

118TH CONGRESS
1ST SESSION

S. 2397

To amend section 495 of the Public Health Service Act to require inspections of foreign laboratories conducting biomedical and behavioral research to ensure compliance with applicable animal welfare requirements, and for other purposes

IN THE SENATE OF THE UNITED STATES

JULY 19, 2023

Mr. SCHMITT (for himself and Mr. MERKLEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend section 495 of the Public Health Service Act to require inspections of foreign laboratories conducting biomedical and behavioral research to ensure compliance with applicable animal welfare requirements, 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 TITLES.**

4 This Act may be cited as the “Worldwide Animal
5 Testing Compliance and Harmonization Act of 2023” or
6 the “WATCH Act”.

1 **SEC. 2. FOREIGN LABORATORY INSPECTIONS AND CERTIFI-**
2 **CATION.**

3 (a) IN GENERAL.—Section 495 of the Public Health
4 Service Act (42 U.S.C. 289d) is amended by adding at
5 the end the following:

6 “(f) INSPECTION AND CERTIFICATION OF FOREIGN
7 LABORATORIES.—

8 “(1) IN GENERAL.—As a condition of eligibility
9 to perform research involving animals under a grant,
10 contract, or cooperative agreement administered by
11 the National Institutes of Health or any national re-
12 search institute, a laboratory located outside the
13 United States that receives Federal funds shall be
14 subject to quarterly inspections to evaluate compli-
15 ance with the requirements under this title.

16 “(2) INSPECTION AND CERTIFICATION RE-
17 QUIREMENTS.—

18 “(A) QUARTERLY INSPECTION PROCESS.—

19 The Secretary, in consultation with appropriate
20 foreign regulatory authorities and international
21 organizations, shall establish and implement a
22 process for conducting quarterly inspections of
23 foreign laboratories that have received an Ani-
24 mal Welfare Assurance (as defined in section
25 9.2 of title 42, Code of Federal Regulations) to

1 ensure their continued compliance with the re-
2 quirements under this title.

3 “(B) ASSURANCES.—The inspection proc-
4 ess established by the Secretary pursuant to
5 subparagraph (A) shall evaluate the compliance
6 of foreign laboratories with the requirements
7 under subsection (c)(1), including—

8 “(i) the establishment and operation
9 of animal care committees;

10 “(ii) the review and evaluation of ani-
11 mal care and treatment; and

12 “(iii) proper record-keeping and re-
13 porting procedures.

14 “(3) CERTIFICATION OF COMPLIANCE AND PUB-
15 LIC ACCESS.—

16 “(A) ISSUANCE.—Following each quarterly
17 inspection required under paragraph (2), the in-
18 specting authority shall issue a certification of
19 compliance to the laboratories determined to be
20 in compliance with the requirements under
21 paragraph (2)(B).

22 “(B) PUBLIC ACCESS.—Copies of the cer-
23 tificates of compliance issued pursuant to sub-
24 paragraph (A) shall be maintained by the Office
25 of Laboratory Animal Welfare and shall remain

1 publicly accessible with other information about
2 currently issued Animal Welfare Assurances.

3 “(C) CORRECTIVE ACTION.—Laboratories
4 that fail to comply with the requirements under
5 paragraph (2)(B) shall be given a reasonable
6 opportunity to take corrective action.

7 “(4) SUSPENSION OR REVOCATION OF GRANT
8 OR CONTRACT FOR NON-COMPLIANT FOREIGN LAB-
9 ORATORIES.—If the Secretary determines that a for-
10 eign facility is not in compliance with the require-
11 ments under subsection (c)(1) and does not take ap-
12 propriate corrective action after given a reasonable
13 opportunity to do so, the Secretary shall suspend or
14 revoke the applicable grant, contract, or cooperative
15 agreement involving research on animals under such
16 conditions as the Director of NIH determines appro-
17 priate, in accordance with subsection (d).

18 “(5) DESIGNATION OF INSPECTING AUTHOR-
19 ITY.—The Secretary, in consultation with the Direc-
20 tor of NIH, shall designate an appropriate authority
21 to conduct the quarterly inspections required under
22 paragraph (2) and issue certifications of compliance
23 in accordance with paragraph (3).

24 “(6) COORDINATION WITH FOREIGN AUTHORI-
25 TIES.—The Secretary and the Director of NIH shall

1 coordinate with appropriate foreign regulatory au-
2 thorities and enter into agreements with foreign gov-
3 ernments, as needed, to facilitate the implementation
4 and enforcement of this subsection, while respecting
5 the sovereignty and laws of foreign nations.”.

6 (b) EFFECTIVE DATE.—The amendment made by
7 subsection (a) shall take effect on the date that is 180
8 days after the date of the enactment of this Act.

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