

115TH CONGRESS
2D SESSION

S. 2742

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

APRIL 24, 2018

Mr. HATCH (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 2018” or the “SARMs
6 Control Act of 2018”.

1 **SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES**
 2 **ACT.**

3 (a) DEFINITION.—Section 102 of the Controlled Sub-
 4 stances Act (21 U.S.C. 802) is amended by adding at the
 5 end the following:

6 “(57)(A) The term ‘SARM’—

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

11 “(ii) includes—

12 “(I) (S)-N-(4-cyano-3-
 13 (trifluoromethyl)phenyl)-3-(4-cyanophenoxy)-2-
 14 hydroxy-2-methylpropanamide (commonly
 15 known as ‘ostarine’ or ‘enobosarm’);

16 “(II) 4-((R)-2-((R)-2,2,2-trifluoro-1-hy-
 17 droxyethyl)pyrrolidin-1-yl)-2-
 18 (trifluoromethyl)benzotrile (commonly known
 19 as ‘LGD-4033’ or ‘ligandrol’);

20 “(III) 9-chloro-2-ethyl-1-methyl-3-(2,2,2-
 21 trifluoroethyl)-3,6-dihydro-7H-pyrrolo[3,2-
 22 f]quinolin-7-one (commonly known as ‘LGD-
 23 3303’);

24 “(IV) isopropyl (S)-(7-cyano-4-(pyridin-2-
 25 ylmethyl)-1,2,3,4-tetrahydrocyclopenta[b]indol-2

1 -yl)carbamate (commonly known as
2 ‘LY2452473’ or ‘TT701’);

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

7 “(VI) (S)-3-(4-acetamidophenoxy)-2-hy-
8 droxy-2-methyl-N-(4-nitro-3-
9 (trifluoromethyl)phenyl)propanamide (com-
10 monly known as ‘andarine’);

11 “(VII) 2-chloro-4-((7R,7aS)-7-hydroxy-1,3-
12 dioxotetrahydro-1H-pyrrolo[1,2-c]imidazol-
13 2(3H)-yl)-3-methylbenzonitrile (commonly
14 known as ‘BMS-564929’);

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

18 “(IX) (S)-3-(4-chloro-3-fluorophenoxy)-N-
19 (4-cyano-3-(trifluoromethyl)phenyl)-2-hydroxy-
20 2-methylpropanamide (commonly known as ‘S-
21 23’); and

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

1 “(B) A substance excluded under subparagraph
2 (A)(i) may at any time be scheduled by the Attorney Gen-
3 eral in accordance with the authority and requirements
4 under subsections (a) through (c) of section 201 (21
5 U.S.C. 811).

6 “(C)(i) A drug or other substance (other than estro-
7 gens, progestins, corticosteroids, and
8 dehydroepiandrosterone, unless scheduled under subpara-
9 graph (B)) that is not listed in subparagraph (A)(ii) and
10 is derived from, or has a chemical structure substantially
11 similar to, 1 or more SARMs listed in subparagraph
12 (A)(ii) shall be considered to be a SARM for purposes of
13 this title if the drug or other substance—

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

16 “(aa) promotes muscle growth; or

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

19 “(II) has been, or is intended to be, marketed
20 or otherwise promoted in any manner suggesting
21 that consuming the drug or other substance will pro-
22 mote muscle growth or any other pharmacological
23 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 2 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(57) 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 OF HEALTH
16 AND HUMAN SERVICES.—

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

22 “(ii) CONSIDERATION.—In issuing a
23 temporary order under subparagraph (A),
24 the Attorney General shall take into con-
25 sideration any comments submitted by the

1 Secretary of Health and Human Services
2 in response to a notice transmitted under
3 this subparagraph.

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

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

12 “(2) PERMANENT ORDERS.—

13 “(A) IN GENERAL.—The Attorney General
14 may by rule issue a permanent order adding a
15 drug or other substance to the definition of the
16 term ‘SARM’ under section 102(57) if the drug
17 or other substance satisfies the criteria for
18 being considered a SARM under that section.

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

23 (d) LABELING REQUIREMENTS.—

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

4 “(f) FALSE LABELING OF SARMS.—

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

14 “(2) EXEMPTION.—

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

24 “(B) EXEMPT PRODUCTS.—A SARM or
25 product containing a SARM is described in this

1 subparagraph if the SARM or product con-
2 taining a SARM—

3 “(i) is the subject of an approved ap-
4 plication as described in subsection (b) or
5 (j) of section 505 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355);
7 or

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

12 “(I) the SARM or product con-
13 taining a SARM is intended solely for
14 investigational use as described in
15 subsection (i) of that section; and

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

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

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

4 (A) in subsection (a)(16)—

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

7 (ii) by striking “825” and inserting
8 “305”; and

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

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

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

15 (1) in paragraph (1), by striking “an anabolic
16 steroid or an analogue of an anabolic steroid” and
17 inserting “an anabolic steroid, a SARM, an analogue
18 of an anabolic steroid, or an analogue of a SARM”;
19 and

20 (2) in paragraph (2)—

21 (A) in subparagraph (A), by striking
22 “and” at the end;

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

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

2 “(C) the term ‘analogue of a SARM’
3 means a substance that has a chemical struc-
4 ture that is substantially similar to the chemical
5 structure of a SARM; and

6 “(D) the term ‘SARM’ has the meaning
7 given the term in section 102(57) of the Con-
8 trolled Substances Act (21 U.S.C. 802(57)).”.

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