

118TH CONGRESS
2D SESSION

S. 5517

To provide for the establishment, within the Food and Drug Administration, of an Abraham Accords Office to promote and facilitate cooperation between the Food and Drug Administration and entities in Abraham Accords countries wishing to work with the agency in order to develop and sell products in the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 12, 2024

Mr. BUDD (for himself and Ms. HASSAN) introduced the following bill; which was read twice and referred to the Committee on Foreign Relations

A BILL

To provide for the establishment, within the Food and Drug Administration, of an Abraham Accords Office to promote and facilitate cooperation between the Food and Drug Administration and entities in Abraham Accords countries wishing to work with the agency in order to develop and sell products in the United States, 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 “United States-Abra-
5 ham Accords Cooperation and Security Act of 2024”.

1 **SEC. 2. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**
2 **WITHIN FOOD AND DRUG ADMINISTRATION.**

3 (a) IN GENERAL.—Chapter X of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
5 ed by adding at the end the following:

6 **“SEC. 1015. ABRAHAM ACCORDS OFFICE.**

7 “(a) IN GENERAL.—The Secretary, acting through
8 the Commissioner of Food and Drugs, shall establish with-
9 in the Food and Drug Administration an office, to be
10 known as the Abraham Accords Office, to be headed by
11 a director.

12 “(b) OFFICE.—Not later than 2 years after the date
13 of enactment of this section, the Secretary shall—

14 “(1) in consultation with the governments of
15 Abraham Accords countries, establish the Abraham
16 Accords Office in an Abraham Accords country; and

17 “(2) assign to such Office such personnel of the
18 Food and Drug Administration as the Secretary de-
19 termines necessary to carry out the functions of the
20 Office.

21 “(c) DUTIES.—The Secretary, acting through the Di-
22 rector of the Abraham Accords Office, shall, not later than
23 30 days after the Abraham Accords Office is established—

24 “(1) provide technical assistance to parties in
25 Abraham Accords countries on oversight of good
26 manufacturing practices and other issues relevant to

1 manufacturing medical products that are regulated
2 by the Food and Drug Administration;

3 “(2) facilitate interactions between the Food
4 and Drug Administration and interested parties in
5 Abraham Accords countries, including by sharing
6 relevant information regarding United States regu-
7 latory pathways with such parties;

8 “(3) offer technical assistance regarding re-
9 search, development, and manufacturing of drugs
10 and devices to parties located in an Abraham Ac-
11 cords country that intend to file an application for
12 approval, licensure, clearance, or authorization of
13 such a drug or device under section 505, 510(k),
14 513(f)(2), or 515 of this Act or section 351 of the
15 Public Health Service Act; and

16 “(4) carry out other functions and activities as
17 the Secretary determines to be necessary to carry
18 out this section.

19 “(d) WAIVER AUTHORITY.—

20 “(1) IN GENERAL.—The Secretary, in consulta-
21 tion with the Secretary of State, may suspend, for
22 a period of not more than 6 months, the application
23 of any of the actions described in subsection (b) or
24 (c) with respect to an Abraham Accords country if

1 the Secretary determines, and reports to the appro-
2 priate congressional committees, that—

3 “(A) the exercise of such waiver authority
4 would further the purposes of this section; or

5 “(B) such a suspension is necessary to
6 protect the national security interests of the
7 United States.

8 “(2) RENEWAL OF WAIVER.—The Secretary, in
9 consultation with the Secretary of State, may renew
10 a waiver under paragraph (1) for an additional pe-
11 riod of not more than 6 months, not later than 15
12 days before the initial waiver expires, if the Sec-
13 retary makes an additional determination and report
14 described in paragraph (1).

15 “(e) DEFINITION.—In this section, the term ‘Abra-
16 ham Accords country’ means a country identified by the
17 Department of State as having signed the Abraham Ac-
18 cords.

19 “(f) SUNSET.—This section shall cease to have force
20 or effect on the date that is 12 years after the date on
21 which the Abraham Accords Office is established under
22 subsection (a).”.

23 (b) REPORT TO CONGRESS.—

24 (1) IN GENERAL.—Not later than 3 years after
25 the date of enactment of this Act, the Secretary of

1 Health and Human Services shall submit to the
2 Congress a report on the Abraham Accords Office
3 established under section 1015 of the Federal Food,
4 Drug, and Cosmetic Act, as added by subsection (a),
5 including—

6 (A) an evaluation of—

7 (i) how such Office has made progress
8 in ensuring that manufacturers in Abra-
9 ham Accords countries comply with appli-
10 cable requirements with respect to applica-
11 tions submitted for approval, licensure,
12 clearance, or authorization of a drug or de-
13 vice under section 505, 510(k), 513(f)(2),
14 or 515 of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355, 360(k),
16 360c(f)(2), 360e) or section 351 of the
17 Public Health Service Act (42 U.S.C.
18 262); and

19 (ii) a list of parties that such Office
20 has assisted pursuant to section 1015(c) of
21 the Federal Food, Drug, and Cosmetic
22 Act, as added by subsection (a), and the
23 drugs and devices that such parties intend
24 to be the subjects of an application de-
25 scribed in clause (i); and

1 (B) recommendations for increasing and
2 improving coordination between the Food and
3 Drug Administration and entities in Abraham
4 Accords countries.

5 (2) DEFINITION.—In this section, the term
6 “Abraham Accords country” has the meaning given
7 such term in section 1015 of the Federal Food,
8 Drug, and Cosmetic Act, as added by subsection (a).

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