AMENDMENT TO H.R. 1919

OFFERED BY M__. _____

Page 2, line 18, through page 3, line 5, strike subparagraph (A) and insert the following (and redesignate the subsequent subparagraph accordingly):

''(A) subject to subparagraph (C), means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control, or any other person authorized by law to dispense or administer prescription drugs, to the extent such pharmacy, group, or person does not act as a wholesale distributor;

''(B) includes warehouses and distribution centers under common ownership or control of entities described in subparagraph (A) that are members of an affiliated group pursuant to section 1504(a) of the Internal Revenue Code of 1986, to the extent such warehouses and distribution centers do not act as a wholesale distributor; and

Page 8, line 4, insert ''or received'' after ''purchased''.

Page 11, line 16, strike ''between'' and insert '', including between''.

Page 16, after line 24, insert the following new clause (and make such conforming changes as may be necessary)

''(xviii)(I) the distribution of a product by a dispenser, or a wholesale distributor acting at the direction of the dispenser, to a repackager registered under section 510 for the purpose of repackaging the drug for use by that dispenser or another health care entity that is under the dispenser's ownership or control, so long as the dispenser retains ownership of the prescription drug product; and

''(II) the saleable or nonsaleable return by such repackager of such prescription drug product.

Page 23, line 11, after ''that is in the supply chain'' insert ''or in a manufacturer's inventory''.

Page 25, lines 15 and 16, strike ''a copy of'' and insert ''the information in''.

Page 34, line 18, insert ''or repackager'' after ''dispenser''.

Page 38, line 15, strike ''manufacturer'' and insert ''wholesale distributor''.

Page 49, lines 24 and 25, strike ''Beginning not later than January 1, 2015, a repackager shall'' and insert ''Beginning not later than April 1, 2015, with respect to a prescription drug product received by a repackager from a wholesale distributor, and beginning not later than January 1, 2015, with respect to any other prescription drug product, a repackager shall''.

Page 50, line 24, through page 51, line 7, strike subparagraph (B) and insert the following:

''(B) NONSALEABLE RETURNS.—Notwithstanding subparagraph (A)(ii), a repackager may return prescription drug product to the trading partner from whom the repackager obtained the prescription drug product without providing the information required under such subparagraph.

Page 63, line 21, strike ''(d)(2)'' and insert ''(e)(2)''.

Page 83, line 8, strike ''or''.

Page 83, line 13, strike the period at the end and insert ''; or''.

Page 83, after line 13, insert the following new paragraph:

''(20)(A) the distribution of a product by a dispenser, or a wholesale distributor acting at the direction of the dispenser, to a repackager registered under section 510 for the purpose of repackaging the drug for use by that dispenser or another health care entity that is under the dispenser's ownership or control, so long as the dispenser retains ownership of the prescription drug product; and

''(B) the saleable or nonsaleable return by such repackager of such prescription drug product.

Page 95, amend section 8 of the bill to read as follows (and conform the table of contents in section 1(b) accordingly):

SEC. 8 ELECTRONIC LABELING.

(a) IN GENERAL.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by adding at the end the following new sentences: ''Required labeling (other than immediate container or carton labels) that is intended for use by a physician, a pharmacist, or another health care professional, and that provides directions for human use of a drug subject to section 503(b)(1), may (except as necessary to miti-

gate a safety risk, as specified by the Secretary in regulation) be made available by electronic means instead of paper form, provided that such labeling complies with all applicable requirements of law, the manufacturer or distributor, as applicable, affords health care professionals and authorized dispensers (as defined in section 581) the opportunity to request the labeling in paper form, and after such a request the manufacturer or distributor promptly provides the requested information without additional cost.''.

(b) REGULATIONS.—The Secretary of Health and Human Services shall promulgate regulations implementing the amendment made by subsection (a).

(c) APPLICATION.—The last sentence of section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as added by subsection (a), shall apply beginning on the earlier of—

(1) the effective date of final regulations promulgated under subsection (b); or

(2) the day that is 180 days after the date of enactment of this Act.