## 117TH CONGRESS 1ST SESSION

## H. R. 4757

To authorize the use of certain drugs, vaccines, and medical technologies to expand military and civilian access to such products, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

July 28, 2021

Mr. Doggett (for himself and Ms. Delauro) introduced the following bill; which was referred to the Committee on Armed Services, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

## A BILL

To authorize the use of certain drugs, vaccines, and medical technologies to expand military and civilian access to such products, 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 titled "Licensing
11	of Federally owned medical interventions", included on
12	page 173 of the report of the Committee on Armed Serv-
13	ices of the Senate accompanying S. 1519 of the 115th
14	Congress (S. Rept. 115–125), which shall include the fol-
15	lowing information:
16	(1) A description of what steps, if any, the Sec-
17	retary has taken to comply with such 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 such 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, pursuant to section 203 or $209(d)(1)$ of title 35,
6	United States Code, shall authorize third parties or Fed-
7	eral agencies to use not fewer than 10 drugs, vaccines,
8	or medical technologies identified under subsection (a)(2) $$
9	for the purpose of expanding military and civilian access
10	to such drugs, vaccines, or technologies.
11	SEC. 3. DEPARTMENT OF DEFENSE DATABASE ON SUPPORT
12	FOR BIOMEDICAL RESEARCH AND DEVELOP-
13	MENT.
13 14	MENT.  (a) Database.—The Secretary of Defense shall—
14	(a) Database.—The Secretary of Defense shall—
14 15	(a) Database.—The Secretary of Defense shall—  (1) compile into a searchable database informa-
<ul><li>14</li><li>15</li><li>16</li></ul>	<ul><li>(a) Database.—The Secretary of Defense shall—</li><li>(1) compile into a searchable database information relating to any support provided before or after</li></ul>
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	<ul> <li>(a) Database.—The Secretary of Defense shall—</li> <li>(1) compile into a searchable database information relating to any support provided before or after the date of enactment of this Act by the Department</li> </ul>
14 15 16 17 18	(a) Database.—The Secretary of Defense shall—  (1) compile into a searchable database information relating to any support provided before or after the date of enactment of this Act by the Department of Defense, or an entity acting on its behalf, for bio-
14 15 16 17 18 19	(a) Database.—The Secretary of Defense shall—  (1) compile into a searchable database information relating to any support provided before or after the date of enactment of this Act by the Department of Defense, or an entity acting on its behalf, for biomedical research and development, including with re-
14 15 16 17 18 19 20	(a) Database.—The Secretary of Defense shall—  (1) compile into a searchable database information relating to any support provided before or after the date of enactment of this Act by the Department of Defense, or an entity acting on its behalf, for biomedical research and development, including with respect to drugs, vaccines, and medical technologies;
14 15 16 17 18 19 20 21	(a) Database.—The Secretary of Defense shall—  (1) compile into a searchable database information relating to any support provided before or after the date of enactment of this Act by the Department of Defense, or an entity acting on its behalf, for biomedical research and development, including with respect to drugs, vaccines, and medical technologies; and
14 15 16 17 18 19 20 21 22	(a) Database.—The Secretary of Defense shall—  (1) compile into a searchable database information relating to any support provided before or after the date of enactment of this Act by the Department of Defense, or an entity acting on its behalf, for biomedical research and development, including with respect to drugs, vaccines, and medical technologies; and  (2) make such database available on a public

1	all contracts, funding agreements, licensing arrangements,
2	other transactions, and other arrangements entered into
3	by, or on behalf of, the Department of Defense with re-
4	spect to the research and development, or the manufac-
5	turing and distribution, of a drug (including a biological
6	product), cell or gene therapy, or 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 entered into
12	pursuant to section 12 of the Stevenson-Wydler
13	Technology Innovation Act of 1980 (15 U.S.C.
14	3710a).
15	(3) Funding agreements, as defined under sec-
16	tion 201 of title 35, United States Code.
17	(4) Transactions, contracts, grants, cooperative
18	agreements, other agreements, and other arrange-
19	ments entered into pursuant to the following au-
20	thorities:
21	(A) Section 2358 of title 10, United States
22	Code.
23	(B) Section 2371 of such title.
24	(C) Section 2371a of such title.
25	(D) Section 2371b of such title.

1	(E) Section 2373 of such title.
2	(e) Information Required.—Notwithstanding any
3	other provision of law, the Secretary shall include in the
4	database under subsection (a) at a minimum, with regard
5	to each contract, funding agreement, licensing agreement,
6	other transaction, or other arrangement, described in sub-
7	section (b), the following information:
8	(1) The element of the Department of Defense
9	providing the grant, cooperative agreement, or other
10	support.
11	(2) The amount and period of financial support
12	provided by the Department, with an itemized break-
13	down.
14	(3) Other nonfinancial support provided by the
15	Department, including the use of personnel, facili-
16	ties, or equipment of the Department.
17	(4) The grant number, if applicable.
18	(5) Associated clinical trial data, upon trial
19	completion.
20	(6) Associated patents and patent applications,
21	specifying—
22	(A) any Department ownership in such
23	patents and patent applications;
24	(B) the expiration date of such patents
25	and filing dates of such patent applications; and

1	(C) the numbers of such patents and pat-
2	ent applications.
3	(7) Associated periods of marketing exclusivity
4	under Federal law and the durations of such peri-
5	ods.
6	(8) The corporation, nonprofit organization,
7	academic institution, person, or other entity receiv-
8	ing the support provided by the Department.
9	(9) Any products (including repurposed prod-
10	ucts) approved, authorized, or cleared for marketing,
11	or for which marketing approval, authorization, or
12	clearance is being sought, the development of which
13	was aided by support provided by the Department,
14	including—
15	(A) the names of such products;
16	(B) the prices of such products; and
17	(C) the current and anticipated manufac-
18	turing capacity to produce such products.
19	(10) The full terms of the contract, funding
20	agreement, licensing agreement, other transaction,
21	or other arrangement.
22	(d) FORMAT OF INFORMATION.—The database under
23	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 30
8	days after the date of enactment of this Act; and
9	(2) updated not less frequently than once every
10	two weeks.
11	(f) Disclosure.—
12	(1) IN GENERAL.—Notwithstanding any other
13	provision of law, to the extent necessary for the Sec-
14	retary to carry out this section, the Secretary may
15	require entities receiving support as described in
16	subsection (a)(1) to disclose to the Secretary any in-
17	formation relating to such support and required to
18	be included in the database under subsection (a).
19	(2) Intermediary cooperation.—Any ar-
20	rangement entered into by the Department of De-
21	fense with an entity providing for such entity to
22	enter into contracts, licensing agreements, grants,
23	other transactions, or other arrangements with third
24	parties on behalf of the Department shall require

such entity to disclose in a timely manner any infor-

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mation necessary for the Secretary of Defense to fulfill the duties of the Secretary under this Act. With respect to any such arrangement in place as of the date of enactment of this Act, the Secretary may require the entity to disclose to the Secretary any information required to be included in the database under subsection (a).

(3) Penalty for nondisclosure.—If an entity that is required to disclose information pursuant to paragraph (1) or (2) fails to disclose such information by the date that is two weeks after the date on which the Secretary requests such information, or by such reasonable deadline as the Secretary may specify, whichever is sooner, then such entity shall be liable to the United States for a civil penalty in an amount not to exceed \$10,000 for each day on which such failure continues.

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