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Randall L. Rutta

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December 13, 2021

The Honorable Patty Murray

Chair

Committee on Health, Education, Labor, and
Pensions

United States Senate

154 Russell Office Building

Washington, DC 20510

The Honorable Richard Burr

Ranking Member

Committee on Health, Education, Labor, and
Pensions

United States Senate

154 Russell Office Building

Washington, DC 20510

Dear Senators Murray and Burr:

The National Health Council (NHC) supports President Joseph Biden's nomination of Robert Califf, MD, as Commissioner of the Food and Drug Administration (FDA) and urges you to confirm him without delay.

Created by and for patient organizations 100 years ago, the National Health Council (NHC) brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The FDA has weathered one of the most challenging periods in its history. While the existing staff has admirably responded to COVID-19 and other challenges, President Biden's selection of former Commissioner Dr. Califf to head the agency can bring stability and help build on the lessons learned during the pandemic, boosting staff morale, and paving the way for future innovation at a critical time.

Without question, the FDA has accomplished a great deal over the past 18 months, and the current leadership has done an outstanding job navigating this unprecedented time. COVID-19 vaccines, tests, and treatments were thoroughly reviewed and swiftly approved to address the pandemic, a historic accomplishment by all accounts. Despite the pandemic challenges, FDA continued to review and approve numerous treatments for rare and other complex diseases.

A presidential-appointed Commissioner, with all the influence and respect that support from the White House and the Senate bestows, can be a champion for millions of Americans, particularly those with chronic diseases and disabilities. The FDA can be a robust agent for transformational change in our health care ecosystem. As we look to 2022, we also need a Commissioner to guide this evolution with Congress and the agency entering into user fee agreement (UFA) negotiations.

The patient community is proud to have worked with Dr. Califf before, during, and after his time as Commissioner to advance patient engagement at FDA. Under his leadership as Commissioner, patients became active participants in making decisions that will ultimately impact their health. Meaningful patient engagement has led to higher-value products that promote better health outcomes that meet individual's unique needs.

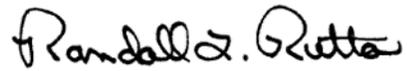
The PDUFA VII commitment letter includes significant continuation of patient-supported priorities that further the science of patient engagement and infuse patient input into a variety of priority areas such as the use of digital health tools in clinical trials, real-world evidence, and the regulation of cell and gene therapies. Given his long-standing championing of patient engagement, we feel strongly he would be a great leader to ensure the UFA implementation will successfully launch or further these important initiatives.

In addition, there are health equity challenges and opportunities at FDA that Dr. Califf is qualified to address. The NHC and our member organizations have redoubled our efforts on finally undoing decades of harm the health care system has caused for marginalized communities by targeting and dismantling health disparities. As part of our [work](#), Dr. Califf has engaged with our members to provide thought leadership on the role FDA and medical product developers can have to address health equity such as greater diversification of clinical trials and patient engagement activities.

As the Senate HELP Committee makes the important decision to confirm the next FDA Commissioner, please consider the voice of people with chronic conditions and disabilities and confirm Dr. Califf.

Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs if you or your staff would like to discuss these issues in greater detail. He is reachable via e-mail at egascho@nhcouncil.org.

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive style with a large initial 'R' and a distinct 'L'.

Randall L. Rutta
Chief Executive Officer