FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Brief Summary of the General Hospital and Personal Use Devices Panel Meeting February 6, 2024

Introduction:

The General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee for the Food and Drug Administration (FDA) met on February 6, 2024, to discuss and make recommendations on medical device supply chain resiliency and shortage issues, including the proposed 506J Device List which was developed as a requirement of section 2514 of the Consolidated Appropriations Act, 2023 ("Fiscal Year (FY) 2023 Omnibus"). The Panel also discussed how the 506J Device List relates to medical devices used in pandemic preparedness and response to satisfy, in part, a requirement under section 3302 of the FY 2023 Omnibus.

Panel Deliberations/FDA Questions:

1. **Do the device types (by product code) on the proposed 506J Device List meet the requirements for a critical device as outlined in section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act?**
    a. **Are there device types (by product code) on the proposed 506J Device List that are not critical to public health during a public health emergency and should be removed from the list?**
    b. **Are there device types (by product code) that are not on the proposed 506J Device List that are critical to public health during a public health emergency and should be added to the list?**
    c. **What additional devices would be needed for national emergency preparedness?**

In reviewing the devices for inclusion on the 506J Device List, the Panel discussed the spectrum of public health emergencies, which can range from an extremely catastrophic event such as a chemical, biological, radiological, or nuclear (CBRN) event to a smaller, more localized public health emergency such as the regional impact resulting from a hurricane. The Panel discussed the possibility of prioritizing or tiering the list to reflect the variation and severity of different types of public health emergencies. The Panel also discussed whether there was a need for FDA to prioritize, tier, or categorize the list of devices that would be "necessities" vs. those that would be "nice to have" included on the list. The Panel also suggested that FDA consider how listed devices are used in pediatric or other special populations, and that FDA specifically indicate if there are certain "sizes" of devices included on the list for use in pediatric populations.

With regards to subpart a, the Panel indicated that less than 10 product codes should be considered for removal from the proposed list.

For subpart b, the Panel described additional device types that they believed would be critical to providing patient care in a public health emergency and should be considered for inclusion on the 506J Device List, including, but not limited to device types used in surgery, respiratory care, and diagnostic testing. The Panel also noted the importance of ensuring that the 506J Device List contained accessories that are necessary to support, supplement, and/or augment any parent devices included on the list.

For subpart c, the Panel agreed that it is not possible to anticipate all medical devices required for all types of emergencies.

The Panel recommended that the 506J Device List should be updated regularly.

In response to the overarching question, the Panel discussed the complexity in determining the specific devices and accessories that FDA considered to meet the statutory criteria, and the wide range of products that may be included in product code descriptions. The Panel acknowledged the directive included in the FY 2023 Omnibus to issue guidance that included a list of each device, by product code, for which a manufacturer of such device is required to notify FDA in accordance with section 506J of the FD&C Act. However, the Panel did recommend that, if possible, FDA elaborate on the types of devices within each product code that met the 506J statutory criteria and were proposed for inclusion.

2. **How should supply chain resilience and vulnerabilities be considered when determining device types (by product code) for inclusion or exclusion on the 506J Device List?**

Though different perspectives were considered, the Panel recommended that supply chain resilience and vulnerabilities should not be considered when determining a medical device's criticality for providing patient care, and therefore should not be considered when determining device types for inclusion on and exclusion from the 506J Device List.

The Panel also noted that rapid fluctuations in product resiliency could pose challenges to maintaining an updated list if such factors were considered.

3. **How should the following device types be addressed with regard to the proposed 506J Device List?**
    a. **Single-use disposable vs. multi-patient reusable devices**
    b. **Convenience kits**
    c. **Capital equipment (e.g., imaging devices)**

The Panel recommended that FDA consider the differences between true "single-use" medical devices and those "single-use" medical devices that could be safely reprocessed and reused during an emergency event (e.g. blood pressure cuffs).

The Panel also recommended that FDA consider for inclusion on the 506J Device List those kits that are used to gain vascular access to include: 1) central venous line kits, 2) paracentesis kits, 3) dialysis line kits, 4) umbilical kits, and 5) arterial line kits. The Panel's recommendation to add these kits reflected their discussions and deliberations around the clinical need for use in emergency medical settings and the need to maintain sterility during the clinical procedures for which these are used.

Regarding capital equipment, the Panel generally recommended that FDA consider and evaluate for inclusion on the 506J Device List the accessories and supplies that are required to perform diagnostic imaging (e.g., X-ray tubes) and cartridges and reagents used in diagnostic testing.

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Transcripts may be downloaded from:
February 6, 2024: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting

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