

Suspend the Rules and Pass the Bill, HR. 4771, with An Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

113TH CONGRESS
2^D SESSION

H. R. 4771

To amend the Controlled Substances Act to more effectively regulate anabolic steroids.

IN THE HOUSE OF REPRESENTATIVES

MAY 29, 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 to more effectively regulate anabolic steroids.

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 “Designer Anabolic
5 Steroid Control Act of 2014”.

1 **SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES**

2 **ACT.**

3 (a) DEFINITIONS.—Section 102(41) of the Controlled
4 Substances Act (21 U.S.C. 802(41)) is amended—

5 (1) in subparagraph (A)—

6 (A) in clause (xlix), by striking “and” at
7 the end;

8 (B) by redesignating clause (xlx) as clause
9 (lxxv); and

10 (C) by inserting after clause (xlix) the fol-
11 lowing:

12 “(l) 5 α -Androstan-3,6,17-trione;

13 “(li) 6-bromo-androstan-3,17-dione;

14 “(lii) 6-bromo-androsta-1,4-diene-3,17-dione;

15 “(liii) 4-chloro-17 α -methyl-androsta-1,4-diene-
16 3,17 β -diol;

17 “(liv) 4-chloro-17 α -methyl-androst-4-ene-
18 3 β ,17 β -diol;

19 “(lv) 4-chloro-17 α -methyl-17 β -hydroxy-androst-
20 4-en-3-one;

21 “(lvi) 4-chloro-17 α -methyl-17 β -hydroxy-
22 androst-4-ene-3,11-dione;

23 “(lvii) 4-chloro-17 α -methyl-androsta-1,4-diene-
24 3,17 β -diol;

25 “(lviii) 2 α ,17 α -dimethyl-17 β -hydroxy-5 α -
26 androstan-3-one;

- 1 “(lix) $2\alpha,17\alpha$ -dimethyl- 17β -hydroxy- 5β -
2 androstan-3-one;
3 “(lx) $2\alpha,3\alpha$ -epithio- 17α -methyl- 5α -androstan-
4 17β -ol;
5 “(lxi) [3,2-c]-furan- 5α -androstan- 17β -ol;
6 “(lxii) 3β -hydroxy-estra-4,9,11-trien-17-one;
7 “(lxiii) 17α -methyl-androst-2-ene-3, 17β -diol;
8 “(lxiv) 17α -methyl-androsta-1,4-diene-3, 17β -
9 diol;
10 “(lxv) Estra-4,9,11-triene-3, 17 -dione;
11 “(lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-
12 17-one;
13 “(lxvii) 6α -Methyl-androst-4-ene-3, 17 -dione;
14 “(lxviii) 17α -Methyl-androstan-3-hydroxyimine-
15 17β -ol;
16 “(lxix) 17α -Methyl- 5α -androstan- 17β -ol;
17 “(lxx) 17β -Hydroxy-androstano[2,3-d]isoxazole;
18 “(lxxi) 17β -Hydroxy-androstano[3,2-c]isoxazole;
19 “(lxxii) 4-Hydroxy-androst-4-ene-3, 17 -
20 dione[3,2-c]pyrazole- 5α -androstan- 17β -ol;
21 “(lxxiii) [3,2-c]pyrazole-androst-4-en- 17β -ol;
22 “(lxxiv) [3,2-c]pyrazole- 5α -androstan- 17β -ol;
23 and”); and
24 (2) by adding at the end the following:

1 “(C)(i) Subject to clause (ii), a drug or hormonal sub-
2 stance (other than estrogens, progestins, corticosteroids,
3 and dehydroepiandrosterone) that is not listed in subpara-
4 graph (A) and is derived from, or has a chemical structure
5 substantially similar to, 1 or more anabolic steroids listed
6 in subparagraph (A) shall be considered to be an anabolic
7 steroid for purposes of this Act if—

8 “(I) the drug or substance has been created or
9 manufactured with the intent of producing a drug or
10 other substance that either—

11 “(aa) promotes muscle growth; or

12 “(bb) otherwise causes a pharmacological
13 effect similar to that of testosterone; or

14 “(II) the drug or substance has been, or is in-
15 tended to be, marketed or otherwise promoted in any
16 manner suggesting that consuming it will promote
17 muscle growth or any other pharmacological effect
18 similar to that of testosterone.

19 “(ii) A substance shall not be considered to be a drug
20 or hormonal substance for purposes of this subparagraph
21 if it—

22 “(I) is—

23 “(aa) an herb or other botanical;

1 “(bb) a concentrate, metabolite, or extract
2 of, or a constituent isolated directly from, an
3 herb or other botanical; or

4 “(cc) a combination of 2 or more sub-
5 stances described in item (aa) or (bb);

6 “(II) is a dietary ingredient for purposes of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 301 et seq.); and

9 “(III) is not anabolic or androgenic.

10 “(iii) In accordance with section 515(a), any person
11 claiming the benefit of an exemption or exception under
12 clause (ii) shall bear the burden of going forward with the
13 evidence with respect to such exemption or exception.”.

14 (b) CLASSIFICATION AUTHORITY.—Section 201 of
15 the Controlled Substances Act (21 U.S.C. 811) is amend-
16 ed by adding at the end the following:

17 “(i) TEMPORARY AND PERMANENT SCHEDULING OF
18 RECENTLY EMERGED ANABOLIC STEROIDS.—

19 “(1) The Attorney General may issue a tem-
20 porary order adding a drug or other substance to
21 the definition of anabolic steroids if the Attorney
22 General finds that—

23 “(A) the drug or other substance satisfies
24 the criteria for being considered an anabolic
25 steroid under section 102(41) but is not listed

1 in that section or by regulation of the Attorney
2 General as being an anabolic steroid; and

3 “(B) adding such drug or other substance
4 to the definition of anabolic steroids will assist
5 in preventing abuse or misuse of the drug or
6 other substance.

7 “(2) An order issued under paragraph (1) shall
8 not take effect until 30 days after the date of the
9 publication by the Attorney General of a notice in
10 the Federal Register of the intention to issue such
11 order and the grounds upon which such order is to
12 be issued. The order shall expire not later than 24
13 months after the date it becomes effective, except
14 that the Attorney General may, during the pendency
15 of proceedings under paragraph (6), extend the tem-
16 porary scheduling order for up to 6 months.

17 “(3) The Attorney General shall transmit notice
18 of an order proposed to be issued under paragraph
19 (1) to the Secretary of Health and Human Services.
20 In issuing an order under paragraph (1), the Attor-
21 ney General shall take into consideration any com-
22 ments submitted by the Secretary in response to a
23 notice transmitted pursuant to this paragraph.

1 “(4) A temporary scheduling order issued under
2 paragraph (1) shall be vacated upon the issuance of
3 a permanent scheduling order under paragraph (6).

4 “(5) An order issued under paragraph (1) is
5 not subject to judicial review.

6 “(6) The Attorney General may, by rule, issue
7 a permanent order adding a drug or other substance
8 to the definition of anabolic steroids if such drug or
9 other substance satisfies the criteria for being con-
10 sidered an anabolic steroid under section 102(41).
11 Such rulemaking may be commenced simultaneously
12 with the issuance of the temporary order issued
13 under paragraph (1).”.

14 **SEC. 3. LABELING REQUIREMENTS.**

15 (a) IN GENERAL.—Section 305 of the Controlled
16 Substances Act (21 U.S.C. 825) is amended by adding at
17 the end the following:

18 “(e) FALSE LABELING OF ANABOLIC STEROIDS.—

19 “(1) It shall be unlawful to import, export,
20 manufacture, distribute, dispense, or possess with
21 intent to manufacture, distribute, or dispense, an
22 anabolic steroid or product containing an anabolic
23 steroid, unless the steroid or product bears a label
24 clearly identifying an anabolic steroid or product
25 containing an anabolic steroid by the nomenclature

1 used by the International Union of Pure and Applied
2 Chemistry (IUPAC).

3 “(2)(A) A product described in subparagraph
4 (B) is exempt from the International Union of Pure
5 and Applied Chemistry nomenclature requirement of
6 this subsection if such product is labeled in the man-
7 ner required under the Federal Food, Drug, and
8 Cosmetic Act.

9 “(B) A product is described in this subpara-
10 graph if the product—

11 “(i) is the subject of an approved applica-
12 tion as described in section 505(b) or (j) of the
13 Federal Food, Drug, and Cosmetic Act; or

14 “(ii) is exempt from the provisions of sec-
15 tion 505 of such Act relating to new drugs be-
16 cause—

17 “(I) it is intended solely for investiga-
18 tional use as described in section 505(i) of
19 such Act; and

20 “(II) such product is being used ex-
21 clusively for purposes of a clinical trial
22 that is the subject of an effective investiga-
23 tional new drug application.”.

24 (b) CLARIFICATION TO IMPORT AND EXPORT STAT-
25 UTE.—Section 1010 of the Controlled Substances Import

1 and Export Act (21 U.S.C. 960) is amended, in subsection
2 (a)(1), by inserting “305,” before “1002”.

3 (c) CIVIL PENALTIES.—Section 402 of the Controlled
4 Substances Act (21 U.S.C. 842) is amended—

5 (1) in subsection (a)—

6 (A) in paragraph (14), by striking “or” at
7 the end;

8 (B) in paragraph (15), by striking the pe-
9 riod at the end and inserting “; or”; and

10 (C) by inserting, after paragraph (15), the
11 following:

12 “(16) to violate section 305(e) (relating to false
13 labeling of anabolic steroids).”; and

14 (2) in subsection (c)(1)—

15 (A) by inserting, in subparagraph (A),
16 after “subparagraph (B)” the following: “, (C),
17 or (D)”; and

18 (B) by inserting after subparagraph (B)
19 the following:

20 “(C) In the case of a violation of subsection (a)(16)
21 by an importer, exporter, manufacturer, or distributor
22 (other than as provided in subparagraph (D)), up to
23 \$500,000 per violation. For purposes of this subpara-
24 graph, a violation is defined as each instance of importa-
25 tion, exportation, manufacturing, distribution, or posses-

1 sion with intent to manufacture or distribute, in violation
2 of subsection (a)(16).

3 “(D) In the case of a distribution, dispensing, or pos-
4 session with intent to distribute or dispense in violation
5 of subsection (a)(16) at the retail level, up to \$1000 per
6 violation. For purposes of this paragraph, the term ‘at the
7 retail level’ refers to products sold, or held for sale, di-
8 rectly to the consumer for personal use. Each package,
9 container or other separate unit containing an anabolic
10 steroid that is distributed, dispensed, or possessed with
11 intent to distribute or dispense at the retail level in viola-
12 tion of subsection (a)(16) shall be considered a separate
13 violation.”.

14 **SEC. 4. IDENTIFICATION AND PUBLICATION OF LIST OF**
15 **PRODUCTS CONTAINING ANABOLIC**
16 **STEROIDS.**

17 (a) IN GENERAL.—The Attorney General may, in the
18 Attorney General’s discretion, collect data and analyze
19 products to determine whether they contain anabolic
20 steroids and are properly labeled in accordance with this
21 Act and the amendments made by this Act. The Attorney
22 General may publish in the Federal Register or on the
23 website of the Drug Enforcement Administration a list of
24 products which the Attorney General has determined,
25 based on substantial evidence, contain an anabolic steroid

1 and are not labeled in accordance with this Act and the
2 amendments made by this Act.

3 (b) ABSENCE FROM LIST.—The absence of a product
4 from the list referred to in subsection (a) shall not con-
5 stitute evidence that the product does not contain an ana-
6 bolic steroid.