II

116TH CONGRESS
1ST SESSION

S. 2895

To amend the Controlled Substances Act to more effectively regulate selective androgen receptor modulators, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 19, 2019

Mr. GRASSLEY (for himself and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To amend the Controlled Substances Act to more effectively regulate selective androgen receptor modulators, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Selective Androgen Receptor Modulators Control Act of 2019'' or the ''SARMs Control Act of 2019''.

SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES ACT.

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

(1) by redesignating paragraph (58) as paragraph (59);

(2) by redesignating the second paragraph designated as paragraph (57) as paragraph (58);

(3) by moving paragraphs (57), (58) (as so redesignated), and (59) (as so redesignated) 2 ems to the left; and

(4) by adding at the end the following:

''(60)(A) The term 'SARM'—

''(i) means any drug or other substance that is a selective androgen receptor agonist chemically unrelated to testosterone, estrogens, progestins, corticosteroids, and dehydroepiandrosterone; and

''(ii) includes—

''(I) (S)-N-(4-cyano-3-(trifluoromethyl)phenyl)-3-(4-cyanophenoxy)-2-hydroxy-2-methylpropanamide (commonly known as 'ostarine' or 'enobosarm');

''(II) 4-((R)-2-((R)-2,2,2-trifluoro-1-hydroxyethyl)pyrrolidin-1-yl)-2-(trifluoromethyl)benzonitrile (commonly known as 'LGD-4033' or 'ligandrol');

''(III) 9-chloro-2-ethyl-1-methyl-3-(2,2,2-trifluoroethyl)-3,6-dihydro-7H-pyrrolo[3,2-

f]quinolin-7-one (commonly known as 'LGD-3303');

"(IV) isopropyl (S)-(7-cyano-4-(pyridin-2-ylmethyl)-1,2,3,4-tetrahydrocyclopenta[b]indol-2-yl)carbamate (commonly known as 'LY2452473' or 'TT701');

"(V) 2-chloro-4-(((1R,2S)-1-(5-(4-cyanophenyl)-1,3,4-oxadiazol-2-yl)-2-hydroxypropyl)amino)-3-methylbenzonitrile (commonly known as 'RAD-140');

"(VI) (S)-3-(4-acetamidophenoxy)-2-hydroxy-2-methyl-N-(4-nitro-3-(trifluoromethyl)phenyl)propanamide (commonly known as 'andarine');

"(VII) 2-chloro-4-((7R,7aS)-7-hydroxy-1,3-dioxotetrahydro-1H-pyrrolo[1,2-c]imidazol-2(3H)-yl)-3-methylbenzonitrile (commonly known as 'BMS-564929');

"(VIII) 6-ethyl-4-(trifluoromethyl)-6,7,8,9-tetrahydropyrido[3,2-g]quinolin-2(1H)-one (commonly known as 'LG-121071');

"(IX) (S)-3-(4-chloro-3-fluorophenoxy)-N-(4-cyano-3-(trifluoromethyl)phenyl)-2-hydroxy-2-methylpropanamide (commonly known as 'S-23'); and

''(X) any salt, ester, ether, or substituted analogue of a drug or other substance described in subclauses (I) through (IX).

''(B) A substance excluded under subparagraph (A)(i) may at any time be scheduled by the Attorney General in accordance with the authority and requirements under subsections (a) through (c) of section 201.

''(C)(i) A drug or other substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone, unless scheduled under subparagraph (B)) that is not listed in subparagraph (A)(ii) and is derived from, or has a chemical structure substantially similar to, one or more SARMs listed in subparagraph (A)(ii) shall be considered to be a SARM for purposes of this title if the drug or other substance—

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

''(aa) promotes muscle growth; or

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

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

''(ii) A drug or other substance shall not be considered to be a SARM for purposes of this subparagraph if the drug or other substance—

''(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 two 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 that exemption or exception.''.

(b) AMENDMENT TO SCHEDULE III.—Schedule III in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

''(f) SARMs.''.

(c) TEMPORARY AND PERMANENT SCHEDULING OF RECENTLY EMERGED SARMS.—Section 201 of the Con-

trolled Substances Act (21 U.S.C. 811) is amended by adding at the end the following:

''(k) TEMPORARY AND PERMANENT SCHEDULING OF RECENTLY EMERGED SARMS.—

''(1) TEMPORARY ORDERS.—

''(A) IN GENERAL.—The Attorney General may issue a temporary order adding a drug or other substance to the definition of the term 'SARM' under section 102(60) if the Attorney General finds that—

''(i) the drug or other substance satisfies the criteria for being considered a SARM but is not listed in that section or by regulation of the Attorney General as being a SARM; and

''(ii) adding the drug or other substance to the definition of the term SARM will assist in preventing abuse or misuse of the drug or other substance.

''(B) EFFECTIVE DATE; DURATION.—A temporary order issued under subparagraph (A)—

''(i) shall take effect not earlier than 30 days after the date of publication by

the Attorney General of a notice in the Federal Register of—

"(I) the intention of the Attorney General to issue the temporary order; and

"(II) the grounds on which the temporary order is to be issued; and

"(ii) shall expire not later than 2 years after the date on which the temporary order becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (2), extend the temporary order for not more than 6 months.

"(C) NOTICE TO SECRETARY.—

"(i) IN GENERAL.—The Attorney General shall transmit notice of a temporary order proposed to be issued under subparagraph (A) to the Secretary.

"(ii) CONSIDERATION.—In issuing a temporary order under subparagraph (A), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted under this subparagraph.

''(D) EFFECT OF PERMANENT SCHEDULING.—A temporary order issued under subparagraph (A) shall be vacated upon the issuance of a permanent order under paragraph (2).

''(E) JUDICIAL REVIEW.—A temporary order issued under subparagraph (A) shall not be subject to judicial review.

''(2) PERMANENT ORDERS.—

''(A) IN GENERAL.—The Attorney General may by rule issue a permanent order adding a drug or other substance to the definition of the term 'SARM' under section 102(60) if the drug or other substance satisfies the criteria for being considered a SARM under that section.

''(B) TIMING.—The Attorney General may commence a rulemaking under subparagraph (A) simultaneously with the issuance of a temporary order under paragraph (1).''.

(d) LABELING REQUIREMENTS.—

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

''(f) FALSE LABELING OF SARMS.—

''(1) PROHIBITION.—It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a SARM or product containing a SARM, unless the SARM or product containing the SARM bears a label clearly identifying the SARM or product containing the SARM by the nomenclature used by the International Union of Pure and Applied Chemistry.

''(2) EXEMPTION.—

''(A) IN GENERAL.—A SARM or product containing a SARM described in subparagraph (B) shall be exempt from the International Union of Pure and Applied Chemistry nomenclature requirement under paragraph (1) if the SARM or product containing a SARM is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

''(B) EXEMPT PRODUCTS.—A SARM or product containing a SARM is described in this subparagraph if the SARM or product containing a SARM—

''(i) is the subject of an approved application as described in subsection (b) or

(j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

''(ii) is exempt from the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) relating to new drugs because—

''(I) the SARM or product containing a SARM is intended solely for investigational use as described in subsection (i) of that section; and

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

(2) CLARIFICATION REGARDING FELONY DRUG OFFENSES.—Section 102(44) of the Controlled Substances Act (21 U.S.C. 802(44)) is amended by inserting ''SARMs,'' after ''anabolic steroids,''.

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

(A) in subsection (a)(16)—

(i) by inserting ''or (f)'' after ''subsection (e)''; and

(ii) by striking ''825'' and inserting ''305''; and

(B) in subsection (c)(1)(D), by inserting ''or a SARM'' after ''an anabolic steroid''.

SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Section 413(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b(c)) is amended—

(1) in paragraph (1), by striking ''an anabolic steroid or an analogue of an anabolic steroid'' and inserting ''an anabolic steroid, a SARM, an analogue of an anabolic steroid, or an analogue of a SARM''; and

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''and'' at the end;

(B) in subparagraph (B), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following:

''(C) the term 'analogue of a SARM' means a substance that has a chemical struc-

ture that is substantially similar to the chemical structure of a SARM; and

"(D) the term 'SARM' has the meaning given the term in section 102(60) of the Controlled Substances Act (21 U.S.C. 802(60))."

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