

113TH CONGRESS
2^D SESSION

H. R. 4771

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 16, 2014

Received; read twice and referred to the Committee on the Judiciary

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Designer Anabolic
3 Steroid Control Act of 2014”.

4 **SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES**
5 **ACT.**

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

8 (1) in subparagraph (A)—

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

11 (B) by redesignating clause (xlix) as clause
12 (lxxv); and

13 (C) by inserting after clause (xlix) the fol-
14 lowing:

15 “(l) 5 α -Androstan-3,6,17-trione;

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

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

18 “(liii) 4-chloro-17 α -methyl-androsta-1,4-diene-
19 3,17 β -diol;

20 “(liv) 4-chloro-17 α -methyl-androst-4-ene-
21 3 β ,17 β -diol;

22 “(lv) 4-chloro-17 α -methyl-17 β -hydroxy-androst-
23 4-en-3-one;

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

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

1 “(lxxiv) [3,2-c]pyrazole-5 α -androstan-17 β -ol;
2 and”;

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

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

11 “(I) the drug or substance has been created or
12 manufactured with the intent of producing a drug or
13 other substance that either—

14 “(aa) promotes muscle growth; or

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

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

22 “(ii) A substance shall not be considered to be a drug
23 or hormonal substance for purposes of this subparagraph
24 if it—

25 “(I) is—

1 “(aa) an herb or other botanical;

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

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

7 “(II) is a dietary ingredient for purposes of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 301 et seq.); and

10 “(III) is not anabolic or androgenic.

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

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

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

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

24 “(A) the drug or other substance satisfies
25 the criteria for being considered an anabolic

1 steroid under section 102(41) but is not listed
2 in that section or by regulation of the Attorney
3 General as being an anabolic steroid; and

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

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

18 “(3) The Attorney General shall transmit notice
19 of an order proposed to be issued under paragraph
20 (1) to the Secretary of Health and Human Services.
21 In issuing an order under paragraph (1), the Attor-
22 ney General shall take into consideration any com-
23 ments submitted by the Secretary in response to a
24 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 subsection (e) of section 825 of
13 this title.”; and

14 (2) in subsection (c)(1)—

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

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

20 “(C) In the case of a violation of paragraph (16) of
21 subsection (a) of this section by an importer, exporter,
22 manufacturer, or distributor (other than as provided in
23 subparagraph (D)), up to \$500,000 per violation. For pur-
24 poses of this subparagraph, a violation is defined as each
25 instance of importation, exportation, manufacturing, dis-

1 tribution, or possession with intent to manufacture or dis-
2 tribute, in violation of paragraph (16) of subsection (a).

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

Passed the House of Representatives September 15,
2014.

Attest:

KAREN L. HAAS,
Clerk.