AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4421

OFFERED BY M__. _____

Page 26, after line 12, add the following:

SEC. 114. MEDICAL DEVICE SHORTAGE REDUCTION.

(a) IN GENERAL.—If the Secretary of Health and Human Services (in this Section referred to as the ''Secretary'') determines that it would support public health security and all-hazards preparedness and response for emergency periods (as defined in section 1135(g)(1) of the Social Security Act (42 U.S.C. 1320b-5(g)(1))), the Secretary may issue a regulation requiring manufacturers of devices that are critical to public health during a public health emergency to notify the Secretary of a permanent discontinuance in the manufacture of the device (except for discontinuances as a result of an approved modification of the device) or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for such discontinuance or interruption. Such regulation may require notification at any time the Secretary determines such notification requirement would

support public health security and all-hazards preparedness and response.

(b) DEFINITIONS.—In this section:

(1) DEVICE.—The term ''device'' has the meaning given in Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(2) MEANINGFUL DISRUPTION.—The term ''meaningful disruption''—

(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a device by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product;

(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time, not to exceed 6 months;

(C) does not include interruptions in manufacturing of components or raw materials so long as such interruptions do not result in a shortage of the device and the manufacturer ex-

pects to resume operations in a reasonable period of time; and

(D) does not include interruptions in manufacturing that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform more than one procedure or diagnostic test.

(3) SHORTAGE.—The term ''shortage'', with respect to a device, means a period of time when the demand or projected demand for the device within the United States exceeds the supply of the device.