AMENDMENT

OFFERED BY M__. _____

Add at the end the following:

SEC. _____. INTERNATIONAL REFERENCE PRICING FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section:

(1) BIOLOGICAL PRODUCT.—The term ''biological product'' means a biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) DRUG.—The term ''drug'' means a drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) CAP ON RETAIL LIST PRICE OF PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS.—The retail list price in the United States for a drug or a biological product may not exceed the average retail list price for the drug or biological product among Canada, France, Ger-

many, Italy, Japan, and the United Kingdom, as calculated under subsection (c).

(c) CALCULATION OF AVERAGE RETAIL LIST PRICE.—The Secretary shall calculate on an annual basis the average retail list price for each drug and biological product sold in Canada, France, Germany, Italy, Japan, and the United Kingdom, through a combination of data reported by manufacturers of drugs and biological products under subsection (e) and data obtained through review of publicly filed materials by manufacturers of drugs and biological products in such countries.

(d) CIVIL MONETARY PENALTY.—

(1) IN GENERAL.—Any manufacturer that violates subsection (b) with respect to a drug or biological product shall be subject to a civil monetary penalty imposed by the Secretary in amount equal to the product obtained by multiplying—

(A) the difference between—

(i) the list price for the drug or biological product sold in the United States; and

(ii) the average retail list price for the drug or biological product sold in Canada, France, Germany, Italy, Japan, and the

United Kingdom, as calculated under subsection (c); and

(B) 10.

(2) REQUIREMENT.—The amount of a civil monetary penalty under paragraph (1) shall be calculated and charged for each unit of drug or biological product sold.

(e) DATA COLLECTION.—Each manufacturer of a drug or biological product shall submit to the Secretary on an annual basis—

(1) the list price for the drug or biological product sold in the United States; and

(2) the list price for the drug or biological product sold in each of Canada, France, Germany, Italy, Japan, and the United Kingdom.

(f) GUIDANCE AND REGULATIONS.—The Secretary shall issue guidance and promulgate regulations to implement this section.

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