

113TH CONGRESS
2^D SESSION

H. R. 4299

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Improving Regulatory
5 Transparency for New Medical Therapies Act”.

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

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

6 “(i) Within 45 days of receiving a recommendation
7 from the Secretary to add a drug or substance that has
8 never been marketed in the United States to a schedule
9 under this title, the Attorney General shall, without regard
10 to the findings required by subsection (a) of this section
11 or section 202(b), issue an interim final rule, under the
12 exception for good cause described in subparagraph (B)
13 of section 553(b) of title 5, United States Code, placing
14 the drug or substance into the schedule recommended by
15 the Secretary. The interim final rule shall be made imme-
16 diately effective under section 553(d)(3) of title 5, United
17 States Code.”.

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

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

22 “(h)(1) A person who submits an application for reg-
23 istration to manufacture or distribute a controlled sub-
24 stance in accordance with this section may indicate on the
25 registration application that the substance will be used
26 only in connection with clinical trials of a drug in accord-

1 ance with section 505(i) of the Federal Food, Drug, and
2 Cosmetic Act.

3 “(2) When an application for registration to manu-
4 facture or distribute a controlled substance includes an in-
5 dication that the controlled substance will be used only
6 in connection with clinical trials of a drug in accordance
7 with section 505(i) of the Federal Food, Drug, and Cos-
8 metic Act, the Attorney General shall—

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

11 “(B) provide notice to the applicant in writing
12 of—

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

16 “(ii) the estimated date on which a final
17 decision on the application will be made.”.

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