INSIGHTS FROM THE BDO LIFE SCIENCES PRACTICE

UNPACKING THE CARES ACT FOR THE LIFE SCIENCES INDUSTRY

Quickened OTC, Zoonotic Approvals & New Reporting Requirements Among Key Provisions

By Andrew Stiles and Stephen Morris *This piece was last updated on April 28, 2020.*

The Coronavirus Aid, Relief and Economic Security Act (CARES Act), a $2.2 trillion stimulus package enacted on March 27, provides aid to businesses of all sizes as well as individuals suffering from economic hardship due to the COVID-19 pandemic.

Life sciences organizations developing products critical to the country's preparedness for and response to the pandemic may pursue new opportunities through additional funding by several federal agencies:

1. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) AGENCIES

- The Food and Drug Administration (FDA) will receive $80 million to fund its salaries and expense costs so the agency can continue operations necessary to effectively respond to the pandemic. This includes approving necessary medical devices, vaccines and therapeutic agents, monitoring U.S. medical supply chains and other activities critical to public health using traditional regulatory pathways as well as Emergency Use Authorization.

- The Public Health and Social Services Emergency Fund, which is a part of the Office of the Secretary, will receive more than $27 billion for the development of necessary measures and vaccines to combat the pandemic, prioritizing platform-based technologies with U.S. manufacturing capabilities.
  - The HHS secretary will purchase vaccines developed using these funds to respond to the coronavirus pandemic. These vaccines and other related products may be procured and deposited in the Strategic National Stockpile (SNS). In terms of funding, no more than $16 billion will be reserved for the SNS.
  - $250 million shall be reserved for grants to/cooperative agreements with entities that are either grantees or sub-grantees of the Hospital Preparedness Program.
  - $3.5 billion shall be reserved for the Biomedical Advanced Research and Development Authority (BARDA) for necessary expenses of manufacturing, production and procurement of vaccines, therapeutics, diagnostics and small molecule active pharmaceutical ingredients (API). The funds can be used for the development, translation and demonstration at scale of innovations in manufacturing platforms. This includes awards using BARDA's Other Transactional Authority.

2. THE NATIONAL INSTITUTES OF HEALTH (NIH)

- The NIH's National Institute of Allergy and Infectious Diseases (NIAID) will receive $706 million to respond to the coronavirus pandemic. This includes $156 million for the study, construction, demolition, renovation and acquisition of equipment for vaccine and infectious disease research facilities of or used by the NIH.

3. SMALL BUSINESS ADMINISTRATION

- Economic Injury Disaster Loan (EIDL) program has received nearly $660 billion.
- The CARES Act temporarily expands eligibility to include most businesses with 500 employees or fewer, though there are affiliation rules to consider and other ways to qualify. These businesses can receive a $10,000 advance on loans through the EIDL. Even if a business is denied a loan under the program, that business will not be required to repay the advance.
- Businesses can receive up to $2 million and pay an interest rate of 3.75%. Nonprofit organizations pay an interest rate of 2.75%.
- Businesses can apply online for an EIDL loan **here**.
- The Paycheck Protection Program (PPP) received billions in federal funds for the purpose of making potentially forgivable loans to help businesses keep workers on the payroll and pay certain fixed expenses with an interest rate of 1%. With added billions more in funding approved for the program in late April, the program allows qualifying small businesses to borrow up to the average total monthly payroll costs during calendar year 2019 or the one year immediately before the loan multiplied by 2.5, or 250% of average monthly payroll expenses. The cap is $10 million.

Additional Tax Incentives Under the CARES Act

The CARES Act includes several other tax incentives, which:

- Provide certain employers with a refundable credit against payroll tax liability. If an employer received an SBA PPP loan, this tax credit is not available
- Postpone for certain employers the due date for payment of employers' share of Social Security taxes. Deferral is unavailable to employers that received PPP loan forgiveness
- Defer the effective date of Section 461(l), which limits non-corporate taxpayers in their use of net business losses to offset other income sources, for three years while making important technical corrections that will take effect when the limitation on excess business losses becomes applicable
- Amend Section 163(j) for taxable years beginning in 2019 and 2020 to allow taxpayers to deduct a higher amount of interest than originally permitted under the Tax Cuts & Jobs Act
- Provide for an elective five-year carryback of net operating losses generated in taxable years beginning after Dec. 31, 2017 and before Jan. 1, 2021

Learn more on these tax incentives—and others.

The life sciences industry should also pay close attention to the following provisions included within the CARES Act:

- **Quicker Review and Approval of Over-the-Counter (OTC) Drugs:** The CARES Act awarded the FDA $80 million to overhaul the regulatory process for OTC drugs to speed up the review and approval of new drugs. According to the FDA, the provision will allow for innovation and improved safety and effectiveness of OTC monograph drugs. This category of drugs includes products like acetaminophen and hand sanitizer, both of which play a crucial role in the coronavirus pandemic. Being able to expedite the review and approval process will hopefully provide Americans with more reliable OTC products in case of a future public health emergency.

- **Faster Review and Approval of Zoonotic Animal Drugs:** If a new animal drug has the potential to treat zoonotic diseases (those that can be transferred from animals to humans) that can seriously threaten public health, the CARES Act allows the FDA to expedite its review process. This has particular implications for the management and mitigation of COVID-19, which is itself a zoonotic disease. Zoonotic diseases have been responsible for several public health emergencies in the past, including rabies, swine flu, West Nile virus, malaria, Lyme disease, Ebola and Avian influenza (H5N1). Being able to treat these diseases before they appear in humans is a crucial step to preventing the next zoonotic public health emergency.

- **National Institute of Biomedical Imaging and Bioengineering (NIBIB), and National Library of Medicine (NLM) funding:** Both organizations will receive $60 million and $10 million, respectively, to "prevent, prepare for and respond to coronavirus, domestically or internationally." NIBIB focuses on using biomedical imaging and bioengineering to help study, diagnose and treat human diseases. The NLM keeps records, including books, journals, microfilms, photographs and technical reports, on medicine and related sciences. Both organizations are part of the NIH.

- **Medical supply chain security report:** The legislation tasks the National Academies of Sciences, Engineering and Medicine with carrying out a report on the security of the U.S. medical supply chain, considering issues of national security and the potential for increasing domestic manufacturing of certain medical supplies. As part of the report, the National Academies may consult with medical product manufacturers in order to determine if their products are sourced or manufactured outside of the U.S. Once the report is completed, the National Academies will provide recommendations and suggestions to confront and remedy supply chain vulnerabilities that could be detrimental to public health.

- **New reporting requirements for drug manufacturers:** The CARES Act subjects drug manufacturers to new reporting requirements related to drug shortages. As part of these requirements, drug manufacturers will need to implement a risk management plan and prepare annual reports for each drug they produce as listed in the Federal Food, Drug and Cosmetic Act. The goal of these requirements is to prevent drug shortages that could worsen a pandemic. During the COVID-19 pandemic, the U.S. has seen several medical product shortages that have exacerbated the situation.

- **New reporting requirements for medical device manufacturers:** The CARES Act also mandates that the FDA more closely monitors devices that could impact public health and safety during a public health crisis, which will require manufacturers to report when production of a medical device is interrupted or discontinued. The goal of these requirements is to ensure that medical devices, such as ventilators, will not be in short supply when needed most, namely during a public health emergency.

- **SNS funding:** The CARES Act designates $16 billion to the U.S. stockpile of critical medical supplies, which has struggled to provide ample personal protective equipment (PPE) and other necessary medical equipment during the COVID-19 pandemic. The intent behind these funds is to enable the stockpile to purchase items useful for responding to the spread of COVID-19, including ventilators and PPE.

4 TAKEAWAYS

We foresee four key outcomes for the healthcare industry from the CARES Act:

1. **A shift in R&D priorities**: In light of expanded federal funding to support the public health response to the pandemic, life sciences organizations able to shift R&D activities to focus on products that could support that response will be able to realize new funding opportunities and could benefit from a more streamlined FDA review and approval process.
2. **Greater focus on and increased opportunity in zoonotic animal drugs**: Organizations focused on these drugs should take note of the truncated approval time and plan their projects accordingly. They should also be prepared for increased scrutiny placed on their products.
3. **A shift from 'just-in-time' to 'just-in-case' inventory strategies:** 'Just-in-case' inventory strategies could address the shortage of critical medical supplies, such as ventilators and PPE, that the U.S. has seen during this crisis. Companies should consider what implications this could have for their product portfolio and pivot relevant manufacturing plans and inventories accordingly.
4. **Increased transparency into supply chains:** Drug, device and supply manufacturers will need to increase visibility into their supply chains to comply with regulations in the CARES Act. As part of this effort, manufacturers will need to consider whether and where their supply chains have blind spots, then work to address them. Technological tools like smart logistics, cloud-based GPS and radio frequency identification technologies can help.

The CARES Act encourages expedited medical innovation, implements new reporting requirements for drug and medical device manufacturers and quickens the review and approval processes of OTC drugs.

To respond to these changes, life sciences organizations should start by considering the following questions:

1. **Does my company manufacture a product that may be critical in a public health crisis**, and if so, how does the CARES Act impact my operations, R&D plans and manufacturing strategies?
2. **What will the timeline for our R&D pipeline look like** now that the review and approval process for certain products has been expedited? Will it change, and if so, how much?
3. **Where are the vulnerabilities or blind spots in my supply chain**, and what does my organization need to do to address them?
4. **Do I need to implement new supply chain reporting processes and procedures** to comply with new reporting requirements?

To learn more about how your organization can respond to these changes, reach out:

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