Report of the AAMI and GEDSA information session on 80369-3 connectors
October 14, 2015
AAMI, Arlington, VA

Scott Colburn, Convenor of ISO/TC 210/JWG4, Small-bore connectors, welcomed everyone to the meeting, which was convened by AAMI, who holds the Secretariat for ISO/TC 210 and ISO/TC 210/JWG4, and GEDSA (Global Enteral Devices Supplier Association) to hear patient concerns about ENFit connectors (a trade name of ISO 80369-3 connectors). Concerns that have been brought forward are particularly related to blended diets. He stated that another goal of the meeting was to provide context and an update about the ISO 80369 series of small-bore connector standards. Colleen Elliott served as recording secretary. In the interest of time, introductions of those in attendance and on the WebEx were not made. A list of in-person and WebEx attendees is attached.

Mr. Colburn stated that the effort to develop the series of ISO 80369 small-bore connectors was initiated in response to a global health issue of dangerous and fatal misconnections. He stated that an enormous amount of work has been done by many manufacturers and other stakeholders over many years to reduce misconnections between Luer (intravascular), enteral and other applications. Manufacturers have made choices to make changes to their products in order to increase safety. Mr. Colburn also noted that there are known risks associated with medical device misconnection, such as the tracheostomy tube, where critical dimensions are not fully called out. It was noted from this it has not been possible to do a full misconnection analysis, but efforts are underway in the US to address and correct this where possible.

Tom Hancock, Executive Director of GEDSA, gave a presentation on the mission of GEDSA and the historical development of the ISO 80369-3 connectors and ENFit (see attached). His update included information on an issue of dead space, which was identified due to the reverse orientation of the ENFit system. A meeting was convened at CHOP (Children’s Hospital of Philadelphia) in July during which many clinicians provided feedback about this issue, stating their preference for one syringe for all applications and for a simple procedure. In response, GEDSA members have drafted a design that is currently undergoing evaluation for performance and misconnection to address this issue.

Don McMichael, representing Halyard Health, gave a presentation on testing done by Halyard on ENFit connectors compared to other products previously on the market (see attached). He noted that some information is still unknown and that the company continues its’ work to understand how various factors, such as tubing, affect flow rates. He discussed flow rate variables, such as French size of feeding tubes, aperture through feeding adapter(s), length of flow restriction and characteristics of fluids. He concluded that ENFit was appropriate for its intended uses and the Halyard felt confident in its products adopting the design to its devices in this clinical application.

Mr. Hancock asked Mr. McMichael to explain how the identified clinically acceptable delivery flow rate 120 ml/min rate was determined. Mr. McMichael responded that he and Peggi Guenter, PhD, RN, FAAN; Senior Director of Clinical Practice, Quality, and Advocacy; American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), came up with this based on feeding two catheter tip syringes in a minute, which was felt to be an acceptable clinical rate.

Rork Swisher stated that the internal diameter was agreed upon several years ago in ISO/TC 210/JWG4 based upon the technical requirements for non-interconnectability with other applications.
Rory Jaffe, MD, representing California Hospital Patient Safety Organization (CHPSO), asked if anyone had approached patients using adapters regarding their experience and what their feeding habits are. Mr. McMichael responded that he received pictures from one of the patients on the call, David Rowland, and deduced that he uses a MIC-KEY. Mr. McMichael stated that there is a lot of variability in blenderized diets, not only from person to person but meal to meal. He stated that he would welcome more input to understand typical blenderized diets.

Mr. Hancock stated that to his knowledge there are not any ENFit tip syringes or feeding tubes currently on the market, so the criticisms being brought forward by tube feeders are based on information being delivered to them rather than experience or data from actual manufactured products on the market. Dr. Jaffe asked if patient groups are involved in implementation efforts. Lisa Metzger, representing the Oley Foundation, stated that they have received a lot of the same concerns, but they have not been able to use the system yet, so it is hard to evaluate. A lot of users use the 24French and have developed their own adaptations and off label use over time. She stated that there is a concern that watering down blenderized diets is not a good option, because of the calorie/volume ratio. The Oley Foundation did an informal survey and found that blenderized diets was one of the biggest concerns, but at this point agreed that this concern cannot be confirmed as real due to the lack of devices that have yet to be manufactured (feeding tubes and syringes).

Traci Nagy, Founder and Chief Executive Momma at Feeding Tube Awareness Foundation stated that her association services the pediatric population, which mostly use the button device. Most of the patients use the syringe push method, so there is not a significant problem. She has not had problems with pump feeding using the adaptors. They need to wait and get a better understanding of what the changes related to ENFit will mean clinically.

Ronald Coppinger, a tube feeder, stated that he has not tested ENFit yet. He stated that he has a 24French PEG tube with a Y-port connector/adaptor. He stated that the size of the orifice of current system is about 3.2 mm, and sometimes he has problems with that, so he anticipates more of a problem with the 2.9mm orifice in ENFit. Shelley Buma, representing GI Design Associates, asked if real user data would be accumulated before the launch of ENFit. Mr. Colburn responded that the transition has hit giving sets and syringes, but has not hit all devices yet. He said that there are four or five designs that accept the step connector. There are challenges associated with the use of a transitional component, which is needed to address supply chain availability; the adaptor is not meeting the criteria in all applications. Mr. Colburn continued to explain that each manufacturer needs to do their own risk analysis, including working with patients, to determine if ENFit is the right decision for their products, considering factors such as how it affects performance. Mr. Colburn stated that there was a large simulated use usability study done on the ISO 80369-3 connectors in the standards development process, but there was not a full clinical study.

Ms. Metzger stated that the Oley Foundation coordinated some focus groups for testing the ENFit connection, but not for blenderized diets.

Mr. Colburn explained that existing tubes and devices will be maintained in patients who have them long-term, in consultation with their health care providers. Manufacturers are also assessing their products to determine if the design is adequate and meet patient needs. All products are slightly different. Manufacturers can come up with other solutions in the future if this design does not meet patient needs.

Dr. Jaffe stated that this is not just change for sake of change. There is significant risk with the current connectors, and the intention of standardization is to achieve a better user experience and increase safety and prevent harm that has occurred with current designs. Ms. Buma asked when different users would have an opportunity to test the connectors with different modalities to ensure that there will in fact be a better user experience, because based on Mr. Coppinger’s experience, this does not seem like it will be the case. Mr. Hancock stated that the transition period is estimated to be about three years; current
products will not be taken away overnight. Overall, GEDSA does anticipate an acceptable user experience.

Mr. Flach expressed concerns about feeding with ENFit, noting that bolus feeding is extremely messy and time consuming. Mr. Colburn acknowledged his concerns and stated that manufacturers are looking at these type of concerns as they are finalizing their designs. More evaluations will be done, including in home care environments. He continued to state that even though there is a pending legal requirement in California, the most important requirement is patient safety. ISO/TC 210/JWG4 feels strongly about not negatively affecting clinical applications and the group has taken a great deal of time to address this.

Joan Bishop, Executive Director of the Oley Foundation asked everyone to come together again in a similar open forum to allow individuals to express their feedback, positive and negative, troubleshoot and work through the issues. Mr. Hancock stated that this is a jumping off point to establish an ongoing forum to have real time feedback as products are introduced.). Feedback represents valuable input opportunities for manufacturers to evaluate and determine the best path to ensure a positive user experience. Feedback is very helpful for manufacturers to improve upon future systems. Devices will have ENFit in the future, but there is ample opportunity with the device designs to address the performance and drive continuous improvement.

Ms. Buma asked when the FDIS ballot would be opened and suggested that the concerns need to be resolved before then. Ms. Elliott stated that the ISO/FDIS 80369-3 ballot was scheduled to open on December 3, 2015.

Mr. Colburn stated that the users in this meeting represent a subset of devices within the enteral application. The connector’s design for reducing fatalities is critical. He stated that the group needs to focus on medical device standards that incorporate the connectors, especially for specific applications such as blenderized diets. There also needs to be a focus on performance requirements of the medical devices. He stated that a failure to move towards publication of ISO 80369-3 is not in the best interest for public health.

A question was raised about cleaning and breeding of bacteria, which is especially a concern for patients with cancer. Mr. Colburn mentioned a lack of negative incidents or rise in infections after years of use in enteral applications in the UK over their 10+ year use of a reverse orientation. He also noted that Japan did some studies to assess the residual amount of fluid with reversed direction of flow to support their decision and vote on the standard.

Mr. Colburn encouraged the Oley Foundation, GEDSA, AAMI and other organizations to work together with patients on implementation efforts.

Ms. Buma and tube feeders David Rowland, Dr. L.D. Elfrink (by proxy), Sanford Flach, Ronald Coppinger (by proxy) and Richard Reynolds made comments, which are attached to this report.

Mr. McMichael gave a demonstration comparing flow rates of the existing system (20 French PEG Halyard tube) and of ENFit using the same tub, using Peptamen AF 1.2 formula. The rates were equivalent, approximately 28 seconds for each. A video is available here: http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/HT_Smallbore/Demonstration_Flow_Rate_ENFit.mp4.

Mr. Colburn stated that AAMI and ISO/TC 210/JWG4 would continue efforts to hear patient voices and to respond to their concerns. He thanked everyone for their participation. The meeting was adjourned.
Thank you for this opportunity.

My name is Shelley Buma, and I’m president of GI Design Associates, an independent medical device design consulting company.

I intend to forward my comments to you for inclusion into the record.

By way of background: GI Design does not manufacture product. We are not a tube, formula, or syringe marketer.

I’ve been involved in the enteral marketplace for the last 27 years, including work with Superior Biosystems -- one of the first PEG manufacturers, and also with Cook Endoscopy and their line of PEG, low profile and balloon replacement G-tubes, and jejunal tubes.

I have not received any monies from any individual or entity in connection with my comments today or in the past relating to the 80369-3 standard and ENFit. I was, however, threatened in writing to be sued by a corporate member of GEDSA for comments I made some time ago. Perhaps more intimidation is forthcoming. This is the world we live in.

I have knowledge and passion of this marketplace, and I’ve come to know end users. A white paper analysis of ENFit can be found at GiDesignAssoc.com

Over nearly 3 decades, progressively larger tubes with correspondingly larger connectors to mate with large bore catheter tip syringes have been introduced. ENFit, however, is a reversal of years of user feedback that bigger is better in terms of flow, clogging, and manageability.

Current connectors and large bore syringes are associated with a high level of user and nursing care satisfaction.

In contrast, I believe ENfit is utterly backwards and an unconscionable attempt to introduce a not thoroughly tested, unsafe, unvetted, unworthy product into a marketplace that serves so many hospital, nursing home, rehab, and at-home patients. In all markets, ENfit is un-fit.

Users and organizations have been told by GEDSA and by individuals at the FDA that the process is a “done deal”, that the standard has been adopted, that product is in inventory just waiting to be shipped, and that nothing can be done to stop that.

It’s insulting therefore, to just now invite members of the tube feeding community when the issue is a stated “done deal” to hear how these connectors will impact their lives…as if they and their lives are simply part of a bureaucratic check list. The most important thing, is the most important thing – and that is the end user. Surely the proper process would have been to involve
them early and often, and to conduct real world, real patient testing, in many locations with the various feeding and medication modalities.

Instead, it appears only bench testing has been done. And those tests, have not been able to be duplicated by other testers.

Nevertheless, the dimensions speak for themselves. The existing 24fr bolus connector is 4.65 mm I.D. and the existing catheter tip syringe through which users feed, administer crushed meds and flush is 3.82mm I.D. However, the male patient side constricted ENFit connector is only 2.9 mm I.D. The smaller dimension will reduce flow and cause clogging. Years of experience and clinical literature tell us that. Also, Links to video demonstrations showing the reduced flow and clogging can be seen at GIDesignAssoc.com.

Some years ago the FDA calendar showed an infant mannequin with an orange Christmas tree delivery set lodged into its tracheostomy tube. This has been the poster child of misconnection. And rightfully so. One misconnection death is one misconnection death too many. That’s one reason why I’m opposed to ENFit -- The female ENFit connector unsafely misconnects to all adult Shiley tracheostomy tubes. It creates a perfect, positive, interference friction fit with the airway just as if it was designed to do so. It creates a perfect, intuitive seal with the airway, allowing pumped formula, or syringe formula, to enter a patient’s lungs. Precisely what the FDA Calendar alerted against, and precisely contrary to the stated goal of 80369-3. It’s Unconscionable.

Current connectors in commercialization are safer than ENFit.

Yet the 80369-3 standard presses aggressively onward, looking to somehow back-fill with other yet un-adopted standards to brace against unsafe misconnection--- and to promise that somehow better education about ENFit or future innovation years from now will make the connector beneficial to the population it seeks to help.

As I’ve noted before, the female connector also connects to some rigid female I.V. luer slip side ports and vascular needle cannulas. But of course those who have married themself to the standard or cut steel or have shelves of inventory, are quick to dismiss those deadly concerns -- or quick to point to other un-adopted proposals which would still leave millions of devices with misconnection potential in commercial distribution at the time of ENFit launch. Again, unconscionable.

The proposed Female EnFit syringe has a large dead space which impacts medication delivery in the infant population. You’ve all heard about that and about the deadly consequences.

As the standard itself refers to, even if the gender is reversed and the male connector is on the syringe side, then the syringe can dangerously connect to flexible airway access ports on closed tracheal suction systems. The standard is not salvageable. There is no safe pathway within this standard. It’s unfit in all respects.
Still ENFit marches toward its rehearsed introduction date. After all, GEDSA put the cart before the horse and counted the votes before they were taken and now it’s more about meeting deadlines than about meeting patient need and patient safety.

How far will this go? How many lives will be impacted?

Real lives hang in the balance. I urge you to do the right thing. Walk away.

Divorce yourself from this debacle.

I pray that wisdom will prevail, and that you will have the courage to stop the madness, to un-do this process.

Thank you.
My name is David Rowland. Thank you for this forum and the opportunity to speak.

I will email the following comments to you for inclusion into the record.

I am 76 years old and have been tube feeding for 3 years and 3 months. Despite my challenges, I am a very active person.

I’d like to touch on 2 areas:
First – gravity feeding. And second, my limited dexterity.

I have a low profile Mic-Key and gravity feed formula directly into my stomach.

I tried pump feeding for a very short time but found it very bothersome.

For me, the drawbacks of the pump were:
- I was tethered to a pole and therefore felt a loss of independence.
- I didn’t want to haul around a backpack during the day – again, a loss of independence.
- I had trouble sleeping due to the pump’s noise and alarms going off for unknown reasons.
- I wanted my life to be as normal as possible.

I currently use a catheter tip syringe with a large bore opening of 3.82 mm attached to the large funnel female opening of the Mic-Key extension set. This has served me well in delivering formula and crushed medications due to the large flow path.

Adoption of the ENFit standard would cause me difficulties in gravity formula and med delivery. The use of the ENFit syringe into a 2.9mm male mating fitting would cause a choke point.

Simply put, ENFit would add another constriction to my Mic-Key. My Mic-Key extension tube would now have a 2.9 mm constriction on its proximal end. This would significantly slow down the flow of formula and increase the risks of clogging. One constriction is difficult enough - two constrictions would not be manageable. I’m not sure what I would do if I had to resort to a pump, as it would cause me to become less independent.

For many patients, the gravity method is the clinically preferred method – and common in the nursing home and rehab setting. My concern is that Nursing is short on time and staff. Increasing the time to gravity feed through an ENFit gastrostomy tube – keeping in mind that the nurse must physically hold the syringe, and then properly flush the tube --- will only compound the institution’s existing time constraints.

Not to mention the time it will take to properly clean and unclog the patient’s connector. Quality of care, therefore, may be compromised in these settings. More time with one patient, means less time with another.

Now, regarding my limited dexterity:
I have limited use of my right arm and hand as I have subclavian arterial blockage to my right arm caused by radiation damage. With the current system and its press-fit design, I can make the connection with one hand. ENFit, however, will require the use of 2 hands, and require sufficient torque on the parts to twist together and secure the connections. It will be impossible for me to do that by myself.

All I want is to continue to live as independently as I can, and to maintain my quality of life. ENFit will mean a major step backwards for me. It will take away – and rob me of my ability to feed myself. Each feeding will require the assistance of another person – and I don’t want that.

Many others with limited dexterity and arthritic hands will be adversely affected. ENfit will present a tremendous human cost, and psychological cost for the currently active and managing tube feeder. ENFit will marginalize us. No doubt there is also the financial burden for those who currently live alone and will need paid caregiver help during each feeding.

The proposed ENFit release is very disturbing. In addition to what I’ve already mentioned – ENFit simply puts people’s lives at risk with the safety issues it creates (with misconnection potential and the syringe dead space issue).

In conclusion: I survived cancer but I have difficulties and residual effects of the radiation. Still, I’ve reached a stage where I can function reasonably well with the existing catheter tip syringe and Mic-Key funnel extension tube. The adoption of this standard will make my life miserable. I’m absolutely appalled that this process has gone on for so long, and without the involvement of actual users, without extensive data, and without full blown clinical trials in various settings. It’s outrageous that the FDA would allow such a product to reach the market.

I can tube feed myself right now and I’m satisfied with that. Why would anyone want to make things harder and more miserable for me and other tube feeders. We already have enough challenges in our lives. I absolutely hope that you put a bullet in this standard and give it its proper burial.

Thank you for your time!
To: Colleen Elliott, AAMI
celliott@aami.org

cc: Scott Colburn, Co-Chair 80369-3 standard
scott.colburn@fda.hhs.gov

Dear Ms. Elliott,

Regrettably I am unable to participate by phone in the forum discussion on October 14, 2015 regarding the practicality and/or concerns for implementation of the ENFit connector for PEG tube users. I would appreciate my forthcoming comments to be included as part of the record of this meeting.

The principal reason I cannot participate is that I have significant radiation-associated nerve damage to my tongue received 23 years ago that renders vocalization on a phone very challenging for me.

I am a retired physician with a 20fr PEG tube and also a tracheostomy tube. I feed with blenderized food through a catheter tip syringe into my tube.

I previously had a 24fr PEG tube but now use a 20fr tube after my most recent hospital stay in June 2015. The reason for the downsizing is the hospital placed a temporary 18fr tube that leaked a lot. By the time I was able to see my GI doctor the PEG tube stoma had stenosed and would only except a 20fr size tube. Through the 20fr tube I still blenderize and use catheter tip syringe to feed.

Implementation of the ENFit would create more harm than benefit for those using current PEG systems.

There are serious concerns associated with this connector device; especially the slow flow rate and very narrow caliber that greatly prolongs feeding time and essentially prohibits anyone from using home blended meals as is a common practice today.

I can only imagine the outcry from anyone using alternative sources of nutrition like blender prepared meals versus commercially prepared formulas. Nestle and other formula based companies stand to benefit the most if PEG tube users are forced to only consume their or similar products.

I have yet to meet or talk with an adult PEG tube user who prefers such commercial formulas over blended nutrition when this is an option.

I have been blending my meals for years after many failures to tolerate any of the commercial formulas on the market including intermittent use during two prolonged hospital stays in the past 2 years.
My diet is based upon very healthy home blended foods. Since stopping commercial food formulas, I no longer feel ill or suffer from chronic diarrhea.

I am physically quite active and thoroughly enjoy the benefits of a diet based solely on home blended meals. To reiterate, ENFit would prohibit anyone from using home blended meals. Such use is a common practice today.

I am genuinely concerned about implementing use of the ENFit without thorough impact studies and input from real-time PEG users.

I think anyone who truly believes ENFit is going to be a blessing to the active ambulatory patient, should try using ENFit for their nutrition and fluid needs for a minimum period of 2-4 weeks. It will quickly dispel the myth of how beneficial the ENFit connector will be.

Thank you,

Loui Don Elfrink (MD, retired)

Tulsa, OK
I was able to listen in on the AAMI/GEDSA information meeting of October 14, 2015. In addition to my comments which were read aloud, I would like to add the following comments to the record:

Mandating universal use of the ENFit for all tube users without considering multiple other factors will create more calamity then resolution.

There is a perceived sense that the underlying proposal to change to a small caliber connector is being orchestrated by the big commercial formula companies. The ENFit with its small caliber is not an appropriate functional solution.

As previously noted, this is extremely bad news for the growing mass of users relying upon home prepared natural food blended meals. I am unaware of any PEG tube users who prefer commercial formula over natural food blended meals when this is a viable option. Our food desires and needs are no different than people without a tube.

Many of us are completely happy with our PEG tubes and syringes. They represent a significantly efficient and convenient way to bolus blended meals. I have several years of personal use using this feeding method without complications.

It seems each PEG tube manufacturer designs and implements their own preferred tube product. There is no universal agreement for manufacturers to follow in tube design to date. From a personal preference, I have migrated to exclusive use of a tube made by Boston Scientific. As the tube exits the abdomen it takes an abrupt 90 degree turn and is flush against the abdominal wall. No dangling long tube length or loops projecting anterior from the abdomen. The tubes that have protruding loops leak pretty badly, are visible and get caught in clothing easily. I love my current PEG design.

Issues of great importance to many long term PEG users include:
- Individual physical activity level (from low level to intense) with heightened fluid and nutrition requirements.
- Ability to maintain independence.
- Dignity.
- Self care.
- Cognitive and emotional satisfaction, etc.

Many of us have survived various cancers and other chronic progressive disease.

The failure of the small caliber ENFit male patient side connector to not accommodate continuing use of home prepared and blended meals with ability to bolus feed is a crippling defect that absolutely needs to be addressed before any further push such a device.

Thank you.

Loui Don Elfrink, (retired MD)
Tulsa, OK
Good afternoon, my name is Sanford Flach and I am a 69yo retired Navy Master Chief who has had a gastric feeding tube for 2 years, as a result of radiation treatment for cancer 10 years ago. Please excuse my inability to speak clearly due to the numbness of my tongue.

My feeding tube is my LIFELINE. I don’t ask for your pity, only for your understanding of my tube feeding needs and physical limitations.

It is quite obvious that the designers of ENFit did not consult end users when designing ENFit.

Are you aware that the inside bore of the ENFit male connector is only 2.95mm?

The gold standard of tubes is a 24Fr. dangling type tube that tubies currently use to gravity feed their home blended foods.

I use a 24Fr. dangling type feeding tube for consuming a healthy blenderized diet. I cannot tolerate formula very well, as it causes me to have extreme mucus problems which lead to choking and coughing.

The large bore of a 24fr tube and a catheter tip syringe accommodates my meals extremely well. But a 2.9mm narrow lumen will take away my ability to feed myself. It won’t accept my blended food. ISO 80369-3 means that I cannot eat the real foods I eat now, and my existence will be diminished greatly as I cannot tolerate formula well.

I’m fighting for my LifeLine. I’m fighting to be able to eat the food my body responds well to. I don’t want to be worse off than I am right now.

Forcing ENFit upon a world-wide group of unsuspecting people who already have more than enough difficulty in their daily lives is nothing short of a criminal act.

I can’t raise my arms beyond parallel with the ground and I can’t eat food or swallow my saliva.

I don’t want your sympathy -- I want your common sense. ENFit creates even more problems for me – it removes my absolute need and requirement to put homemade blended food into my body. Everyone can see that a 2.9mm inner bore patient side connector will be problematic.

All year, I, and many others, have been warning tube manufacturers about the poor design and dangers of ENFit. End users do not want this product. It will degrad e our lives. There’s nothing helpful to us about it.

And, yes babies will die from medicinal overdosing due to the ENFit syringes. Would you want your infant to be medicated with one of these dangerous ENFit syringes?

I also predict that many cancer treatment patients will die, due to infections caused by the unsanitary "dirty plates" they will be forced to eat from.
I’m referring to the large internal circular crevice moat area on the patient side ENFit connector. The crevice area is only 1.5mm wide but 7mm deep, creating an area for the continual breeding of bacteria and viruses capable of causing illness and death of already immune system compromised cancer treatment patients. The internal screw thread area presents an additional breeding ground for CDIF and other infectious organisms. How will we constantly and properly clean this narrow and deep crevice area? It will be virtually impossible. Do we have to dispose of the connector every day? Who will pay for that? Do you care? In comparison, current connectors have a smooth laminar flow area with no crevices or breeding grounds.

Which of your loved ones undergoing cancer treatments would you force to eat from a dirty plate?

Another problem with ENFit is the positive screw thread connection which eliminates the slip joint connections of the delivery set. The current slip connection is a safety feature as it comes apart if the user inadvertently snags their tube on something. Yes, an occasional mess is caused by these unexpected disconnects.

But I would much rather clean up a small mess, than have the inadvertent snag cause my G-tube to be snatched completely out of my stomach, requiring me to go to the Emergency Room for a new tube installation and possible personal injuries.

When ENFit gets approved and the proverbial ENFit hits the fan, I, and many others, will offer up our services and testimonies to personal injury lawyers who will open the floodgates of discovery. Our extensive records of public warnings in the social media, personal emails, etc. and our pleas to ENFit suppliers to step away from ENFit, will also become evidence as we involve the U.S. Justice Department in the investigation of the biggest and most deadly collusive act ever perpetrated on an unsuspecting and helpless group of citizens, who are fully dependent on a feeding tube for their very lives.

Tom Hancock, of GEDSA, has been saying in recent months that "the train has already left the station".

Is YOUR COMPANY going to be involved in the ensuing TRAIN WRECK?

As I’ve stated, ENFit will make my life worse. The narrow constriction will force me onto formula which I cannot tolerate well.

Please de-rail the train immediately.

Thank you for allowing me to speak today!
My Name is Ron Coppinger, I am 64 years old, 24 years as a base of the tongue cancer survivor (squamous cell carcinoma). I fought swallowing issues, saliva depletion, aspirated pneumonia and a paralyzed vocal cord which has impacted my ability to speak because of complications with treatments in the early '90's. I lost all my teeth 2 years after completion of treatments, jaw bone deterioration in 1992 and muscle atrophy over the last 24 years, which has finally led me to being NPO (nothing by mouth) and a full time tube feeder since November 10th 2011.

I will email my comments to you and ask that you include them in the formal record.

I have a 20 French PEG tube. I am 100% home blenderize feed with a catheter tip syringe.

I was originally placed on formula but had a difficult time adjusting to it and digesting. I suffered constipation, acid reflux with heartburn, and coughing or regurgitating formula up into my throat and mouth risking more aspiration pneumonias.

Over the first 6 months of tube feeding, my formula was changed 4 times, all with pretty much the same poor results. The cost was also depleting my savings at $648.00 a month for 7 cases using two cans/cartons three times a day which was supposed to be enough formula to try and gain back needed weight and to survive. It didn’t help. My independance was stifled, tied to a pump and bag either on an IV pole or in a backpack. Feeding issues, alarms going off all times of the day and night disturbing much needed rest not only for me, but everyone else in the household. Frustrating and depressing so I finally decided that I could no longer afford to pay for the expense of formula or the added metal and physical health complications issues being experienced with this stuff.

So I stopped taking formula and went to total blending natural foods in June of 2012 and haven't returned to voluntary formula use. I gained all my needed weight back, reduced mucus, reflux and have the energy and stamina I had before becoming a tube feeder.

My blends work well through my 20fr tube, using a large bore catheter tip syringe and a combination of Bolus push and Gravity feeding method.

I am speaking out today because I will not be able to continue with either of my feeding methods using blended tube feeding because of the restriction 2.9 mm constricting fluid flow associated with the New ENFit connectors. It will be impossible. Bottom line – my life will be extremely altered in a huge negative way because of ENFit.

When I look at the benefits of blending over formula use i did more than just relied on my feeling better while using my blends. I coordinated with my physicians about blending and what was needed to maintain a healthy diet showing real results. I decided and my physicians concurred that I should monitor my nutritional aspect through my medical lab test annually and based upon my annual physical lab tests results, my primary care physician, pulmonary specialist, and my Gastroenterologist all agree that blending whole natural foods have improved my overall health. This gives me positive proof that blending is adequate and even beneficial for
my needs where as formulas created higher than normal labs associated to all my sugars levels, cholesterol levels and showed deficiencies in other levels monitored by my primary care physician.

Home blending of foods is gaining in popularity, due to scientific data that natural foods are more beneficial. From all my research, I’ll mention just one:

The Oral Cancer Foundation not only recommends a blended diet for long term tube feeding, but feels that using commercial formula products long term has drawbacks, while blending a nutritious diet of real food is the best solution. The Foundation lists the benefits of blending on their web site: I’ll quote from their website about the benefits they perceive:

"One of the biggest is that it allows you to limit your sugar intake. Cancer feeds on sugar, so reducing added sugar in our diet is especially important for oral cancer patients and survivors. One bottle of milk chocolate Ensure Plus has 22 grams of sugar. Seven bottles a day (2,450 calories) gives you 154 grams of sugar every day.

According to the American Heart Association, you should have no more than 37.5 grams of sugar each day. These problems are on top of your immediate concern about sugar's effect on oral cancer."

So what does all the research and my personal story mean to those wishing to re-engineer the connectors to ENFit? It means that blenderized tube feeding for a healthier individual over the long term, will be eliminated entirely. It means that I will have to return to the formula that did not agree with me and which I did not thrive upon nor can afford. My overall health and survive-ability will be diminished by ENFit.

Please reconsider ENFit and please allow me to keep my current connector and catheter tip syringe.

I have done my own evaluations and modest testing of what it takes to feed blended foods. ENFit will not, honestly folks --- it will not allow those thousands of tube feeders using blended diets to continue to do so.

In order to tube feed even the thinnest blend with the nutrition from natural foods (after straining to insure there are no large bits and pieces to clog a tube) I need at least a 20fr tube and a large lumen catheter tip syringe.

For feeders that desire a thicker unstrained blend, they require a 24fr tube with the large bolus connector and a catheter tip syringe.

You see, I had throat cancer, not a digestive disease. So my digestive system works just fine. In fact, I do better when my blend is on the thicker side, as it allows my digestive system to perform normally as it used to do.
By introducing ENFit, you will be limiting nutrition to commercial formula, and place all tube feeders in the same category.

I am aware that the Orphan Drug Act of 1988 administered by the FDA, provides guidance to medical manufacturers that refer to drugs or devices “of necessity” cannot be deleted. Further, if changes are incorporated in those devices, those changes need to keep the same “form, fit and function” of the medical device it replaces. It’s clear to me that ENFit cannot perform, with all aspects of formula and individual blends, as well as the current connectors and catheter tip syringes. This would seem to place manufacturers and those implementing this change to a medical device in violation of that legislation, which may lead to a legal focus for the thousands of tube feeders now blending real foods as a medical necessity of nutrition for survival, health and therapy management of their disease.

In my opinion, the design of ENFit was not for the benefit of tube feeders. ENFit seems driven by commercial formula advocates, who are afraid of the growing popularity and trend of blenderized diets, which ENFit would eliminate. This seems like a financial scheme.

Perhaps the introduction of ENFit has a chosen winner in formula. But the clear loser will be those who require a Blenderized Diet, like myself.

I ask you to not manufacture and market ENFit. Thank you.

(See photos on attached pages)
This is a photo of a catheter syringe where I blew out the body of the syringe while trying to feed through my Y-Port adapter and its small connector which is a 3.2mm diameter. I feel we will experience more of this with us folks that use thicker homemade blends.
This is how I have to feed my homemade blends to get around the restriction in the adapter. Remember that restriction is 3.2mm so placing a restriction in the syringe will end my using my homemade blends.
Good evening, I am Richard Reynolds, a feeding tube user because of therapeutic radiation damage to my neck that makes swallowing unsafe and makes me not speak clearly.

I will email my comments to the secretary.

I have an 18" long dangling feeding tube gravity supplied via a catheter tip. This works very well for me and I just love it.

Since learning of ENFIT, I have been baffled, if not horrified and dumbfounded, by worry about how it will affect my life and the lives of other feeding tube users.

Being a scientist by education and an engineer by mentality, I am astounded by the preventable shortcomings of ENFIT and its absolute lack of benefits and its disregard for users.

For example:

Measurements of the ENFIT male connector show the inside diameters to be smaller than the current devices.

Elementary physics says this HAS to slow flow rates.

The flow rates of nutrients through ENFIT devices have to be slower in spite of the Guenter/McMichael study.

Although feeding flow rate might not seem to be a medical issue, it is.

The burden of slow feeding rate makes it easy for one to skip a meal.

Flow rate is a quality of life issue that should not, and need not, be disregarded.

Further, there is no reason for feeding tube devices to be smaller.

Far more significantly, ENFIT’s smaller inside diameters will cause more clogging.

It just has to.

Food as thin as commercial orange juice with pulp gets clogged in ENFIT devices.

Clogging may make using home-blenderized foods impossible because of their dramatically more granular and fibrous consistency compared to orange juice.

Because of the small outside diameter of only half an inch, arthritics and many others may not be able to manipulate ENFIT connections.

This small size along with the insertion and screw thread effort to make a connection will make their use more difficult, if not impossible.

It will require two well functioning hands.

I know that my arthritic grandmother in her later years could not have fed herself with ENFIT, but could have with the present system.

Those not able to manipulate the ENFIT connectors will have to have a caregiver for every meal and may have to move to a nursing facility.

In my mind, this is grossly insensitive and unconscionable.

And, it is unnecessary.

Clogging will severely affect people who use home-blenderized foods.

Some opt for home-blenderized food because they want to choose their own foods or because of medical necessity such as food intolerances or allergies.

Denying home-blenderized foods users of this option or making it far more difficult affects the core of their quality of life and well-being.

To the careful reader, the Guenter/McMichael flow rate study radiates investigator bias.

It is so contrary to elementary physics that some aspects seem to have been contrived.

It has not been peer reviewed.

With the lack information about some tested substances, it is not possible for independent parties to conduct independent studies.

With this said, the study should be regarded as having no integrity.
To help solve the ENFIT created **misconnection** problem, adopting different connector standards for other tubing devices might help.

However, **in the interim** before adoption, we do not want to be responsible for deaths that might occur.

Ordinary **medical products** launch only after extensive confirmed data of safety and efficacy.

That has not occurred.

I gather the **push** for the ENFIT launch is based on the effective date of the California Assembly Bill 1867 that says:

*Quote: “a health facility…is prohibited from using an enteral feeding connector that would fit into a connector other than the type it was intended.”* *End quote.*

Because ENFIT **does mate** with other connectors, it seems it could NOT legally be used in California health facilities.

Actually, I think ENFIT **should not be used any place**.

To users, ENFIT **has absolutely no advantages** and in every regard has disadvantages -- including the risk of **death** from misconnection with trach, some rigid IV luer side ports, and vascular needle cannulas.

ENFIT risks **potentially lethal** medication overdoses to **infants**.

Further, it will be more difficult to use and for impossible some.

**A study of flow rates does not solve these life-threatening issues.**

The strong industry drive to adopt ENFIT makes us very **uncomfortable** and highly **suspicious**. We feel **coerced**.

It **astounds me** that a product that **affects so many people** and has known life-threatening risks would be promoted.

A **morally responsible person** would resist adoption.

There is **no reason to adopt** a system that reduces quality of life and that is life threatening to both adults and infants.

**Why jump** to a **known** inferior system?

ENFIT is **NOT essentially equivalent** to the currently used connectors.

My comments are a **Cautionary Tale** to all of you.

I **urge** you to **retain the** existing catheter tip syringes and connectors.

**Please, do not proceed** with the marketing and sale of ENFIT.

Thank you.
### Attendance at AAMI/GEDSA – Information Session
Arlington, VA October 14, 2015

*NOTE:* This attendance list has been drawn up in accordance with the ISO Privacy policy (item 1 of ISO/TMB Communiqué 14), which states:
"Published or circulated membership rosters and lists of meeting attendees shall be restricted to the names of individuals and to their affiliations (nominating member body, liaison organization, etc.); these rosters/lists shall not contain any contact details."

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