From: Tubies Against ENFit
Subj: Response to GEDSA position statement

In a September 7, 2018 FDA letter https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM619782.pdf to manufacturers of enteral feeding tubes, health care professionals, hospital purchasing departments, and distributors, the FDA states:

> *"FDA recommends hospitals and clinicians use enteral devices with connectors that meet the… ISO 80369-1 or ISO 80369-3 standard,* ***or that are otherwise designed to reduce the risk of misconnections."***

The FDA:

- Does not a mandate the manufacture, purchase or use of ENFit connectors.
- Recommends the use of connectors that are demonstrated to reduce misconnection events.
- Acknowledges that ENFit is not efficacious for certain tube feeders due to ENFit flow constriction. It seems to be an admission from the FDA that ENFit should not have received 510k clearance under the "substantially equivalent" metric as to "safety and efficacy."

It's unseemly that GEDSA (Global Enteral Device Supplier Association) has mischaracterized the FDA letter by stating:

> "*The… FDA writes a letter reemphasizing the need to make the transition to ISO 80369-3 compliant connectors*." (on its website), and "*adoption of new ENFit® connectors as called for in the FDA's letter*." (in its position statement) http://stayconnected.org/wp-content/uploads/2018/10/GEDSA-Position-Statement-on-FDA-Letter-2018-.pdf

Contrary to GEDSA's assertions, the FDA's letter is clear:

- Connectors simply must reduce the risk of misconnections, regardless of being ENFit or not.
- ENFit is not required or mandated by the FDA or any other agency or organization.

GEDSA further outrageously states that it, "*plans…. to develop a coordinated phase out plan for connectors that do not meet ISO 80369-3, to accelerate adoption."*

GEDSA members are the very manufacturers who seek to profit from the sale of ENFit products and who appear desperate to recoup their investment. At meetings with tube feeders, GEDSA and its members repeatedly stated that safe funnel connectors would remain on the market, but now are retreating from their promises and spinning an FDA letter to suit their financial plans.

Tubies recognize that FDA cleared catheter tip syringes and mating funnel ports have been proven safe and efficacious over the last 30 years and clearly comply with the September 2018 recommendation of the FDA. Hospital, distributors and patient groups will best serve tube feeders by recognizing the same.

- ENFit misconnects with adult trach tubes.
- ENFit does not solve misconnections (note the every-present IV luer balloon inflation port on dangler g-tubes and note the IV luer main port on low profile balloon tubes).
- ENFit is not efficacious for the growing group of feeders who choose to blenderize.
- Build-up of formula and debris in the ENFit moat area presents significant contamination.

In conclusion, don't be fooled by large corporations seeking to push their clinically shaky, non-mandated ENFit product. Stick with tried and true, highly efficacious and safe funnel connectors and catheter tip syringes.