

118TH CONGRESS
1ST SESSION

S. 2819

To protect and expand access to pasteurized, donor human milk, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 14, 2023

Mr. DURBIN for (Ms. DUCKWORTH (for herself and Mr. RUBIO)) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To protect and expand access to pasteurized, donor human milk, 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 “Access to Donor Milk
5 Act of 2023”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) The term “donor human milk” means
9 human milk that is collected, pasteurized, and dis-
10 pensed without additives.

1 (2) The term “donor human milk bank” means
2 an organization that—

3 (A) meets standards established by the
4 Food and Drug Administration for purposes of
5 ensuring the safety of donor human milk and
6 human milk banks; and

7 (B) collects, tests, processes, pasteurizes,
8 and distributes donor human milk, in compli-
9 ance with applicable law.

10 (3) The term “nonprofit donor human milk
11 bank” means a donor human milk bank (as defined
12 in paragraph (2)) that is an organization described
13 in section 501(c)(3) of the Internal Revenue Code of
14 1986 (26 U.S.C. 501(c)(3)) and exempt from tax
15 under section 501(a) of such Code (26 U.S.C.
16 501(a)).

17 **SEC. 3. SUPPORT FOR DONOR HUMAN MILK ACTIVITIES.**

18 Section 17 of the Child Nutrition Act of 1966 (42
19 U.S.C. 1786) is amended—

20 (1) in subsection (b)(4), by inserting “(includ-
21 ing support for donor human milk (as defined in
22 section 2 of the Access to Donor Milk Act of 2023)
23 activities)” after “promotion”; and

24 (2) in subsection (h)(1)(C)—

1 (A) in clause (i), by striking “clause (ii)”
 2 and inserting “clauses (ii) and (iii)”; and

3 (B) by adding at the end the following:

4 “(iii) DONOR HUMAN MILK.—A State
 5 agency may use amounts made available
 6 under clause (i) for—

7 “(I) collecting and storing dona-
 8 tions of unprocessed human milk; and

9 “(II) the transfer of the milk de-
 10 scribed in subclause (I) to a nonprofit
 11 donor human milk bank (as defined in
 12 section 2 of the Access to Donor Milk
 13 Act of 2023) registered with the Food
 14 and Drug Administration.”.

15 **SEC. 4. EMERGENCY CAPACITY FUNDING FOR HUMAN MILK**
 16 **BANKS.**

17 (a) IN GENERAL.—The Secretary of Health and
 18 Human Services (referred to in this section as the “Sec-
 19 retary”) shall award competitive grants, subject to sub-
 20 section (f), to eligible entities for expanding emergency ca-
 21 pacity with respect to banking donor human milk.

22 (b) APPLICATION.—An eligible entity seeking a grant
 23 under this section shall submit an application to the Sec-
 24 retary at such time, in such manner, and containing such
 25 information as the Secretary may require.

1 (c) USE OF FUNDS.—Expanding emergency capacity
2 pursuant to a grant under this section may include—

3 (1) publicizing the need for donor human milk,
4 especially for high-risk infants;

5 (2) raising awareness and providing resources
6 to families, especially families of high-risk infants,
7 about donor human milk;

8 (3) covering donor human milk collection, stor-
9 age, pasteurization, transfer, and processing fees;

10 (4) increasing staffing and supplies needed at
11 donor human milk banks;

12 (5) purchasing consumable products needed for
13 donor human milk processing; and

14 (6) acquiring equipment for safe and quality
15 processing of donor human milk.

16 (d) ELIGIBLE ENTITY.—For purposes of this section,
17 the term “eligible entity” means an entity that—

18 (1) is a nonprofit donor human milk bank reg-
19 istered with the Food and Drug Administration; and

20 (2) in the application submitted under sub-
21 section (b), demonstrates, with respect to such enti-
22 ty—

23 (A) a rapid increase in demand for donor
24 human milk; or

1 (B) a shortage of supplies needed to oper-
2 ate a donor human milk bank.

3 (e) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purposes of carrying out this section, there are authorized
5 to be appropriated \$3,000,000 for fiscal year 2024, and
6 such sums as may be necessary for each fiscal year there-
7 after.

8 (f) CRITERIA.—The Secretary may award grants
9 under subsection (a) only in the event of any of the fol-
10 lowing:

11 (1) The Secretary determines that expanded ca-
12 pacity is necessary to respond to any major disaster
13 declared by the President under section 401 of the
14 Robert T. Stafford Disaster Relief and Emergency
15 Assistance Act (42 U.S.C. 5170) or to any public
16 health emergency declared under section 319 of the
17 Public Health Service Act (42 U.S.C. 247d).

18 (2) The Secretary determines that Federal as-
19 sistance is needed to supplement State and local ef-
20 forts and capabilities to save lives and to protect
21 property and public health and safety, or to lessen
22 or avert the threat of a catastrophe in any part of
23 the United States.

24 (3) The Secretary determines emergency capac-
25 ity is needed to ensure adequate supply is available

1 to meet the demand for donor human milk from an
2 eligible entity.

3 **SEC. 5. PUBLIC AWARENESS CAMPAIGN WITH RESPECT TO**
4 **DONOR HUMAN MILK.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services—

7 (1) shall, acting through the Administrator of
8 the Health Resources and Services Administration,
9 develop a public awareness campaign with respect to
10 the benefits and safety of donor human milk from
11 donor human milk banks registered with the Food
12 and Drug Administration; and

13 (2) is encouraged to work with nonprofit donor
14 human milk banks registered with the Food and
15 Drug Administration.

16 (b) DISTRIBUTION OF EDUCATIONAL MATERIALS.—
17 The public awareness campaign under subsection (a) shall
18 include the distribution of educational materials to—

19 (1) clinicians, such as pediatric specialists, pedi-
20 atricians, obstetricians, pediatric nutritionists, mid-
21 wives, and lactation consultants, including inter-
22 national board-certified lactation consultants;

23 (2) expectant and new parents, with a focus on
24 expectant and new parents that are participating in
25 the special supplemental nutrition program for

1 women, infants, and children program under section
2 17 of the Child Nutrition Act of 1966 (42 U.S.C.
3 1786); and

4 (3) community-based organizations.

5 **SEC. 6. REGULATORY STATUS OF DONOR HUMAN MILK.**

6 (a) PUBLIC MEETING.—Not later than 180 days
7 after the date of the enactment of this Act, the Secretary
8 of Health and Human Services (referred to in this section
9 as the “Secretary”) shall convene a public meeting to in-
10 form the draft guidance required under subsection (b).

11 (b) GUIDANCE.—Not later than 18 months after the
12 date of enactment of this Act, the Secretary shall issue
13 draft guidance that—

14 (1) addresses the appropriate standards for the
15 collection and preparation, storage, handling, proc-
16 esses used in pasteurization, and transfer of donor
17 human milk and donor human-milk derived prod-
18 ucts; and

19 (2) considers the appropriateness of screening
20 and other processes, as determined by the Secretary.

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