Congress of the United States

Washington, DC 20515

February 21, 2025

The Honorable Robert F. Kennedy Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Subject: Rescind the FDA's May 6, 2024, Rule on Laboratory Developed Tests

Dear Secretary Kennedy,

We write to express our concerns regarding the Food and Drug Administration's (FDA) rule, *Medical Devices: Laboratory Developed Tests*. This rule, issued by the Biden Administration's FDA, has raised significant concerns within the healthcare and research communities due to its potential negative implications. As Members of Congress and advocates for the advancement of healthcare, we respectfully request that the FDA revoke this rule, allowing Congress to examine the issue and determine any necessary regulatory changes.

The FDA's rule on Laboratory Developed Tests (LDTs) has generated widespread apprehension among healthcare professionals, researchers, and the broader scientific community. The changes outlined in this rule will have far-reaching effects on patient care, innovation, and the ability of laboratories to develop and implement timely and effective diagnostic tests.

Several key concerns warrant careful consideration:

- **Impact on Innovation:** The rule imposes regulatory burdens that will stifle innovation and hinder the development and deployment of new and improved LDTs.
- **Patient Access to Testing:** Increased regulatory requirements may delay patients' access to critical diagnostic tests.
- **Collaboration and Research:** The research community has expressed concerns that the rule could hinder collaborative efforts and research initiatives that rely on the flexibility provided by LDTs.
- **Economic and Small Business Impact:** Small and medium-sized laboratories, which play a vital role in healthcare, may face financial difficulties in complying with the rule.

During President Trump's first term, the Department of Health and Human Services (HHS) blocked the FDA from implementing its plan to transfer oversight of LDTs from the HHS Clinical Laboratory Improvement Amendments (CLIA) program to the FDA. The FDA

subsequently withdrew its guidance on regulating LDTs, stating that it would defer to Congress on the matter. When Congress declined to grant the FDA explicit authority over LDTs in 2022, the agency asserted that it already possessed the necessary authority and expedited the finalization of this rule to ensure its implementation before the 2024 election.

Thank you for your attention to this matter. We stand ready to assist you in any way necessary.

Sincerely,

Brad Finstad
Member of Congress

Dan Crenshaw
Member of Congress