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 NOTIFICATION, NONDISTRIBUTION, AND RECALL OF DRUGS.

(a) ORDER TO CEASE DISTRIBUTION AND RECALL.—

(1) IN GENERAL.—If the Secretary determines there is a reasonable probability that a drug, including a countermeasure, would cause serious adverse health consequences or death, and continued availability of such drug could harm 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, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such drug to immediately cease distribution of such drug.

(2) HEARING.—An order under paragraph (1) shall provide the person subject to the order with an

opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify an amendment to the order, and what actions are required by such amended order pursuant to subparagraph (3).

(3) ORDER RESOLUTION.—After an order is issued according to the process under paragraphs (1) and (2), the Secretary shall, except as provided in paragraph (4)—

(A) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

(B) continue the order ceasing distribution of the drug until a date specified in such order; or

(C) amend the order to require a recall of the drug, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

(4) RISK ASSESSMENT.—If the Secretary determines that the risk of recalling a drug presents a greater health risk than the health risk of not recalling such drug from use, an amended order under

subparagraph (B) or (C) of paragraph (3) shall not include either a recall order for, or an order to cease distribution of, such drug, as applicable.

(5) ACTION FOLLOWING ORDER.—Any person who is subject to an order pursuant to subparagraph (B) or (C) of paragraph (3) shall immediately cease distribution of or recall, as applicable, the drug and provide notification as required by such order.

(b) NOTICE TO PERSONS AFFECTED.—If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to paragraph (1) of subsection (a) or an amended order pursuant to subparagraph (B) or (C) of paragraph (3) to provide either a notice of a recall order for, or an order to cease distribution of, such drug, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public. In providing such notice, the Secretary may use the assistance of health professionals who prescribed or dispensed such drugs.

(c) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting—

(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, any drug under any other provision of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.); or

(2) the ability of the Secretary to request any person to perform a voluntary activity related to any drug subject to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.).

(d) DEFINITIONS.—In this section:

(1) The term ''countermeasure'' means a drug—

(A) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 247d–6b); or

(B) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent.

(2) The term ''drug'' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

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