

# Union Calendar No. 434

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4771

**[Report No. 113–587, Parts I and II]**

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

SEPTEMBER 15, 2014

Additional sponsors: Mr. CHAFFETZ, Mr. BEN RAY LUJÁN of New Mexico, Ms. SHEA-PORTER, Mr. AMODEI, and Ms. DUCKWORTH

SEPTEMBER 15, 2014

Reported from the Committee on Energy and Commerce with an amendment  
[Strike out all after the enacting clause and insert the part printed in *italic*]

SEPTEMBER 15, 2014

Reported from the Committee on the Judiciary with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in **boldface roman**]

[For text of introduced bill, see copy of bill as introduced on May 29, 2014]

# **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 Ster-*  
5 *oid Control Act of 2014”.*

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

7                    **ACT.**

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

10                    (1) *in subparagraph (A)—*

11                            (A) *in clause (xlix), by striking “and” at*  
12 *the end;*

13                            (B) *by redesignating clause (xlx) as clause*  
14 *(lxxv); and*

15                            (C) *by inserting after clause (xlix) the fol-*  
16 *lowing:*

17                            “(l) *5 $\alpha$ -Androstan-3,6,17-trione;*

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

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

20                            “(liii) *4-chloro-17 $\alpha$ -methyl-androsta-1,4-diene-*  
21 *3,17 $\beta$ -diol;*

22                            “(liv) *4-chloro-17 $\alpha$ -methyl-androst-4-ene-3 $\beta$ ,17 $\beta$ -*  
23 *diol;*

24                            “(lv) *4-chloro-17 $\alpha$ -methyl-17 $\beta$ -hydroxy-androst-*  
25 *4-en-3-one;*

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

1           “(lxxiii) [3,2-c]pyrazole-androst-4-en-17 $\beta$ -ol;  
2           “(lxxiv)     [3,2-c]pyrazole-5 $\alpha$ -androstan-17 $\beta$ -ol;  
3           and”; and

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

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

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

16                         “(aa) promotes muscle growth; or

17                         “(bb) otherwise causes a pharma-  
18                         cological effect similar to that of testos-  
19                         terone; or

20                 “(II) the drug or substance has been, or is  
21                 intended to be, marketed or otherwise promoted  
22                 in any manner suggesting that consuming it will  
23                 promote muscle growth or any other pharma-  
24                 cological effect similar to that of testosterone.

1           “(ii) A substance shall not be considered to be a  
2 drug or hormonal substance for purposes of this sub-  
3 paragraph if it—

4           “(I) is—

5           “(aa) an herb or other botanical;

6           “(bb) a concentrate, metabolite, or ex-  
7 tract of, or a constituent isolated directly  
8 from, an herb or other botanical; or

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

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

14           “(III) is not anabolic or androgenic.

15           “(iii) In accordance with section 515(a), any  
16 person claiming the benefit of an exemption or excep-  
17 tion under clause (ii) shall bear the burden of going  
18 forward with the evidence with respect to such exemp-  
19 tion or exception.”.

20           (b) CLASSIFICATION AUTHORITY.—Section 201 of the  
21 Controlled Substances Act (21 U.S.C. 811) is amended by  
22 adding at the end the following:

23           “(i) TEMPORARY AND PERMANENT SCHEDULING OF  
24 RECENTLY EMERGED ANABOLIC STEROIDS.—

1           “(1) *The Attorney General may issue a tem-*  
2           *porary order adding a drug or other substance to the*  
3           *definition of anabolic steroids if the Attorney General*  
4           *finds that—*

5                   “(A) *the drug or other substance satisfies*  
6           *the criteria for being considered an anabolic ster-*  
7           *oid under section 102(41) but is not listed in*  
8           *that section or by regulation of the Attorney*  
9           *General as being an anabolic steroid; and*

10                   “(B) *adding such drug or other substance to*  
11           *the definition of anabolic steroids will assist in*  
12           *preventing abuse or misuse of the drug or other*  
13           *substance.*

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

24           “(3) *The Attorney General shall transmit notice*  
25           *of an order proposed to be issued under paragraph (1)*

1       to the Secretary of Health and Human Services. In  
2       issuing an order under paragraph (1), the Attorney  
3       General shall take into consideration any comments  
4       submitted by the Secretary in response to a notice  
5       transmitted pursuant to this paragraph.

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

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

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

19       (c) LABELING REQUIREMENTS.—

20               (1) IN GENERAL.—The Controlled Substances Act  
21       is amended by inserting after section 305 (21 U.S.C.  
22       825) the following:

23       **“SEC. 305A. OFFENSES INVOLVING FALSE LABELING OF AN-**  
24       **ABOLIC STEROIDS.**

25               “(a) UNLAWFUL ACTS.—



1           “(1) *It shall be unlawful—*

2                   “(A) *to import into the United States or to*  
3                   *export from the United States;*

4                   “(B) *to manufacture, distribute, dispense,*  
5                   *sell, or offer to sell; or*

6                   “(C) *to possess with intent to manufacture,*  
7                   *distribute, dispense, sell, or offer to sell;*

8           *any anabolic steroid, or any product containing an*  
9           *anabolic steroid, that does not bear a label clearly*  
10           *identifying any anabolic steroid contained in such*  
11           *steroid or product by the nomenclature used by the*  
12           *International Union of Pure and Applied Chemistry*  
13           *(IUPAC).*

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

20                   “(B) *A product is described in this subpara-*  
21                   *graph if the product—*

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

1           “(ii) is exempt from the provisions of sec-  
2           tion 505 of such Act relating to new drugs be-  
3           cause—

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

7                   “(II) such product is being used exclu-  
8                   sively for purposes of a clinical trial that is  
9                   the subject of an effective investigational  
10                  new drug application.

11           “(b) *CRIMINAL PENALTIES.*—Any person who violates  
12           subsection (a) knowing, intending, or having reasonable  
13           cause to believe, that the substance or product is an anabolic  
14           steroid, or contains an anabolic steroid, shall be sentenced  
15           to a term of imprisonment of not more than 10 years, a  
16           fine not to exceed the greater of that authorized in accord-  
17           ance with the provisions of title 18, United States Code,  
18           or \$500,000 if the defendant is an individual or \$2,500,000  
19           if the defendant is other than an individual, or both.

20           “(c) *CIVIL PENALTIES.*—

21                   “(1) Any person who violates subsection (a) shall  
22           be subject to a civil penalty as follows:

23                   “(A) In the case of an importer, exporter,  
24                   manufacturer, or distributor (other than as pro-  
25                   vided in subparagraph (B)), up to \$500,000 per

1           *violation. For purposes of this subparagraph, a*  
2           *violation is defined as each instance of importa-*  
3           *tion, exportation, manufacturing, or distribu-*  
4           *tion, and each anabolic steroid or product im-*  
5           *ported, exported, manufactured, or distributed.*

6           *“(B) In the case of a sale or offer to sell at*  
7           *retail, up to \$25,000 per violation. For purposes*  
8           *of this subparagraph, each sale and each product*  
9           *offered for sale shall be considered a separate vio-*  
10          *lation. Continued offers to sell by a person 10 or*  
11          *more days after written notice (including*  
12          *through electronic message) to the person by the*  
13          *Attorney General or the Secretary shall be con-*  
14          *sidered additional violations.*

15          *“(2) In this subsection, the term ‘product’ means*  
16          *a discrete article, either in bulk or in finished form*  
17          *prepared for sale. A number of articles, if similarly*  
18          *packaged and bearing identical labels, shall be consid-*  
19          *ered as one product, but each package size, form, or*  
20          *differently labeled article shall be considered a sepa-*  
21          *rate product.*

22          *“(d) IDENTIFICATION AND PUBLICATION OF LIST OF*  
23          *PRODUCTS CONTAINING ANABOLIC STEROIDS.—*

24          *“(1) The Attorney General may, in his discre-*  
25          *tion, collect data and analyze products to determine*

1       *whether they contain anabolic steroids and are prop-*  
 2       *erly labeled in accordance with this section. The At-*  
 3       *torney General may publish in the Federal Register*  
 4       *or on the website of the Drug Enforcement Adminis-*  
 5       *tration a list of products that he has determined,*  
 6       *based on substantial evidence, contain an anabolic*  
 7       *steroid and are not labeled in accordance with this*  
 8       *section.*

9               *“(2) The absence of a product from the list re-*  
 10       *ferred to in paragraph (1) shall not constitute evi-*  
 11       *dence that the product does not contain an anabolic*  
 12       *steroid.”.*

13               (2) *TABLE OF CONTENTS.—The table of contents*  
 14       *for the Comprehensive Drug Abuse Prevention and*  
 15       *Control Act of 1970 is amended by inserting after the*  
 16       *item relating to section 305 the following:*

*“Sec. 305A. Offenses involving false labeling of anabolic steroids.”.*

17 **SECTION 1. SHORT TITLE.**

18       **This Act may be cited as the “Designer An-**  
 19       **abolic Steroid Control Act of 2014”.**

20 **SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES**  
 21       **ACT.**

22       **(a) DEFINITIONS.—Section 102(41) of the**  
 23       **Controlled Substances Act (21 U.S.C. 802(41))**  
 24       **is amended—**

25               **(1) in subparagraph (A)—**

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

3 (B) by redesignating clause (xlx)  
4 as clause (lxxv); and

5 (C) by inserting after clause (xlix)  
6 the following:

7 “(I) 5 $\alpha$ -Androstan-3,6,17-trione;

8 “(II) 6-bromo-androstan-3,17-dione;

9 “(III) 6-bromo-androsta-1,4-diene-3,17-  
10 dione;

11 “(IV) 4-chloro-17 $\alpha$ -methyl-androsta-  
12 1,4-diene-3,17 $\beta$ -diol;

13 “(V) 4-chloro-17 $\alpha$ -methyl-androst-4-  
14 ene-3 $\beta$ ,17 $\beta$ -diol;

15 “(VI) 4-chloro-17 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
16 androst-4-en-3-one;

17 “(VII) 4-chloro-17 $\alpha$ -methyl-17 $\beta$ -hy-  
18 droxy-androst-4-ene-3,11-dione;

19 “(VIII) 4-chloro-17 $\alpha$ -methyl-androsta-  
20 1,4-diene-3,17 $\beta$ -diol;

21 “(IX) 2 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxy-  
22 5 $\alpha$ -androstan-3-one;

23 “(X) 2 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxy-5 $\beta$ -  
24 androstan-3-one;

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

1           “(lxxiii) [3,2-c]pyrazole-androst-4-en-  
2           17 $\beta$ -ol;

3           “(lxxiv) [3,2-c]pyrazole-5 $\alpha$ -androstan-  
4           17 $\beta$ -ol; and”;

5           (2) by adding at the end the fol-  
6           lowing:

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

16                   “(I) the drug or substance has  
17                   been created or manufactured with  
18                   the intent of producing a drug or  
19                   other substance that either—

20                           “(aa) promotes muscle growth;

21                           or

22                           “(bb) otherwise causes a phar-  
23                           macological effect similar to that  
24                           of testosterone; or

1           “(II) the drug or substance has  
2           been, or is intended to be, marketed  
3           or otherwise promoted in any manner  
4           suggesting that consuming it will pro-  
5           mote muscle growth or any other  
6           pharmacological effect similar to that  
7           of testosterone.

8           “(ii) A substance shall not be consid-  
9           ered to be a drug or hormonal substance  
10          for purposes of this subparagraph if it—

11           “(I) is—

12           “(aa) an herb or other botan-  
13           ical;

14           “(bb) a concentrate, metabo-  
15           lite, or extract of, or a constituent  
16           isolated directly from, an herb or  
17           other botanical; or

18           “(cc) a combination of 2 or  
19           more substances described in  
20           item (aa) or (bb);

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



1           **“(III) is not anabolic or**  
2           **androgenic.**

3           **“(iii) In accordance with section**  
4           **515(a), any person claiming the benefit of**  
5           **an exemption or exception under clause**  
6           **(ii) shall bear the burden of going for-**  
7           **ward with the evidence with respect to**  
8           **such exemption or exception.”.**

9           **(b) CLASSIFICATION AUTHORITY.—Section**  
10          **201 of the Controlled Substances Act (21**  
11          **U.S.C. 811) is amended by adding at the end**  
12          **the following:**

13          **“(i) TEMPORARY AND PERMANENT SCHED-**  
14          **ULING OF RECENTLY EMERGED ANABOLIC**  
15          **STERIODS.—**

16                 **“(1) The Attorney General may issue a**  
17                 **temporary order adding a drug or other**  
18                 **substance to the definition of anabolic**  
19                 **steroids if the Attorney General finds**  
20                 **that—**

21                         **“(A) the drug or other substance**  
22                         **satisfies the criteria for being consid-**  
23                         **ered an anabolic steroid under sec-**  
24                         **tion 102(41) but is not listed in that**  
25                         **section or by regulation of the Attor-**

1           ney General as being an anabolic  
2           steroid; and

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

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

21          “(3) The Attorney General shall trans-  
22          mit notice of an order proposed to be  
23          issued under paragraph (1) to the Sec-  
24          retary of Health and Human Services. In  
25          issuing an order under paragraph (1), the

1     **Attorney General shall take into consid-**  
2     **eration any comments submitted by the**  
3     **Secretary in response to a notice trans-**  
4     **mitted pursuant to this paragraph.**

5             **“(4) A temporary scheduling order**  
6     **issued under paragraph (1) shall be va-**  
7     **cated upon the issuance of a permanent**  
8     **scheduling order under paragraph (6).**

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

11            **“(6) The Attorney General may, by**  
12    **rule, issue a permanent order adding a**  
13    **drug or other substance to the definition**  
14    **of anabolic steroids if such drug or other**  
15    **substance satisfies the criteria for being**  
16    **considered an anabolic steroid under sec-**  
17    **tion 102(41). Such rulemaking may be**  
18    **commenced simultaneously with the**  
19    **issuance of the temporary order issued**  
20    **under paragraph (1).”.**

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

22            **(a) IN GENERAL.—Section 305 of the Con-**  
23    **trolled Substances Act (21 U.S.C. 825) is**  
24    **amended by adding at the end the following:**

1       **“(e) FALSE LABELING OF ANABOLIC**  
2 **STEROIDS.—**

3           **“(1) It shall be unlawful to import, ex-**  
4 **port, manufacture, distribute, dispense,**  
5 **or possess with intent to manufacture,**  
6 **distribute, or dispense, an anabolic ster-**  
7 **oid or product containing an anabolic**  
8 **steroid, unless the steroid or product**  
9 **bears a label clearly identifying an ana-**  
10 **bolic steroid or product containing an an-**  
11 **abolic steroid by the nomenclature used**  
12 **by the International Union of Pure and**  
13 **Applied Chemistry (IUPAC).**

14           **“(2)(A) A product described in sub-**  
15 **paragraph (B) is exempt from the Inter-**  
16 **national Union of Pure and Applied**  
17 **Chemistry nomenclature requirement of**  
18 **this subsection if such product is labeled**  
19 **in the manner required under the Fed-**  
20 **eral Food, Drug, and Cosmetic Act.**

21           **“(B) A product is described in this**  
22 **subparagraph if the product—**

23                   **“(i) is the subject of an approved**  
24 **application as described in section**

1           **505(b) or (j) of the Federal Food,**  
2           **Drug, and Cosmetic Act; or**

3           **“(ii) is exempt from the provisions**  
4           **of section 505 of such Act relating to**  
5           **new drugs because—**

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

9           **“(II) such product is being**  
10           **used exclusively for purposes of a**  
11           **clinical trial that is the subject of**  
12           **an effective investigational new**  
13           **drug application.”.**

14           **(b) CLARIFICATION TO IMPORT AND EXPORT**  
15           **STATUTE.—Section 1010 of the Controlled Sub-**  
16           **stances Import and Export Act (21 U.S.C. 960)**  
17           **is amended, in subsection (a)(1), by inserting**  
18           **“305,” before “1002”.**

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

22           **(1) in subsection (a)—**

23           **(A) in paragraph (14), by striking**  
24           **“or” at the end;**

1           **(B) in paragraph (15), by striking**  
2           **the period at the end and inserting “;**  
3           **or”;** and

4           **(C) by inserting, after paragraph**  
5           **(15), the following:**

6           **“(16) to violate subsection (e) of sec-**  
7           **tion 305 of the Controlled Substances**  
8           **Act.”;** and

9           **(2) in subsection (c)(1)—**

10           **(A) by inserting, in subparagraph**  
11           **(A), after “subparagraph (B)” the fol-**  
12           **lowing: “, (C), or (D)”;** and

13           **(B) by inserting after subpara-**  
14           **graph (B) the following:**

15           **“(C) In the case of a violation of para-**  
16           **graph (16) of subsection (a) of this section by**  
17           **an importer, exporter, manufacturer, or dis-**  
18           **tributor (other than as provided in subpara-**  
19           **graph (D)), up to \$500,000 per violation. For**  
20           **purposes of this subparagraph, a violation is**  
21           **defined as each instance of importation, ex-**  
22           **portation, manufacturing, distribution, or**  
23           **possession with intent to manufacture or dis-**  
24           **tribute, in violation of paragraph (16) of sub-**  
25           **section (a).**

1       “(D) In the case of a distribution, dis-  
2       pensing, or possession with intent to dis-  
3       tribute or dispense in violation of paragraph  
4       (16) of subsection (a) of this section at the re-  
5       tail level, up to \$1000 per violation. For pur-  
6       poses of this paragraph, the term ‘at the retail  
7       level’ refers to products sold, or held for sale,  
8       directly to the consumer for personal use.  
9       Each package, container or other separate  
10      unit containing an anabolic steroid that is dis-  
11      tributed, dispensed, or possessed with intent  
12      to distribute or dispense at the retail level in  
13      violation of paragraph (16) of subsection (a)  
14      shall be considered a separate violation.”.

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

18      (a) The Attorney General may, in his dis-  
19      cretion, collect data and analyze products to  
20      determine whether they contain anabolic  
21      steroids and are properly labeled in accord-  
22      ance with this section. The Attorney General  
23      may publish in the Federal Register or on the  
24      website of the Drug Enforcement Administra-  
25      tion a list of products that he has determined,

1 based on substantial evidence, contain an an-  
2 abolic steroid and are not labeled in accord-  
3 ance with this section.

4 (b) The absence of a product from the list  
5 referred to in subsection (a) shall not con-  
6 stitute evidence that the product does not  
7 contain an anabolic steroid.





Union Calendar No. 434

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 4771**

[Report No. 113-587, Parts I and II]

---

---

## **A BILL**

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

---

---

SEPTEMBER 15, 2014

Reported from the Committee on Energy and Commerce  
with an amendment

SEPTEMBER 15, 2014

Reported from the Committee on the Judiciary with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed