

113TH CONGRESS
2D SESSION

S. _____

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, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. HATCH (for himself and Mr. WHITEHOUSE) introduced the following bill;
which was read twice and referred to the Committee on

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, and for other purposes.

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 “Regulatory Trans-
5 parency, Patient Access, and Effective Drug Enforcement
6 Act of 2014”.

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.”.

18 **SEC. 4. REGISTRATION PROCESS UNDER CONTROLLED**
19 **SUBSTANCES ACT.**

20 (a) DEFINITIONS.—

21 (1) FACTORS AS MAY BE RELEVANT TO AND
22 CONSISTENT WITH THE PUBLIC HEALTH AND SAFE-
23 TY.—Section 303 of the Controlled Substances Act
24 (21 U.S.C. 823) is amended by adding at the end
25 the following:

1 “(i) In this section, the phrase ‘factors as may be rel-
2 evant to and consistent with the public health and safety’
3 means factors that are relevant to and consistent with the
4 findings contained in section 101.”.

5 (2) IMMINENT DANGER TO THE PUBLIC
6 HEALTH OR SAFETY.—Section 304(d) of the Con-
7 trolled Substances Act (21 U.S.C. 824(d)) is amend-
8 ed—

9 (A) by striking “(d) The Attorney Gen-
10 eral” and inserting “(d)(1) The Attorney Gen-
11 eral”; and

12 (B) by adding at the end the following:

13 “(2) In this subsection, the phrase ‘imminent danger
14 to the public health or safety’ means that, in the absence
15 of an immediate suspension order, controlled substances
16 will continue to be distributed or dispensed by a registrant
17 who knows or should know through fulfilling the obliga-
18 tions of the registrant under this Act, or has reason to
19 believe that—

20 “(A) the dispensing is outside the usual course
21 of professional practice;

22 “(B) the distribution or dispensing poses a
23 present or foreseeable risk of adverse health con-
24 sequences or death due to the abuse or misuse of the
25 controlled substances; or

1 “(C) the controlled substances will continue to
2 be diverted outside of legitimate distribution chan-
3 nels.”.

4 (b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION
5 PLAN PRIOR TO REVOCATION OR SUSPENSION.—Sub-
6 section (c) of section 304 of the Controlled Substances Act
7 (21 U.S.C. 824) is amended—

8 (1) by striking the last two sentences;

9 (2) by striking “(c) Before” and inserting
10 “(c)(1) Before”; and

11 (3) by adding at the end the following:

12 “(2) An order to show cause under paragraph (1)
13 shall—

14 “(A) contain a statement of the basis for the
15 denial, revocation, or suspension, including specific
16 citations to any laws or regulations alleged to be vio-
17 lated by the applicant or registrant;

18 “(B) direct the applicant or registrant to ap-
19 pear before the Attorney General at a time and
20 place stated in the order, but not less than 30 days
21 after the date of receipt of the order; and

22 “(C) notify the applicant or registrant of the
23 opportunity to submit a corrective action plan on or
24 before the date of appearance.

1 “(3) Upon review of any corrective action plan sub-
2 mitted by an applicant or registrant pursuant to para-
3 graph (2), the Attorney General shall determine whether
4 denial, revocation or suspension proceedings should be dis-
5 continued, or deferred for the purposes of modification,
6 amendment, or clarification to such plan.

7 “(4) Proceedings to deny, revoke, or suspend shall
8 be conducted pursuant to this section in accordance with
9 subchapter II of chapter 5 of title 5, United States Code.
10 Such proceedings shall be independent of, and not in lieu
11 of, criminal prosecutions or other proceedings under this
12 title or any other law of the United States.

13 “(5) The requirements of this subsection shall not
14 apply to the issuance of an immediate suspension order
15 under subsection (d).”.

16 **SEC. 5. REPORT TO CONGRESS ON EFFECTS OF LAW EN-**
17 **FORCEMENT ACTIVITIES ON PATIENT AC-**
18 **CESS TO MEDICATIONS.**

19 (a) IN GENERAL.—Not later than 1 year after the
20 date of enactment of this Act, the Secretary of Health and
21 Human Services, acting through the Commissioner of
22 Food and Drugs and the Director of the Centers for Dis-
23 ease Control and Prevention, and in consultation with the
24 Administrator of the Drug Enforcement Administration
25 and the Director of National Drug Control Policy, shall

1 submit a report to the Committees on the Judiciary of
2 the House of Representatives, the Committee on Energy
3 and Commerce of the House of Representatives, the Com-
4 mittee on the Judiciary of the Senate, and the Committee
5 on Health, Education, Labor and Pensions of the Senate
6 identifying—

7 (1) obstacles to legitimate patient access to con-
8 trolled substances;

9 (2) issues with diversion of controlled sub-
10 stances; and

11 (3) how collaboration between Federal, State,
12 local, and tribal law enforcement agencies and the
13 pharmaceutical industry can benefit patients and
14 prevent diversion and abuse of controlled substances.

15 (b) CONSULTATION.—The report under subsection
16 (a) shall incorporate feedback and recommendations from
17 the following:

18 (1) Patient groups.

19 (2) Pharmacies.

20 (3) Drug manufacturers.

21 (4) Common or contract carriers and ware-
22 housemen.

23 (5) Hospitals, physicians, and other health care
24 providers.

25 (6) State attorneys general.

1 (7) Federal, State, local, and tribal law enforce-
2 ment agencies.

3 (8) Health insurance providers and entities that
4 provide pharmacy benefit management services on
5 behalf of a health insurance provider.

6 (9) Wholesale drug distributors.