117TH CONGRESS 1ST SESSION

H. R. 5515

To direct the Secretary of Health and Human Services to ensure that certain biomedical research is conducted in a manner that considers national security risks, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

October 8, 2021

Mr. Dunn introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

- To direct the Secretary of Health and Human Services to ensure that certain biomedical research is conducted in a manner that considers national security risks, 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 "Protecting Americans"
 - 5 Genomic Information Act of 2021".

1	SEC. 2. SECURING IDENTIFIABLE, SENSITIVE INFORMA-
2	TION.
3	(a) Consideration of National Security
4	Risks.—
5	(1) IN GENERAL.—The Secretary of Health and
6	Human Services (referred to in this section as the
7	"Secretary"), in consultation with the Director of
8	National Intelligence, the Secretary of State, the
9	Secretary of Defense, and other national security ex-
10	perts, as appropriate, shall ensure that biomedical
11	research described in paragraph (2) is conducted in
12	a manner that appropriately considers national secu-
13	rity risks, including national security implications re-
14	lated to potential misuse of such data.
15	(2) BIOMEDICAL RESEARCH DESCRIBED.—For
16	purposes of paragraph (1), biomedical research is
17	described in this paragraph if it—
18	(A) is conducted or supported, directly or
19	indirectly, including through subgrants, by the
20	National Institutes of Health or other relevant
21	agencies and offices within the Department of
22	Health and Human Services; and
23	(B) involves the sequencing of human
24	genomic information, and collection, analysis, or
25	storage of identifiable, sensitive information, as

1	defined in section 301(d)(4) of the Public
2	Health Service Act (42 U.S.C. 241(d)(4)).
3	(b) RISK FRAMEWORK.—Not later than 2 years after
4	the date of enactment of this Act, the Secretary shall en-
5	sure that the National Institutes of Health and other rel-
6	evant agencies and offices within the Department of
7	Health and Human Services, working with the heads of
8	agencies and national security experts, including the Of-
9	fice of the National Security within the Department of
10	Health and Human Services—
11	(1) develop a comprehensive framework for as-
12	sessing and managing national security risks re-
13	ferred to in subsection (a) that includes—
14	(A) criteria for how and when to conduct
15	risk assessments for projects that may have na-
16	tional security implications;
17	(B) security controls and training for re-
18	searchers or entities, including peer reviewers,
19	that manage or have access to such data; and
20	(C) methods to incorporate risk-reduction
21	in the process for funding such projects that
22	may have national security implications;
23	(2) not later than 1 year after the risk frame-
24	work is developed under paragraph (1), develop and
25	implement controls to—

- 1 (A) ensure that researchers or entities that
 2 manage or have access to such data have com3 plied with the requirements of paragraph (1)
 4 and ongoing requirements with such paragraph;
 5 and
 - (B) ensure that data access committees reviewing data access requests for projects that may have national security risks, as appropriate, include members with expertise in current and emerging national security threats, in order to make appropriate decisions related to access to such identifiable, sensitive information; and
 - (3) not later than 2 years after the risk framework is developed under paragraph (1), update data access and sharing policies related to human genomic data, as appropriate, based on current and emerging national security threats.
- 19 (c) Congressional Briefing.—Not later than 2
 20 years after the date of enactment of this Act, the Sec21 retary shall provide a briefing to the Committee on
 22 Health, Education, Labor, and Pensions and the Select
 23 Committee on Intelligence of the Senate and the Com24 mittee on Energy and Commerce and the Permanent Se25 lect Committee on Intelligence of the House of Represent-

1 atives on the activities required under subsections (a) and

2 (b).

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