SUPPLY CHAIN RESOURCE COUNCIL

AHRMM Advancing Health Care through Supply Chain Excellence

Supply Chain Resource Council (SCRC) Report

May 13, 2024

Executive Summary

This month Council members discussed expanded communications from the FDA regarding plastic syringes manufactured in China, and the continued expansion of kit manufacturer recalls affected by the Nurse Assist, LLC Class I recall of sterile water and saline. Backorders for MedGyn tubing, Olympus' recommended substitute for their 3/8" tubing, and both Integra and Medtronic CSF Drainage systems and kits continue to pose challenges with access to inventory being further constrained. Several post-meeting Field Updates have been included in this report as well. Details can be found in the full report below, and on our newly developed Supply Chain Resource Council webpage.

▲ Supply Chain Watch List – current situations under observation

- **Since our last meeting, the FDA has released a number of additional communications regarding plastic syringes manufactured in China.** Below is a timeline of communications released since April 25:
  - May 23, 2024. The FDA is announced that Medline Industries, LP, a firm marketing and distributing plastic syringes made in China within the U.S., initiated a recall to stop using affected products which includes unauthorized plastic syringes made in China.
  - May 21, 2024. The FDA announced that Jiangsu Shenli Medical Production Co. Ltd, a China-based manufacturer of plastic syringes, initiated a recall to stop using its unauthorized plastic syringes.
  - May 16, 2024: The FDA announced an import alert for Zhejiang Longde Pharmaceutical Co. Ltd. and Shanghai Kindly Enterprise Development Group Co. Ltd. for not meeting device quality system requirements, to prevent plastic syringes made by these China-based manufacturers from entering the United States.
  - May 9, 2024. The FDA announced **Sol-Millennium Medical, Inc.** initiated a recall to stop using affected products, which includes unauthorized plastic syringes made in China such as "combined" syringes with needle and syringe components packaged together, low dead space ("LDS") syringes, luer slip tip syringes, eccentric tip syringes, and syringe accessories.
  - April 25, 2024. The FDA announced a warning letter was issued to **Cardinal Health** that describes violations related to the sale and distribution of unauthorized plastic syringes made in China and quality system regulations for syringe products.
- **DeRoyal Industries Inc. is the latest kit manufacturer affected by the Nurse Assist, LLC Class I Recalls for Sterile Water and Saline.** DeRoyal is recalling certain Surgical Tracecarts that contain a Nurse Assist 16FR Silver Urine Meter Foley. Model Numbers are 53-1829 Laminectomy Tracecart; 53-1831 Ortho Total Joint Tracecart; and the 53-1836 General Surgery Tracecart. This recall is in direct response to Nurse Assist LLC's, November 6, 2023, recall over sterility concerns. The rest of the items contained in the tracecart are not affected or impacted by this recall.

  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. backorders continue to pose challenges for some health care organizations.** Their tubing set has been recommended by Olympus as a suitable substitute product (#022310) for their backordered vacuum curettage 3/8" tubing sets (#23116).

- **Pharmaceutical shortages hit an all-time high.** ASHP reported that ongoing and active shortages are the highest number (323) since they began tracking data in 2001. Click here to read more and view the latest trends.
- **The U.S Department of Health and Human Services white paper** regarding Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States describes policy concepts for consideration, including collaboration with the private sector to develop and implement a Hospital Resilient Supply Program (HRSP). HRSP could establish incentives and/or penalties that prioritize supply chain resilience. In response to the white paper, AHA released the following statement:

  > "HHS is to be commended for considering actions to improve the resiliency of the supply chain for vital medications. When shortages happen, hospitals undertake an enormous effort to obtain stock from other sources or offer alternate medications that can provide similar benefit. They may have to retrain staff, recalibrate machines and perform many other steps to ensure patients get the care they need when they need it.
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  > It is in hospitals' ethical and financial interest to do what they can to ensure a smooth supply chain, but their role in the supply chain is really that of a customer. There are those that mine or produce the raw ingredients, those that manufacturer or transport the drugs, group purchasing entities and regulators such as the FDA – all of whom have a more direct role in ensuring the adequacy of the supply and resilience of the supply chain.
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  > It is misguided to punish hospitals if their purchasing practices do not conform to an arbitrary set of principles crafted by a federal agency, and to hold hospitals accountable for manufacturer resiliency metrics. Hospitals would have no control over the manufacturer metrics, which may or may not contribute to drug supply resiliency. The focus should be on how to support those with the key roles in building a resilient supply chain."

▲ Field Updates – Post-Meeting Developments

- **Integra CSF Drainage Systems.** As reported in January of 2023 and highlighted in June 2023, Integra CSF Drainage Systems, catalog #INS8400, continue to be on backorder. Production of cranial access kits and access to these critical products is a growing concern and becoming increasingly difficult to source. Codman related product is unavailable, Medtronic and Natus products are on manual allocation. Integra's response is that all "INS" codes are not being produced at this time due to raw material shortages. Below are affected product codes, by manufacturer, shared by one of our SCRC members:

  Integra codes unable to get (entire line of products is currently unavailable):
  INSHITH
  INSHITHRZN
  INSHITHND
  INS5HND

  Integra/Codman sub codes unable to get (entire line of products currently unavailable):
  82-6614

  Medtronic codes unable to get:
  46156
  46154

  Natus codes unable to get (entire line of products currently unavailable to us since we would use as subs):
  HITHND
- **Integra Bactiseal.** Integra LifeSciences has temporarily halted shipments and production of all Bactiseal® products, including Bactiseal EVDs, Bactiseal Shunt Catheters and Bactiseal Catheters provided with programmable valves. *See the attached Dear Valued Customer letter* for more details and impacted products.

- **NIOSH Counterfeit chemical cartridge filters warning.** The National Institute for Occupational Safety and Health (NIOSH) has identified many combination chemical/filter cartridges being sold on well-known online marketplaces claiming to have chemical and P100® protection that are not part of a NIOSH Approved® respirator configuration. Examples and more information can be found on the NIOSH Counterfeit Respirators/Misrepresentation of NIOSH Approval webpage under Counterfeit or Misrepresented Respirator Examples.
- **Tariff Increases. Tariffs have been increased on Chinese imports** of medical device categories, syringes and needles, facemasks, and medical gloves. AHA issued a statement that "supports incentivizing greater domestic manufacturing of essential medical supplies, improving the resiliency of the health care supply chain and diversifying the manufacturing base, but is concerned that these tariffs will lead to higher prices for high-volume medical supplies such as PPE and syringes that will exacerbate and prolong the financial headwinds that hospitals face today."
- **Tariff exclusions. The United States Trade Representative (USTR) extended certain exclusions from China Section 301 Tariffs.** The USTR has determined not to extend beyond the 14-day transition period the items listed in Annex D of the attached **Notice of Extension of Certain Exclusions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation.** Items listed in Annex C of the attached notice are receiving further extensions through May 31, 2025.
- **NIOSH Recission requests have been honored** for the following companies: Scott Health & Safety, Ltd, 3M Scott Fire & Safety, and Honeywell International Inc. Any respirator marked with a NIOSH approval label and approval number listed in the tables below are no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these approval numbers.

Voluntary Rescission of four Scott Health & Safety, Ltd. Approvals:

Approval Number	Part/Model
13F-0453	Pathfinder/3M Air-Mate 2000
13F-0454	Pathfinder/3M Air-Mate SCBAG
13F-0477	Air-Mate 5
13F-0478	Air-Mate 15

Voluntary Rescission of 15 3M Scott Fire & Safety Approvals

Approval Number	Part/Model
21C-0769	Proflo 2 or 3 PAPR
21C-0777	Proflo 2 or 3 PAPR
21C-0903	Proflo 2 or 3 PAPR
21C-0938	Proflo 2 or 3 PAPR
23C-2202	Proflo 2 or 3 PAPR
23C-2227	Proflo 2 or 3 PAPR
23C-2261	Proflo 2 or 3 PAPR
23C-2328	Proflo 2 or 3 PAPR
23C-2348	Proflo 2 or 3 PAPR
23C-2727	Proflo 2 or 3 PAPR
23C-2728	Proflo 2 or 3 PAPR
23C-2729	Proflo 2 or 3 PAPR
23C-2887	Proflo 2 or 3 PAPR
23C-2888	Proflo 2 or 3 PAPR
23C-2889	Proflo 2 or 3 PAPR

Voluntary Rescission of 22 Honeywell International Inc. Approvals

Approval Number	Blower Series	Mask/Hood	Cartridge/Filter
21C-1156	PA510 / PA510C	PA112/PA122	PA5HE
21C-1157	PA510 / PA510C	PA112/PA122	PA5HE
21C-1158	PA510 / PA510C	PA810	PA5HE
21C-1159	PA510 / PA510C	PA810	PA5HE
21C-1160	PA510 / PA510C	PA811	PA5HE
21C-1161	PA510 / PA510C	PA811	PA5HE
21C-1163	PA510 / PA510C	PA132/PA142	PA5HE
21C-1164	PA510 / PA510C	PA132/PA142	PA5HE
21C-1165	PA510 / PA510C	PA102S/PA102M	PA5HE
21C-1166	PA510 / PA510C	PA102S/PA102M	PA5HE
21C-1167	PA510 / PA510C	PA202/PAE2XX	PA5HE
21C-1168	PA510 / PA510C	PA202/PAE2XX	PA5HE
21C-1176	PA510 / PA510C	PA921	PA5HE
21C-1177	PA510 / PA510C	PA921	PA5HE
21C-1180	PA510 / PA510C	50008118-003	PA5HE
21C-1181	PA510 / PA510C	50008118-003	PA5HE
21C-1190	PA510 / PA510C	PA9312AM	PA5HE
21C-1191	PA510 / PA510C	PA9312AM	PA5HE
21C-1194	PA510 / PA510C	PA9311AM	PA5HE
21C-1195	PA510 / PA510C	PA9311AM	PA5HE
21C-1212	PA510 / PA510C	PA932AM	PA5HE
21C-1213	PA510 / PA510C	PA932AM	PA5HE

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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