

Supply Chain Resource Council (SCRC) Report

January 8, 2024 Meeting

Executive Summary

Council members discussed the expanded recall of affected kits and trays containing 0.9% sodium chloride irrigation USP and sterile water for irrigation USP supplied by Nurse Assist. The Office of Civil Rights proposed rule around nondiscrimination and Accessible Medical Devices requirements was discussed as well as the expansion of hostilities in the Red Sea region and the impact of ocean transports and potential alternative shipping options. BLM sale of the Federal Helium Reserves, importation of drugs Canada and the Unique Device Identifier rounded out the conversations. Details can be found in the full report below.

▲ Field Updates

- **Sterile Saline and Water recalls expanded to include kits and trays.** Cardinal, Busse and ROi CPS, LLC products have been added to the expanded recall affecting their kits and trays. Links to the recalls and additional information are listed below.
- **Cardinal Health Issues Medical Device Recall for Nurse Assist Products Contained Within Kits/Trays**
Covidien and Cardinal Health brand urology and operating room-specific kits and trays that contain 0.9% sodium chloride irrigation USP and sterile water for irrigation USP supplied by Nurse Assist.
[Affected Covidien and Cardinal Health brand codes and lot numbers](#)
- **Busse Hospital Disposables Issues Nationwide Recall of Kits/Trays Containing Sterile Water Based Products Under Recall by Nurse Assist**
Medical device kits and trays, such as, tracheostomy care trays, tracheostomy care sets, and dressing change trays dressing kits, containing 1 Nurse Assist part 6240, Stericare 100ML Sterile Saline Bottle.
- **ROi CPS, LLC Recalls Regard Operative Lap P&S Surgical Kit Due to Possible Lack of Sterility.** *The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*
ROi CPS, LLC is recalling their Regard Operative Lap P&S Surgical Kit due to the possibility they may not be sterile. The surgical kits were built with a recalled item from a separate Class I recall from [Nurse Assist](#). Nurse Assist, LLC recalled their 0.9% sodium chloride irrigation USP and sterile water for irrigation USP due to the potential for a lack of sterility.
- **Office of Civil Rights is proposing a new rule around nondiscrimination.** The [proposed rule](#) includes new requirements prohibiting discrimination in the areas of medical treatment; the use of value assessments; web, mobile, and kiosk accessibility; and requirements for accessible medical equipment, so that persons with disabilities have an opportunity to participate in or benefit from health care programs and activities that is equal to the opportunity afforded others. Subpart J – addresses Accessible Medical Equipment.

▲ Supply Chain Watch List – current situations under observation

- **Houthi attacks, Red Sea situational awareness.** Houthi attacks against naval and merchant ships continue with more than one in five vessels electing to avoid the Suez Canal on routes between Asia and Europe. The leader of the Houthis, Mohammed Ali Al-Houthi, urged all ships planning to transit the Red Sea to notify his militia in advance with details of their destinations as well as declaring no

connections with Israel to avoid being attacked.

Many major shipping companies have switched to the longer and more costly route around the Africa's Cape of Good Hope rather than pass through the Suez Canal, which handles about 12% of global trade.

As reported in the December SCRC Report, Abby Pratt, Senior Vice President, Global Strategy & Analysis, Staff Lead, Supply Chain at AdvaMed shared that they polled their members to determine what, if any, impact this might have on medical supplies and equipment. Manufacturer responses at this time state that they are using west coast ports or air transportation.

- **FedEx Pilot contract negotiations.** Worth watching due to the Red Sea situation and the potential for more product to be shipped to the West Coast ports vs. extended routes and passage through the Cape of Good Hope (17 days vs. 43 days respectfully) in Africa. Air freight may become a viable option. Additional concerns include the med tech sector which relies quite a bit on FedEx.
- **Florida importing prescription drugs from Canada.** The question was raised if this may be the start of a trend as a result of the current drug shortages with health care organizations considering this as an option to augment their existing pharma inventories. A council member shared that she is aware of a health care organization exploring importing FDA approved, prescription drugs from India. To gain a better understanding whether other organizations are considering a similar approach, let me know if your hospital is exploring this as an option. All responses will be blinded and aggregated. One question that was raised is the potential impact this may have on the Canadian pharma supply chain shortages.
- **Bureau of Land Management sale of Federal Helium Reserve.** The sale of the Federal helium reserve is scheduled to take place the end of this month. While there is no objection to the sale, ensuring that there is no disruption of supply is one of several concerns expressed by the Compressed Gas Association (see attached). The AHA reached out to the FDA, and whether the FDA is aware off/satisfied with the transition plan to ensure adequate supplies for MRIs and breathing support needs.

▲ Other Updates

- **UDI-DI (Device Identifier)/GTIN compliance Update.** Back in November, council members discussed monitoring disparities between supplier GTIN information on labels and the Global UDI Database (GUDID), multiple device identifiers, and other scan related challenges. A template to begin compiling and reporting on scan failures and data disparities has been identified. If you are interested in reviewing and finalizing the data fields, please email Mike Schiller at mschiller@aha.org

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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