Client Alert | Pharmaceutical & Healthcare / Antitrust/Competition

Impact of the CARES Act on the Pharmaceutical and Medical Devices Industries

March 2020

Authors: **Michael Gallagher**, **Elliott Dionisio**, **Dan Grossbaum**, **Eugene Hutchinson, J. Mark Gidley**

On March 27, 2020, the President signed the Coronavirus Aid, Relief, and Economic Security ("CARES") Act. The purpose of the CARES Act is to provide emergency assistance and health care response for individuals, families, and businesses (primarily in specific large industries such as airlines, hotels, and restaurants) affected by the 2020 coronavirus pandemic.

For the pharmaceutical and medical device industries, the CARES Act focuses on ensuring the availability of lifesaving drugs in a public health crisis by addressing supply chain security and supply shortages of critical drugs and medical products, as well as by encouraging innovation through loosening restrictions on government collaboration with the private sector on research and development of pandemic, epidemic, and countermeasure products. Further, the CARES Act provides funding to the federal government to aid the development, manufacture, and production of countermeasures, vaccines, and small molecule active ingredients, as well as other preparedness and response activities.

Specifically, the CARES Act applies to the pharmaceutical and medical device industries in three key ways:

(1) creates a new system to **report and mitigate drug product and medical device supply shortages,** including addressing security and other vulnerabilities of the supply chain for drug products (Section 3101), and adding new manufacturer reporting requirements for the discontinuation or interruption of the production of drugs and medical devices critical to the public health during emergencies (Sections 3112, 3121),

(2) facilitates the Biomedical Advanced Research and Development Authority ("BARDA") of the Department of Health and Human Services ("HHS") to more easily and rapidly **collaborate with the private sector on developing countermeasure, pandemic, and epidemic products** (Section 3301), and

(3) provides to the Public Health and Social Services Emergency Fund a total of **$27 billion for developing countermeasures, vaccines, and other preparedness and response measures**, with **$3.5 billion** allocated to the **Biomedical Advanced Research and Development Authority** (**"BARDA") for the production and manufacture of vaccines and small molecule active ingredients, including to support**

early scaling-up of manufacturing capacity, at risk prior to new drug approval or label expansion of existing medications addressing COVID-19.

Overview of Provisions Related to Pharmaceutical Manufacturers

Division A – Keeping Workers Paid and Employed, Health Care System Enhancements, and Economic Stabilization

Title III, Subtitle A addresses in part the prevention of, and reporting requirements for, any drug and medical product supply shortages.

- **Report on Drug and Device Supply Chain Security.** The CARES Act directs HHS to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to, in part, examine the security of the US supply chain including: (1) to determine which "critical drugs and devices" are sourced or manufactured outside the US; and (2) to provide recommendations to address any supply chain vulnerabilities that would pose a threat to public health, such as identifying strategies regarding supply chain redundancy/contingency planning, encouraging domestic manufacturing, and improving supply chain capacity. These National Academies are to consult pharmaceutical manufacturers and other industry stakeholders. (Section 3101).

- **Revision to the US strategic national stockpile.** The Act amends the Public Health Service Act to add personal protective medical equipment, and other supplies required for the administration of drugs and vaccines, to the Strategic National Stockpile. (Section 3102).

- **Liability protection for protective equipment.** The Act modifies the Public Health Service Act to provide state and federal liability protection for manufacturers of personal respiratory protective equipment, such as masks and respirators, in the event of a public health emergency, to incentivize production and distribution. (Section 3103).

- **Additional manufacturer reporting requirements in response to drug shortage:** Federal Food, Drug, and Cosmetic Act provisions regarding discontinuation or interruption of production of lifesaving drugs amended to (a) include drugs "critical to the public health during a public health emergency declared by" the Secretary of HHS; (b) require notification to the FDA of "permanent discontinuance" or a "meaningful interruption" of an API; (c) require manufacturers to develop, maintain and implement a "redundancy risk management plan" that identifies risks to the supply of the drug; (d) require that any inspection of plants included on the drug shortage list in the last five years also be provided to the appropriate office in the FDA; and (e) require drug manufacturers to provide information about drug volumes, but exempts certain biologic products or categories of biologic products if the Secretary determines that applying such reporting requirements to such biologic product "is not necessary to protect public health." (Section 3112).

- **Discontinuation or interruption in the production of medical devices.** The Act adds a requirement that a medical device manufacturer of a device that is "critical to public health during a public health emergency," or one for which the Secretary determines that information on a "potential meaningful disruption" is needed during or before a public health emergency, must submit information on device shortages or a device component shortage at the request of the FDA during or in advance of a public health emergency. (Section 3121). A "meaningful shortage" is defined as one that is likely to lead to a "more than negligible" reduction in supply.

    - The notice must be submitted to the FDA at least six months prior to the date of the discontinuation or interruption or as soon as practicable (Section 3121 at p. 224).

    - If the manufacturers fail to provide the requested information, the Secretary shall (1) send a letter informing such failure, and (2) within 30 days, the manufacturer shall submit to the FDA a written response providing the required information, which will be made public unless the FDA determines that the letter to the manufacturer was made in error or there was a reasonable basis for the manufacturing not notifying the FDA. (Section 3121 at pp. 225-26).

    - The FDA shall prioritize and expedite review of approval applications for devices that can help mitigate or prevent shortages. (Section 3121 at pp. 226-27).

- The FDA shall create a list of device shortages similar to that created for drug shortages (Section 3121 at pp. 227-28).

- **The Act provides up to $1.32 billion to health centers serving medically underserved communities to fund expenditures for the prevention, diagnosis, and treatment of COVID-19.** (Section 3211).

Title III, Subtitle A, Part III of the CARES Act addresses product innovation, and amends the Public Health Service act to allow more collaboration between the federal government and pharmaceutical manufacturers.

- **Remove certain restrictions on government collaboration with private sector on research and development.** The Act amends the Public Health Service Act to remove a cap on "other transaction authority" (other transaction defined as "transactions other than procurement contracts, grants, and cooperative agreements") during a public health emergency to allow BARDA to more easily and rapidly collaborate with the private sector on research and development of qualified countermeasures or qualified pandemic or epidemic products. Research and development activities include, but are not limited to, testing of the product and scaling up manufacturing as appropriate. (Section 3301; see also 42 U.S.C. 247d-7e(a); 42 U.S.C. 247d-7e(c)(5)(A)).

    - The amendment removes the requirement for the Secretary of HHS to receive a written determination that the project is essential from the Assistant Secretary for Financial Resources prior to entering "other transactions" expected to cost HHS more than $100 million during a public health emergency. Instead, the Secretary must submit a report after the public health emergency to Senate and House committees regarding the use of funds for the transaction under the amended provisions, which details the outcomes, benefits, and risks of the transaction. (Section 3301; see also 42 U.S.C. 247d-7e(c)(5)(A)(ii)).

    - Any project conducted under the amended procedure shall not terminate upon the expiration of the public health emergency. (Section 3301).

- **Expedites development and approval of animal drugs to treat and prevent animal disease that can spread to humans.** Amends Chapter V of the Federal Food, Drug, and Cosmetic Act to expedite development and review of animal drugs that treat a zoonotic disease in animals that has the potential to "cause serious adverse health consequences for, or serious or life-threatening diseases in, humans." Actions to expedite approval include, but are not limited to, utilizing novel trial designs and development tools. (Section 3302).

Title III, Subtitle C of the CARES Act addresses various matters related to Medicare and Medicaid benefits and reporting, including patient deductibles and prescription filling, and payment reporting periods.

- **Temporary suspension of Medicare sequestration.** From May 1, 2020 to December 31, 2020, Medicare programs under Title 18 of the Social Security Act "shall be exempt from reduction under any sequestration order" issued before, on, or after the date of the CARES Act. Such programs include, for example, hospital insurance benefits for the aged and disabled; supplementary medical insurance benefits for the aged and disabled; Medicare+Choice program; and the voluntary prescription drug benefit program. (Section 3709).

- **Part B beneficiaries receive COVID-19 vaccine without deductibles.** Modifies the Social Security Act to provide that, in the event a vaccine for COVID-19 is discovered, Medicare Part B beneficiaries may receive the vaccine without paying deductibles ("such deductible shall not apply with respect [to] a COVID-19 vaccine and its administration"). (Section 3713).

- **Ninety-day fill for covered Part D drugs.** Modifies the Social Security Act to require, during the COVID-19 emergency period, Medicare prescription drug plans and Medicare Advantage Part D plans to allow individuals enrolled in such plans to obtain in a single fill or refill the total day supply (not to exceed a 90-day supply) prescribed for such individuals for a covered Part D drug. (Section 3714).

- **Payment reporting periods for clinical laboratory diagnostic tests extended.** Modifies the Social Security Act to revise reporting periods for reporting private sector payment rates for clinical

laboratory diagnostic tests (including the payment rate and the volume of such tests) for the purposes of establishing Medicare payment rates. For clinical diagnostic laboratory tests, no reporting is required beginning January 1, 2020 to December 31, 2021, and reporting begins during the period January 1, 2022 to March 31, 2022, and is thereafter required every three years after that period. (Section 3718).

Division B – Emergency Appropriations for Coronavirus Health Response and Agency Operations provides for different categories of emergency funds to prepare for and respond to COVID-19, namely the Public Health and Social Services Emergency Fund.

Title I and Title VIII allocate different categories of emergency funds to prepare for and respond to COVID-19, including development, manufacture, and purchase of necessary medical products, medical supplies, and vaccines.

- **$80 million in additional funding for FDA "to prevent, prepare for, and respond to coronavirus, domestically or internationally."** The Act provides funding for the "development of necessary medical countermeasures and vaccines, advanced manufacturing for medical products, the monitoring of medical product supply chains, and related administrative activities." (Division B, Title I, Related Agencies and Food and Drug Administration, Salaries and Expenses, at pp. 616-17).

- **$27 billion in additional funding to "Public Health and Social Services Emergency Fund" for development and purchase of products to "prevent and prepare for, and respond to the coronavirus domestically or internationally."**

    - The Act provides funding for activities including, but not limited to, the "development of necessary countermeasures and vaccines, prioritizing of platform-based technologies with US-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, as well as medical surge capacity," and "initial advanced manufacturing, novel dispensing, enhancements to the US Commissioned Corps, and other preparedness and response activities." The provision directs the Secretary of HHS to take steps "authorized under current law" to ensure that products developed from the funding "will be affordable in the commercial market," but such steps "shall not" delay the development of such products. Products purchased by the Government will be purchased in accordance with the Federal Acquisition Regulation guidance on fair and reasonable pricing. (Division B, Title VIII, Office of the Secretary, Public Health and Social Services Emergency Fund (Including Transfer of Funds), at pp. 743-44).

    - The Act gives the Secretary of HHS the authority to use up to $16 billion of the funding at the Secretary's discretion to purchase medical products for the Strategic National Stockpile. (Division B, Title VIII, Office of the Secretary, Public Health and Social Services Emergency Fund (Including Transfer of Funds), at p. 744).

    - The Coronavirus Preparedness and Response Supplemental Authority Act, 2020, enacted on March 6, 2020, provided $3.1 billion for similar categories of emergency funding as authorized in the CARES Act to prepare for and respond to COVID-19, that also includes the manufacture and purchase of vaccines and necessary medical supplies. This funding, already enacted into US law, is in addition to the authorized funding in the CARES Act. (Title III, Office of the Secretary Public Health and Social Services Fund (Including Transfer of Funds), at pp. 4-5).

- **$3.5 billion funding to Biomedical Advanced Research and Development Authority.** The emergency appropriations provision provides $3.5 billion of the $27 billion funding to the Public Health and Social Services Fund to BARDA for expenses concerning the manufacturing and production of vaccines and small molecule active ingredients. This funding may provide opportunities for pharmaceutical companies to manufacture potential vaccines, and to construct manufacturing facilities to manage surge capacity. Specifically, the funding is directed to the "manufacturing, production, and purchase of vaccines, therapeutics, diagnostics, and small molecule active pharmaceutical ingredients, including the development, translation, and demonstration at scale of

innovations in manufacturing platforms." (Division B, Title VIII, Office of the Secretary, Public Health and Social Services Emergency Fund (Including Transfer of Funds), at pp. 743-44).

White & Case LLP
1221 Avenue of the Americas
New York, New York 10020-1095
United States

T +1 212 819 8200