



August 7, 2004

Dockets Management Branch
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition to request the Commissioner of Food and Drugs to issue an administration action.

Action requested

I am requesting action be taken towards medical device manufacturers regarding the interchangeability of medical devices with one another.

Statement of grounds

With the recent national emphasis on patient safety, I've come to recognize that there are significant barriers to patient safety at many turns, although they are not always where they are expected. The barrier which I, and most of my peers, are struggling against now is interchangeability of equipment. For instance, pulse ox sensors that work on one machine, but not another; blood pressure cuffs with different connectors which don't all work together, etc.

To illustrate why this directly affects patient safety, allow me to share with you the story of a patient for whom I cared. My particular specialty is pediatric emergency nursing. I work at a busy (60,000+) E.D., which has a pediatric emergency department which is open for 12 hours a day. As the manager of the pediatric E.D., I am usually in the office prior to the noon opening time of the pediatric E.D. When the main emergency department has a sick child, they call me to assist. So, on this particular morning, the paramedics called in with a 3 year old in Status Epilepticus. By the time she arrived, she had been seizing for approximately 30 minutes. As Status Epilepticus is an emergent condition, the girl was appropriately attached to cardiorespiratory and pulse oximetry monitoring, IV lines were placed, and benzodiazepines and anti-convulsants were given in an attempt to break the seizure activity. Although the initial seizure stopped, she continued to have intermittent seizures thereafter.

In light of this patient condition and unknown diagnosis, this patient needed an emergent CT scan of the head, which was promptly ordered. When radiology called to inform us that CT was ready, we tried to transfer the girl to the portable monitoring equipment, so we could continue to monitor her in CT. Unfortunately, the room monitors employ one type of pulse oximetry technology, while the portable monitors employ

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another. Additionally, all of the blood pressure cuff connectors were different. It took 20 minutes while the staff scrambled to find a bp cuff with the correct type of connection, and a pulse ox sensor which could be used. While the pulse ox sensor was eventually located, even after jury-rigging the bp cuff tubing, we were never able to find a successful solution, so we opted for our second choice, a manual bp cuff.

While in the CT scanner, the girl had some type of episode where her heart rate dropped precipitously. Unfortunately, we had no reading of the bp, since by the time we got into the scanner to pull her out and obtain a manual bp, the pulse had normalized.

There are those who question why it would be an issue to just change pulse ox sensors to fit the portable machine. I have heard this question before, and believe I can answer this. In pediatrics, the primary cause of cardiac arrest is respiratory failure, thereby clearly making pulse oximetry vital. Since children come in numerous sizes, picking both the correct site for placement, as well as the correct size, can be challenging. It often takes several attempts at placement of a sensor to obtain an adequate and accurate reading. To then have to take this one off and place another one is clearly not in the patient's best interests.

After this situation occurred, I contacted the manufacturers of all of the equipment involved, to see if I could get some sort of adaptor so each piece of equipment could be used on each machine. Many of the manufacturers had exclusive contracts with another company, for instance, LifePack® with Masimo®, so no adaptors were available. While this may have been in their best business interests, it most certainly does not serve our patients in the best way possible.

I consider this to be a huge gap in patient safety. When patient care is delayed because of situations like this, patients are put at risk. I always have and always will place the well-being of my patients above anyone's business interests, and feel that any nurse or doctor to whom you spoke would agree. As the Immediate Past President of the Illinois Emergency Nurses Association, as well as a member of the National Emergency Nurses Association's Managers Committee and the chair of the Media/Public Relations Group, I am very well aware of those issues which are important to emergency nurses across the country. The issue of equipment compatibility continues to be a discussion point, due to the inter-related issues of patient safety, staff frustration, and delays in patient care as the nursing staff struggles to find parts which are compatible. I would ask that this issue be put on your agenda to be dealt with.

Certification

The undersigned certified, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Barbara Weintraub, RN, MSN, MPH, PCCNP, CEN". The signature is fluid and cursive, with the first name being the most prominent.

Barbara Weintraub, RN, MSN, MPH, PCCNP, CEN
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Sec. 25.41 Findings of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a FONSI is a document prepared by a Federal agency stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

The proposed regulation of medical device connectors will not significantly affect the human environment; therefore, no EIS is attached.

Barbara Weintraub, RN, MSN, MPH, PCCNP, CEN