

117TH CONGRESS
1ST SESSION

S. _____

To authorize the use of drugs, vaccines, and medical technologies to expand military and civilian access to such products and to improve transparency in taxpayer-funded biomedical research investments by the Department of Defense, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Ms. WARREN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To authorize the use of drugs, vaccines, and medical technologies to expand military and civilian access to such products and to improve transparency in taxpayer-funded biomedical research investments by the Department of Defense, 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 “Make Taxpayer-Fund-
5 ed Department of Defense Medical Interventions Afford-
6 able Act”.

1 **SEC. 2. AUTHORIZATION OF USE OF DRUGS, VACCINES,**
2 **AND MEDICAL TECHNOLOGIES TO EXPAND**
3 **MILITARY AND CIVILIAN ACCESS TO SUCH**
4 **PRODUCTS.**

5 (a) REPORT AND IDENTIFICATION OF PRODUCTS.—

6 Not later than one year after the date of the enactment
7 of this Act, the Secretary of Defense shall submit to the
8 Committees on Armed Services of the Senate and the
9 House of Representatives a report on the efforts of the
10 Secretary to comply with the paragraph entitled, “Licens-
11 ing of Federally owned medical interventions” included on
12 page 173 of the report of the Committee on Armed Serv-
13 ices of the Senate to accompany the National Defense Au-
14 thorization Act for Fiscal Year 2018 (Public Law 115–
15 91), which shall include the following information:

16 (1) A description of what steps, if any, the Sec-
17 retary has taken to comply with that paragraph.

18 (2) A complete list of the drugs, vaccines, and
19 medical technologies that, as of the date of the en-
20 actment of this Act, meet the requirements outlined
21 in that paragraph.

22 (3) For each drug, vaccine, or medical tech-
23 nology identified under paragraph (2), a discussion
24 of the plans of the Secretary to utilize the authori-
25 ties of the Secretary under section 203 or 209(d)(1)
26 of title 35, United States Code, to authorize a third

1 party or Federal agency to use the drug, vaccine, or
2 medical technology.

3 (b) AUTHORIZATION OF USE.—Not later than one
4 year after the date of the enactment of this Act, the Sec-
5 retary of Defense, pursuant to section 203 or 209(d)(1)
6 of title 35, United States Code, shall authorize third par-
7 ties or Federal agencies to use not fewer than 10 drugs,
8 vaccines, or medical technologies identified under sub-
9 section (a)(2) for the purpose of expanding military and
10 civilian access to such drugs, vaccines, or technologies.

11 **SEC. 3. TRANSPARENCY IN TAXPAYER-FUNDED BIO-**
12 **MEDICAL RESEARCH INVESTMENTS BY THE**
13 **DEPARTMENT OF DEFENSE.**

14 (a) IN GENERAL.—The Secretary of Defense shall—

15 (1) compile into a searchable database informa-
16 tion relating to Federal support (before or after the
17 date of enactment of this Act) provided by the De-
18 partment of Defense or an entity acting on behalf of
19 the Department of Defense for biomedical research
20 and development, including drugs, vaccines, and
21 medical technologies; and

22 (2) make such database available on the public
23 website of the Department of Defense.

24 (b) COVERED INFORMATION.—The information relat-
25 ing to Federal support described in subsection (a)(1) shall

1 include all contracts, funding agreements, licensing ar-
2 rangements, other transactions, and other arrangements
3 entered into by, or on behalf of, the Department of De-
4 fense with respect to research and development, manufac-
5 turing, and distribution of a drug (including a biological
6 product), cell or gene therapy, medical device, or other
7 medical technology, including the following:

8 (1) Licensing agreements pursuant to section
9 207 or 209 of title 35, United States Code.

10 (2) Cooperative research and development
11 agreements and licensing agreements pursuant to
12 section 3710a of title 15, United States Code.

13 (3) Funding agreements, as defined in section
14 201 of title 35, United States Code.

15 (4) Transactions, contracts, grants, cooperative
16 agreements, other agreements, and other arrange-
17 ments entered into pursuant to the following:

18 (A) The Public Health Service Act (42
19 U.S.C. 201 et seq.), including sections 301,
20 319L, 421, and 480 of such Act (42 U.S.C.
21 241, 247d–7e, 285b–3, 287a).

22 (B) Section 105 of the National Institutes
23 of Health Reform Act of 2006 (42 U.S.C.
24 284n).

1 (C) Chapter 139 of title 10, United States
2 Code, including sections 2358, 2371, 2371a,
3 2371b, and 2373.

4 (c) INFORMATION REQUIRED.—Notwithstanding any
5 other provision of law, the Secretary of Defense shall in-
6 clude in the database under subsection (a), with regard
7 to each contract, funding agreement, licensing agreement,
8 other transaction, or other arrangement described in sub-
9 section (b), at least the following information:

10 (1) The agency, program, institute, or other en-
11 tity of the Department of Defense providing the
12 Federal grant, cooperative agreement, or other sup-
13 port.

14 (2) The amount and period of Federal financial
15 support with an itemized breakdown.

16 (3) Other Federal nonfinancial support, includ-
17 ing the use of Federal personnel, Federal facilities,
18 and Federal equipment.

19 (4) The grant number, if applicable.

20 (5) Associated clinical trial data, upon trial
21 completion.

22 (6) Associated patents and patent applications,
23 specifying—

24 (A) any Federal ownership in such patents
25 and patent applications;

1 (B) the expiration date of such patents
2 and filing dates of such patent applications; and

3 (C) the numbers of such patents and pat-
4 ent applications.

5 (7) Associated periods of marketing exclusivity
6 under Federal law and the durations of such peri-
7 ods.

8 (8) The corporation, nonprofit organization,
9 academic institution, person, or other entity receiv-
10 ing the Federal support.

11 (9) Any products (including repurposed prod-
12 ucts) approved, authorized, or cleared for marketing,
13 or for which marketing approval, authorization, or
14 clearance is being sought, the development of which
15 was aided by Federal support, including—

16 (A) the names of such products;

17 (B) the prices of such products; and

18 (C) the current and anticipated manufac-
19 turing capacity to produce such products.

20 (10) The full terms of the contract, funding
21 agreement, licensing agreement, other transaction,
22 or other arrangement described in subsection (b).

23 (d) **FORMAT OF INFORMATION.**—The database under
24 subsection (a) shall be—

1 (1) searchable and filterable according to the
2 categories of information described in subsection (c);
3 and

4 (2) presented in a user-friendly format.

5 (e) TIMING.—The database under subsection (a)
6 shall be—

7 (1) made publicly available not later than one
8 month after the date of the enactment of this Act;
9 and

10 (2) updated not less frequently than once every
11 two weeks.

12 (f) DISCLOSURE.—

13 (1) IN GENERAL.—Notwithstanding any other
14 provision of law, to the extent necessary for the Sec-
15 retary of Defense to carry out this section, the Sec-
16 retary may require entities receiving Federal support
17 described in subsection (a)(1) to disclose to the Sec-
18 retary any information relating to such Federal sup-
19 port and required to be included in the database
20 under subsection (a).

21 (2) INTERMEDIARY COOPERATION.—

22 (A) IN GENERAL.—Any arrangement en-
23 tered into by the Department of Defense with
24 an entity providing for such entity to enter into
25 contracts, licensing agreements, grants, other

1 transactions, or other arrangements with third
2 parties on behalf of the Department shall re-
3 quire such entity to disclose in a timely manner
4 any information necessary for the Department
5 to fulfill its duties under this section.

6 (B) EXISTING ARRANGEMENTS.—With re-
7 spect to any arrangement described in subpara-
8 graph (A) with an entity in place as of the date
9 of the enactment of this Act, the Secretary of
10 Defense may require the entity to disclose to
11 the Secretary any information required to be in-
12 cluded in the database under subsection (a).

13 (3) PENALTY FOR NONDISCLOSURE.—If an en-
14 tity that is required to disclose information pursuant
15 to paragraph (1) or (2) fails to disclose such infor-
16 mation by the date that is two weeks after the date
17 on which the Secretary of Defense requests such in-
18 formation, or by such reasonable deadline as the
19 Secretary may specify, whichever is sooner, then
20 such entity shall be liable to the United States for
21 a civil penalty in an amount not to exceed \$10,000
22 for each day on which such failure continues.