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PETITION FOR INVESTIGATION)
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Docket No.: _____

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SUBMITTED TO

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INTRODUCTION

Decades of research have established that breastfeeding provides essential nutrients as well as hormones and antibodies that protect newborn infants against infectious disease. Known health benefits of breastfeeding include better overall nutrition, protection against common childhood infections, and better survival during an infant's first year, including a lower risk of Sudden Infant Death Syndrome.¹ Breastfeeding may reduce the risk for certain allergic diseases, asthma, obesity, and type 2 diabetes and also may help improve an infant's cognitive development.² Research also shows that very early skin-to-skin contact and suckling may have physical and emotional benefits for infants.³

Leading health authorities warn that consuming dairy products can adversely affect the health of infants and children. The American Academy of Pediatrics recommends that infants below one year of age not be given whole cow's milk,⁴ as iron deficiency is more likely due to the low amount of iron found in cow's milk as compared with human breast milk.⁵ A study published in the journal *Diabetologia* found that insulin-dependent (type 1 or childhood-onset) diabetes is linked to consumption of dairy products in infancy.⁶

In 2011, the U.S. Surgeon General issued a call to action for a society-wide approach to support breastfeeding, lamenting "poor advice" that discouraged breastfeeding over much of the last century "to the point that breastfeeding became an unusual choice in this country."⁷ A study published in *The Lancet* in January 2016 found that universal breastfeeding would prevent 823,000 child deaths per year across the globe.⁸

Since the beginning of 2016, the dairy industry has spent more than \$16,000,000 lobbying the federal government⁹ and contributed more than \$4,500,000 to the current administration's

¹ American Academy of Pediatrics. Breastfeeding and the use of human milk. *Pediatrics*. 2012;129: e827–e841. Available at <http://pediatrics.aappublications.org/content/129/3/e827.full.pdf+html>. Accessed August 7, 2018.

² U.S. Department of Health and Human Services. Eunice Kennedy Shriver National Institute of Child Health and Human Development. What are the benefits of breastfeeding? 2017. Available at <https://www.nichd.nih.gov/health/topics/breastfeeding/conditioninfo/benefits>. Accessed August 7, 2018.

³ Feldman-Winter L, Goldsmith JP, Committee on Fetus and Newborn, Task Force on Sudden Infant Death Syndrome. Safe sleep and skin-to-skin care in the neonatal period for healthy term newborns. *Pediatrics*. 2016;138: e20161889. Available at <http://pediatrics.aappublications.org/content/early/2016/08/18/peds.2016-1889>. Accessed August 7, 2018.

⁴ Gartner LM, Morton J, Lawrence RA, et al. Breastfeeding and the use of human milk. *Pediatrics*. 2005;115:496–506.

⁵ U.S. Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory. USDA National Nutrient Database for Standard Reference. Version Current: April 2018. Internet: <http://www.ars.usda.gov/nutrientdata>.

⁶ Saukkonen T, Virtanen SM, Karppinen M, et al. Significance of cow's milk protein antibodies as risk factor for childhood IDDM: interaction with dietary cow's milk intake and HLA-DQB1 genotype. Childhood Diabetes in Finland Study Group. *Diabetologia*. 1998;41:72–78.

⁷ U.S. Department of Health and Human Services. *The Surgeon General's Call to Action to Support Breastfeeding*. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2011.

⁸ Victora CG, Bahl R, Barros AJD, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet*. 2016;387:475–490.

⁹ Center for Responsive Politics, *Dairy: Industry Profile: Summary, 2018*, <https://www.opensecrets.org/lobby/>

political party during federal elections.¹⁰ These investments have paid off, literally and figuratively.

At the annual meeting of the World Health Organization's decision-making body in May, the U.S. delegation—led by the Department of Health and Human Services (“HHS”)—sought to remove from a proposed resolution language calling on governments to “protect, promote and support breast-feeding.”¹¹ U.S. officials also threatened Ecuador with trade measures¹² and, in other meetings around that same time, withdrawal of U.S. military aid¹³ if Ecuador were to introduce the resolution. As a result, the delegations of at least a dozen countries, including Ecuador, refused to introduce the resolution, citing fears of retaliation.¹⁴ The U.S. delegation also successfully removed from the proposed resolution language calling on the World Health Organization to provide technical support to member states seeking to halt “inappropriate promotion of foods for infants and young children.”¹⁵

The administration is harming infants by discouraging breastfeeding and instead promoting commercial dairy-based infant formula products. For the reasons set forth below, the Offices of the Inspector General should promptly

- 1) investigate HHS and the U.S. Department of Agriculture (“USDA”) for failing to adhere to the Federal Advisory Committee Act in developing the upcoming Dietary Guidelines for Americans; and
- 2) investigate USDA's dairy checkoff for violating the prohibition on using checkoff funds to influence governmental policy or action by submitting policy recommendations to HHS, a federal agency.

indusclient.php?id=A04&year=2018 (last visited Aug. 7, 2018); Center for Responsive Politics, *Dairy: Industry Profile: Summary, 2017*, <https://www.opensecrets.org/lobby/indusclient.php?id=A04&year=2017> (last visited Aug. 7, 2018); Center for Responsive Politics, *Dairy: Industry Profile: Summary, 2016*, <https://www.opensecrets.org/lobby/indusclient.php?id=A04&year=2016> (last visited Aug. 7, 2018).

¹⁰ Center for Responsive Politics, *Dairy: Top Contributors to Federal Candidates, Parties, and Outside Groups*, <https://www.opensecrets.org/industries/contrib.php?ind=A04&Bkdn=DemRep&cycle=2018> (last visited Aug. 7, 2018); Center for Responsive Politics, *Dairy: Top Contributors to Federal Candidates, Parties, and Outside Groups*, <https://www.opensecrets.org/industries/contrib.php?ind=A04&Bkdn=DemRep&cycle=2016> (last visited Aug. 7, 2018).

¹¹ Andrew Jacobs, *Opposition to Breast-Feeding Resolution by U.S. Stuns World Health Officials*, N.Y. TIMES, July 8, 2018, <https://www.nytimes.com/2018/07/08/health/world-health-breastfeeding-ecuador-trump.html>.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

FACTUAL BACKGROUND

Earlier this year, HHS announced that it would be “leading the U.S. delegation to the 71st World Health Assembly,”¹⁶ the annual meeting of the World Health Organization’s decision-making body.¹⁷ Delegations from all World Health Organization member states attend the World Health Assembly to determine the World Health Organization’s policies and perform other functions.¹⁸

HHS thereafter held a “Stakeholder Listening Session” purportedly to help it “prepare the U.S. delegation for the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all individuals interested in and affected by agenda items to be discussed at the 71st World Health Assembly.”¹⁹

Three major dairy industry associations—the National Milk Producers Federation (“NMPF”), U.S. Dairy Export Council (“USDEC”), and International Dairy Foods Association (“IDFA”)—attended and submitted a joint comment at the Stakeholder Listening Session.²⁰ The comment described NMPF as “the voice of dairy producers on Capitol Hill and with government agencies,” characterizing its efforts as “aimed at improving the economic interests of dairy farmers.”²¹ The comment stated that IDFA “represents the nation’s dairy manufacturing and marketing industry, which supports nearly 3 million jobs, generates more than \$39 billion in direct wages and has an overall economic impact of more than \$200 billion. . . . Our diverse membership includes numerous food retailers, suppliers and companies that offer infant formula and a wide variety of milk-derived ingredients.”²²

The comment described USDEC as “a non-profit, independent membership organization that represents the global trade interests of U.S. dairy producers, proprietary processors and cooperatives, ingredient suppliers and export traders. Dairy Management Inc. founded USDEC in 1995 and, through the dairy checkoff program, is the organization’s primary funder.”²³ Indeed, the dairy checkoff’s most recent annual report shows that 93.6% of USDEC’s funding comes from USDA or Dairy Management Inc., which was created to administer the checkoff.²⁴

¹⁶ Stakeholder Listening Session in Preparation for the 71st World Health Assembly; Meeting, 83 Fed. Reg. 19,566 (May 3, 2018).

¹⁷ World Health Organization, *World Health Assembly* (2018), <http://www.who.int/mediacentre/events/governance/wha/en/>.

¹⁸ *Id.*

¹⁹ 83 Fed. Reg. at 19,566.

²⁰ Comment to the Department of Health and Human Services (HHS) Stakeholder Listening Session in Preparation for the 71st World Health Assembly (WHA) Submitted May 11, 2018, https://www.idfa.org/docs/default-source/d-news/20180510-final_nmpf-idfa-usdec_submission-for-hhs-wha-listening-session-docx.pdf.

²¹ *Id.* at 1.

²² *Id.*

²³ *Id.*

²⁴ USDA, *U.S. Department of Agriculture Report to Congress on the Dairy Promotion and Research Program and the Fluid Milk Processor Promotion Program, 2015 Program Activities* 8, 10 (2017), <https://www.ams.usda.gov/sites/default/files/media/2015DairyReportToCongress.pdf>.

All three dairy associations expressed “concerns” with a 2016 World Health Assembly resolution regarding breastfeeding,²⁵ in particular the resolution’s characterization of “all milk products for children up to age three as ‘breastmilk substitutes.’”²⁶ They also asserted that “[i]t is essential that international policy recommendations, international standards, and national regulations continue to encourage the consumption of milk and other dairy products for young children[.]”²⁷ Thus, the comment concluded, “NMPF and IDFA urge the U.S. government to ensure the WHA does not endorse the Guidance or call on member states to implement the Guidance.”²⁸ Nestlé, a major marketer of dairy-based infant formula, attended the Session and similarly announced its opposition to the 2016 resolution.²⁹

At the World Health Assembly two weeks later, HHS heeded the dairy industry’s wishes by seeking, on behalf of the U.S. delegation, to remove from a proposed resolution³⁰ language that called on governments to “protect, promote and support breast-feeding.”³¹ The U.S. delegation threatened the Ecuadorean delegation with trade measures if it were to introduce the resolution.³² In other meetings around that same time, U.S. officials also threatened Ecuador with withdrawal of military aid.³³ Members of the U.S. delegation also suggested that the United States might cut its contribution to the World Health Organization if the resolution were passed.³⁴ In light of these threats, the delegations of at least a dozen countries, including Ecuador, refused to introduce the resolution, citing fears of retaliation.³⁵

The U.S. delegation also successfully removed from the proposed resolution language calling on the World Health Organization to provide technical support to member states seeking to halt “inappropriate promotion of foods for infants and young children” and insisted that the phrase “evidence-based” accompany references to initiatives that promote breastfeeding.³⁶

ARGUMENT

The National Nutrition Monitoring and Related Research Act requires the Secretaries of USDA and HHS to periodically “publish a report entitled ‘Dietary Guidelines for Americans.’”³⁷ This report must “contain nutritional and dietary information and guidelines for the general public”³⁸

²⁵ World Health Assembly, *Ending Inappropriate Promotion of Foods for Infants and Young Children*, WHA69.9 (May 28, 2016), http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf.

²⁶ Comment, *supra* note 20, at 2.

²⁷ *Id.*

²⁸ *Id.* at 2–3.

²⁹ Olga Khazan, *The Epic Battle Between Breast Milk and Infant-Formula Companies*, ATLANTIC, July 10, 2018, <https://www.theatlantic.com/health/archive/2018/07/the-epic-battle-between-breast-milk-and-infant-formula-companies/564782/>.

³⁰ World Health Assembly, *DRAFT RESOLUTION WHA71.XX Infant and Young Child Feeding* (May 14, 2018), available at <http://www.babymilkaction.org/wp-content/uploads/2018/05/CLEAN-FINAL-CONSENSUS-TEXT-14-May-2018-Infant-and-young-child-feeding-WH...-002.pdf>.

³¹ Andrew Jacobs, *supra* note 11.

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ 7 U.S.C. § 5341(a)(1).

³⁸ *Id.*

“based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.”³⁹

A recently added subsection of the Act entitled “Pregnant women and young children” mandates that by “the 2020 report and in each report thereafter, the Secretaries shall include national nutritional and dietary information and guidelines for pregnant women and children from birth until the age of 2.”⁴⁰ The 2020-2025 Dietary Guidelines will be the first to include such information and guidelines.⁴¹

Every five years, HHS and USDA create a Dietary Guidelines Advisory Committee to recommend content for the upcoming Dietary Guidelines. The Federal Advisory Committee Act requires the agencies to “assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee’s independent judgment.”⁴² Federal law also prohibits the USDA’s dairy checkoff from using its funds “for the purpose of influencing governmental policy or action” other than policy or action related to the workings of the checkoff itself.⁴³

HHS and USDA are expected to empanel the Dietary Guidelines Advisory Committee for the 2020-2025 Dietary Guidelines any day now. Although the Committee’s charter is not yet available, the prior charter directed the Committee to “examine the current Dietary Guidelines for Americans, take into consideration new scientific evidence and current resource documents, and then develop a report to be submitted to the Secretaries that outlines its science-based recommendations and rationale[.]”⁴⁴

Despite longstanding evidence demonstrating the health benefits of breastfeeding, HHS, as lead agency for the U.S. delegation to the World Health Assembly, and USDEC, which is controlled by USDA’s dairy checkoff, are undermining efforts to provide breastfeeding advice and support. The agencies’ attempts to influence the 2020-2025 Dietary Guidelines Advisory Committee to recommend dairy-based infant formula products over breastfeeding violates the Federal Advisory Committee Act’s requirement that committee recommendations “not be inappropriately influenced by the appointing authority or by any special interest.”⁴⁵ The dairy checkoff’s submission, via USDEC, of policy recommendations at the HHS’s Stakeholder Listening Session also violates the prohibition on using checkoff funds to influence governmental policy or action.

³⁹ 7 U.S.C. § 5341(a)(2).

⁴⁰ 7 U.S.C. § 5341(a)(3).

⁴¹ U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.

⁴² 5 U.S.C. App. 2 § 5(b)(3), (c).

⁴³ 7 U.S.C. § 4504(j); 7 C.F.R. § 1150.154.

⁴⁴ Secretary of Health & Human Services, Charter: 2015 Dietary Guidelines Advisory Committee 1 (2013), <https://health.gov/dietaryguidelines/dgac2015-charter-final.pdf>.

⁴⁵ 5 U.S.C. App. 2 § 5(b)(3), (c).

CONCLUSION

It is well-established that breastfeeding protects against infectious disease, provides nutritionally balanced meals, and improves survival during an infant’s first year. Breastfeeding also reduces the risk for certain allergic diseases, asthma, obesity, and type 2 diabetes and improves cognitive development. Universal breastfeeding would prevent 823,000 child deaths per year.

The Dietary Guidelines Advisory Committee is federal advisory committee that must provide nutrition guidance based solely on current scientific and medical knowledge and in the best interests of the general public—not in the interests of commercial industries. Because the Dietary Guidelines are “promoted by each Federal agency in carrying out any Federal food, nutrition, or health program,”⁴⁶ it is crucial that the Dietary Guidelines be issued in accordance with the law.

To ensure that the upcoming Dietary Guidelines “better prevent chronic disease, ensure nutritional sufficiency for all Americans” and “reflect balanced sound science,”⁴⁷ the Offices of the Inspector General should promptly investigate 1) HHS and USDA for failing to adhere to the Federal Advisory Committee Act in developing the upcoming Dietary Guidelines for Americans and 2) USDA’s dairy checkoff for violating the prohibition on using checkoff funds to influence governmental policy or action.

⁴⁶ 7 U.S.C. § 5341(a)(1).

⁴⁷ See Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 735(b) (2015).