260) which directs CDC to award grants or contracts for a national, evidence-based campaign on the safety and effectiveness of vaccines.

Other appropriations in the law also have implications for vaccination programs, for example, funding for public health workforce in Section 2501, community health centers in Section 2601, and outreach to older adults in Section 2921. Additional funding of $50 billion for the Disaster Relief Fund has also been provided in Section 4005 that can support FEMA's expanded activities.

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