Union Calendar No. 451

113TH CONGRESS
2D SESSION

H. R. 4299

[Report No. 113–565, Parts I and II]

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2014

Mr. PITTS (for himself and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

JULY 29, 2014

Reported from the Committee on Energy and Commerce

JULY 29, 2014

Referral to the Committee on the Judiciary extended for a period ending not later than September 19, 2014

SEPTEMBER 19, 2014

Additional sponsors: Mr. BURGESS, Mrs. MCMORRIS RODGERS, Mrs. BLACKBURN, Mr. GINGREY of Georgia, Mr. GRIFFITH of Virginia, Mr. GENE GREEN of Texas, Mr. LATTA, Mr. ENGEL, Ms. SHEA-PORTER, Mr. BUTTERFIELD, Mr. TONKO, Mr. JOHNSON of Ohio, Mr. HARPER, and Mr. COLLINS of Georgia

SEPTEMBER 19, 2014
Reported from the Committee on the Judiciary with an amendment
[Strike out all after the enacting clause and insert the part printed in italic]
[For text of introduced bill, see copy of bill as introduced on March 26, 2014]

A BILL

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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(a) of the Controlled Substances Act (21 U.S.C. 811(a)) is amended by adding at the end the following: "Any such proceedings initiated at the request of the Secretary under this subsection to control a drug or other substance not previously scheduled, where the Secretary has recommended the drug or other substance be placed in schedule II, III, IV, or V, shall be commenced not later than 120 days after receipt of written recommendations from the Secretary. The final rule shall be issued not later than 60 days after the date on which both the public comment period has closed and the drug or other substance is the subject of an approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act, unless a hearing on the proposed rule is granted by the Attorney General.".

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(i)(1) For the purposes of registration to manufacture a controlled substance under subsection (d) of this section for use only in a clinical trial, the Attorney General shall register an applicant or serve an order to show cause upon an applicant pursuant to section 304(c) of this Act not later than 180 days after receipt of an application and all information the Attorney General deems necessary to make a determination under subsection (d).

"(2) For the purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with regulations issued by the Attorney General, issue a notice of application not later than 90 days after receipt of an application and all information the Attorney General deems necessary to issue a notice of application. Following the close of the comment period and receipt of all information the Attorney General deems necessary to make a determination under subsection (a), the Attorney General shall register an applicant or serve an order to show cause upon an applicant pursuant to section 304(c) of this Act within 180 days, unless a hearing on the application has been granted by the Attorney General pursuant to section 1008(i) of the Controlled Substances Import and Export Act.".

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