FDA Medical Device Recalls: What Orthopedic Surgeons Should Know

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INTRODUCTION: Recalls are defined by the U.S. Food and Drug Administration (FDA) as “a firm’s removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers against which the agency would initiate legal action” (21 CFR part 7). Medical device manufacturers can initiate voluntary recalls for a variety of reasons, some of which may result in serious patient adverse events while others are unlikely to result in significant patient harm. The purpose of this investigation is to analyze the causes of orthopedic medical device recalls and compare them to medical device recalls in other medical specialties. Raising awareness of the uniqueness of orthopedic recalls improves the orthopedic surgeon’s understanding of these devices and treatment options.

METHODS: The two highest risk medical device recall types (Class I and Class II) from FDA’s recall database were reviewed over a 10-year period (January 1, 2014 – December 31, 2023), with a focus on the FDA identified cause of the recall and marketing pathway of the recalled device. Since a single recall event in the database can include multiple recalled products (e.g., stem, cup, liner), the analysis focused on the individual recall events. For example, one recall event included 13 different products (femoral heads, femoral stems, knee femoral components, tibial components, and humeral heads) which were all recalled for the same packaging issue. The recalls were sorted by medical specialty. The FDA identified causes of the recall were grouped into 10 general categories (Design, Labeling, Manufacturing Process, Material, Packaging, Reprocessing, Software, Use Error, Other, and Unknown). Chi-squared tests were conducted to compare the proportion of orthopedic recalls to the proportion of recalls of other medical specialties. In order to identify any potential association between marketing pathways and the number of recalls, FDA’s pre-market databases were also reviewed to identify the total number of devices authorized through 510(k) Premarket Notification, Premarket Approval (PMA) and other marketing pathways (De Novo Classification Request, Humanitarian Device Exemption (HDE).

RESULTS: During the 10-year study period, FDA classified 9975 Class I and Class II medical device recalls (Figure 1). Orthopedic medical devices accounted for 12.8% (1276/9975) of all recalls which was the third highest across medical specialty areas. Radiology devices (1464/9975; 14.7%) were the highest, followed by cardiovascular devices (1297/9975; 13.0%), general and plastic surgery devices (1063/9975; 10.7%), and general hospital devices (960/9975; 9.6%). Considering the marketing pathway for the recalled devices in these five specialty areas, more than 50% of the devices were cleared through the 510(k) pathway. Radiology devices had the largest percentage recalled devices cleared via the 510(k) pathway (94.9%) while cardiovascular had the largest percentage of recalled devices approved via the PMA pathway (20.2%). For orthopedic devices, 77.4% of the recalled devices were cleared via the 510(k) pathway and 1.65% were approved via the PMA pathway. While the percentage of recalled devices cleared through the 510(k) pathway appears high, it is important to acknowledge that the 510(k) pathway is the predominant marketing pathway for most of the medical specialties. Specifically, during this same period, most radiology (96%), general hospital (93%), orthopedic (82%), and general and plastic surgery devices (76%) were cleared via the 510(k) pathway. In contrast, cardiovascular had the smallest percentage of devices cleared through the 510(k) pathway (28%), with most of these devices approved via PMA (71%). Compared to the other medical specialties (Table 1), orthopedic devices had a significantly higher percentage of recalls related to labeling (12.5% vs 6.3%), packaging (7.5% vs 3.8%), and manufacturing process (24.8% vs 18.3%), and significantly lower percentage of recalls related to software (1.6% vs 16.1%). There was no significant difference among other causes of recalls.

DISCUSSION AND CONCLUSION: Over the 10-year period included in this analysis, orthopedic medical devices had the third most recalls, with most of these devices cleared via the 510(k) pathway, which is also the most common marketing pathway for these devices. Compared to the other medical specialties, orthopedic devices had a significantly higher percentage of recalls related to labeling, packaging, and manufacturing process, suggesting areas for improvement. Orthopedics also had significantly lower percentage of recalls related to software. Design related recalls, which were most common for the other medical specialties, occurred in similar proportion in orthopedics. Further analysis is underway to determine factors causing the observed differences in the causes of the recalls, and any differences between Class I and II recalls. It is important that orthopedic surgeons be aware of the causes of orthopedic device recalls.

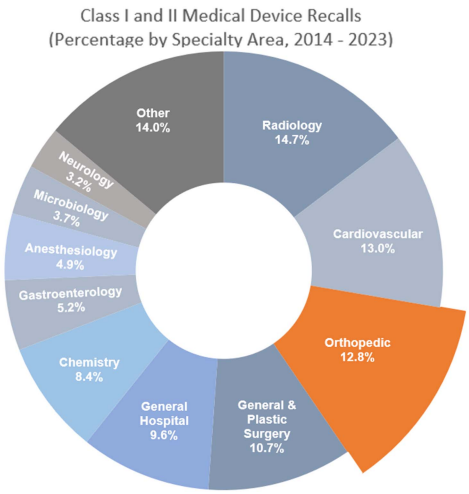

Figure 1. Pie chart depicting the percentage of recalls by medical specialty area over the 10-year study period.

Table 1. FDA Identified Cause of Medical Device Recalls for Orthopedics and Other Medical Specialty Areas

FDA Identified Cause	Orthopedic n (%) (n=1276)	Other Medical Specialty Areas n (%) (n=8699)	*P* Value[a]
Manufacturing Process	317 (24.8%)	1588 (18.3%)	<.00001
Design	236 (18.5%)	1656 (19.0%)	0.645
Material	176 (13.8%)	1087 (12.5%)	0.193
Labeling	156 (12.2%)	551 (6.3%)	<.00001
Unknown	135 (10.6%)	1041 (12.0%)	0.152
Other	125 (9.8%)	958 (11.0%)	0.192
Packaging	96 (7.5%)	327 (3.8%)	<.00001
Software	20 (1.6%)	1401 (16.1%)	<.00001
Use Error	10 (0.8%)	77 (0.9%)	0.716
Reprocessing	5 (0.4%)	13 (0.1%)	0.057

[a]Chi-squared test was conducted to compare 2 categorical variables using Microsoft Excel These statistical testing and p-values were obtained for exploratory purpose with the understanding of the limitations of the data.