# <sup>115TH CONGRESS</sup> 2D SESSION S. 3773

To require review and approval for future research on nonhuman primates, and for other purposes.

#### IN THE SENATE OF THE UNITED STATES

DECEMBER 18, 2018

Mr. BOOKER introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

## A BILL

To require review and approval for future research on nonhuman primates, 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 "Primate Protection

5 and Research Modernization Act of 2018".

#### 6 SEC. 2. FINDINGS.

7 Congress finds that—

8 (1) numerous recent high-profile research stud9 ies involving nonhuman primates, both in private
10 and government facilities, raise serious concerns

1	about animal welfare, government waste, and the
2	scientific validity of the studies;
3	(2) most nonhuman primates used in research
4	are owned or financially supported by the Federal
5	Government;
6	(3) nonhuman primates are highly intelligent
7	and social animals, and most research laboratory en-
8	vironments do not meet the complex physical, social,
9	and psychological needs of nonhuman primates;
10	(4) the Institute of Medicine and National Re-
11	search Council report entitled "Chimpanzees in Bio-
12	medical and Behavioral Research" concluded that
13	while the chimpanzee has been a valuable research
14	model in the past, most current uses of chimpanzees
15	are unnecessary;
16	(5) the concerns relating to the scientific valid-
17	ity of using chimpanzees to model human disease
18	are magnified in the case of research involving other
19	nonhuman primates, with whom humans are even
20	less genetically and morphologically similar;
21	(6) nonhuman primate research is very often
22	not effective in leading to treatments for humans, as
23	demonstrated by high failure rates for new drugs
24	and the nonreproducibility of preclinical research re-
25	sults;

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1 (7) alternatives to nonhuman primate research 2 such as organs-on-chips technology and computer modeling are now available; and 3 4 (8) nonhuman primates should only be used in 5 research to fulfill an important public health objec-6 tive and if no alternative research method exists. 7 **SEC. 3. DEFINITIONS.** 8 In this Act: 9 (1) ACTIVE PROTOCOL.—The term "active pro-10 tocol" means a valid, non-expired experimental plan 11 approved by the animal use committee of a research 12 institution. 13 (2) ETHOLOGICALLY APPROPRIATE ENVIRON-14 MENT.—The term "ethologically appropriate environment" means a set of species-specific standards 15 16 for the living conditions for captive nonhuman pri-17 mates that— 18 (A) is informed by scientific evidence and 19 expertise from animal behaviorists; 20 (B) promotes the full range of the natural 21 cognitive abilities of the nonhuman primate, in-22 cluding healthy outlets to fulfill needs for in-23 quisitiveness and inventiveness; 24 (C) comports with the natural social ar-25 rangements of the nonhuman primate as ob-

1	served in the wild, including the preservation of
2	healthy maternal relationships, familial groups,
3	colonies, and pair-bonds;
4	(D) consists of a secure, contained physical
5	habitat that, at a minimum—
6	(i) is sufficiently complex and appro-
7	priately sized so that the inhabitants can
8	establish and maintain stable dominance
9	hierarchies, including the provision of se-
10	cluded areas for submissive individuals to
11	escape or hide from aggressors;
12	(ii) has access to the outdoors with
13	complex, natural features and substrates,
14	such as grass, dirt, mulch, and vegetation;
15	(iii) provides foraging opportunities
16	and diets that are varied, nutritious, and
17	challenging to obtain; and
18	(iv) includes not fewer than 1 climb-
19	ing structure of sufficient height and com-
20	plexity such that multiple individuals can
21	climb or descend at the same time, with
22	the ability to rest on separate tiers; and
23	(E) offers frequently changed enrichment
24	that provides ample opportunities for inter-
25	action, choice, and self-determination.

(3) NONHUMAN PRIMATE.—The term
 "nonhuman primate" means any living animal of the
 taxonomic order Primates except for individuals who
 belong to the genus Homo.

5 (4) NONHUMAN PRIMATE RESEARCH.—The 6 term "nonhuman primate research" means any re-7 search performed involving a nonhuman primate, in-8 cluding basic research, translational or applied re-9 search, observational research of nonhuman pri-10 mates in captivity, testing, or other scientific proce-11 dures.

12 (5) PERSON.—The term "person" means—

13 (A) an individual, corporation, partnership,
14 trust, association, or any other private or non15 profit entity;

16 (B) any officer, employee, agent, depart17 ment, or instrumentality of the Federal Govern18 ment, a State, a political subdivision of a State,
19 or a unit of local government; or

20 (C) any other entity subject to the jurisdic-21 tion of the United States.

(6) STANDING COMMITTEE.—The term "standing committee" means the committee established
under section 6(a).

1	(7) SUITABLE SANCTUARY.—The term "suit-
2	able sanctuary" means a nonprofit organization
3	that—
4	(A) operates a place of refuge where
5	abused, neglected, unwanted, impounded, aban-
6	doned, orphaned, displaced, or retired animals
7	are provided care for the lifetime of the animal;
8	(B) does not conduct research on the ani-
9	mals that involves accompanying pain or dis-
10	tress;
11	(C) does not conduct any commercial activ-
12	ity with respect to the animals, including, at a
13	minimum—
14	(i) the sale, trade, auction, lease, or
15	loan of animals or animal parts; or
16	(ii) the use of animals in any manner
17	in a for-profit business or operation;
18	(D) does not use the animals for entertain-
19	ment purposes or in a traveling exhibit;
20	(E) does not breed any animals, whether
21	intentionally or by failing to use adequate birth
22	control methods;
23	(F) does not allow members of the public
24	the opportunity to come into physical contact
25	with the animals; and

1	(G) provides an ethologically appropriate
2	environment.
3	(8) Systematic review.—The term "system-
4	atic review" means an analysis of evidence that is
5	conducted based on a predetermined, comprehensive
6	search strategy, which is designed—
7	(A) to capture all appropriate studies; and
8	(B) to reduce bias in analyzing the data
9	gleaned from those studies.
10	SEC. 4. SYSTEMATIC REVIEWS BY THE NATIONAL ACADEMY
11	OF SCIENCES.
12	(a) PREEXISTING FIELDS OF RESEARCH.—
13	(1) IN GENERAL.—Not later than 180 days
14	after the date of enactment of this Act, the National
15	Academy of Sciences shall conduct a systematic re-
16	view for each preexisting field of research in which
17	the field of research has conducted nonhuman pri-
18	mate research to determine whether the nonhuman
19	primate research has, with respect to the field of re-
20	search—
21	(A) an established history of advancing
22	that field of research; and
23	(B) resulted in meaningful clinical inter-
24	ventions.

(2) CONTINUED REVIEW.—For any preexisting
 field of research for which a systematic review under
 paragraph (1) has concluded that the use of
 nonhuman primates meets the requirements de scribed in subparagraphs (A) and (B) of paragraph
 (1), a systematic review shall be reconducted every
 5 years.

8 (b) NEW FIELDS OF RESEARCH.—For any new field 9 of research in which the standing committee approves the 10 use of nonhuman primates, the National Academy of 11 Sciences shall, on request of the standing committee, con-12 duct a systematic review to determine whether the 13 nonhuman primate research has—

14 (1) advanced that field of research; and

15 (2) resulted in meaningful clinical interventions.

### 16 SEC. 5. PROHIBITIONS.

17 (a) PROHIBITED NONHUMAN PRIMATE RESEARCH.—

18 (1) IN GENERAL.—Subject to paragraph (2), no
19 person shall perform any nonhuman primate re20 search unless that person has received prior approval
21 for the nonhuman primate research from the stand22 ing committee.

23 (2) EXCEPTION.—During the period ending on
24 the date that is 2 years after the date of enactment
25 of this Act, the prohibition under paragraph (1)—

1	(A) shall not apply to any active protocol
2	commenced prior to the date of enactment of
3	this Act; but
4	(B) shall apply to any renewal of an active
5	protocol.
6	(b) PROHIBITION ON FOREIGN GRANTS.—No Fed-
7	eral funds may be awarded to a foreign organization or
8	entity—
9	(1) to support nonhuman primate research; or
10	(2) to support an entity conducting nonhuman
11	primate research.
12	(c) Restriction on Domestic Awards.—
13	(1) IN GENERAL.—No Federal funds may be
14	awarded to any domestic organization to support
15	nonhuman primate research unless the nonhuman
16	primate research has received prior approval from
17	the standing committee.
18	(2) EXCEPTION.—The prohibition under para-
19	graph $(1)$ —
20	(A) shall not apply to any awards or funds
21	allocated prior to the date of enactment of this
22	Act; but
23	(B) shall apply to any renewal of a
24	nonhuman primate research project funded
25	prior to the date of enactment of this Act.

1 (d) CONSUMER PRODUCTS.—Nonhuman primate re-2 search for consumer goods and products, including 3 nonhuman primate research to compare 1 consumer prod-4 uct with another consumer product for marketing pur-5 poses, is prohibited.

6 (e) TRANSFER OF OWNERSHIP PROHIBITED.—No
7 Federal agency may transfer ownership of a nonhuman
8 primate to a non-Federal entity unless the non-Federal en9 tity is a suitable sanctuary.

10 (f) EXEMPTIONS.—Nothing in this section limits or11 prevents—

(1) individualized medical care performed on a
nonhuman primate by a licensed veterinarian or physician conducted for the well-being of the individual
nonhuman primate, including a surgical procedure
or a chemical treatment for birth control; or

17 (2) the collection of biological samples to fur18 ther the well-being of an individual nonhuman pri19 mate or a social group of nonhuman primates.

#### 20 SEC. 6. STANDING COMMITTEE.

(a) ESTABLISHMENT.—Not later than 1 year after
the date of enactment of this Act, the Secretary of Health
and Human Services shall convene a standing committee
to assess proposals for new nonhuman primate research,
in accordance with the criteria described in subsection (c).

1 (b) Composition.—

2	(1) DEFINITION OF ADVANCED EXPERTISE IN
3	NONANIMAL RESEARCH METHODS.—In this sub-
4	section, the term "advanced expertise in nonanimal
5	research methods", with respect to an individual,
6	means that not less than 50 percent of the body of
7	work of the individual is completed using nonanimal
8	research methodologies.
9	(2) REQUIREMENTS.—With respect to the
10	membership of the standing committee—
11	(A) $\frac{1}{4}$ shall be Federal employees of the
12	Department of Health and Human Services, the
13	Department of Veterans Affairs, or the Depart-
14	ment of Defense;
15	(B) $\frac{1}{4}$ shall be ethologists or other individ-
16	uals who have expertise in the behavioral and
17	psychological needs of nonhuman primates, but
18	do not use or directly benefit from the use of
19	nonhuman primates in invasive experimen-
20	tation;
21	(C) $\frac{1}{4}$ shall be individuals who have ad-
22	vanced expertise in nonanimal research meth-
23	ods;
24	(D) $\frac{1}{8}$ shall be clinicians actively treating
25	human patients; and

1	(E) $\frac{1}{8}$ shall be individuals who represent
2	the interests of the nonhuman primates.
3	(c) Criteria for Approval of Research.—The
4	standing committee may not approve any nonhuman pri-
5	mate research unless—
6	(1) the standing committee determines that—
7	(A) the research is for the prevention, di-
8	agnosis, or treatment of debilitating or life-
9	threatening clinical conditions in human beings;
10	(B) no alternative research method exists;
11	and
12	(C) the nonhuman primates will be housed
13	in an ethologically appropriate environment;
14	and
15	(2) if the National Academy of Sciences has
16	commenced a systematic review under section 4 for
17	the field of research in which the use of a nonhuman
18	primate is being proposed, the systematic review
19	concluded that the use of nonhuman primates meets
20	the requirements described in subparagraphs (A)
21	and (B) of section $4(a)(1)$ .
22	SEC. 7. FUNDING CONSIDERATIONS.

All Federal funding for nonhuman primate research
provided after the date of enactment of this Act shall include funding for the eventual retirement of the nonhuman

primates used in the funded projects to a suitable sanc tuary.

#### **3** SEC. 8. PENALTIES AND ENFORCEMENT.

4 (a) CIVIL FINES.—Any person who violates this Act
5 may be assessed a civil penalty of up to \$10,000 per
6 nonhuman primate, per violation, per day.

7 (b) INELIGIBILITY FOR FEDERAL FUNDS.—Any per8 son who violates this Act shall be permanently precluded
9 from receiving Federal research funds.

(c) DISTRICT COURT JURISDICTION.—The district
courts of the United States shall have jurisdiction over any
actions arising under this Act.

13 (d) REWARDS AND CERTAIN INCIDENTAL EX-14 PENSES.—

(1) IN GENERAL.—The Attorney General shall
pay, from sums received as fines for any violation of
this Act, a reward to any person who furnishes information that leads to a civil fine.

19 (2) AMOUNT.—The amount of the reward is to20 be determined by the Attorney General.

21 (e) ENFORCEMENT.—

(1) IN GENERAL.—This Act shall be enforcedby the Attorney General.

24 (2) WARRANTS.—The judges of the district25 courts of the United States and the magistrate

1	judges may, within their respective jurisdictions, on
2	proper oath or affirmation showing probable cause,
3	issue any warrants or other process as may be re-
4	quired for enforcement of this Act.
5	(3) Forfeiture.—
6	(A) NONHUMAN PRIMATES.—Any
7	nonhuman primates used or held contrary to
8	the provisions of this Act shall be subject to
9	forfeiture to the United States and shall be
10	placed in a suitable sanctuary.
11	(B) Equipment.—Any equipment or other
12	materials used in the course of holding or using
13	nonhuman primates contrary to the provisions
14	of this Act shall be subject to forfeiture to the
15	United States.
16	(f) CITIZEN SUITS.—
17	(1) Civil action on own behalf.—Except as
18	provided in paragraph (3), any person may com-
19	mence a civil action on his or her own behalf to en-
20	join any person, including the United States and any
21	other governmental instrumentality or agency, who
22	is alleged to be in violation of any provision of this
23	Act.
24	(2) CIVIL ACTION ON BEHALF OF FEDERAL
25	GOVERNMENT.—

1	(A) IN GENERAL.—Except as provided in
2	paragraph (3), any person may commence a
3	civil action in the name of the Federal Govern-
4	ment against any person, except for the United
5	States and any other governmental instrumen-
6	tality or agency, who is alleged to be in viola-
7	tion of any provision of this Act, and may seek
8	injunctive relief and civil fines under that civil
9	action.
10	(B) FINES.—
11	(i) IN GENERAL.—A court may award
12	a person bringing a civil action under sub-
13	paragraph (A) an amount that the court
14	decides is reasonable for collecting the civil
15	fine under subsection (a).
16	(ii) LIMITATION.—The amount under
17	clause (i) shall be not less than 25 percent
18	and not more than 30 percent of the pro-
19	ceeds of the action or settlement and shall
20	be paid out of those proceeds.
21	(3) EXCEPTIONS.—No civil action may be com-
22	menced under paragraphs $(1)$ or $(2)$ —
23	(A) earlier than the date that is 60 days
24	after the date on which written notice of the
25	violation has been given to—

1	(i) the Attorney General; and
2	(ii) the alleged violator; or
3	(B) if the Department of Justice has com-
4	menced action to impose a civil fine under sub-
5	section (a).
6	(4) INTERVENTION.—In any suit under this
7	subsection in which the United States is not a party,
8	the Attorney General may intervene on behalf of the
9	United States as a matter of right.
10	(5) Costs of Litigation.—The court, in
11	issuing any final order in any suit brought under
12	this subsection, may award costs of litigation (in-
13	cluding reasonable attorney and expert witness fees)
14	to any party, if the court determines the award is
15	appropriate.

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