AMENDMENT TO

RULES COMMITTEE PRINT 116-14

OFFERED BY MR. GOLDEN OF MAINE

At the end of title I of the Rules Committee Print, add the following new subtitle:

Subtitle D—Forcing Limits on Abusive and Tumultuous Prices

SEC. 131. REDUCED MARKET EXCLUSIVITY.

(a) PENALTY.—If the manufacturer of a prescription drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) increases the price of such drug as described in subsection (b), any remaining period of market exclusivity with respect to such drug shall be reduced as follows:

(1) With respect to any price increase described in subsection (b), such market exclusivity shall be reduced by 180 days.

(2) For every 5 percent price increase over the 10 percent, 18 percent, or 25 percent, respectively, threshold price increases described in subsection (b), such market exclusivity shall be reduced for an additional 30 days.

(b) PRICE INCREASE.—A price increase described in this subsection is an increase in the wholesale acquisition cost (as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B))) of a prescription drug of more than 10 percent over a 1-year period, more than 18 percent over a 2-year period, or more than 25 percent over a 3-year period.

(c) REPORT ON PRICE INCREASE.—

(1) IN GENERAL.—A drug manufacturer that increases the price of a prescription drug as described in subsection (b) shall report such increase to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') within 30 days of meeting the criteria for a price increase under such subsection.

(2) FAILURE TO SUBMIT REPORT.—In the case of a drug manufacturer that does not submit a report required under paragraph (1) within the 30-day period described in such paragraph, in addition to the penalty under subsection (a), the period of market exclusivity with respect to such drug shall be reduced by 30 days for each day after the due date of the report until the report is submitted.

(d) WAIVER.—The Secretary may waive, or decrease, the reduction in the period of market exclusivity that

would otherwise apply under subsection (a) with respect to a prescription drug if—

(1) the manufacturer of such drug submits—

(A) a report under subsection (c)(1); and

(B) an application for such a waiver, at such time, in such manner, and containing such information as the Secretary may require; and

(2) based upon the information in such application, the Secretary determines that—

(A) the price increase is necessary to enable production of the drug, does not unduly restrict patient access to the drug, and does not negatively impact public health; and

(B) such waiver or decrease constitutes a deviation from the reduction in market exclusivity that would otherwise apply under subsection (a) only to the extent necessary to achieve drug production objectives.

(e) PERIOD OF MARKET EXCLUSIVITY.—For purposes of this section, the term ''period of market exclusivity'' means any period of market exclusivity granted with respect to a prescription drug under clause (ii), (iii), or (iv) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)), section 505(j)(5)(B)(iv) of such Act, clause (ii), (iii), or (iv) of

section 505(j)(5)(F) of such Act, or paragraphs (6) or (7) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).