GEDSA
ADVANCING PATIENT SAFETY

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GEDSA Engaged with the FDA on its Safety Concerns with Plastic Syringes Made in China

The Global Enteral Device Supplier Association (GEDSA), on behalf of its membership, is actively engaged in ongoing discussions with the Food and Drug Administration (FDA) regarding their recent Safety Communications[1,2] about plastic syringes manufactured in China. This has been and continues to be a positive collaboration that aims to better understand the FDA's concerns, collectively determine pathways to resolve these concerns, and to discuss and hopefully mitigate potential supply chain impacts. As a consolidated conduit of information flow with the FDA, GEDSA encourages manufacturers, suppliers, hospitals, clinicians, and other stakeholders to communicate their concerns, questions, and other information related to this matter to GEDSA. This will allow for the information to be aggregated and communicated in a manner that is the most efficient for processing by the FDA. GEDSA appreciates the FDA's collaborative efforts and we are confident that these efforts will continue, as affirmed by the FDA, "*We will continue to work with . . . medical device manufacturers . . . to help ensure the safety of syringes being used in the U.S.*" [2].

We suggest that stakeholders contemplating changes in their medical supply procurement or usage strategies conduct thorough evaluations for potential supply chain, device compatibility, and device usage impacts before changes are made. In particular, compatibility of syringes with the existing syringe pump infrastructure within a facility should carefully be considered. Syringe pumps may only have compatibility within their software for a select few syringes that are prequalified and validated on each model of syringe pump. To avoid delays in therapy, syringe pump compatibility should be verified before implementing a change in syringe supply. It has also been noted that, while intravenous and enteral syringes are both included in the FDA's safety communications, for the most part these syringes have significantly different risk profiles for their uses. Enteral syringes generally carry much less risks than intravenous syringes and facilities should bear this in mind when considering a change in their enteral syringes.

GEDSA and its members remain committed to the advancement of patient safety and ensuring that all stakeholders are informed and prepared to make the best decisions for their operational needs and patient safety outcomes.

[1] https://public4.pagefreezer.com/browse/FDA/13-03-2024T15:34/https://www.fda.gov/medical-devices/safety-communications/evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication
[2] https://www.fda.gov/medical-devices/safety-communications/update-evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication