

118TH CONGRESS
2D SESSION

H. R. 8299

To require the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, the Council for Technology and Innovation of the Centers for Medicare & Medicaid Services, and the Commissioner of Food and Drugs, to carry out a program to facilitate and coordinate efforts between the United States and Israel to expand and enhance collaboration on the development and delivery of health care products and services.

IN THE HOUSE OF REPRESENTATIVES

MAY 8, 2024

Mr. BUCHANAN (for himself, Mr. SOTO, and Mrs. MILLER-MEEKS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Maximizing Israel-U.S.
3 Research Advancement and Collaborative Leadership in
4 Emerging Medical Technology Act of 2024” or the “MIR-
5 ACLE Medical Technology Act of 2024”.

6 **SEC. 2. PROGRAM FOR FACILITATION AND COORDINATION**

7 **OF UNITED STATES-ISRAEL EFFORTS ON THE**
8 **DEVELOPMENT AND DELIVERY OF HEALTH**
9 **CARE PRODUCTS AND SERVICES.**

10 (a) IN GENERAL.—Subject to the availability of ap-
11 propriations, the Secretary of Health and Human Serv-
12 ices, in consultation with the Secretary of Commerce, the
13 Council for Technology and Innovation of the Centers for
14 Medicare & Medicaid Services, and the Commissioner of
15 Food and Drugs, shall carry out a program to facilitate
16 and coordinate efforts between the United States and
17 Israel to expand and enhance collaboration on—

18 (1) the development of health care products and
19 services; and

20 (2) the delivery of such products and services to
21 those in need.

22 (b) PROGRAM COMPONENTS.—The program under
23 subsection (a) shall include facilitation and coordination
24 of efforts including each of the following:

25 (1) RESEARCH AND DEVELOPMENT.—

(A) Joint research projects between United States and Israeli institutions and companies.

(B) Promoting collaboration in areas such as medical device technology, pharmaceuticals including biological products, genomics, and innovative digital health care solutions and health care systems management, including a special focus on early-stage clinical trials.

(C) With respect to biological products,
supporting—

(i) innovation:

(ii) process optimization; and

(iii) the development of advanced manufacturing techniques that can enhance productivity, reduce costs, and improve product quality.

(D) Work toward developing a framework for sharing health data for research purposes with the Ministry of Health of Israel.

(2) INNOVATION AND START-UP ECOSYSTEM.—

(A) Fostering collaboration between United States and Israeli start-up and other companies in the health care sector.

(B) Facilitating innovative technology acceptance by the marketplace.

(C) Facilitating mechanisms for technology transfer and joint venture opportunities.

(D) Supporting innovation hubs to accelerate the development and commercialization of United States health care technologies in the Israeli market, including by encouraging cybersecurity standards for sharing data, promoting patient privacy, and encouraging research.

(3) REGULATORY HARMONIZATION AND INTELLECTUAL PROPERTY PROTECTION.—Establishing joint efforts—

(A) to ensure intellectual property protection;

(B) to increase regulatory harmonization, including with respect to regulatory data protection for biological products;

(C) to formulate plans for a commercialization framework for medical device technologies;

(D) to encourage a potential mutual recognition agreement for pharmaceutical good manufacturing Practices between the Food and Drug Administration and Israeli regulators;

(E) to strengthen and reaffirm the confidentially commitment with the Food and

1 Drug Administration and the Pharmaceutical
2 Division, the Medical Devices Department, and
3 the National Food Services and Nutrition Divi-
4 sion of the Ministry of Health of Israel;

5 (F) to encourage Israel's participation in
6 regulatory harmonization and cooperation orga-
7 nizations; and

8 (G) to expand international collaboration
9 under Project Orbis for concurrent submission
10 and review of oncology products.

11 (4) HEALTH CARE SYSTEM STRENGTHENING.—
12 Facilitating the sharing of best practices, knowledge,
13 and skills in areas such as clinical care and health
14 care management.

15 (5) TELEMEDICINE AND DIGITAL HEALTH CO-
16 OPERATION.—Establishing initiatives—

17 (A) to enhance telemedicine infrastructure;
18 (B) to promote interoperability between
19 United States and Israeli health care systems;
20 and

21 (C) to facilitate collaboration on digital
22 health technologies, data analytics, and cyberse-
23 curity.

24 (6) DISEASE PREVENTION INITIATIVES.—Col-
25 laborating in disease prevention, including joint ef-

1 forts to combat infectious diseases, develop vaccines,
2 and share epidemiological data.

3 (7) BIOLOGICAL PRODUCT MANUFACTURING.—

4 (A) Promoting biological product manufac-
5 turing.

6 (B) Establishing joint manufacturing fa-
7 cilities for biological products in facilities in the
8 United States that leverage the strengths and
9 expertise of both countries.

10 (C) Pursuing accelerated development of
11 life-saving treatments and new sources of nutri-
12 tion that are both healthier and more available
13 at an affordable cost.

14 (D) Workforce training and skill develop-
15 ment, including promoting exchange programs
16 and training initiatives to develop a skilled
17 workforce in biological product manufacturing.

18 (E) Supply chain resilience through stra-
19 tegic collaboration to identify and develop con-
20 tingency plans to mitigate biological product
21 supply disruptions.

22 (F) Facilitating public-private partnerships
23 to support the development and scale-up of bio-
24 logical product manufacturing capabilities.

1 (c) UNITED STATES-ISRAEL HEALTH CARE COL-
2 LABORATION CENTER.—In carrying out the program
3 under subsection (a), the Secretary of Health and Human
4 Services may establish a joint United States-Israel Health
5 Care Collaboration Center in the United States leveraging
6 the experience, knowledge, and expertise of institutions of
7 higher education, national laboratories, entities in the pri-
8 vate sector, and others in the development and delivery
9 of health care products and services.

10 (d) COMMENCEMENT OF IMPLEMENTATION.—Not
11 later than 6 months after the date of enactment of this
12 Act, the Secretary of Health and Human Services shall
13 commence implementation of the program under this sec-
14 tion.

15 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry
16 out this Act, there is authorized to be appropriated
17 \$8,000,000 for each of fiscal years 2025 through 2029.

