

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 4771
OFFERED BY M . _____**

Strike all that follows after the enacting clause and
insert the following:

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;

- 1 “(liii) 4-chloro-17 α -methyl-androsta-1,4-diene-
2 3,17 β -diol;
- 3 “(liv) 4-chloro-17 α -methyl-androst-4-ene-
4 3 β ,17 β -diol;
- 5 “(lv) 4-chloro-17 α -methyl-17 β -hydroxy-androst-
6 4-en-3-one;
- 7 “(lvi) 4-chloro-17 α -methyl-17 β -hydroxy-
8 androst-4-ene-3,11-dione;
- 9 “(lvii) 4-chloro-17 α -methyl-androsta-1,4-diene-
10 3,17 β -diol;
- 11 “(lviii) 2 α ,17 α -dimethyl-17 β -hydroxy-5 α -
12 androstan-3-one;
- 13 “(lix) 2 α ,17 α -dimethyl-17 β -hydroxy-5 β -
14 androstan-3-one;
- 15 “(lx) 2 α ,3 α -epithio-17 α -methyl-5 α -androstan-
16 17 β -ol;
- 17 “(lxi) [3,2-c]-furazan-5 α -androstan-17 β -ol;
- 18 “(lxii) 3 β -hydroxy-estra-4,9,11-trien-17-one;
- 19 “(lxiii) 17 α -methyl-androst-2-ene-3,17 β -diol;
- 20 “(lxiv) 17 α -methyl-androsta-1,4-diene-3,17 β -
21 diol;
- 22 “(lxv) Estra-4,9,11-triene-3,17-dione;
- 23 “(lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-
24 17-one;
- 25 “(lxvii) 6 α -Methyl-androst-4-ene-3,17-dione;

1 “(lxviii) 17 α -Methyl-androstan-3-hydroxyimine-
2 17 β -ol;

3 “(lxix) 17 α -Methyl-5 α -androstan-17 β -ol;

4 “(lxx) 17 β -Hydroxy-androstano[2,3-d]isoxazole;

5 “(lxxi) 17 β -Hydroxy-androstano[3,2-c]isoxazole;

6 “(lxxii) 4-Hydroxy-androst-4-ene-3,17-
7 dione[3,2-c]pyrazole-5 α -androstan-17 β -ol;

8 “(lxxiii) [3,2-c]pyrazole-androst-4-en-17 β -ol;

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

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

12 “(C)(i) Subject to clause (ii), a drug or hor-
13 monal substance (other than estrogens, progestins,
14 corticosteroids, and dehydroepiandrosterone) that is
15 not listed in subparagraph (A) and is derived from,
16 or has a chemical structure substantially similar to,
17 1 or more anabolic steroids listed in subparagraph
18 (A) shall be considered to be an anabolic steroid for
19 purposes of this Act if—

20 “(I) the drug or substance has been cre-
21 ated or manufactured with the intent of pro-
22 ducing a drug or other substance that either—

23 “(aa) promotes muscle growth; or

1 “(bb) otherwise causes a pharma-
2 cological effect similar to that of testos-
3 terone; or

4 “(II) the drug or substance has been, or is
5 intended to be, marketed or otherwise promoted
6 in any manner suggesting that consuming it
7 will promote muscle growth or any other phar-
8 macological effect similar to that of testos-
9 terone.

10 “(ii) A substance shall not be considered to be
11 a drug or hormonal substance for purposes of this
12 subparagraph if it—

13 “(I) is—

14 “(aa) an herb or other botanical;

15 “(bb) a concentrate, metabolite, or ex-
16 tract of, or a constituent isolated directly
17 from, an herb or other botanical; or

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

20 “(II) is a dietary ingredient for purposes
21 of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 301 et seq.); and

23 “(III) is not anabolic or androgenic.

24 “(iii) In accordance with section 515(a), any
25 person claiming the benefit of an exemption or ex-

1 ception under clause (ii) shall bear the burden of
2 going forward with the evidence with respect to such
3 exemption or exception.”.

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

7 “(i) TEMPORARY AND PERMANENT SCHEDULING OF
8 RECENTLY EMERGED ANABOLIC STEROIDS.—

9 “(1) The Attorney General may issue a tem-
10 porary order adding a drug or other substance to
11 the definition of anabolic steroids if the Attorney
12 General finds that—

13 “(A) the drug or other substance satisfies
14 the criteria for being considered an anabolic
15 steroid under section 102(41) but is not listed
16 in that section or by regulation of the Attorney
17 General as being an anabolic steroid; and

18 “(B) adding such drug or other substance
19 to the definition of anabolic steroids will assist
20 in preventing abuse or misuse of the drug or
21 other substance.

22 “(2) An order issued under paragraph (1) shall
23 not take effect until 30 days after the date of the
24 publication by the Attorney General of a notice in
25 the Federal Register of the intention to issue such

1 order and the grounds upon which such order is to
2 be issued. The order shall expire not later than 24
3 months after the date it becomes effective, except
4 that the Attorney General may, during the pendency
5 of proceedings under paragraph (6), extend the tem-
6 porary scheduling order for up to 6 months.

7 “(3) The Attorney General shall transmit notice
8 of an order proposed to be issued under paragraph
9 (1) to the Secretary of Health and Human Services.
10 In issuing an order under paragraph (1), the Attor-
11 ney General shall take into consideration any com-
12 ments submitted by the Secretary in response to a
13 notice transmitted pursuant to this paragraph.

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

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

19 “(6) The Attorney General may, by rule, issue
20 a permanent order adding a drug or other substance
21 to the definition of anabolic steroids if such drug or
22 other substance satisfies the criteria for being con-
23 sidered an anabolic steroid under section 102(41).
24 Such rulemaking may be commenced simultaneously

1 with the issuance of the temporary order issued
2 under paragraph (1).”.

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

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

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

8 “(1) It shall be unlawful to import, export,
9 manufacture, distribute, dispense, or possess with
10 intent to manufacture, distribute, or dispense, an
11 anabolic steroid or product containing an anabolic
12 steroid, unless the steroid or product bears a label
13 clearly identifying an anabolic steroid or product
14 containing an anabolic steroid by the nomenclature
15 used by the International Union of Pure and Applied
16 Chemistry (IUPAC).

17 “(2)(A) A product described in subparagraph
18 (B) is exempt from the International Union of Pure
19 and Applied Chemistry nomenclature requirement of
20 this subsection if such product is labeled in the man-
21 ner required under the Federal Food, Drug, and
22 Cosmetic Act.

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

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

4 “(ii) is exempt from the provisions of sec-
5 tion 505 of such Act relating to new drugs be-
6 cause—

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

10 “(II) such product is being used ex-
11 clusively for purposes of a clinical trial
12 that is the subject of an effective investiga-
13 tional new drug application.”.

14 (b) CLARIFICATION TO IMPORT AND EXPORT STAT-
15 UTE.—Section 1010 of the Controlled Substances Import
16 and Export Act (21 U.S.C. 960) is amended, in subsection
17 (a)(1), by inserting “305,” before “1002”.

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

20 (1) in subsection (a)—

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

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

1 (C) by inserting, after paragraph (15), the
2 following::

3 “(16) to violate subsection (e) of section 825 of
4 this title.”; and

5 (2) in subsection (c)(1)—

6 (A) by inserting, in subparagraph (A),
7 after “subparagraph (B)” the following: “, (C),
8 or (D)”; and

9 (B) by inserting after subparagraph (B)
10 the following:”.

11 “(C) In the case of a violation of para-
12 graph (16) of subsection (a) of this section by
13 an importer, exporter, manufacturer, or dis-
14 tributor (other than as provided in subpara-
15 graph (D)), up to \$500,000 per violation. For
16 purposes of this subparagraph, a violation is de-
17 fined as each instance of importation, expor-
18 tation, manufacturing, distribution, or posses-
19 sion with intent to manufacture or distribute, in
20 violation of paragraph (16) of subsection (a).

21 “(D) In the case of a distribution, dis-
22 pensing, or possession with intent to distribute
23 or dispense in violation of paragraph (16) of
24 subsection (a) of this section at the retail level,
25 up to \$1000 per violation. For purposes of this

1 paragraph, the term ‘at the retail level’ refers
2 to products sold, or held for sale, directly to the
3 consumer for personal use. Each package, con-
4 tainer or other separate unit containing an ana-
5 bolic steroid that is distributed, dispensed, or
6 possessed with intent to distribute or dispense
7 at the retail level in violation of paragraph (16)
8 of subsection (a) shall be considered a separate
9 violation.”.

10 **SEC. 4. IDENTIFICATION AND PUBLICATION OF LIST OF**
11 **PRODUCTS CONTAINING ANABOLIC**
12 **STERIODS.**

13 (a) The Attorney General may, in his discretion, col-
14 lect data and analyze products to determine whether they
15 contain anabolic steroids and are properly labeled in ac-
16 cordance with this section. The Attorney General may
17 publish in the Federal Register or on the website of the
18 Drug Enforcement Administration a list of products that
19 he has determined, based on substantial evidence, contain
20 an anabolic steroid and are not labeled in accordance with
21 this section.

22 (b) The absence of a product from the list referred
23 to in subsection (a) shall not constitute evidence that the
24 product does not contain an anabolic steroid.

