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SONIA NATH AND SON NGUYEN - COOLEY LLP

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SONIA NATH, PARTNER AND **SON NGUYEN,**
SPECIAL COUNSEL, **COOLEY LLP**

COMPANIES BEWARE: MORE FDA ENFORCEMENT ACTIONS AHEAD

Medical device recalls have already received considerable attention in 2024. In January, the U.S. Government Accountability Office (GAO) accepted a request from Senators Richard Durbin (D-Illinois) and Richard Blumenthal (D-Connecticut) to review the U.S. Food and Drug Administration's (FDA)'s oversight of medical device recalls. The senators' request was made following multiple high-profile medical device recalls in the past several years involving ventilators, bilevel positive airway pressure machines, and continuous positive airway pressure (CPAP) machines. Hundreds of deaths have been linked to these products.

In their December 2023 letter to the GAO, Senators Durbin and Blumenthal suggested that "FDA missed several opportunities to mitigate the harm done to the millions of patients who have used these recalled medical devices."

In September 2023, a CPAP machine manufacturer agreed to pay at least $479 million in a settlement over alleged health risks. On January 29, 2024, the manufacturer announced that it had entered a consent decree with the government and would cease selling products used to treat sleep apnea in the U.S. While the terms of the decree were not disclosed because it had not yet been granted by the court, the company's full compliance with the decree will likely take significant time and resources. Recalls can be costly, both financially and in terms of a company's reputation.

FDA's medical device recall authority

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines "device" broadly to include any product intended to diagnose, cure, mitigate, prevent, or treat a disease or condition. It also applies to any product intended to affect the structure or any function of the body. To be considered a medical device, the product should not rely on chemical action within or on the body to achieve its primary intended purposes. Certain software functions are excluded from the device definition under the FD&C Act.

The FD&C Act authorizes the FDA to regulate medical devices in both premarket and postmarket settings to prevent adulterated and misbranded devices from being distributed in interstate commerce. If a medical device violates FDA regulations or poses a health risk to patients or users, under the FD&C Act the manufacturer may propose to correct or remove the device. Corrections may include repair, modification, adjustment, relabeling, destruction, or inspection, including patient monitoring. The FDA considers both corrections and removals to be recalls, which may involve not only the manufacturers, but also distributors, health care providers, and/or patients.

Most medical device recalls are conducted voluntarily by the manufacturer after it discovers a problem or the FDA raises a concern. In rare instances, if the manufacturer seems unwilling to initiate a voluntary recall and the FDA determines there is a "reasonable probability" that a device would cause "serious, adverse health consequences or death," the agency may order the manufacturer to recall the violative device and notify health professionals and device user facilities. The FDA may also initiate a seizure action to remove the device from market.

Trends in medical device recalls

Class I recalls have increased over the last few years. This classification is the most serious and reserved for situations in which use of the product presents a reasonable probability of serious adverse health consequences or death. There was a 59.5% increase in the number of Class I recalls between 2020 and 2021, rising from 42 to 67. The number then increased steadily from 67 in 2021 to 70 in 2022 and 85 in 2023. Class I recalls in 2024 are projected to continue to increase at the rate of eight Class I recalls per month based on FDA data for January 2024.

However, Class I recalls only make up approximately seven percent of medical device incidents. Class II recalls are responsible for roughly 90% of all medical device recalls in the U.S. and are used for violative devices that may cause temporary medically-reversible adverse health consequences or that have a remote probability of causing serious adverse health consequences. Class III recalls, the least serious type of event, constitute an average of three percent of all medical device recalls.

Recall data from January 2023 through January 2024

Class I recalls

In January 2024, FDA issued eight Class I recalls that impacted more than 20 million units and were linked to more than 100 injuries. All of the eight events were voluntary recalls by the manufacturer.

A notable Class I recall in January 2024 involved patient return electrodes, which are used in medical procedures involving electrosurgical instruments. The devices are designed to safely remove electrical currents from patients during surgery. There were reports of patient injuries associated with use of these electrodes, including third-degree burns that require intervention and may lead to extended hospital stays, scarring, and additional surgeries in both pediatric and adult patients. Moreover, severe burns could lead to long-term effects on patients, especially those under 12. These recalls have impacted 9,428 units, with 99 reported injuries linked to the recalls. The device's instructions for use and labeling are being updated to restrict use of the device to patients 12 years and older.

Another notable Class I recall in January 2024 was for possible magnetic interference between certain medical devices and CPAP masks containing magnets. Under certain circumstances, when a magnet is less than two inches from certain medical devices, the magnet might disrupt the devices' function or position, possibly causing serious harm or death. While the existing label for the CPAP masks advises keeping magnets two inches away from affected medical devices, it does not list all the specific devices that could be affected by the magnets in the device. The manufacturer is recalling the masks to update the labels and add more warnings and information to guide patients and health care professionals on safe usage. This recall impacted more than 20 million units, and six reported injuries have been linked to the device.

In 2023, there were 85 device recall events designated as Class I, which impacted more than 164.67 million units. All of these were voluntary recalls.

One notable Class I recall in 2023 began with a voluntary recall in December 2022 for a continuous ambulatory delivery device (CADD). The event continued into 2023 due to reports of at least two deaths, 14 injuries, and 1,571 incidents. Although this CADD system is intended to deliver controlled amounts of medication to a patient through a vein or other cleared rounds of administration, defects in the system caused under-delivery or non-delivery of medication while falsely displaying that the medication had been administered. In response, the manufacturer sent an Urgent Medical Device Correction Letter to customers warning of the issues and proposing safety measures to mitigate the problems.

SONIA NATH, PARTNER AND **SON NGUYEN,**
SPECIAL COUNSEL, **COOLEY LLP**
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One of the most significant recalls in recent years was first issued in 2021 for sleep apnea and respiratory care products (i.e., ventilators, bilevel positive airway pressure machines, and CPAP machines). Hundreds of deaths have been linked to those events, and as mentioned, one manufacturer has agreed to pay $479 million and cease selling products used to treat sleep apnea in the U.S.

Class II recalls

In January 2024, 91% of all reported medical device recall events were designated as Class II. These 160 recalls included issues such as intraocular lens containing an angle out of specification, the potential for a light system to fail in the operating room, a loss of vacuum in the inner-most vacuum bag of the tibial inserts, and suction canister liners possibly experiencing loss of suction on low settings due to a misalignment of the liner with the outer hard canister.

In 2023, 869 events, or nearly 90% of all reported medical device recalls, were designated as Class II. These included issues such as sterile product pouches that were not sealed and labeling containing incorrect information in the maintenance schedule.

Class III recalls

In January 2024, there was only one event classified as Class III. It was a voluntary recall due to decreased reactivity of a reagent in an in vitro diagnostic product.

Similarly, in 2023, less than three percent of medical device recalls were designated as Class III. These 21 reported events were voluntary and included recalls for issues such as boxes of face masks incorrectly labeled as having ties rather than ear loops and some incorrect expiration dates.

Consent decrees associated with recalls and best practices

A consent decree is a court-approved order for permanent injunction that reflects a negotiated agreement between the FDA and an FDA-regulated company. Although litigation is always an option, companies typically resolve complaints brought by the government under the FD&C Act through consent decrees rather than litigating such cases due to the uncertainty and costs associated with actions in federal court. Although such cases are generally tried before judges in "bench trials" rather than jury trials, judges tend to be swayed by the agency's interest in protecting the public health. Additionally, the agency usually brings such cases after using other tools to encourage voluntary compliance such as requesting recalls or issuing warning letters.

In most cases the FDA's observations of product quality and safety issues associated with the recalled products and the agency's subsequent warnings to the manufacturer precede any consent decrees. Based on data reported by Sedgwick, 152 medical device recalls (or approximately 15% of recalls) from January 1, 2023 through December 31, 2023 were due to issues with the quality of the devices, such as flawed designs and sterility concerns. The second-most-likely cause for a medical device recall was parts issues which was linked to 111 recalls.

By being alert to recent recall trends, companies can be ahead of the curve and implement prudent practices to minimize the possibility of recalls and ensure that if recalls do occur they are conducted effectively. Possible steps include adhering to the quality management system (QMS) controls for design and development of devices; ensuring that there is an adequate process for sourcing conforming materials and components; developing recall procedures that include "downstream" recalls; having adequate product coding; and maintaining distribution records to facilitate faster, more accurate recall actions.

It is likely that at some point every medical device company may face a recall. Being well-prepared helps minimize the negative impact of an event.

For further insight on U.S. product safety spanning the Automotive, Medical device, Pharmaceutical, Food and drink, and Consumer product industries, download the full edition of the **Recall Index report:**

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Website: sedgwick.com/brandprotection
Telephone: 1.888.732.3901
Email: brand.protection@sedgwick.com

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