November 8th, 2016

Mr. Bruce Culleton, MD, MBA
VP WW Medical Affairs
BD Medication and Procedural Solutions

Mr. Amardeep Singh Chahal
Senior Business Director, Injection Systems
BD Medication and Procedural Solutions

Dear Mr. Culleton and Mr. Chahal,

GEDSA remains at the forefront of the important patient safety initiative to reduce the risk of misconnections and would like to formally clarify misconstrued information that we believe BD has been circulating throughout the healthcare community. In response to your email dated July 20th, 2016, a technical team of experts representing member companies including Halyard, NeoMed, Medtronic, Baxter, Medela, Medicina, and GBUK have diligently worked to address each concern you have expressed in your letter. A position statement and frequently asked questions document can be found on our website for clarification to the broader healthcare community.

In the beginning of your letter you refer back to the ENFit® Syringe and the ENFit® Low Dose Tip syringe stating "…both of these proposed designs fail to meet the accepted syringe dose accuracy standards on which clinicians around the world have come to rely." The entire premise of your letter is misleading because you are describing tolerance on graduated capacity and comparing it to dose accuracy data, published by GEDSA, as if the two were the same thing. As outlined below, dose accuracy and tolerance on graduated capacity are not the same and we believe you are purposely using those terms interchangeably to mislead the healthcare community. GEDSA and its members have worked collaboratively to arrive at the best solution for patients that delivers highly accurate doses consistent with what is commonly in use today for even the most vulnerable patients. The following offer counter points to each item outlined in your letter.

<u>Dose Accuracy</u>

1. Since there are no standards applicable directly for existing enteral/oral syringes, each manufacturer has determined the requirements suitable for their product and customer base. In general, many manufacturers use the performance requirements in ISO 7886-1, as a proxy, specifically referencing Tolerance on Graduated Capacity (TOGC) to test their syringes. As clearly outlined in section 3.3 of ISO 7886-1, TOGC defines the required precision of the scale or the markings on a syringe barrel only. Dose accuracy is different from TOGC in that dose accuracy is the actual dose delivered to the patient by the entire system, including the syringe. Dose accuracy is not defined in ISO 7886-1, nor any other generally recognized ISO standard today.
    a. When discussing TOGC, ± 5% is not applicable to all syringe sizes or use scenarios.
    b. The TOGC depends upon the volume in the syringe. For small volume syringes such as a 1mL syringe with a 0.10mL dose, TOGC can be as high as +/-17%
2. Since there is currently no ISO design standard for enteral/oral syringes on dose accuracy, GEDSA evaluated 3 of the most commonly used male enteral/oral syringes and took an aggregate of the results to determine a baseline for dose accuracy.
    a. The aggregate of male oriented syringes in wide spread use throughout the world tested under the same protocol (0.20 mL dose with a 1.0 mL syringe) were found to

deliver dose inaccuracies with an average value of -7.37% to 9.69% with a 95% confidence interval.

b. Testing was performed and validated by an independent third party NHS laboratory accredited for testing medical devices.
Reference note: Reverse systems that are being used today (such as the reverse Luer system used for enteral feeding in the UK for the last 10 years) tested with the same protocol resulted with a dose inaccuracy with average value of -3.96% to 21.22% with a 95% confidence interval.

3. Concerns were raised regarding small volume doses while using the ENFit design. To appropriately address these concerns, a technical team of industry experts worked collaboratively to select and vet a solution to address small volume dose accuracy. The ENFit LDT design has been validated through rigorous misconnections risk analysis and performance testing, as well as usability and human factors testing. We believe the LDT design provides a solution for accurate enteral dosing for all populations, including neonates, while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections. In short, we believe the LDT provides a clinical benefit that outweighs the risk of its use. In addition, The ENFit LDT Syringe has been thoroughly reviewed and received FDA 510(k) clearance for at least three manufacturers.
    a. Performance testing did reveal that the ENFit LDT was substantially equivalent to the aggregate of the 3 enteral/oral syringes evaluated
    b. Testing also revealed the ENFit LDT performs significantly better than reverse orientation systems available on the market today.

In light of your comment, "BD remains very open to re-evaluating alternate solutions as long as they comply with the existing standards for dosage accuracy to ensure patient safety", as there is no standard on dose accuracy, GEDSA and its members have determined the data generated for the ENFit Syringe and the ENFit Low Dose Tip Syringe designs demonstrate compliance with the clinical expectations of dose accuracy.

<u>Workflow Concern</u>

As stated in our most recent position statement and frequently asked questions document available at www. StayConnected.org, there are no new techniques needed when using the ENFit Syringe or the ENFit Low Dose Tip.

- It is common practice to tap/flick a syringe to remove air bubbles for many different types of syringes on the market today; GEDSA recommends the same practice to remove fluid outside the fluid pathway.
- Usability studies were conducted with respondents worldwide using current practices and methods for filling and administering enteral doses and found the ENFit LDT design acceptable by all user groups.

As you state, BD is pursuing a male enteral syringe design that complies with the ISO 80369-3. This represents a significant concern for healthcare providers throughout the globe as the introduction of a male enteral syringe will represent a "second" feeding system that could lead to disruption of therapy to patients due to compatibility issues and continuity of care concerns. GEDSA believes that the introduction of a second design would undermine the intent of the ISO standard overall and can put patients at risk. Furthermore, BD's proposal of another male oriented syringe will not only be a major disruption in work flow, but will also require validated data that BD's proposed design meets clinician requirements. BD's proposal that a male oriented syringe will outperform the ENFit LDT syringe is currently only speculative in nature as there has been no design nor data disclosed by BD that we are

aware of which supports this position. Any data generated should assess dose accuracy using the ISO 80369-3 connectors in a realistic test system supported by usability studies conducted around the world acknowledging the ENFit design already adopted in the market.

A Path Forward

Deployment of the ENFit connector introduces an immediate patient safety benefit. Any delay in the introduction of ENFit continues to put patients worldwide at risk. It is GEDSA's mission to promote safe and optimal delivery of enteral feeding and we would like to invite BD to rejoin this important patient safety initiative they once aligned with.

Respectfully,

Thomas J Hancock
Executive Director
GEDSA

Justin Martin
Chairmen
GEDSA

The Global Enteral Device Supplier Association (GEDSA) is a 501(c)(6) nonprofit trade association formed to help introduce international standards for healthcare tubing connectors. Comprised of manufacturers, distributors, and suppliers of enteral nutrition devices worldwide, GEDSA facilitates information flow about the three-phase initiative, which is designed to increase patient safety and optimal delivery of enteral feeding by reducing the risk of tubing misconnections.

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