

AMENDMENT TO H.R. _____

OFFERED BY M____. _____

[Page and line numbers refer to May 3 discussion draft]

Page 4, line 20, strike “licence” and insert “license”.

Page 6, lines 6 to 11, amend paragraph (8) to read as follows:

1 “(8) PACKAGE.—
2 “(A) IN GENERAL.—The term ‘package’
3 means the smallest individual saleable unit of
4 prescription drug product for distribution in
5 interstate commerce by a manufacturer or re-
6 packager that is intended by the manufacturer
7 for ultimate sale to the dispenser of such pre-
8 scription drug product.
9 “(B) INDIVIDUAL SALEABLE UNIT.—The
10 term ‘individual saleable unit’ means the small-
11 est container of prescription drug product intro-
12 duced into interstate commerce by the manufac-
13 turer or repackager that is intended by the
14 manufacturer for individual sale to a dispenser.

Page 7, after line 8, insert the following new paragraph (and make such conforming changes as may be necessary):

1 “(12) QUARANTINE.—The term ‘quarantine’
2 means to store or identify a product, for the purpose
3 of preventing distribution or transfer of the product,
4 in a physically separate area clearly identified for
5 such use, or through use of other procedures such
6 as automated designation.

Beginning on page 13, line 6, strike clause (xii) and insert the following:

7 “(xii) the distribution of a combina-
8 tion product that consists of—
9 “(I) a product comprised of two
10 or more components that are each a
11 drug, biological product, or device and
12 that are physically, chemically, or oth-
13 erwise combined or mixed and pro-
14 duced as a single entity;
15 “(II) two or more separate prod-
16 ucts packaged together in a single
17 package or as a unit and comprised of
18 a drug and device or a device and bio-
19 logical product; or

1 “(III) two or more finished de-
2 vices plus one or more drug or biologi-
3 cal products which are packaged to-
4 gether in a medical convenience kit
5 described in clause (xiv);

Page 23, line 23, page 31, line 9, page 31, line 13,
page 41, line 7, page 41, line 10, page 49, line 8, and
page 49, line 11, strike “prior to” and insert “prior to,
or at the time of,”.

Page 79, lines 20 to 22, strike paragraph (1) (and
make such conforming changes as may be necessary).

Page 93, strike lines 20 and 21 and insert the fol-
lowing (and redesignate the subsequent subparagraphs
accordingly):

6 “(3) ENFORCEMENT, SUSPENSION, AND REV-
7 OCATION OF LICENSES.—Notwithstanding paragraph
8 (1), a State—

9 “(A) may take administrative action, in-
10 cluding fines, to enforce a licensure requirement
11 promulgated by the State in accordance with
12 this Act;

