## United States Senate

WASHINGTON, DC 20510

February 21, 2025

The Honorable Robert F. Kennedy, Jr. Secretary
U.S. Department of Health & Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Kennedy,

We write today to raise grave concerns about the recent mass firings of hundreds of federal workers at the Food and Drug Administration (FDA) by the so-called Department of Government Efficiency (DOGE). The FDA's mission is to protect public health by assuring the safety, efficacy and security of our human and veterinary drugs, food and cosmetics products and the regulation of tobacco products. We are concerned that the mass firings of probationary staff at the FDA, many of whom with scientific backgrounds, will prevent us from staying on the cutting edge of drug and device approvals, maintaining food safety and responding to new threats, like avian flu.

Unlike other agencies within the Department of Health and Human Services (HHS), the FDA is funded through a combination of annual appropriations and user fees from industry. This strategic move, proposed and passed under a Republican administration, occurred to enhance the FDA's research program and approve drugs and devices more quickly. But, we understand that federal workers in probationary periods who work for the Center for Devices and Radiological Health (CDRH), the Center for Tobacco Products (CTP) and the Office of Generic Drugs (OGD) at the Center for Drug Evaluation and Research (CDER) were fired over the weekend. All of the salaries at CTP and many of the salaries at CDRH and OGD are paid for through user fees¹; this raises the alarm of whether DOGE, responsible for identifying probationary employees to fire, truly understands the nuances of funding at the FDA.

Outlined in the individual statutes for each user fee program, there are trigger rates that must be met in order for FDA to unlock vital user fee funding.<sup>2</sup> Without adequate staff at each center that receives user fees, the FDA may not be able to collect or spend user fees for the upcoming fiscal year. This would be seriously detrimental to our medical drug and device programs by slowing the premarket review process, stifling innovation and preventing patients from accessing potentially lifesaving products. This decision will only hurt the American people by preventing

<sup>&</sup>lt;sup>1</sup>https://aspe.hhs.gov/sites/default/files/documents/e4a7910607c0dd76c40aa61151d154f9/FDA-User-Fee-Issue-Brief.pdf p.4

<sup>&</sup>lt;sup>2</sup>https://crsreports.congress.gov/product/pdf/R/R44750 p.2

advancements in patient care and is directly in conflict with President Trump's stated health care goal of, "providing more choice, better care, and lower costs".<sup>3</sup>

There are also centers at the FDA that do not receive user fees, such as the Unified Human Foods Program (HFP). The HFP is almost exclusively funded by annual appropriations and was reorganized in 2024 in order to better protect food safety and prevent food borne illnesses. Many of these challenges were illuminated during the infant formula crisis, which prompted the Reagan-Udall Foundation evaluation to improve the foods programs at the FDA.<sup>4</sup> Inexplicably, the HFP had over 80 probationary employees fired over the weekend.<sup>5</sup> Jim Jones, the Deputy Commissioner for the HFP, resigned from his post on February 17, 2025, saying the cuts were "indiscriminate" and that DOGE fired the very staff that would move forward the purported Make America Healthy Again (MAHA) Agenda, and that it would be, "fruitless for me to continue in this role".<sup>6</sup> We are concerned about how these firings will impact FDA's ability to protect the American public from foodborne illness and harmful chemicals.

Reports and recent Executive Orders<sup>7</sup> suggest that additional cuts to the federal workforce will come in the near future, which is evermore concerning. Despite promises of "radical transparency," HHS has failed to provide notification of these staffing reductions to the Senate and House Appropriations Committees, as required by Section 716 of Division B of PL 118-42. We urge you to end the indiscriminate cuts that will cause lasting harm to FDA's public health mission, protect FDA's statutory obligations, and prevent the stifling of American innovation.

Sincerely,

<sup>&</sup>lt;sup>3</sup>https://trumpwhitehouse.archives.gov/issues/healthcare/

<sup>&</sup>lt;sup>4</sup>https://reaganudall.org/operational-evaluation-fdas-human-foods-programs

<sup>&</sup>lt;sup>5</sup>https://www.bloomberg.com/news/articles/2025-02-18/food-head-at-fda-resigns-citing-numerous-job-cuts-in-division?leadSource=uverify%20wall

<sup>&</sup>lt;sup>6</sup>https://www.bloomberg.com/news/articles/2025-02-18/food-head-at-fda-resigns-citing-numerous-job-cuts-in-division?leadSource=uverify%20wall

<sup>&</sup>lt;sup>7</sup> https://www.whitehouse.gov/fact-sheets/2025/02/fact-sheet-president-donald-j-trump-works-to-remake-americas-federal-workforce/

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Jeanne Shaheen United States Senator Ranking Member, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Committee on Appropriations

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