# AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 639 OFFERED BY MR. PITTS OF PENNSYLVANIA

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Improving Regulatory Transparency for New Medical Therapies Act''.

**SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.**

Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (h) the following:

''(i) Within 45 days of receiving a recommendation from the Secretary to add a drug or substance that has never been marketed in the United States to a schedule under this title, the Attorney General shall, without regard to the findings required by subsection (a) of this section or section 202(b), issue an interim final rule, under the exception for good cause described in subparagraph (B) of section 553(b) of title 5, United States Code, placing the drug or substance into the schedule recommended by the Secretary. The interim final rule shall be made imme-

diately effective under section 553(d)(3) of title 5, United States Code.''.

**SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.**

Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by inserting after subsection (g) the following:

''(h)(1) A person who submits an application for registration to manufacture or distribute a controlled substance in accordance with this section may indicate on the registration application that the substance will be used only in connection with clinical trials of a drug in accordance with section 505(i) of the Federal Food, Drug, and Cosmetic Act.

''(2) When an application for registration to manufacture or distribute a controlled substance includes an indication that the controlled substance will be used only in connection with clinical trials of a drug in accordance with section 505(i) of the Federal Food, Drug, and Cosmetic Act, the Attorney General shall—

''(A) make a final decision on the application for registration within 180 days; or

''(B) provide notice to the applicant in writing of—

"(i) the outstanding issues that must be resolved in order to reach a final decision on the application; and

"(ii) the estimated date on which a final decision on the application will be made.".

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