

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

A BILL

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

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 “Selective Androgen Re-
5 ceptor Modulators Control Act of 2019” or the “SARMs
6 Control Act of 2019”.

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

8 **ACT.**

9 (a) DEFINITION.—Section 102 of the Controlled Sub-
10 stances Act (21 U.S.C. 802) is amended—

1 (1) by redesignating paragraph (58) as para-
2 graph (59);

3 (2) by redesignating the second paragraph des-
4 igned as paragraph (57) as paragraph (58);

5 (3) by moving paragraphs (57), (58) (as so re-
6 designated), and (59) (as so redesignated) 2 ems to
7 the left; and

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

9 “(60)(A) The term ‘SARM’—

10 “(i) means any drug or other substance that is
11 a selective androgen receptor agonist chemically un-
12 related to testosterone, estrogens, progestins,
13 corticosteroids, and dehydroepiandrosterone; and

14 “(ii) includes—

15 “(I) (S)-N-(4-cyano-3-(trifluorometh-
16 yl)phenyl)-3-(4-cyanophenoxy)-2-hydroxy-2-
17 methylpropanamide (commonly known as
18 ‘ostarine’ or ‘enobosarm’);

19 “(II) 4-((R)-2-((R)-2,2,2-trifluoro-1-hy-
20 droxyethyl)pyrrolidin-1-yl)-2-(trifluorometh-
21 yl)benzotrile (commonly known as ‘LGD-
22 4033’ or ‘ligandrol’);

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

1 f]quinolin-7-one (commonly known as ‘LGD-
2 3303’);

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

7 “(V) 2-chloro-4-(((1R,2S)-1-(5-(4-cyano-
8 phenyl)-1,3,4-oxadiazol-2-yl)-2-hydroxypro-
9 pyl)amino)-3-methylbenzonitrile (commonly
10 known as ‘RAD-140’);

11 “(VI) (S)-3-(4-acetamidophenoxy)-2-hy-
12 droxy-2-methyl-N-(4-nitro-3-(trifluorometh-
13 yl)phenyl)propanamide (commonly known as
14 ‘andarine’);

15 “(VII) 2-chloro-4-((7R,7aS)-7-hydroxy-1,3-
16 dioxotetrahydro-1H-pyrrolo[1,2-c]imidazol-
17 2(3H)-yl)-3-methylbenzonitrile (commonly
18 known as ‘BMS-564929’);

19 “(VIII) 6-ethyl-4-(trifluoromethyl)-6,7,8,9-
20 tetrahydropyrido[3,2-g]quinolin-2(1H)-one
21 (commonly known as ‘LG-121071’);

22 “(IX) (S)-3-(4-chloro-3-fluorophenoxy)-N-
23 (4-cyano-3-(trifluoromethyl)phenyl)-2-hydroxy-
24 2-methylpropanamide (commonly known as ‘S-
25 23’); and

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

4 “(B) A substance excluded under subparagraph
5 (A)(i) may at any time be scheduled by the Attorney Gen-
6 eral in accordance with the authority and requirements
7 under subsections (a) through (c) of section 201.

8 “(C)(i) A drug or other substance (other than estro-
9 gens, progestins, corticosteroids, and dehydroepiandroster-
10 one, unless scheduled under subparagraph (B)) that is not
11 listed in subparagraph (A)(ii) and is derived from, or has
12 a chemical structure substantially similar to, one or more
13 SARMs listed in subparagraph (A)(ii) shall be considered
14 to be a SARM for purposes of this title if the drug or
15 other substance—

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

18 “(aa) promotes muscle growth; or

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

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

1 “(ii) A drug or other substance shall not be consid-
 2 ered to be a SARM for purposes of this subparagraph if
 3 the drug or other substance—

4 “(I) is—

5 “(aa) an herb or other botanical;

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

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

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

14 “(III) is not anabolic or androgenic.

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

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

23 “(f) SARMS.”.

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

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

3 “(k) TEMPORARY AND PERMANENT SCHEDULING OF
4 RECENTLY EMERGED SARMS.—

5 “(1) TEMPORARY ORDERS.—

6 “(A) IN GENERAL.—The Attorney General
7 may issue a temporary order adding a drug or
8 other substance to the definition of the term
9 ‘SARM’ under section 102(60) if the Attorney
10 General finds that—

11 “(i) the drug or other substance satis-
12 fies the criteria for being considered a
13 SARM but is not listed in that section or
14 by regulation of the Attorney General as
15 being a SARM; and

16 “(ii) adding the drug or other sub-
17 stance to the definition of the term SARM
18 will assist in preventing abuse or misuse of
19 the drug or other substance.

20 “(B) EFFECTIVE DATE; DURATION.—A
21 temporary order issued under subparagraph
22 (A)—

23 “(i) shall take effect not earlier than
24 30 days after the date of publication by

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

3 “(I) the intention of the Attorney
4 General to issue the temporary order;
5 and

6 “(II) the grounds on which the
7 temporary order is to be issued; and

8 “(ii) shall expire not later than 2
9 years after the date on which the tem-
10 porary order becomes effective, except that
11 the Attorney General may, during the
12 pendency of proceedings under paragraph
13 (2), extend the temporary order for not
14 more than 6 months.

15 “(C) NOTICE TO SECRETARY.—

16 “(i) IN GENERAL.—The Attorney
17 General shall transmit notice of a tem-
18 porary order proposed to be issued under
19 subparagraph (A) to the Secretary.

20 “(ii) CONSIDERATION.—In issuing a
21 temporary order under subparagraph (A),
22 the Attorney General shall take into con-
23 sideration any comments submitted by the
24 Secretary in response to a notice trans-
25 mitted under this subparagraph.

1 “(D) EFFECT OF PERMANENT SCHED-
 2 ULING.—A temporary order issued under sub-
 3 paragraph (A) shall be vacated upon the
 4 issuance of a permanent order under paragraph
 5 (2).

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

9 “(2) PERMANENT ORDERS.—

10 “(A) IN GENERAL.—The Attorney General
 11 may by rule issue a permanent order adding a
 12 drug or other substance to the definition of the
 13 term ‘SARM’ under section 102(60) if the drug
 14 or other substance satisfies the criteria for
 15 being considered a SARM under that section.

16 “(B) TIMING.—The Attorney General may
 17 commence a rulemaking under subparagraph
 18 (A) simultaneously with the issuance of a tem-
 19 porary order under paragraph (1).”.

20 (d) LABELING REQUIREMENTS.—

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

24 “(f) FALSE LABELING OF SARMS.—

1 “(1) PROHIBITION.—It shall be unlawful to im-
2 port, export, manufacture, distribute, dispense, or
3 possess with intent to manufacture, distribute, or
4 dispense, a SARM or product containing a SARM,
5 unless the SARM or product containing the SARM
6 bears a label clearly identifying the SARM or prod-
7 uct containing the SARM by the nomenclature used
8 by the International Union of Pure and Applied
9 Chemistry.

10 “(2) EXEMPTION.—

11 “(A) IN GENERAL.—A SARM or product
12 containing a SARM described in subparagraph
13 (B) shall be exempt from the International
14 Union of Pure and Applied Chemistry nomen-
15 clature requirement under paragraph (1) if the
16 SARM or product containing a SARM is la-
17 beled in the manner required under the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 301
19 et seq.).

20 “(B) EXEMPT PRODUCTS.—A SARM or
21 product containing a SARM is described in this
22 subparagraph if the SARM or product con-
23 taining a SARM—

24 “(i) is the subject of an approved ap-
25 plication 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 con-
taining a SARM is intended solely for
investigational use as described in
subsection (i) of that section; and

“(II) the SARM or product con-
taining a SARM is being used exclu-
sively for purposes of a clinical trial
that is the subject of an effective in-
vestigational new drug application.”.

(2) CLARIFICATION REGARDING FELONY DRUG
OFFENSES.—Section 102(44) of the Controlled Sub-
stances Act (21 U.S.C. 802(44)) is amended by in-
serting “SARMs,” after “anabolic steroids,”.

(3) CIVIL PENALTIES.—Section 402 of the Con-
trolled Substances Act (21 U.S.C. 842) is amend-
ed—

(A) in subsection (a)(16)—

1 (i) by inserting “or (f)” after “sub-
2 section (e)”; and

3 (ii) by striking “825” and inserting
4 “305”; and

5 (B) in subsection (c)(1)(D), by inserting
6 “or a SARM” after “an anabolic steroid”.

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

9 Section 413(c) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 350b(c)) is amended—

11 (1) in paragraph (1), by striking “an anabolic
12 steroid or an analogue of an anabolic steroid” and
13 inserting “an anabolic steroid, a SARM, an analogue
14 of an anabolic steroid, or an analogue of a SARM”;
15 and

16 (2) in paragraph (2)—

17 (A) in subparagraph (A), by striking
18 “and” at the end;

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

22 (C) by adding at the end the following:

23 “(C) the term ‘analogue of a SARM’
24 means a substance that has a chemical struc-

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

3 “(D) the term ‘SARM’ has the meaning
4 given the term in section 102(60) of the Con-
5 trolled Substances Act (21 U.S.C. 802(60)).”.

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