## Congress of the United States Washington, DC 20515

January 30<sup>th</sup>, 2023

Dr. Robert Califf Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Califf,

We are writing to you to express concerns about how the Food and Drug Administration (FDA) regulates food, and specifically how the Agency handles infant nutrition. In light of the resignation of Deputy Commissioner for the Office of Food Policy and Response Frank Yiannas, it is clear that major changes are needed in the Human Foods Program.

On December 6<sup>th</sup>, 2022, independent experts at the Reagan-Udall Foundation released a report on their evaluation of the FDA's Human Foods Program. In their report, these experts expressed serious concerns about the overlapping jurisdictions of the Office of Food Policy & Response (OFPR), the Center for Food Safety & Applied Nutrition (CFSAN), and the Office of Regulatory Affairs. As the report explains, "There is no clear Human Foods Program leader or decision-maker, outside of the Commissioner. Although the missions of CFSAN and OFPR have differences on paper, staff are often left wondering which program is responsible for decision-making."

This finding is particularly concerning given the important role the FDA's regulators are playing in helping to resolve the crisis around infant formula, and infant nutrition. The Reagan-Udall Foundation report makes clear that during the "infant formula foodborne-illness outbreak and subsequent product shortage, a review of events indicates that lack of communication and engagement across the Agency accounted, in part, for missteps." In December 2022, the FDA acknowledged the release of the Reagan-Udall Foundation's report and committed to reviewing how to modernize and strengthen the Human Foods Program. The Food and Drug Omnibus Reform Act of 2022, passed at the end of December, also established within CFSAN an Office of Critical Foods (OCF) which is intended to assist in the regulation of infant nutrition.

In his resignation letter dated January 25<sup>th</sup>, 2023, Deputy Commissioner Yiannas wrote that "the decentralized structure of the foods program...significantly impaired the FDA's ability to

<sup>&</sup>lt;sup>1</sup> Reagan-Udall Foundation for the Food and Drug Administration, Evaluation of FDA's Human Foods Program, December 6<sup>th</sup>, 2022, https://reaganudall.org/operational-evaluation-fdas-human-foods-programs

<sup>&</sup>lt;sup>2</sup> Reagan-Udall Foundation for the Food and Drug Administration, Evaluation of FDA's Human Foods Program, December 6<sup>th</sup>, 2022, https://reaganudall.org/operational-evaluation-fdas-human-foods-programs

operate as an integrated food team and protect the public." Clearly both independent experts outside the FDA, and within the Agency, agree that there must be a central decision maker on food regulation, including infant nutrition policy. The establishment of the Office of Critical Foods does not necessarily clarify the different jurisdictions of CFSAN and OFPR broadly, or about infant nutrition in particular.

As you are finalizing and implementing possible structural changes to the FDA's Human Foods Program, we, the undersigned, urge you to resolve this conflict of mission between the Center for Food Safety & Applied Nutrition, the Office of Food Policy & Response, and the Office of Regulatory Affairs.<sup>4</sup> It is absolutely essential that there is a clear Human Foods Program decision maker.

While the creation of the Office of Critical Foods is a positive step forward because it demonstrates the FDA's focus on better infant food regulation, the FDA should provide more clarity on how it is setting up this office, and how it will impact decision making. Given this change, we believe that the FDA should prioritize appointing an individual with the relevant background and expertise of infant nutrition within the Agency.

Whether this person reports to a new Deputy Commissioner for Food, as Deputy Commissioner Yiannas calls for the creation of in his resignation letter, or to the FDA Commissioner directly, it is absolutely essential that this individual ensure that any conflicting decisions issued by the various Human Foods Program offices would be quickly resolved in the area of this vulnerable population. In fact, Deputy Commissioner Yiannas' recommendation that the staff of OFPR be moved into the office of a new Deputy Commissioner for Food should be looked at closely. Furthermore, this individual could assist the FDA's review of how the Agency's actions contributed to the infant formula shortage crisis. Although the Office of Critical Foods will have a director, unless this person can settle disputes between CFSAN and OFPR, or OFPR ceases to exist, this new position won't be sufficient to address these issues. The creation of these positions, such as "czars," to solve acute issues and implement reform effectively has a long track record of success across many previous administrations, including within the Food and Drug Administration.<sup>5</sup>

We urge you to follow in your predecessors' footsteps and make an appointment that will help prioritize infant nutrition and regulation over infant formula, donor breast milk, and human milk-derived products, each of which currently faces various regulation challenges. We urge you to prioritize infant nutrition and ensure reforms are enacted now so we can avoid any future crises

<sup>&</sup>lt;sup>3</sup> Letter of Resignation, Frank Yiannas, January 25<sup>th</sup>, 2022, https://docdro.id/PHYSXRR

<sup>&</sup>lt;sup>4</sup> Food and Drug Administration, FDA Statement: FDA Provides Updates on External Evaluation to Strengthen Agency's Human Foods Program, Dr. Robert Califf, December 6<sup>th</sup>, 2022, https://www.fda.gov/news-events/press-announcements/fda-provides-update-external-evaluation-strengthen-agencys-human-foods-program

<sup>&</sup>lt;sup>5</sup> Congressional Research Service, Memorandum: Selected Presidential Assistants and Advisors in the Administration of President Barack H. Obama, Barbara Schwemle and Henry Hoge, December 16<sup>th</sup>, 2013

and protect infant nutrition and health. We also ask that you act boldly to reform the Human Foods Program writ large, to better protect Americans of all ages.

Thank you for your consideration and we look forward to hearing from you.

Sincerely,

Rep. Chrissy Houlahan

Rep. Rosa L. Delauro

Rep. Brian Fitzpatrick