Michael Best

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Impact of CARES Act on Medical Product Manufacturers

The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which President Donald J. Trump signed into law on March 27, 2020, affects drug and medical device manufacturers in several ways. The following are important takeaways from the CARES Act with regard to drug and medical device approvals.

1. **The CARES Act addresses potential or real supply shortages of medical products (i.e. drugs and medical devices) in the U.S. supply chain.**

- The Secretary of Health and Human Services ("HHS") must report on medical product supply chain security in the U.S.

HHS has been tasked with engaging the National Academies of Science, Engineering, and Medicine ("National Academies") to understand and report on the security of the medical product supply chain in the U.S. The report will be based on assessments and evaluations of the supply chain and will include input from various entities, including health care providers, medical professional societies, medical product manufacturers, health care distributers, wholesalers, and pharmacists, among others.

The emphasis of the report will include an assessment and evaluation of the dependence of the U.S. on drugs and devices that are sourced or manufactured outside the U.S., as well as provide recommendations to improve the resiliency, including vulnerabilities or potential disruptions, of the supply chain for critical drugs and devices.

- The CARES Act seeks to mitigate emergency drug shortages and prevent medical device shortages.

Drug and medical device manufacturers spend a significant amount of time in the review process for their medical product. The CARES Act prioritizes reviews and inspections of medical product applications.

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- The CARES Act imposes additional reporting requirements on drug manufacturers regarding discontinuation or meaningful disruption of the manufacture of a drug.

Reporting requirements have been expanded to cover any drug that is critical to public health during a public health emergency. As such, a manufacturer of a drug with an active pharmaceutical ingredient is subject to the reporting requirements under 21 U.S.C. 356c. The reporting requirements also force drug manufacturers to identify the source of the active pharmaceutical ingredient and any alternative sources that may be known. To the extent that the reason for the disruption or discontinuation is due to a device that is used to prepare or administer the drug, drug manufacturers must report it.

Drug manufacturers must also develop and implement a redundancy risk management plan that identifies and evaluates any risks to supply of a drug at each manufacturing facility. In addition, drug manufacturers must annually report the amount of each drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution.

- The CARES Act requires medical device manufacturers to report any discontinuance or meaningful disruptions in the manufacture of devices that are intended for use in emergency medical care, during surgery, or during or in advance of a public health emergency.

Medical device manufacturers must report any interruption or discontinuance at least 6 months prior to the date of interruption or discontinuance. If the manufacturer cannot comply with this timeframe, the manufacturer must report interruption or discontinuance as soon as it is known. The CARES Act also provides expedited inspections and reviews of medical devices that are intended to mitigate or prevent shortage of the medical device at issue.

2. **The CARES Act prioritizes zoonotic animal drug reviews for drugs with the potential to prevent or treat a zoonotic disease in animals that may cause serious adverse health issues in humans.**

- The CARES Act seeks to expedite FDA's approval of investigational animal drugs intended for the treatment of animal diseases that have the potential to spread to humans ("Zoonotic Diseases").

Approval has been expedited for drugs that treat an animal disease and that have the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in humans. Such drugs will be designated as a "priority zoonotic animal drug" for approval purposes and eligible for expedited FDA review and approval. Companies seeking to take advantage of this program must request designation from FDA. A decision on the request will be made within 60 days of receipt. Once designated, the drug company is eligible for FDA approval of streamlined clinical trials, more interactive communication and in-person meetings with the Agency, and available enhancements to advance product development and ultimate commercialization.

3. **The CARES Act modernizes and substantially revises the Over-the-Counter Drug Review ("OTC Drug Review"), and dramatically changes the way OTC drugs are regulated by FDA.**

- The OTC Drug Review program was developed to evaluate the safety and effectiveness of OTC drugs marketed in the U.S. before 1972. Although it has been existence for almost 50 years, the

review process remains incomplete for many categories of OTC drugs.

OTC drugs that were part of the original OTC Drug Review are for the most part to be deemed Generally Recognized as Safe and Effective ("GRASE") and not new drugs when 4 established criteria are satisfied.An example of one of the 4 criteria includes that the drugs in question are subject to an FDA OTC final monograph, conform to that monograph, and are in a dosage form that immediately prior to enactment has been used to a material extent and for a material time.

If an OTC drug was classified in Category II during the OTC drug review (meaning the drug was found not to be GRASE or that the indication(s) for the drug were unacceptable), a company currently selling such drugs will need to file a new drug application within 180 days after enactment of the CARES Act unless the FDA determines that it is in the interest of public health to extend the 180-day period.

A company that obtains FDA drug approval for an OTC drug containing an entirely new active ingredient will now be entitled to 18 months of market exclusivity.

Also, the FDA is now required to provide an annual report to Congress on the OTC cough and cold drug monograph with respect to children under the age of 6.

- Payment of User Fees: Companies selling OTC drugs will now be responsible to pay an annual User Fee to FDA. Beginning in 2020, a company that owns a facility engaged in manufacturing or processing of a finished OTC drug will be required to pay the user fee. Contract manufacturers will pay 2/3rds of the total annual user fee. FDA is required to publish the proposed amount of such annual fees by May 11, 2020. For 2020, the fees are due the later of the first business day of July 2020 or 45 days after FDA publishes a notice in the federal register setting forth the fees.

Related People

Gayle Bush
Partner
gabush@michaelbest.com
T 608.283.0127

Karl Nobert
Senior Counsel
kmnobert@michaelbest.com
T 202.844.3831

Aaron Nodolf
Partner
aknodolf@michaelbest.com
T 262.956.6536