

Supply Chain Resource Council (SCRC) Report

March and April 2024

Executive Summary

This month Council members discussed the expansion of kit manufacturer recalls affected by the Nurse Assist, LLC Class I recall of sterile water and saline, as well as adverse events associated with the BD Insyte Autoguard Retractable Syringes. Nationally and globally, discussions focused on the pending FedEx pilot contract negotiations and the ongoing effect the Change Healthcare cybersecurity event is having on health care organizations, and supply chain's role in managing the revenue impact. There are a number of items post-meeting that have been included, specifically the FDA safety communication, warning letters and expanded actions regarding Chinese manufactured plastic syringes. Details on these topics and other updates can be found in the full report.

▲ Field Updates

- **Avanos Medical Inc. is the latest kit manufacturer affected by the Nurse Assist, LLC Class I Recalls for Sterile Water and Saline.** Avanos Medical Inc's MIC Gastric Feeding Tube Kits includes pre-filled, sterile water Nurse Assist-supplied syringes essential for inflating the retention balloon of the feeding tube. [Click here to review the list of kit manufacturer recalls.](#) At this time, it appears that these recalls are not impacting patient care or hospital inventory levels.
- **MedGyn, Inc. is experiencing backorders for their tubing set recommended** as a suitable substitute product (#022310) by Olympus for their backordered vacuum curettage 3/8" tubing sets (#23116). *Attached* are two IFU's from MedGyn for their non-sterile/collection sets.

▲ Supply Chain Watch List – current situations under observation

- **FedEx pilots seek release from federally mediated contract talks.** The union representing some 5,800 pilots at FedEx Express has asked the National Mediation Board to be [officially released from mediation](#) for the anticipated purpose to go on strike against the company to achieve a new contract.
- **Change Healthcare and supply chain's role** in managing the significant revenue impact health care organizations are facing as a result of the cyber incident. Cash conservation strategies include assessing contracts and potential terms extensions, curbing or pausing bulk buys, and recognizing any outstanding credits. Expanded concerns include the potential impact to Moody's credit ratings based upon Days Cash On-hand. It has been posited that \$15B in annual revenue passes through this channel.
- Several hospitals have filed adverse event reports for the BD Insyte Autoguard Straight 20g, 1" retractable needles. Catalog numbers reported are 381433 & 381434. BD is aware of the issue and is working with their quality department.
- **Ethicon discontinuation of various sutures and alternative product codes** (see *attached Ethicon Customer letter*), some of which appear to not be clinically acceptable substitutes. Please work with your sales representative should you need to identify suitable substitutes.

▲ Post-Meeting Developments

- **Pharmaceutical shortages hit an all-time high.** ASHP reported [the highest number of drug shortages](#), 323 active shortages, during the first quarter of 2024, surpassing the previous record of 320 shortages in 2014. The shortages involve generic sterile injectable medications, including cancer chemotherapy drugs and emergency medications.

- **Opioid and stimulant shortages.** *See the attached Pfizer letter* regarding challenges for existing shortages of injectable opioids. Per Pfizer, additional supply interruptions have emerged due to recent changes described in the U.S. Drug Enforcement Administration's (DEA) 2024 Annual Aggregate Quotas and Assessment of Annual Needs Final Order. Pfizer continues to work collaboratively with the U.S. Food and Drug Administration (FDA) and DEA to address this challenge as soon as possible. Pfizer encourages customers to check their [Availability Report](#), updated weekly and accessible on the [Pfizer Hospital US homepage](#) for the latest information.
- **Medline Industries Recalls Certain Kits and Trays Containing Sterile Water Based Products Under Recall by Nurse Assist.** [Medline Industries is recalling certain kits, trays and packs](#) in direct response to Nurse Assist LLC's, November 6, 2023, recall of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP, over sterility concerns. These kits contain Nurse Assist saline solution that were recalled due to a lack of sterility.
- The FDA has followed up on their initial [safety communication](#), first released in November 2023, regarding the potential for failure with plastic syringes manufactured in China. Warning letters have been issued to the following three companies:
 - [Jiangsu Shenli Medical](#)
 - [Sol-Millennium Medical](#)
 - [Medline Industries](#)

Additionally, [the FDA announced expanded actions](#) for Jiangsu Shenli Medical Production Co. Ltd. with an additional import alert for not meeting device quality system requirements, to prevent ALL plastic syringes by this manufacturer from entering the United States.

In conversations with the FDA, existing global capacity is expected to absorb the current demand for plastic syringes and shortages are not anticipated. In conversations with BD, they have confirmed production capacity has been expanded at their two U.S. facilities.

Please email me at mschiller@aha.org should your organization begin to experience supply shortages or disruption to patient care. This information will be anonymized and shared our policy team.

- Panama Canal authorities have increased the number of canal transits to 27 up from 24.
- Dräger Safety AG & Company, KGaA posted a notice to make users aware that multiple batches of 6738020 Particle filter N95 pads and 6738021 Particle filter R95 pads were manufactured a few millimeters too small and will not fit properly resulting in reduced filter performance. See the user notice dated November 2023 for more information. It can be found on the [NIOSH Respirator User Notices Issued by Manufacturers](#) webpage under the Dräger Safety AG & Company, KGaA section.
- Thank you for your insightful responses to our request regarding the approach, feasibility and potential burden the variety of approaches policymakers are considering in addressing the growing number of pharma shortages. The anonymized information was compiled by our policy team.

About the Supply Chain Resource Council (SCRC)

The Supply Chain Resource Council (SCRC) is comprised of over 90 supply chain and health care leaders from across the health care field with the goal of understanding the extent and impact supply shortages and disruptions are having within the hospital and patient care settings, as well as a capturing and documenting solutions to these challenges. Information collected during these calls is drafted into a report and shared with AHA, AHRMM and Professional Management Group (PMG) senior leaders, the White House Response Team, various Federal Agencies and the broader health care field. *The content of this report represents information, strategies and solutions from SCRC members but does not necessarily reflect policy positions of the AHA.*



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