Mossy Houldon

(Original Signature of Member)

117TH CONGRESS 2D SESSION

## H.R.

To protect and expand access to donor milk, and for other purposes.
Ms. Houlahan introduced the following bill; which was referred to the Committee on

## A BILL

To protect and expand access to donor 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 2022".
- 6 SEC. 2. DEFINITIONS.
- 7 In this Act:

1	(1) The term "donor milk" means human milk
2	that is processed without additives by a nonprofit
3	milk bank.
4	(2) The term "nonprofit milk bank" means a
5	milk bank that—
6	(A) is accredited by an accrediting body
7	that is recognized by, or meets standards estab-
8	lished by, the Food and Drug Administration
9	for purposes of accrediting milk banks;
10	(B) collects, tests, processes, pasteurizes,
11	and distributes donor milk; and
12	(C) is described in section 501(c)(3) of the
13	Internal Revenue Code of 1986 (26 U.S.C.
14	501(c)(3)) and exempt from tax under section
15	501(a) of such Code (26 U.S.C. 501(a)).
16	SEC. 3. FINDINGS.
17	Congress finds the following:
18	(1) Human milk is the optimal first food for in-
19	fants.
20	(2) Medically vulnerable infants, including those
21	born prematurely and those with congenital or ac-
22	quired conditions, derive significant health benefits
23	from human milk.
24	(3) Mothers of medically vulnerable infants
25	often face unique obstacles to producing enough

1	milk. When a parent's milk is not available, the pro-
2	vision of donor milk improves health outcomes.
3	(4) Nonprofit milk banks provide an essential
4	medical service.
5	(5) The nonprofit milk banking model of donor
6	non-remuneration and standardized processing of
7	single ingredient pools ensures a safe and high-qual-
8	ity product for the Nation's most vulnerable infants.
9	SEC. 4. SUPPORT FOR DONOR MILK ACTIVITIES.
10	Section 17 of the Child Nutrition Act of 1966 (42
11	U.S.C. 1786) is amended—
12	(1) in subsection (b)(4), by inserting "(includ-
13	ing support for donor milk activities)" after "pro-
14	motion"; and
15	(2) in subsection (h)(1)(C), by adding at the
16	end the following:
17	"(iii) Donor MILK.—A State agency
18	may use amounts made available under
19	clause (i) for the collection and storage of
20	unprocessed donations of human milk, the
21	transfer of such milk to a nonprofit milk
22	bank, and to make donor milk available to
23	program participants.".

1	SEC. 5. EMERGENCY CAPACITY FUNDING FOR MILK BANKS.
2	(a) IN GENERAL.—The Secretary shall award com-
3	petitive grants to eligible entities for expanding emergency
4	capacity with respect to banking donor milk.
5	(b) APPLICATION.—An eligible entity seeking a grant
6	under this section shall submit an application to the Sec-
7	retary at such time, in such manner, and containing such
8	information as the Secretary may require.
9	(c) USE OF FUNDS.— Expanding emergency capacity
10	pursuant to a grant under this section may include—
11	(1) publicizing the need for donor milk;
12	(2) providing resources to patients, making pa-
13	tients aware of donor milk, and providing informa-
14	tion to clinicians about donor milk;
15	(3) covering donor milk processing fees;
16	(4) increasing staffing and supplies needed at
17	nonprofit milk banks; and
18	(5) purchasing consumable products needed for
19	donor milk processing.
20	(d) Definitions.—In this section:
21	(1) ELIGIBLE ENTITY.—The term "eligible enti-
22	ty" means an entity that—
23	(A) is recognized by the Food and Drug
24	Administration as an accrediting body for non-
25	profit milk banks; and

1	(B) in the application submitted under
2	subsection (b), demonstrates, with respect to
3	such entity—
4	(i) a rapid increase in demand for
5	donor milk; or
6	(ii) a shortage of supplies needed to
7	operate a nonprofit milk bank.
8	(2) Secretary.—The term "Secretary" means
9	the Secretary of Health and Humans Services, act-
10	ing through the Commissioner of Food and Drugs.
11	(e) AUTHORIZATION OF APPROPRIATIONS.—For the
12	purposes of carrying out this section, there are authorized
13	to be appropriated \$3,000,000 for fiscal year 2023, and
14	such sums as may be necessary for each fiscal year there-
15	after.
16	SEC. 6. DONOR MILK AWARENESS PROGRAM.
17	The Child Nutrition Act of 1966 (42 U.S.C. 1771
18	et seq.) is amended by adding at the end the following:
19	"SEC. 24. DONOR MILK AWARENESS PROGRAM.
20	"(a) In General.—The Secretary, in coordination
21	with the Secretary of Health and Human Services, shall
22	establish a donor milk awareness program to—
23	"(1) educate the public on donor milk and non-
24	profit milk banks; and

1	"(2) publicize the need for donor milk at non-
2	profit milk banks.
3	"(b) Conduct of Program.—In carrying out the
4	program described in subsection (a), the Secretary may—
5	"(1) develop or assist others to develop appro-
6	priate educational materials, including public service
7	announcements, promotional publications, and press
8	kits for the program described in subsection (a);
9	"(2) publish information about the program de-
10	scribed in subsection (a) on the Department's
11	website; and
12	"(3) distribute or assist other to distribute such
13	materials appropriate for public and private individ-
14	uals and entities.
15	"(c) Cooperative Agreements.—The Secretary is
16	authorized to enter into cooperative agreements with Fed-
17	eral agencies, State and local governments, and other enti-
18	ties to carry out the program described in subsection (a).
19	"(d) Definition of Donor Milk.—In this section,
20	the term 'donor milk' has the meaning given the term in
21	section 2 of the Access to Donor Milk Act of $2022$ .
22	"(e) Authorization of Appropriations.—For
23	purposes of carrying out this section, there are authorized
24	to be appropriated \$1,000,000 for fiscal year 2023, and

1	such sums as may be necessary for each fiscal year there-
2	after.".
3	SEC. 7. CDC PUBLIC AWARENESS CAMPAIGN WITH RE-
4	SPECT TO DONOR MILK FROM NONPROFIT
5	MILK BANKS.
6	(a) In General.—The Secretary of Health and
7	Human Services, acting through the Director of the Cen-
8	ters for Disease Control and Prevention, shall expand and
9	intensify the activities of the Centers to include a public
10	awareness campaign with respect to donor milk from non-
11	profit milk banks.
12	(b) Distribution of Educational Materials.—
13	The public awareness campaign under subsection (a) shall
14	include the distribution of educational materials to—
15	(1) clinicians, such as pediatric specialists, pedi-
16	atricians, obstetricians, pediatric nutritionists, mid-
17	wives, and lactation specialists; and
18	(2) expecting and new parents.
19	SEC. 8. CLARIFYING THE REGULATORY STATUS OF DONOR
20	MILK.
21	(a) In General.—Not later than 1 year after the
22	date of the enactment of this Act, the Secretary of Health
23	and Human Services, acting through the Commissioner of
24	Food and Drugs, shall issue a rule to clarify the regulatory

- 1 status (and any associated categorization) of donor milk
- 2 provided by a nonprofit milk bank.
- 3 (b) Report.—Not later than 180 days after the date
- 4 of the enactment of this Act, the Secretary of Health and
- 5 Human Services, acting through the Commissioner of
- 6 Food and Drugs, shall submit to Congress a report speci-
- 7 fying the regulatory categorization of donor milk provided
- 8 by a nonprofit milk bank under the rule issued under sub-
- 9 section (a).