

114TH CONGRESS
1ST SESSION

H. R. 639

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

FEBRUARY 2, 2015

Mr. PITTS (for himself, Mr. PALLONE, and Mr. GENE GREEN of Texas) 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(a) of the Controlled Substances Act (21
4 U.S.C. 811(a)) is amended by adding at the end the fol-
5 lowing: “Any such proceedings initiated at the request of
6 the Secretary under this subsection to control a drug or
7 other substance not previously scheduled, where the Sec-
8 retary has recommended the drug or other substance be
9 placed in schedule II, III, IV, or V, shall be commenced
10 not later than 120 days after receipt of written rec-
11 ommendations from the Secretary. The final rule shall be
12 issued not later than 60 days after the date on which both
13 the public comment period has closed and the drug or
14 other substance is the subject of an approved new drug
15 application under section 505 of the Federal Food, Drug,
16 and Cosmetic Act, unless a hearing on the proposed rule
17 is granted by the Attorney General.”.

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

19 Section 303 of the Controlled Substances Act (21
20 U.S.C. 823) is amended by adding at the end the fol-
21 lowing:

22 “(i)(1) For the purposes of registration to manufac-
23 ture a controlled substance under subsection (d) of this
24 section for use only in a clinical trial, the Attorney General
25 shall register an applicant or serve an order to show cause
26 upon an applicant pursuant to section 304(c) of this Act

1 not later than 180 days after receipt of an application and
2 all information the Attorney General deems necessary to
3 make a determination under subsection (d).

4 “(2) For the purposes of registration to manufacture
5 a controlled substance under subsection (a) for use only
6 in a clinical trial, the Attorney General shall, in accord-
7 ance with regulations issued by the Attorney General,
8 issue a notice of application not later than 90 days after
9 receipt of an application and all information the Attorney
10 General deems necessary to issue a notice of application.
11 Following the close of the comment period and receipt of
12 all information the Attorney General deems necessary to
13 make a determination under subsection (a), the Attorney
14 General shall register an applicant or serve an order to
15 show cause upon an applicant pursuant to section 304(c)
16 of this Act within 180 days, unless a hearing on the appli-
17 cation has been granted by the Attorney General pursuant
18 to section 1008(i) of the Controlled Substances Import
19 and Export Act.”.

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