

DESIGNER ANABOLIC STEROID CONTROL ACT OF 2014

SEPTEMBER 15, 2014.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 4771]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4771) to amend the Controlled Substances Act to more effectively regulate anabolic steroids, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

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

SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES ACT.

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

(1) in subparagraph (A)—

- (A) in clause (xlix), by striking “and” at the end;
- (B) by redesignating clause (xli) as clause (lxxv); and
- (C) by inserting after clause (xlix) the following:
 - “(l) 5a-Androstan-3,6,17-trione;
 - “(li) 6-bromo-androstan-3,17-dione;
 - “(lii) 6-bromo-androsta-1,4-diene-3,17-dione;
 - “(liii) 4-chloro-17a-methyl-androsta-1,4-diene-3,17β-diol;
 - “(liv) 4-chloro-17a-methyl-androst-4-ene-3β,17β-diol;
 - “(lv) 4-chloro-17a-methyl-17β-hydroxy-androst-4-ene-3-one;
 - “(lvi) 4-chloro-17a-methyl-17β-hydroxy-androst-4-ene-3,11-dione;
 - “(lvii) 4-chloro-17a-methyl-androsta-1,4-diene-3,17β-diol;
 - “(lviii) 2a,17a-dimethyl-17β-hydroxy-5a-androstan-3-one;
 - “(lix) 2a,17a-dimethyl-17β-hydroxy-5β-androstan-3-one;
 - “(lx) 2a,3a-epithio-17a-methyl-5a-androstan-17β-ol;
 - “(lxi) [3,2-c]-furazan-5a-androstan-17β-ol;
 - “(lxii) 3β-hydroxy-estra-4,9,11-trien-17-one;
 - “(lxiii) 17a-methyl-androst-2-ene-3,17β-diol;
 - “(lxiv) 17a-methyl-androsta-1,4-diene-3,17β-diol;
 - “(lxv) Estra-4,9,11-triene-3,17-dione;
 - “(lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;
 - “(lxvii) 6a-Methyl-androst-4-ene-3,17-dione;
 - “(lxviii) 17a-Methyl-androstan-3-hydroxyimine-17β-ol;
 - “(lxix) 17a-Methyl-5a-androstan-17β-ol;
 - “(lxx) 17β-Hydroxy-androstano[2,3-d]isoxazole;
 - “(lxxi) 17β-Hydroxy-androstano[3,2-c]isoxazole;
 - “(lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5a-androstan-17β-ol;
 - “(lxxiii) [3,2-c]pyrazole-androst-4-en-17β-ol;
 - “(lxxiv) [3,2-c]pyrazole-5a-androstan-17β-ol; and”;

(2) by adding at the end the following:

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

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

“(aa) promotes muscle growth; or

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

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

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

“(I) is—

“(aa) an herb or other botanical;

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

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

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

“(III) is not anabolic or androgenic.

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

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

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

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

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

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

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

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

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

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

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

(c) LABELING REQUIREMENTS.—

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

“SEC. 305A. OFFENSES INVOLVING FALSE LABELING OF ANABOLIC STEROIDS.

“(a) UNLAWFUL ACTS.—

“(1) It shall be unlawful—

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

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

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

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

“(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act.

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

“(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act; or

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

“(I) it is intended solely for investigational use as described in section 505(i) of such Act; and

“(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.

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

“(c) CIVIL PENALTIES.—

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

“(A) In the case of an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (B)), up to \$500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance

of importation, exportation, manufacturing, or distribution, and each anabolic steroid or product imported, exported, manufactured, or distributed.

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

“(2) In this subsection, the term ‘product’ means a discrete article, either in bulk or in finished form prepared for sale. A number of articles, if similarly packaged and bearing identical labels, shall be considered as one product, but each package size, form, or differently labeled article shall be considered a separate product.

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

“(1) The Attorney General may, in his discretion, collect data and analyze products to determine whether they contain anabolic steroids and are properly labeled in accordance with this section. The Attorney General may publish in the Federal Register or on the website of the Drug Enforcement Administration a list of products that he has determined, based on substantial evidence, contain an anabolic steroid and are not labeled in accordance with this section.

“(2) The absence of a product from the list referred to in paragraph (1) shall not constitute evidence that the product does not contain an anabolic steroid.”.

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

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

PURPOSE AND SUMMARY

The bill would amend the Controlled Substances Act (CSA) to expand the definition of “anabolic steroids,” authorize the Attorney General to issue a temporary order adding a drug or substance to the definition of anabolic steroids and to collect data and analyze products to determine whether they contain anabolic steroids and are properly labeled, and impose additional criminal and civil penalties for possessing or trafficking any anabolic steroid that does not bear a label clearly identified the anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry or is not labeled in a manner that is not labeled in the manner required under the Federal Food, Drug, and Cosmetic Act (FFDCA).

BACKGROUND AND NEED FOR LEGISLATION

Misbranded products that contain designer anabolic steroids present serious health risks to consumers. Consumers oftentimes unknowingly purchase products labeled as dietary supplements that contain such ingredients. Anabolic steroids are synthetic forms of testosterone that can be extremely dangerous and are Class III controlled substances under the Controlled Substances Act. To skirt the law, however, certain entities alter the chemical structure of such substances and promote these designer products for their anabolic effects. H.R. 4771 provides the Drug Enforcement Administration (DEA) with the tools and authority to protect consumers from these dangerous products.

HEARINGS

The Committee on Energy and Commerce has not held hearings on H.R. 4771.

COMMITTEE CONSIDERATION

On June 19, 2014, the Subcommittee on Health met in open markup session and approved H.R. 4771 for full Committee consideration by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4771 reported. A motion by Mr. Upton to order H.R. 4771 reported to the House, with amendment, was agreed to by voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of this legislation is to ensure that the DEA has adequate authority to protect consumers from designer anabolic steroids.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4771 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 4771 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 25, 2014.

Hon. FRED UPTON,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4771, the Designer Anabolic Steroid Control Act of 2014.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 4771—Designer Anabolic Steroid Control Act of 2014

CBO estimates that implementing H.R. 4771 would have no significant costs to the federal government. Enacting the bill could affect direct spending and revenues; therefore, pay-as-you-go procedures apply. However, CBO estimates that any effects would be insignificant for each year.

H.R. 4771 would expand the list of anabolic steroids regulated by the Drug Enforcement Administration (DEA) to include about two dozen new substances and would establish new crimes relating to false labeling of steroids. As a result, the government might be able to pursue cases involving drug use that it otherwise would not be able to prosecute. CBO expects that H.R. 4771 would apply to a relatively small number of additional offenders, however, so any increase in costs for law enforcement, court proceedings, or prison operations would not be significant. Any such costs would be subject to the availability of appropriated funds.

Because those prosecuted and convicted under H.R. 4771 could be subject to civil and criminal fines, the federal government might collect additional fines if the legislation is enacted. Civil fines are recorded as revenues. Criminal fines are recorded as revenues, deposited in the Crime Victims Fund, and later spent. CBO expects that any additional revenues and direct spending would not be significant because of the small number of additional cases likely to be affected.

H.R. 4771 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

H.R. 4771 would impose private-sector mandates, as defined in UMRA, on manufacturers, sellers, importers, exporters, distributors, and consumers of products that contain certain chemical compounds that would be defined as anabolic steroids. CBO estimates that the cost of complying with those mandates would probably exceed the annual threshold established in UMRA for private-sector mandates (\$152 million in 2014, adjusted annually for inflation).

The bill would impose private-sector mandates by adding 25 new compounds, and any compounds found to be structurally similar, to the list of anabolic steroids regulated under the Controlled Substances Act. Consumers would need a prescription from a licensed practitioner in order to purchase products containing the newly listed compounds. Sellers, manufacturers, and importers of such

products would be required to obtain an authorization from state and federal authorities in order to make or possess the compounds. However, based on information from the Food and Drug Administration (FDA), the DEA, and industry professionals, CBO expects that the majority of the affected entities would either replace the regulated compounds with new ones or discontinue the distribution of the affected products. Therefore, the cost of the mandate would be the forgone income from lost sales.

Because of the nature of the market being regulated, the scope of sales affected is difficult to determine. As products are found to contain compounds that are structurally similar to the compounds listed, industry sales could decline significantly. Some industry experts estimate that the revenues generated by the sale of products containing such compounds amount to between \$2 billion and \$5 billion annually. (Those figures include sales of some products that already are not in compliance or not being sold in compliance with FDA or DEA regulations.) Although identifying which items would be affected by the legislation would be difficult, given the estimated magnitude of industry profits, even a 10 percent decrease in income as a result of the bill would exceed the annual threshold for private-sector mandates.

The bill also would impose a mandate on importers, exporters, manufacturers, and distributors by requiring that any anabolic steroid or product containing an anabolic steroid be labeled as such, using the nomenclature of the International Union of Pure and Applied Chemistry. The cost of the mandate would probably be small.

The CBO staff contacts for this estimate are Mark Grabowicz (for federal costs) and Marin Burnett (for the private-sector impact). The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4771 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4771 specifically directs to be completed zero specific rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1: Short title

Section 1 provides the short title of the “Designer Anabolic Steroid Control Act of 2014.”

Section 2: Amendments to the Controlled Substances Act

Subsection (a) amends section 102(41) of the CSA by adding 25 substances to the definition of “anabolic steroid.”

In addition, it provides that a drug or hormonal substance that is not listed under section 102(41), but is derived from, or has a chemical structure substantially similar to, one or more of the listed anabolic steroids, such drug or hormonal substance shall be considered an anabolic steroid for purposes of the CSA if it has been created or manufactured with the intent of producing a drug or other substance that either promotes muscle growth or causes a pharmacological effect similar to that of testosterone, or has been, or is intended to be, marketed or otherwise promoted as such.

Further, it clarifies that a substance shall not be considered a drug or hormonal substance for such purposes if any person claiming such exemption provides evidence that it (A) is an herb or other botanical, or a concentrate, metabolite, or extract thereof; (B) is a dietary supplement under the FFDCA; and (C) is not anabolic or androgenic.

Subsection (b) authorizes the Attorney General to issue a temporary order adding a drug or substance to section 102(41) if it meets the criteria under such section and doing so will assist in preventing abuse or misuse of the drug or other substance. In doing so, the Attorney General must transmit notice of such order to the Secretary of Health and Human Services and take into consideration any comments submitted by the Secretary in response. The Attorney General may commence a rulemaking to issue a permanent order adding such drug or substance to section 102(41) simultaneously with the issuance of such temporary order.

Finally, section 2 imposes enhanced criminal and civil penalties for possessing or trafficking in any anabolic steroid or product containing an anabolic steroid that does not bear a label clearly identifying the anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry or is not labeled in a manner that is not labeled in the manner required under the FFDCA.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

TABLE OF CONTENTS

TITLE II—CONTROL AND ENFORCEMENT

*	*	*	*	*	*	*
PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING						
*	*	*	*	*	*	*
Sec. 305A. Offenses involving false labeling of anabolic steroids.						
*	*	*	*	*	*	*

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

SHORT TITLE

SEC. 100. This title may be cited as the “Controlled Substances Act”.

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DEFINITIONS

SEC. 102. As used in this title:

(1) * * *

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(41)

(A) The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes—

(i) * * *

*	*	*	*	*	*	*
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(xlix) trenbolone (17 β -hydroxyestr-4,9,11-trien-3-one); [and]

(l) 5 α -Androstan-3,6,17-trione;

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

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

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

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

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

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

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

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

(lix) 2 α ,17 α -dimethyl-17 β -hydroxy-5 β -androstan-3-one;

(lx) 2 α ,3 α -epithio-17 α -methyl-5 α -androstan-17 β -ol;

(lxi) [3,2-c]-furazan-5 α -androstan-17 β -ol;

(lxii) 3 β -hydroxy-estra-4,9,11-trien-17-one;

(lxiii) 17 α -methyl-androst-2-ene-3,17 β -diol;

(lxiv) 17 α -methyl-androsta-1,4-diene-3,17 β -diol;

(lxv) Estra-4,9,11-triene-3,17-dione;

(lxvi) 18 α -Homo-3-hydroxy-estra-2,5(10)-dien-17-one;

(lxvii) 6 α -Methyl-androst-4-ene-3,17-dione;

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

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

- (lxx) 17 β -Hydroxy-androstano[2,3-d]isoxazole;
 (lxxi) 17 β -Hydroxy-androstano[3,2-c]isoxazole;
 (lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5 α -androstan-17 β -ol;
 (lxxiii) [3,2-c]pyrazole-androst-4-en-17 β -ol;
 (lxxiv) [3,2-c]pyrazole-5 α -androstan-17 β -ol; and
 [(xlx)] (lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 201.

- * * * * *
- (C)(i) *Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (A) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this Act if—*
- (I) *the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—*
- (aa) *promotes muscle growth; or*
 (bb) *otherwise causes a pharmacological effect similar to that of testosterone; or*
- (II) *the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.*
- (ii) *A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it—*
- (I) *is—*
- (aa) *an herb or other botanical;*
 (bb) *a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or*
 (cc) *a combination of 2 or more substances described in item (aa) or (bb);*
- (II) *is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and*
 (III) *is not anabolic or androgenic.*
- (iii) *In accordance with section 515(a), any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to such exemption or exception.*

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) * * *

- * * * * *
- (i) *TEMPORARY AND PERMANENT SCHEDULING OF RECENTLY EMERGED ANABOLIC STEROIDS.—*

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

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

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

(2) *An order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.*

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

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

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

(6) *The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid under section 102(41). Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).*

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

SEC. 305A. OFFENSES INVOLVING FALSE LABELING OF ANABOLIC STEROIDS.

(a) **UNLAWFUL ACTS.—**

(1) *It shall be unlawful—*

(A) to import into the United States or to export from the United States;

(B) to manufacture, distribute, dispense, sell, or offer to sell; or

(C) to possess with intent to manufacture, distribute, dispense, sell, or offer to sell;

any anabolic steroid, or any product containing an anabolic steroid, that does not bear a label clearly identifying any anabolic steroid contained in such steroid or product by the nomen-

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

(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act.

(B) A product is described in this subparagraph if the product—

(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act; or

(ii) is exempt from the provisions of section 505 of such Act relating to new drugs because—

(I) it is intended solely for investigational use as described in section 505(i) of such Act; and

(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.

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

(c) **CIVIL PENALTIES.**—

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

(A) In the case of an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (B)), up to \$500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance of importation, exportation, manufacturing, or distribution, and each anabolic steroid or product imported, exported, manufactured, or distributed.

(B) In the case of a sale or offer to sell at retail, up to \$25,000 per violation. For purposes of this subparagraph, each sale and each product offered for sale shall be considered a separate violation. Continued offers to sell by a person 10 or more days after written notice (including through electronic message) to the person by the Attorney General or the Secretary shall be considered additional violations.

(2) In this subsection, the term “product” means a discrete article, either in bulk or in finished form prepared for sale. A number of articles, if similarly packaged and bearing identical labels, shall be considered as one product, but each package size, form, or differently labeled article shall be considered a separate product.

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

(1) The Attorney General may, in his discretion, collect data and analyze products to determine whether they contain anabolic steroids and are properly labeled in accordance with this

section. The Attorney General may publish in the Federal Register or on the website of the Drug Enforcement Administration a list of products that he has determined, based on substantial evidence, contain an anabolic steroid and are not labeled in accordance with this section.

(2) The absence of a product from the list referred to in paragraph (1) shall not constitute evidence that the product does not contain an anabolic steroid.

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