IADC COMMITTEE NEWSLETTER
SUPERIOR ADVOCATES. GLOBAL PERSPECTIVE.
CELEBRATING 100 YEARS 1920-2020

DRUG, DEVICE AND BIOTECHNOLOGY

MAY 2020

IN THIS ISSUE

Heather Heiskell Jones and James E. Simon report on the "Preventing Essential Medical Device Shortages Act of 2020", a new Senate bill responding to current essential medical device shortages that could have lasting impacts on the medical device manufacturing industry.

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

ABOUT THE AUTHORS

Heather Heiskell Jones is a Member in Spilman Thomas & Battle, PLLC's Charleston, West Virginia office. She is Chair of the firm's Insurance Defense Practice Group and Co-Chair of the firm's Medical Monitoring, Product Liability Litigation, and Toxic Tort Litigation Practice Groups. Her primary practice is litigation, including toxic tort matters, medical monitoring and other class actions, product liability matters, employment discrimination and employer liability claims, deliberate intent claims, and insurance bad faith claims. Heather also is experienced handling cases in the West Virginia Business Court Division and has completed advanced mediation training with the West Virginia State Bar. She can be reached at hheiskell@spilmanlaw.com.

James E. Simon is an Associate in Spilman Thomas & Battle PLLC's Charleston, West Virginia office. His primary area of practice is civil litigation, with particular emphasis on business and commercial litigation. James' business litigation practice includes breach of contract, fraud, construction, eminent domain, and constitutional law disputes. He also defends clients in insurance and bad faith litigation, personal injury and products liability lawsuits, and deliberate intent, premises, and products liability claims in toxic tort actions. He can be reached at JSimon@spilmanlaw.com.

ABOUT THE COMMITTEE

The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the *Defense Counsel Journal* annually. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

Stephen G.A. Myers
Vice Chair of Publications
Irwin Fritchie Urquhart & Moore LLC
smyers@irwinllc.com

I. Introduction

The ongoing COVID-19 pandemic crisis—infecting more than 2.7 million people worldwide, with almost 870,000 cases in the United States alone as of the writing of this article[1]—has thrown nearly every industry into chaos as the world struggles to adjust to the new reality of social distancing and self-quarantining. Shortages of personal protective equipment (PPE) such as N95 masks, surgical masks, gloves, and gowns have become commonplace, as medical professionals struggle to ensure that they have the equipment they need for the daily treatment of patients, and ordinary citizens scramble to obtain the protective equipment they feel is necessary to keep them protected. Heartbreaking stories abound 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.

Faced with an infected population and a shortage of medical equipment, PPE, and other life-saving devices, some state governors have even invoked their emergency powers to authorize their police forces to confiscate medical resources from private citizens and businesses.[2] Such drastic measures, once considered unthinkable outside of the wartime realm, are now necessary so that hospitals can be re-supplied and re-equipped as COVID-19 patients continue to flow in. Amidst these unprecedented circumstances, many in the media and elsewhere have 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 is the Food and Drug Administration (FDA), which has indicated in multiple statements and budget proposals that it will 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 wants 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

[1] *Coronavirus Map: Tracking the Global Outbreak*, NEW YORK TIMES, last updated Apr. 24, 2020, https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html.

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

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.[3] 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.[4] 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.[5]

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—are not legally required to report any anticipated shortages, actual shortages, or supply chain issues to the FDA.[6] 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.[7] 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.[8]

As noted in its March 28, 2020 Update, the FDA is taking measures to adapt and to encourage medical device manufacturers to report anticipated shortages promptly, but remains legally limited to requesting that manufacturers participate in reporting voluntarily.[9]

---

[3] Stephen M. Hahn, M.D., *FDA Statement - Coronavirus (COVID-19) Supply Chain Update*, FDA.gov, Feb. 27, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update. As the past several months have shown, the FDA's projections were indeed correct, as the medical resource supply chain between the United States and China has been significantly affected by COVID-19.

[4] *Id.*

[5] *Id.*; *see also* Sarah Owermohle and David Lim, *The First Coronavirus-Linked Drug Shortage*, POLITICO, February 28, 2020, https://www.politico.com/newsletters/prescription-pulse/2020/02/28/the-first-drug-coronavirus-linked-drug-shortage-488435.

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

[7] *Id.*

[8] *Id.*

[9] 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, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-further-steps-help-mitigate-supply-interruptions-food-and.

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

In large part due to this situation, the FDA has taken 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 is pursuing 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 has 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.[10]

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."[11] 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."[12]

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").[13] 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";

[10] *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 at https://www.fda.gov/media/121408/download).

[11] *Id.*

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

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

- 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.[14]

The Medical Device Act has since been referred to the Committee on Health, Education, Labor, and Pensions, where it remains pending.[15]

V. Potential Effects on Medical Device Manufacturers

Although the purpose of the Medical Device Act may be laudable, medical device manufacturers should be wary of the increased power and authority that would be granted to the FDA through its parent agency HHS, as such regulatory powers could have 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

[14] *See id.*; *see also Casey, Loeffler Introduce Legislation to Address Shortages of Essential Medical Devices*, casey.senate.gov, Mar. 12, 2020, https://www.casey.senate.gov/newsroom/releases/casey-loeffler-introduce-legislation-to-address-shortages-of-essential-medical-devices.

[15] *S. 3468: Preventing Essential Medical Device Shortages Act of 2020*, govtrack.us, last visited Apr. 24, 2020, available at https://www.govtrack.us/congress/bills/116/s3468/text.

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 voluntarily cooperating in COVID-19 shortage reporting 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, as regularly reported by news agencies) 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 regulations are unnecessary. As detailed in the FDA's March 28, 2020 update, the FDA has developed a voluntary device shortage reporting system that would allow manufacturers to update the FDA regarding any anticipated complications in their individual supply chains. While the FDA cannot enforce this reporting system (as yet), full and complete voluntary participation from all manufacturers would convincingly demonstrate the industry's dedication to providing full assistance in emergency situations such as the COVID-19 pandemic. 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 fully cooperate with the FDA's COVID-19 information requests in whatever 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 potentially damaging side effects on all medical device manufacturers making products deemed "essential." Industry members would be well-advised to assuage the FDA's alarms by voluntarily cooperating with its reporting requests, and by employing lobbying efforts as appropriate to highlight the overreaching, unnecessary consequences of the Medical Device Act.

Past Committee Newsletters

Visit the Committee's newsletter archive online at www.iadclaw.org to read other articles published by the Committee. Prior articles include:

OCTOBER 2019
Cracking the Code: Genetic Evidence and Specific Causation
Ali Spindler and Stephen G.A. Myers

AUGUST 2019
U.S. Supreme Court in Prescription Pharmaceutical Case Holds Implied Preemption is Legal Issue for Judge, Not Question of Fact for Jury
Joseph J. Stroble and Stanley E. Blackmon

JULY 2019
Un Update on Efforts to Create a Set of Rules for Multidistrict Litigation
Albert G. Bixler and Immon Shafiei

JUNE 2019
Alert: Deceptive Plaintiff Lawyer Advertising is Harmful to Public Health… and States are Taking Action
Mark Behrens and Ashley Garry

MAY 2019
The Scoop on the FDA's Updated Approach to the Dietary Supplement Market
Elizabeth L. Taylor and Lindsey M. Saad

APRIL 2019
Proposed Changes to Federal Rule of Civil Procedure 30(b)(6)
Albert G. Bixler and Immon Shafiei

FEBRUARY 2019
The Third Circuit is Snap Happy
Jason Rose and Sarah L. Scott

JANUARY 2019
Expert Qualifications Held to be Self-Validating: A Call for Amendments to the Federal Rules of Evidence on the Admissibility of Expert Testimony
Jay M. Mattappally, Claire A. Noonan and Quentin F. Urquhart Jr.

NOVEMBER 2018
Off-Label Promotion of Class III Medical Devices: Parallel Claims and Preemption at the Pleading Stage
David W. O'Quinn, Douglas J. Moore, and Carlos A. Benach

OCTOBER 2018
Innovator Liability: A Recent Resurgence
David L. Ferrera and Michael J. Leard