

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. GOODLATTE, from the Committee on the Judiciary,
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 the Judiciary, 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, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The Amendment

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-en-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).”

SEC. 3. LABELING REQUIREMENTS.

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

“(e) FALSE LABELING OF ANABOLIC STEROIDS.—

“(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid 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) CLARIFICATION TO IMPORT AND EXPORT STATUTE.—Section 1010 of the Controlled Substances Import and Export Act (21 U.S.C. 960) is amended, in subsection (a)(1), by inserting “305,” before “1002”.

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

(1) in subsection (a)—

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

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

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

“(16) to violate subsection (e) of section 305 of the Controlled Substances Act.”; and

(2) in subsection (c)(1)—

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

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

“(C) In the case of a violation of paragraph (16) of subsection (a) of this section by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (D)), up to \$500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (16) of subsection (a).

“(D) In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of paragraph (16) of subsection (a) of this section at the retail level, up to \$1000 per violation. For purposes of this paragraph, the term ‘at the retail level’ refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of paragraph (16) of subsection (a) shall be considered a separate violation.”.

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

(a) 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.

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

Purpose and Summary

H.R. 4771 is intended to more effectively regulate anabolic steroids. It does this by adding 25 new “designer” chemicals, all of which have been marketed as anabolic steroids, to the list of substances that meet the Controlled Substances Act (“CSA”) definition of anabolic steroid.

H.R. 4771 amends the CSA’s scheduling authority to allow the Attorney General to issue a temporary order adding a drug or other substance to the list of anabolic steroids if he determines: (1) that the drug or other substance is an anabolic steroid, and (2) adding the drug or other substance to the list of anabolic steroids will assist in preventing the unlawful importation, manufacture, distribution or dispensing of the drug or other substance.

H.R. 4771 also establishes a new subsection (e) in section 305 of the CSA (21 U.S.C. § 825) criminalizing the false labeling of anabolic steroids or substances containing anabolic steroids, and establishes new civil penalties for violations.

Finally, the legislation gives the Attorney General the authority to publish, in the Federal Register, a list of products that contain anabolic steroids and are improperly labeled.

Background and Need for the Legislation

Anabolic steroids are synthetically-produced variants of the naturally occurring male hormone testosterone (“anabolic” means that the substance affects the body in a similar fashion as testosterone). They are currently listed as controlled substances under Schedule III of the CSA (21 U.S.C. § 802(41)). Only a small number of anabolic steroids are approved for either human or veterinary use. They may be prescribed by a physician for the treatment of a variety of therapeutic uses, including testosterone deficiency, delayed puberty, low red blood cell count, breast cancer, and tissue wasting resulting from AIDS. However, anabolic steroids are also used illicitly as performance-enhancing drugs. Long-term or high-dosage use

of these substances can have severe adverse health effects, including dramatic mood swings, increased feelings of hostility, increased levels of aggression, and stunted level of growth in children, as well as heart and liver damage.

Unlike most other controlled substances, anabolic steroids are often disguised as legal products such as dietary supplements. This poses a substantial risk to consumers. Although anabolic steroids are listed as controlled substances in Schedule III of the CSA, chemists are able to create “designer” anabolic steroids that are chemically distinct from the listed steroids but have the same pharmacological effect. The Drug Enforcement Administration (DEA), which enforces the CSA on behalf of the Attorney General, cannot take enforcement action against those who manufacture, market, or distribute unscheduled anabolic steroids. This poses a significant risk to consumers, especially if the “designer” anabolic steroids are being falsely marketed as dietary supplements.

During full Committee consideration of H.R. 4771, the Judiciary Committee adopted by voice vote an amendment in the nature of a substitute. The amendment preserves several provisions in the bill as reported by the Committee on Energy and Commerce, including the addition of 25 new chemicals to the definition of anabolic steroids in the CSA; the amendment to DEA’s temporary and permanent scheduling authority; and the provision giving the Attorney General the authority to publish a list of improperly labeled substances.

The substitute amendment substantially revises the criminal and civil penalties contained in the bill as reported by the Committee on Energy and Commerce, which created a new section of the CSA criminalizing the false labeling of anabolic steroids and assigning criminal and civil penalties. The Committee on the Judiciary concluded that creation of a new section of the CSA to prohibit the false labeling of anabolic steroids is redundant and unnecessary. Rather, the substitute amendment achieves this prohibition by amending existing section 305 of the CSA (21 U.S.C. § 825) (relating to labeling and packaging). In doing so, the amendment builds upon the existing statutory framework for imposing civil penalties for this type of conduct. *See* 21 U.S.C. § 842. The CSA currently prohibits the unlawful importation, exportation, manufacture, distribution, or dispensation of a schedule III controlled substance. *See* 21 U.S.C. § 841(b)(1)(E)). Therefore, the Committee concluded that it was unnecessary to create a new criminal offense for the false labeling of anabolic steroids where the elements of such offense are largely consistent with existing law.

Hearings

The Committee on the Judiciary held no hearings on H.R. 4771.

Committee Consideration

On September 10, 2014, the Committee met in open session and ordered the bill H.R. 4771 reported, with an amendment, by voice vote, a quorum being present.

Committee Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that there were no recorded votes during the Committee's consideration of H.R. 4771.

Committee Oversight Findings

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

New Budget Authority and Tax Expenditures

Clause 3(c)(2) of rule XIII of the Rules of the House of Representatives is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

Congressional Budget Office Cost Estimate

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R.4771, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 15, 2014.

Hon. BOB GOODLATTE, CHAIRMAN,
Committee on the Judiciary,
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, who can be reached at 226-2860.

Sincerely,

DOUGLAS W. ELMENDORF,
DIRECTOR.

Enclosure

cc: Honorable John Conyers, Jr.
Ranking Member

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

As ordered reported by the House Committee on the Judiciary
on September 15, 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.

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 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), 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 (\$152 million in 2014, adjusted annually for inflation).

The bill also would impose a private-sector 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.

On July 25, 2014, CBO transmitted a cost estimate for H.R. 4771 as ordered reported by the House Committee on Energy and Commerce on July 15, 2014. The estimate of Federal costs is the same for the two versions of the bill.

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.

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 No. 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 H.R. 4771 specifically directs to be completed no specific rule makings within the meaning of 5 U.S.C. § 551.

Performance Goals and Objectives

The Committee states that pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 4771 is intended to more effectively regulate anabolic steroids.

Advisory on Earmarks

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 4771 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of Rule XXI.

Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

Sec. 1. Short Title. This section cites the short title of the bill as the “Designer Anabolic Steroid Control Act of 2014.”

Sec. 2. Amendments to the Controlled Substances Act. This section adds 25 new substances to the list of what constitutes an anabolic steroid under section 402 of the CSA (21 U.S.C. § 802). This section also amends the definition of anabolic steroid to include substances that promote muscle growth, otherwise cause a pharmacological effect similar to testosterone, or are marketed in a manner suggesting that the substances do either of those things. The definition excludes from the definition of anabolic steroid herbs or other botanicals, concentrates, metabolites, or extracts of, or constituents isolated directly from, an herb or other botanical, or any combination of the two; dietary ingredients for purposes of the Fed-

eral Food, Drug, or Cosmetic Act; or substances that are not anabolic or androgenic.

Section 2 also authorizes the Attorney General to issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Attorney General finds (1) that the drug or other substance satisfies the criteria for being considered an anabolic steroid but is not listed in the CSA or the relevant regulations as being an anabolic steroid; and (2) adding the drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance. This section imposes a timeline upon the Attorney General for issuing such an order, and allows the Attorney General to extend the order once for up to six (6) months. This section also requires the Attorney General to transmit notice of a proposed order to the Secretary of Health and Human Services; provides that a temporary scheduling order shall be vacated upon the issuance of a permanent scheduling order; provides that a temporary scheduling order is not subject to judicial review; and provides that the Attorney General may initiate a rulemaking to control a drug or other substance simultaneously with the temporary scheduling order.

Sec. 3. Labeling Requirements. This section adds a new subsection (e) to section 305 of the CSA (21 U.S.C. § 825) prohibiting the importation, exportation, manufacture, distribution, or dispensation—or possession with intent to manufacture, distribute, or dispense—an anabolic steroid unless the anabolic steroid is clearly labeled using the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC). IUPAC has long been recognized as the world authority on chemical nomenclature. This section exempts drugs or other substances from the IUPAC nomenclature requirement if the product(s) are labeled in the manner required under the Federal Food, Drug, and Cosmetic Act. Violations of the new subsection (e) are subject to civil penalties contained in section 402 of the CSA (21 U.S.C. § 842) as described below.

This section adds a new paragraph (16) to section 402(a) of the CSA (21 U.S.C. § 842(a)), which provides that violations of section 825(e) are subject to civil penalties under the CSA. Section 3 creates new civil penalties in subsection (c) of section 402 for violations of paragraph (16). False labeling violations by importers, exporters, manufacturers, or distributors, but not retailers, are punishable by a fine of up to \$500,000 per violation. “Violation” is defined as “each instance” of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (16). In the case, for example, of a shipping container that is wrapped and transported as one cohesive item but holds within it thousands of boxes containing tens of thousands of individual bottles or packages, this section would treat that shipping container as one “instance” (and hence one violation) punishable by a civil fine of up to \$500,000.

With regard to distribution, dispensing, or possession with intent to distribute or dispense at the retail level, Section 3 imposes a civil penalty of up to \$1,000 per violation. “At the retail level” is defined as products sold, or held for sale, directly to the consumer for personal use. This would include not only products held for sale on the shelves of a retail establishment, but also the products held in stock. Each package, container or other separate unit containing

an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level is considered to be a separate violation.

Section 3 also amends the Controlled Substances Import and Export Act (21 U.S.C. § 960 et seq.) to clarify that violations of subsection (e) involving the importation or exportation of falsely-labeled anabolic steroids may be punished in accordance with the provisions of the Import and Export Act.

Sec. 4. Identification and Publication of List of Products Containing Anabolic Steroids. This section gives the Attorney General the authority to collect data and analyze products to determine whether they contain anabolic steroids and are properly labeled in accordance with this section, and to publish in the Federal Register, or on the DEA website, a list of products that he has determined contain an anabolic steroid and are not appropriately labeled.

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 italics, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

* * * * *

TITLE II—CONTROL AND ENFORCEMENT

* * * * *

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

* * * * *

DEFINITIONS

SEC. 102. As used in this title:

(1) * * *

* * * * *

(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) * * *

* * * * *

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

[and]

(l) 5α-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-17α-methyl-androsta-1,4-diene-3,17β-diol;

(liv) 4-chloro-17α-methyl-androst-4-ene-3β,17β-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;
- (lxx) 17 β -Hydroxy-androstano[2,3-d]isoxazole;
- (lxix) 17 α -Methyl-5 α -androstan-17 β -ol;
- (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
- [(xIx)] (lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

* * * * *

(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.

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PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) * * *

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(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).

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

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LABELING AND PACKAGING REQUIREMENTS

SEC. 305. (a) * * *

* * * * *

(e) FALSE LABELING OF ANABOLIC STEROIDS.—

(1) *It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid 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.

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PART D—OFFENSES AND PENALTIES

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PROHIBITED ACTS B—PENALTIES

SEC. 402. (a) It shall be unlawful for any person—

(1) * * *

* * * * *

(14) *who is a regulated seller or an employee or agent of such seller to disclose, in violation of regulations under subparagraph (C) of section 310(e)(1), information in logbooks under subparagraph (A)(iii) of such section, or to refuse to provide such a logbook to Federal, State, or local law enforcement authorities; [or]*

(15) to distribute a scheduled listed chemical product to a regulated seller, or to a regulated person referred to in section 310(b)(3)(B), unless such regulated seller or regulated person is, at the time of such distribution, currently registered with the Drug Enforcement Administration, or on the list of persons referred to under section 310(e)(1)(B)(v) [.] ; or

(16) to violate subsection (e) of section 305 of the Controlled Substances Act.

As used in paragraph (11), the term “laboratory supply” means a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals. For purposes of paragraph (11), there is a rebuttable presumption of reckless disregard at trial if the Attorney General notifies a firm in writing that a laboratory supply sold by the firm, or any other person or firm, has been used by a customer of the notified firm, or distributed further by that customer, for the unlawful production of controlled substances or listed chemicals a firm distributes and 2 weeks or more after the notification the notified firm distributes a laboratory supply to the customer. For purposes of paragraph (15), if the distributor is temporarily unable to access the list of persons referred to under section 310(e)(1)(B)(v), the distributor may rely on a written, faxed, or electronic copy of a certificate of self-certification submitted by the regulated seller or regulated person, provided the distributor confirms within 7 business days of the distribution that such regulated seller or regulated person is on the list referred to under section 310(e)(1)(B)(v).

* * * * *

(c)(1)(A) Except as provided in subparagraph (B), (C), or (D) of this paragraph and paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than \$25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 of the United States Code to enforce this paragraph.

* * * * *

(C) *In the case of a violation of paragraph (16) of subsection (a) of this section by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (D)), up to \$500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (16) of subsection (a).*

(D) *In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of paragraph (16) of subsection (a) of this section at the retail level, up to \$1000 per violation. For purposes of this paragraph, the term “at the retail level” refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of paragraph (16) of subsection (a) shall be considered a separate violation.*

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CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT

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**TITLE III—IMPORTATION AND EXPORTATION;
AMENDMENTS AND REPEALS OF REVENUE LAWS**

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PART A—IMPORTATION AND EXPORTATION

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PROHIBITED ACTS A—PENALTIES

SEC. 1010. (a) Any person who—

**(1) contrary to section 305, 1002, 1003, or 1007, knowingly
or intentionally imports or exports a controlled substance,**

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shall be punished as provided in subsection (b).

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