

115TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

Mr. HATCH introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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## **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-

1 2-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-methylbenz onitrile  
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-methylbenz onitrile (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’); and

18 “(IX) any salt, ester, ether, or substituted  
19 analogue of a drug or other substance described  
20 in subclauses (I) through (VIII).

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

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

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

11                   “(aa) promotes muscle growth; or

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

14           “(II) has been, or is intended to be, marketed  
15       or otherwise promoted in any manner suggesting  
16       that consuming the drug or other substance will pro-  
17       mote muscle growth or any other pharmacological  
18       effect similar to that of testosterone.

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

22                   “(I) is—

23                   “(aa) an herb or other botanical;

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

4           “(cc) a combination of 2 or more sub-  
5           stances described in item (aa) or (bb);

6           “(II) is a dietary ingredient for purposes of the  
7           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8           301 et seq.); and

9           “(III) is not anabolic or androgenic.

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

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

18           “(f) SARMS.”.

19          (c) TEMPORARY AND PERMANENT SCHEDULING OF  
20          RECENTLY EMERGED SARMS.—Section 201 of the Con-  
21          trolled Substances Act (21 U.S.C. 811) is amended by  
22          adding at the end the following:

23           “(k) TEMPORARY AND PERMANENT SCHEDULING OF  
24          RECENTLY EMERGED SARMS.—

25           “(1) TEMPORARY ORDERS.—

1           “(A) IN GENERAL.—The Attorney General  
2           may issue a temporary order adding a drug or  
3           other substance to the definition of the term  
4           ‘SARM’ under section 102(57) if the Attorney  
5           General finds that—

6                   “(i) the drug or other substance satis-  
7                   fies the criteria for being considered a  
8                   SARM but is not listed in that section or  
9                   by regulation of the Attorney General as  
10                  being a SARM; and

11                   “(ii) adding the drug or other sub-  
12                   stance to the definition of the term SARM  
13                   will assist in preventing abuse or misuse of  
14                   the drug or other substance.

15           “(B) EFFECTIVE DATE; DURATION.—A  
16           temporary order issued under subparagraph  
17           (A)—

18                   “(i) shall take effect not earlier than  
19                   30 days after the date of publication by  
20                   the Attorney General of a notice in the  
21                   Federal Register of—

22                           “(I) the intention of the Attorney  
23                           General to issue the temporary order;  
24                           and

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

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

10                  “(C) NOTICE TO SECRETARY OF HEALTH  
11                  AND HUMAN SERVICES.—

12                   “(i) IN GENERAL.—The Attorney  
13                   General shall transmit notice of a tem-  
14                   porary order proposed to be issued under  
15                   subparagraph (A) to the Secretary of  
16                   Health and Human Services.

17                   “(ii) CONSIDERATION.—In issuing a  
18                   temporary order under subparagraph (A),  
19                   the Attorney General shall take into con-  
20                   sideration any comments submitted by the  
21                   Secretary of Health and Human Services  
22                   in response to a notice transmitted under  
23                   this subparagraph.

24                   “(D) EFFECT OF PERMANENT SCHED-  
25                   ULING.—A temporary order issued under sub-

1 paragraph (A) shall be vacated upon the  
2 issuance of a permanent order issued under  
3 paragraph (2).

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

7 “(2) PERMANENT ORDERS.—

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

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

18 (d) LABELING REQUIREMENTS.—

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

22 “(f) FALSE LABELING OF SARMS.—

23 “(1) PROHIBITION.—It shall be unlawful to im-  
24 port, export, manufacture, distribute, dispense, or  
25 possess with intent to manufacture, distribute, or



1 dispense, a SARM or product containing a SARM,  
2 unless the SARM or product containing the SARM  
3 bears a label clearly identifying the SARM or prod-  
4 uct containing the SARM by the nomenclature used  
5 by the International Union of Pure and Applied  
6 Chemistry.

7 “(2) EXEMPTION.—

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

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

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

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

5 “(I) the SARM or product con-  
6 taining a SARM is intended solely for  
7 investigational use as described in  
8 subsection (i) of that section; and

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

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

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

21 (A) in subsection (a)(16)—

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

24 (ii) by striking “825” and inserting  
25 “305”; and

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

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

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

7 (1) in paragraph (1), by striking “an anabolic  
8 steroid or an analogue of an anabolic steroid” and  
9 inserting “an anabolic steroid, a SARM, an analogue  
10 of an anabolic steroid, or an analogue of a SARM”;  
11 and

12 (2) in paragraph (2)—

13 (A) in subparagraph (A), by striking  
14 “and” at the end;

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

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

19 “(C) the term ‘analogue of a SARM’  
20 means a substance that has a chemical struc-  
21 ture that is substantially similar to the chemical  
22 structure of a SARM; and

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