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The "Preventing Essential Medical Device Shortages Act of 2020": A COVID-19 Side Effect That Could Permanently Harm Medical Device Manufacturers

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I. Introduction

The ongoing COVID-19 pandemic crisis — infecting more than 26.2 million people worldwide, with almost 6.2 million cases in the United States alone as of the writing of this article[i] — has thrown nearly every industry into chaos as the world continues to adjust to the new reality of social distancing and self-quarantining. At the beginning of the pandemic, shortages of personal protective equipment (PPE) such as N95 masks, surgical masks, gloves, and gowns were commonplace, as medical professionals struggled to ensure that they had the equipment they needed for the daily treatment of patients, and ordinary citizens scrambled to obtain the protective equipment they felt was necessary to keep them protected. Heartbreaking stories abounded of ventilator shortages forcing hospitals and governments to contemplate incredibly difficult decisions, such as choosing to withhold treatment from the elderly in favor of younger, stronger patients with a better chance of survival.

Throughout the first few months of the pandemic, as state governors were faced with an infected population and a shortage of medical equipment, PPE, and other life-saving devices, some of them invoked their emergency powers to authorize their police forces to confiscate medical resources from private citizens and businesses.[ii] Such drastic measures, once considered unthinkable outside of the wartime realm, were considered necessary so that hospitals could be re-supplied and re-equipped as COVID-19 patients continue to flow in. Amidst these unprecedented circumstances, many in the media and elsewhere expressed their frustration and bewilderment as to how the United States could have been caught so unprepared and lacking in vital medical resources, devices, and equipment.

II. The FDA's Frustration with Lack of Regulation of Medical Device Manufacturers

One of these frustrated parties was the Food and Drug Administration (FDA), which indicated in multiple statements and budget proposals that it would seek to drastically increase its regulation of medical device manufacturers in the wake of the COVID-19 pandemic. In early 2020, the FDA began notifying the United States Congress of a lack of regulation on medical device manufacturers that it considered crucial in the United States' COVID-19 response. In doing so, the FDA used the opportunity to highlight differences between regulations imposed on medical drug manufacturers and regulations imposed on medical device manufacturers —differences that it wanted to change.

According to an FDA statement submitted by Stephen M. Hahn, M.D., Commissioner of Food and Drugs for the FDA, at the outset of the virus the FDA acted proactively to monitor the medical drug and device supply chain between the United States and China, recognizing correctly that the COVID-19 pandemic would likely affect the availability of critical medical resources, and may lead to potential disruptions in their supply.[iii] In furtherance of these efforts, beginning on January 24, 2020, the FDA contacted over one hundred eighty (180) pharmaceutical drug manufacturers, reminded them of their legal obligations to "notify[] the FDA of any anticipated supply disruptions," and asked them to "evaluate their entire supply chain" with China.[iv] These efforts were successful, as the FDA was able to promptly identify a coronavirus-caused drug shortage after the manufacturer reported the shortage as required.[v]

In contrast, manufacturers of medical devices — which include N95 masks and ventilators, devices that are critically important in preventing transmission of the COVID-19 virus and in treating serious cases — were not legally required to report any anticipated shortages, actual shortages, or supply chain issues to the FDA.[vi] Thus, although the FDA was early aware of "63 manufacturers which represent 72 facilities in China that produce essential medical devices," including several facilities "adversely affected by COVID-19," it could only request that these manufacturers report shortage issues to the FDA, without being able to enforce this request.[vii] As Dr. Hahn explained,

"[N]o law exists requiring medical device manufacturers to notify the FDA when they become aware of a circumstance, including discontinuation of a product, that could lead to a potential shortage, and manufacturers are not required to respond when the FDA requests information about potential supply chain disruption."[viii]

As noted in its March 28, 2020 Update, the FDA began taking measures to adapt and to encourage medical device manufacturers to report anticipated shortages promptly, but remained legally limited to requesting that manufacturers participate in reporting voluntarily.[ix]

III. The FDA's Proposed Regulations of Medical Device Manufacturers

In large part due to this situation, the FDA took affirmative steps to increase its regulatory authority over the entire medical device industry, using the COVID-19 pandemic as justification. As detailed in the FDA's FY 2020 Budget Request, the agency pursued a detailed legislative proposal that would have long-lasting effects on medical device manufacturers nationwide. Noting that "[n]o law requires medical device manufacturers to notify the FDA when they become aware of a circumstance that could lead to a device shortage," the FDA requested that Congress authorize it to:

1. require firms to notify the FDA of an anticipated significant interruption in the supply of an essential

device;

2. require all manufacturers of devices determined to be essential to periodically provide the FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and

3. authorize the temporary importation of devices whose risks presented when patients and healthcare providers lack access to critically important medical devices outweigh compliance with U.S. regulatory standards.[x]

Additionally, the FDA requested that Congress "clarify FDA's authority to require information that would improve FDA's ability to assess critical infrastructure as well as manufacturing quality and capacity."[xi] As Dr. Hahn noted, this proposal would "empower" the FDA to require detailed manufacturing and supply information from medical drug and device manufacturers to the extent necessary to improve the FDA's "ability to recognize shortage signals."[xii]

IV. Congressional Response to the FDA's Proposed Regulations

On March 12, 2020, within two weeks of Dr. Hahn's statement, U. S. Senators Bob Casey (D-PA) and Kelly Loeffler (R-GA) introduced Senate Bill 3468, titled as the Preventing Essential Medical Device Shortages Act of 2020 ("Medical Device Act").[xiii] The Medical Device Act directly addresses the FDA's concerns, and, among other things, would take the following actions:

- Require the Secretary of the Department of Health and Human Services ("HHS") to issue public regulations defining the term "essential device";
- Add essential devices to the drug shortage list in the Federal Food, Drug and Cosmetic Act;
- Require essential device manufacturers to notify the Secretary about anticipated permanent discontinuance or interruption in an essential device manufacturing supply chain;
- Make information publicly available about disruptions in order to inform physicians, health providers and patient organizations about anticipated shortages;
- Allow the Secretary to exempt certain device shortages from public disclosure if it may lead to hoarding, price spikes and other issues that could adversely affect public health;
- Allow the Secretary to expedite the review of medical device applications to help mitigate anticipated shortages;

Authorize the Secretary to expedite the inspection or re-inspection of establishments that could help mitigate or prevent shortages; and

- Require a Government Accountability Office report to examine the intra-agency coordination process that assesses risks associated with the essential device supply chain and identify ways to mitigate these risks.[xiv]

The Medical Device Act has since been referred to the Committee on Health, Education, Labor, and Pensions,

where it remains pending.[xv]

V. Stop-Gap Measures Imposed Through Section 506J of the FDCA

As the Medical Device Act sat in committee, Congress passed limited legislation requiring manufacturers to temporarily report medical device shortages to the FDA. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), while providing financial relief to many Americans, also added a section to the Federal Food, Drug, and Cosmetics Act ("FD&C Act") requiring manufacturers of medical devices considered "critical to public health during a public health emergency" and/or "devices for which FDA determines information on potential meaningful supply disruptions is needed during a public health emergency," to comply with certain notice requirements. Specifically, Section 506J requires manufacturers to report expected shortages to the FDA six months in advance of any shortage, or at least as is practicably possible.[xvii] The FDA promptly released a guidance document in June 2020 providing manufacturers with specifics on which devices are considered essential, and providing recommendations for satisfying the reporting requirements.[xviii] Importantly, the FDA noted that the current reporting requirements of Section 506J only remain in effect for the duration of the COVID-19 pandemic, and would be removed once this public health emergency subsides.[xix]

VI. Permanent Effects of the Medical Device Act

In contrast to the temporary nature of Section 506J, which can only be invoked in relation to an officially declared public health emergency, the passage of the Medical Device Act would impose permanent reporting requirements on the medical device industry, and would grant vastly increased power and authority to the FDA with permanent, expensive side effects for the industry. For example, broad-based authority to impose reporting requirements on all essential medical device manufacturers would necessarily result in significant regulatory compliance burdens. The actual depth of these burdens would depend on the breadth of the information that the FDA would seek, the detail requested, and the frequency of reporting requirements, but in any event would result in increased time and expense for all device manufacturers, to say nothing of the incidental scrutiny that the FDA would be allowed to apply.

Another negative effect would be the required assessment of the "essential device supply chain"—defined by the FDA as the critical infrastructure, manufacturing quality, and capacity of each manufacturer of essential medical devices—that would seemingly provide agency authority to interject regulatory objectives into every aspect of the manufacturing process. This is a result that no private entity desires.

VI. Potential Response Opportunities

For these reasons, the medical device manufacturing industry would be well-advised to deter the FDA from achieving these goals, both by thoroughly cooperating with Section 506J and by exercising its lobbying power against the Medical Device Act.

As Dr. Hahn explained, the genesis of the FDA's request for more regulatory authority arose out of its realization that the United States was facing multiple potential shortages of essential medical devices, and yet had no authority to compel medical device manufacturers to notify the government of any anticipated shortages. This, combined with the actual essential medical device shortages that did occur (most notably N95 masks and hospital ventilators) catalyzed the proposal of the Medical Device Act. However, as matters currently stand, the medical device industry possesses an opportunity to demonstrate to the FDA and Congress

that additional, permanent reporting requirements are unnecessary. Section 506J was imposed as a temporary measure to solve temporary shortages of essential medical devices. If Section 506J works as designed, and becomes inert when the COVID-19 pandemic passes, the medical device industry would have a powerful argument that permanent reporting is unnecessary when temporary, emergency reporting measures work just as well. Thus, both for equitable reasons such as contributing to the effectiveness of the United States' COVID-19 response, as well as economical and business purposes in continuing to operate without potentially oppressive regulation, all medical device manufacturers should be encouraged to proactively cooperate with Section 506J in every way possible.

The medical device manufacturing industry should also assess the potential for applying lobbying efforts against the Medical Device Act. During these troubling times, the COVID-19 crisis is increasingly being used as justification for almost any level of government oversight, such as the Medical Device Act. Although many members of Congress might have initial, understandable reactions to offer blanket support to any act that might potentially save lives, a reasoned, logical discussion of the actual necessity of the bill might help temper the appetite for its enactment. In particular, if the industry cooperates with the FDA as recommended above, manufacturing lobbyists would have compelling arguments that it is unnecessary to add additional, onerous regulations to an industry that is already highly regulated, and is already cooperating with all FDA requests for information.

VII. Conclusion

The COVID-19 crisis has presented all aspects of society with unprecedented challenges, and the medical device industry has not been immune. In its ever-evolving response to the COVID-19 pandemic, the FDA has identified certain areas where it is concerned that medical device manufacturers are under-regulated. Certain members of Congress have become alarmed by these concerns, and have responded by introducing a Senate bill with laudable goals that would nonetheless have permanently damaging side effects on all medical device manufacturers of products deemed "essential." However, in the interim, Congress as a whole passed a stop-gap measure imposing temporary reporting requirements that would dissolve when this pandemic goes away. Industry members would be well-advised to assuage the FDA's alarms by fully cooperating with the temporary measures, and by employing lobbying efforts as appropriate to highlight the overreaching, unnecessary consequences of the Medical Device Act.

Endnotes

[i]Coronavirus Map: Tracking the Global Outbreak, NEW YORK TIMES, last updated Apr. 24, 2020.

[ii]See, e.g., Executive Order No. 113 (New Jersey).

[iii]Stephen M. Hahn, M.D., FDA Statement - Coronavirus (COVID-19) Supply Chain Update, FDA.gov, Feb. 27, 2020. As the past months have shown, the FDA's projections were indeed correct, as the medical resource supply chain between the United States and China was significantly affected by COVID-19.

[iv]Id.

[v]Id.; see also Sarah Owermohle and David Lim, The First Coronavirus-Linked Drug Shortage, POLITICO, February 28, 2020.

[vi]Hahn, FDA Statement - Coronavirus (COVID-19) Supply Chain Update .

[vii]Id.

[vii]Id.

[ix]Stephen M. Hahn, M.D., FDA Statement - Coronavirus (COVID-19) Update: FDA takes further steps to help mitigate supply interruptions of food and medical products, FDA.gov, Mar. 28, 2020.

[x]Overview of Legislative Proposals , Budget Exhibit to Food and Drug Administration's Fiscal Year 2020 Justification of Estimates for Appropriations Committees, at p. 37 (available here).

[xi]Id.

[xii]Hahn, FDA Statement - Coronavirus (COVID-19) Supply Chain Update .

[xiii]Preventing Essential Medical Device Shortages Act of 2020 , S. 3468, 116th Cong. (2020).

[xiv]See id.; see also Casey, Loeffler Introduce Legislation to Address Shortages of Essential Medical Devices, casey.senate.gov, Mar. 12, 2020.

[xv]S. 3468: Preventing Essential Medical Device Shortages Act of 2020 , govtrack.us, last visited Apr. 24, 2020.

[xvi]CARES Act, H.R. 748.

[xvii]Id. at H.R. 748-83–86.

[xviii]See Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised), available here.

xix_See id._ at 2 ("This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).").
