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Ralph Nader, Founder

May 7, 1993

Mr. Ronald Johnson
Office of Compliance and Surveillance
HFZ 300
1390 Piccard Drive
Rockville, MD 20850

Dear Mr. Johnson,

On behalf of Public Citizen's Health Research Group, we submit these questions regarding the classification system of device recalls. 1) What is the process whereby a recall is classified as either Class I or Class II? 2) Why were the following device recalls classified as Class II, when it seems clear that their continued use "poses reasonable probability of serious health consequences", the definition of a Class I recall?

Specifically, we are disturbed about the following:

- Adult Star Ventilators, with Versions 216.0 through 217.2 software, recall number Z-252-3. A Class II recall, although "[u]nder certain circumstances the ventilator may prematurely terminate breaths, resulting in insufficient ventilation of the patient, due to software malfunction at certain settings." Is insufficient ventilation of a ventilator-dependant patient not a serious health consequence?

- Therac Model 20 (T20) Cobalt 60 Linear Accelerator Radiation Therapy Devices used to treat cancer patients, recall number Z-267-3. A Class II recall, although "improper dose distribution may occur in electron mode if hand control pushbuttons are operated quickly in a particular sequence." Why does an improper dose not pose a reasonable probability of a serious health consequence to a cancer patient receiving radiation therapy?

- Bicarbonate Control Moniters used in conjunction with the Gambro AK10 Hemodialysis Machines, recall number Z-143-3. A Class II recall, although "[t]he monitor system may fail to detect a mix-up in concentrate combinations which could lead to an incorrect dialysate administered to the patient." An incorrect dialysate given to a kidney failure patient could be lethal.

- Central Telemetry Systems, designed to detect arrhythmia, recall number Z-359/364-3. A Class II recall, although "[s]oftware defect may result in the telemetry system failing to alarm during ventricular fibrillation or ventricular tachycardia." These are

life-threatening cardiac arrhythmias, and without an alarm and subsequent resuscitative measures, such patients may die.

- Sarns MDX Battery Pack, used to supply power to equipment that is used for extracorporeal circulation, recall number Z-466-3. A Class II recall, although "a circuit breaker may trip into the off position which will cause the unit to stop supplying power." What happens if the unit stops supplying power during open heart surgery, when a patient's blood is being circulated through the machine? A more life-threatening situation could hardly be imagined.

Please examine the above, and provide us with the rationale for the classification of these device recalls.

Sincerely,

Joanne Mott

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cc: Dr. Bruce Burlington