AMENDMENT NO._____ Calendar No._____

Purpose: To require persons who undertake Federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

H. R. 2430

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the appropriate place, insert the following:

SEC. ___. REASONABLE PRICE AGREEMENT.

(a) IN GENERAL.—If any Federal agency or any non-profit entity undertakes Federally funded health care research and development and is to convey or provide a patent for a drug, biologic, or other health care technology developed through such research, such agency or entity shall not make such conveyance or provide such patent until the entity (including a non-profit entity) that will receive such patent first agrees to a reasonable pricing

agreement with the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (c).

(b) PROHIBITION OF DISCRIMINATION.—

(1) IN GENERAL.—For purposes of subsection (a), any reasonable pricing formula that is utilized shall not result in discriminatory pricing for the drug, biologic, or other health care technology involved regardless of the number of bidders involved. In carrying out this subparagraph, the Secretary shall ensure that the Federal Government, with respect to the drug, biologic, or other health care technology involved, is charged an amount that is not more than the lowest amount charged to countries in the Organization for Economic Co-Operation and Development for the same drug, biologic, or technology, that have the largest gross domestic product with a per capita income that is not less than half the per capita income of the United States.

(2) DISCRIMINATORY PRICING.—For the purposes of paragraph (1), a cost based reasonable pricing formula that is utilized shall be considered to result in discriminatory pricing if the contract for sale

of the drug, biologic, or other health care technology places a limit on supply, or employs any other measure, that has the effect of—

(A) providing access to such drug, biologic, or technology on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the drug, biologic, or technology; or

(B) restricting access to the drug, biologic, or technology under this section.

(c) WAIVER.—No waiver shall take effect under subsection (a) before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.