THORN RUN PARTNERS
GOVERNMENT RELATIONS

Memorandum *March 30, 2020*

COVID-19 Relief Impacts on Vaccine Development and the Pharmaceutical Industry

Introduction

Through three COVID-19 relief bills, Congress has made several reforms, financial commitments, and coverage requirements affecting the pharmaceutical sector. Congress has appropriated billions through the Department of Defense, Food and Drug Administration (FDA), and Biomedical Advanced Research and Development Authority (BARDA) over the three packages to develop and manufacturer COVID-19 therapies and vaccines. The funding comes with stipulations that therapies and vaccines developed using federal funds be offered at "fair and reasonable" pricing. The COVID-19 response requires plans cover eventual COVID-19 vaccines with no-cost sharing, and Congress has tied supplementary Medicaid funding to the agreement that states will cover COVID-19 treatment and vaccines for their beneficiaries with no cost-sharing. Furthermore, Medicare Part D plans will be required to provide up to a 90-day supply of covered prescription medication if requested by a beneficiary during the COVID-19 emergency period.

The relief legislation comes with funding to modernize and increase the capacity of U.S. manufacturing capabilities and increase transparency around potential drug and medical device shortages. It also requires a National Academies report on the security of the U.S. medical product supply chain.

The third COVID-19 package was used as a vehicle for modernization of over-the-counter (OTC) drug regulation. The reforms establish user fees for OTC-related work and makes monograph issuance subject to administrative order, not notice-and-comment rulemaking. It also allows consumers to use health savings accounts to pay for OTC drugs. These long-awaited reforms have passed the House and Senate at various points but their vehicle has never been signed into law until now. Industry advocates noted that the provisions, particularly the health-savings account provisions, will provide financial relief for consumers who have purchased supplies like OTC pain relievers to respond to COVID-19.

Coronavirus I

The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (H.R. 6074) focused on increasing federal access to potential Coronavirus therapeutics and vaccines, as well as funding to facilitate and speed their development. Additionally, the legislation included language to ensure "fair and reasonable pricing" for federal government purchases of potential therapies and

vaccines developed using funding provided by the bill. Details on the pharmaceutical-related provisions of the bill are below:

- **Drug Pricing** — The supplemental package states that government purchases of COVID-19 therapeutics, vaccinations, and diagnostics shall be made according to Federal Acquisition Regulation guidance on "fair and reasonable pricing." This means that the final price is fair and reasonable to both the Government and outside party, and takes into account advisory recommendations, reports of contributing specialists, the current status of the outside party's purchasing system, and issues of risk and uncertainty to the outside party and the Government.[1] The bill clarifies that the HHS Secretary may act under currently available tools to ensure that vaccines, therapeutics, and diagnostics developed using this funding package will be "affordable" in the commercial market. However, such actions may not delay product development.[2]

- **Development** — The bill appropriates $3.1 billion for vaccine, therapeutic, and diagnostic development and purchase through the Public Health and Social Services Emergency Fund.

- **Contingency Funding** — The bill provides $300 million in contingency funding for vaccines, therapeutics, and diagnostics that may be accessed if the need is certified to the House and Senate Committees on Appropriations.

CORONAVIRUS II

The Families First Coronavirus Response Act (H.R. 6201) included increased federal Medicaid funding for states willing to offer increased access to treatment for COVID-19. The bill provided a 6.2 percent increase in the Federal Medical Assistance Percentage (FMAP) for all states, conditioned on states Medicaid programs covering COVID-19-related treatment, vaccines, and therapeutics at zero cost-sharing and on states not making their eligibility standards more restrictive or increasing any cost sharing.[3]

CORONAVIRUS III

The third COVID-19 relief package continued efforts to facilitate and increase therapeutic and vaccine development, but also included reform for over-the-counter drugs and policies to increase transparency and security around the pharmaceutical supply chain. The Coronavirus Aid, Relief, and Economic Security (CARES) Act (S. 3548) mandates that plans cover COVID-19 vaccines without cost-sharing, forthcoming vaccines developed with federal funding be offered at reasonable prices, and allocates funding for the Department of Defense, Food & Drug Administration (FDA), and the Biomedical Advanced Research and Development Authority (BARDA) to develop, manufacture, an

[1] https://www.acquisition.gov/content/15405-price-negotiation
[2] https://www.congress.gov/116/bills/hr6074/BILLS-116hr6074enr.pdf
[3] https://www.congress.gov/bill/116th-congress/house-bill/6201

stockpile therapies and vaccines. Additionally, the legislation mandated that funding be used to modernize and increase the capacity of U.S. manufacturing capabilities, increase transparency around potential drug and medical device shortages, and allocates $1.5 million for a report with the National Academies on the security of the U.S. medical product supply chain.

The bill also included provisions to modernize over-the-counter drug regulation and mandates Medicare plans provide adequate prescription fills to last through the pandemic if requested. The bill would establish user fees for OTC-related work and make monograph issuance subject to administrative order, not notice-and-comment rulemaking. These long-awaited reforms have passed both the House and Senate in various forms but have never been signed into law. Furthermore, Medicare Part D plans will be required to provide up to a 90-day supply of a prescription medication if requested by a beneficiary during the COVID-19 emergency period.

Vaccine and Pharmaceutical Provisions

Provision	Coronavirus III
Vaccine Coverage	The bill mandates that group health plans and health insurance issuers cover forthcoming COVID-19 vaccines without cost-sharing within 15 days of receiving an "A" or "B" rating from the United States Preventative Services Task Force or a recommendation from the Advisory Committee on Immunization Practices. Furthermore, the bill provides for coverage of a COVID-19 vaccine through Part B with no cost sharing.
OTC Reform	The bill would establish user fees for OTC-related work and make monograph issuance subject to administrative order, not notice-and-comment rulemaking. These long-awaited reforms have passed the House and Senate in various forms but have never been signed into law.
Vaccine, Therapeutic, and Diagnostic Purchasing	The bill directs the HHS Secretary to purchase "sufficient quantities" of vaccines developed using funds made available under this legislation under the Public Health and Social Services Emergency Fund (PHSSEF) in sufficient quantities to address the public health need. Any products including vaccines, diagnostics, and therapeutics shall be purchased at fair and reasonable pricing. The Secretary may take measures to make items developed with these funds affordable in the commercial market. The bill allocates up to $16 billion for procurements of countermeasures for the strategic national stockpile.
BARDA	The bill provides no less than $3.5 billion for BARDA, including necessary expenses of manufacturing, production, and purchase of COVID-19 countermeasures at the discretion of the Secretary.
Manufacturing	The bill provides for funding innovations in manufacturing platforms to support a U.S.-sourced supply chain of vaccines, therapeutics, and small molecule active pharmaceutical ingredients via the PHSSEF. Funds under the PHSSEF may be used for the construction, alteration, or renovation of non-federally owned facilities for the production of vaccines, therapeutics, and diagnostics. BARDA funds provided by the PHSSEF may be used for the

Provision	Coronavirus III
	construction or renovation of U.S.-based next generation manufacturing facilities not owned by the United States Government.
Shortage Reporting	The bill requires drug manufacturers to submit additional information six months prior to the date of discontinuance or interruption of manufacture of a drug that is likely to lead to a meaningful disruption in supply, including information about active pharmaceutical ingredients. Requires manufacturers to maintain risk management plans that identify and evaluate risks to the drug supply. Requires manufacturers to report annually to the Food and Drug Administration the amount of each drug manufactured at each manufacturing establishment. The bill also requires medical device manufacturers to submit information about a medical device or component shortage at FDA's request.
FDA Funding	The bill provides $80 million for the Food and Drug Administration to continue the agencies' work of responding to COVID-19. Funding will be used to continue efforts related to shortages of critical medicines, enforcement work on counterfeit and misbranded products, emergency use authorizations and pre- and post-market work on medical countermeasures, therapies, vaccines, and research.
Department of Defense Funding	The bill allocates $415 million for research and development through military medical research programs. It notes that military medical research programs have developed promising vaccines and anti-viral pharmaceuticals, which require additional investment for testing.
Supply Chain Report	The bill provides $1.5 million for commissioning a National Academies report on the security of the U.S. medical product supply chain.
Three-Month Medicare Prescription Fills	The bill requires that Medicare Part D plans provide up to a 90-day supply of a prescription medication, with limitations for safety edits and utilization management, if requested by a beneficiary during the COVID-19 emergency period.