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Via Electronic Submission

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2022-D-0053, *Select Updates for the 506J Guidance: 506J Device List and Additional Notifications*

To Whom it May Concern,

On behalf of the Medical Device Manufacturers Association (MDMA), below please find comments on the Draft Guidance for Industry, *Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.*

MDMA is a national trade association that provides educational and advocacy assistance to hundreds of innovative companies in the field of medical technology. Our members, the majority of which are small to mid-sized medical device companies, have a strong record of delivering breakthrough therapies to treat chronic diseases and life-threatening conditions while lowering the cost of care. MDMA's mission is to ensure that patients have timely access to the latest advancements of safe and effective medical technologies that improve health outcomes.

We appreciate the opportunity to provide these comments, and we look forward to ongoing collaboration with the U.S. Food and Drug Administration (FDA) to address this important topic.

MDMA shares FDA's goal of ensuring a robust supply of high-quality medical devices. Indeed, MDMA and its members have demonstrated their shared commitment to addressing emergent supply chain issues over many years and have a proud history of working collaboratively with the Center for Devices and Radiological Health (CDRH) on a voluntary basis long before the emergence of the COVID-19 pandemic, including with respect to issues related to closure of a large contract sterilization facility in Illinois and the challenges associated with hurricanes.

As an initial matter, Section 506J of the Federal Food, Drug, and Cosmetic Act (FDCA) provides that manufacturers of devices which are "critical to public health during a public emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery" or for which FDA "determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency" generally must "during, or in advance of, a public health emergency . . . notify [FDA] . . . of a permanent discontinuance in the manufacture of the device . . . an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of

that device in the United States."[1] In turn, Congress has directed FDA to provide draft guidance regarding requirements under Section 506J, including a list of each device product code for which a manufacturer of such device is required to notify FDA.[2]

The draft guidance, among other things, proposes to include in the 506J Device List "devices critical for supporting and sustaining life"[3] without identifying any relevant limiting factors that might be considered by the agency to ensure that the list remains focused on those devices which are uniquely vulnerable to supply chain disruptions or which would pose unique risks if a single manufacturer of such device were to experience an interruption in manufacture. MDMA is concerned that the 506J Device List was informed by the development of the Critical Medical Device List (CMDL). MDMA was invited by FDA to participate in the CMDL workstream. This group did not have equal voting representation from all sectors (ex. a GPO and a hospital that owned the GPO were each provided with separate votes, despite being owned by a single entity.) Furthermore, the market share of manufacturers and the number of companies manufacturing particular products were not considered as part of the CMDL process, despite both factors being essential to accurately assess the resiliency for certain medical products. MDMA is also concerned that a wide ranging list without focus and consideration of market dynamics would prevent the 506J List from achieving its intended purpose by failing to provide a targeted, focused list of those devices most at risk.

Indeed, while Section 506J contemplates reporting requirements for certain life-supporting and life-sustaining devices, it specifically contemplates these as examples of devices which may be "critical to public health during a public emergency."[4] Consistent with this Congressional intent, we believe the list should be targeted to specific devices that could be critical to the public health during a specific public health emergency. MDMA is concerned that an approach that is less targeted and focused has the potential to pose undue burdens on both industry and FDA review staff while frustrating our shared goals of ensuring access for patients and healthcare providers to safe and effective medical devices. In short, an overly broad 506J List has the potential to provide more "noise" than "signal" concerning the medical device supply chain.

Further, the draft guidance fails to acknowledge important aspects of the medical device industry that would help further its public health mission. Unlike the drug and biologics industries, in which it is not uncommon for a single manufacturer to be the sole marketing authorization holder, the medical device industry benefits from a robust and competitive landscape. If the manufacturer of a particular device type experiences an interruption in manufacture or shortages otherwise arise with respect to shortages, often there are several established competitors who are ready, willing and able to fill the gap by supplying their own devices. This relative lack of concentration among manufacturers and its impact on the resilience of the medical device supply chain is a key factor that should inform the agency's approach to the draft guidance.

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[1] 21 U.S.C. § 356j(a).
[2] *See* Pub. L. 117-328, div. FF, title II, § 2514(c), Dec. 29, 2022, 136 Stat. 5806.
[3] FDA, Draft Guidance for Industry and Food and Drug Administration Staff: Select Updates to the 506J Guidance: 506J Device List and Additional Notifications (Nov. 17, 2023), at 2, https://www.fda.gov/media/173800/download.
[4] 21 U.S.C. § 356j(a).

To that end, development of the 506J List should involve consideration of suitable alternatives to devices or device types for potential inclusion. In short, the list should be targeted to focus on those life supporting or sustaining devices that would be critical to public health during a public emergency and for which no suitable treatment alternative exists.[5]

Industry would also appreciate greater clarification regarding the form, content, timing and mechanics for notification of anticipated disruptions, as well as what FDA would consider to constitute a failure to notify. We recommend utilizing CDRH email notifications and posting clearly on the FDA website to alert manufacturers of a situation "in advance of a public health emergency." Similarly, while we appreciate that the Agency has acknowledged that manufacturers need not have obtained all information at the time of a Section 506J notification,[6] we are concerned that certain language in the draft guidance could be construed to require continuous reporting by manufacturers, including of information that goes beyond the scope of the Section 506J reporting obligation. For example, the January 2022 draft guidance includes a "recommend[ation] that manufacturers submit additional information" after a 506J report "that could inform the Agency of current supply chain pressures."[7] In any final guidance, FDA should clarify that manufacturers of devices subject to Section 506J are responsible only for notification of either a permanent discontinuance in the manufacturer or device or certain interruptions likely to lead to a meaningful disruption in supply of the device. Any final guidance should clarify that any additional reporting by a manufacturer with respect to supply chain pressures or the like would be voluntary.

Stakeholders would also appreciate FDA providing the rationale behind a product code's inclusion on the 506J list and an explanation of how these product codes meet the relevant criteria. We also recommend that FDA clarify how stakeholders can provide an appropriate rationale for a specific product code to be removed from the list when suitable alternatives exist.

Beyond these concerns, the initial creation of the 506J List did not follow Good Guidance Practice. Particularly in light of this history, it is critical that the list is not used as a basis to establish a mandatory reporting framework beyond the specific, narrowly-tailored reporting framework established by Congress under Section 506J.

[5] CDRH has experience evaluating potential alternatives in other contexts, including the Breakthrough Devices Program, which requires CDRH to consider whether any cleared or approved alternatives exist for a given device.
[6] *See* FDA, Draft Guidance for Industry and Food and Drug Administration Staff: Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act (Jan. 11, 2022), at 9.
[7] *Id*.

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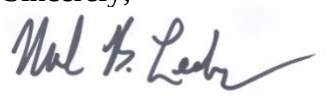
We appreciate the opportunity to comment on this important topic. If we can provide any additional information, please contact me at mleahey@medicaldevices.org or (202) 354-7171.

Sincerely,



Mark Leahey
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