

Congress of the United States

Washington, DC 20515

March 28, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

We write today to call attention to the importance of smoking cessation pharmacotherapies for Americans seeking to quit smoking. Tobacco use remains the leading cause of preventable disease and death in the United States. Despite progress in recent decades to reduce smoking rates in America, the public health impact of the mortality and morbidity associated with smoking remains staggering. We commend the Department of Health and Human Services for its focus on this critical public health issue and appreciate the opportunity to work with you to address a significant unmet need—namely, the availability of new and improved cessation pharmacotherapies.

The draft framework outlined in the Department’s Request for Information: Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation (Framework), as published in the Federal Register on June 30, 2023, includes the goal of strengthening and sustaining cessation services and supports.¹ Such a focus is vital, as less than one-third of the millions of Americans who try to quit smoking each year make use of counseling or medications approved by the Food and Drug Administration (FDA).² On March 8, 2024, HHS released a new Framework, yet neither the draft nor the new framework acknowledge the importance of updating and expanding the cessation “toolkit” available to smokers, including the opportunity to address any existing barriers to the development of vitally needed new therapies³.

To date, there are only three FDA-approved smoking cessation therapies. No new treatment has been approved in almost 20 years.⁴ While these therapies are effective, more effective treatments should be encouraged.

We applaud the ambitious goals of the Administration’s Cancer Moonshot initiative, but are concerned that the Administration will not achieve those important goals unless Americans have access to comprehensive, evidence-based cessation products and programs to meet their needs. It is thus essential that the Department’s framework incorporate a focus on pharmacotherapies as part of its strategy.

Incorporating a focus on innovation in smoking cessation treatments would strengthen the Framework and signal the Administration’s recognition of the important role new safe, effective, and innovative pharmacotherapies can play in helping Americans more successfully stop smoking. Therefore, we urge the Department to ensure that its smoking cessation framework includes meaningful actions to spur safe, effective, and innovative pharmacotherapies.

¹ <https://www.federalregister.gov/documents/2023/06/30/2023-13928/request-for-information-draft-hhs-2023-framework-to-support-and-accelerate-smoking-cessation>

² <https://www.cdc.gov/tobacco/sgr/2020-smoking-cessation/fact-sheets/healthcare-professionals-health-systems/>

³ <https://www.hhs.gov/about/news/2024/03/08/hhs-announces-new-smoking-cessation-framework-support-quit.html>


⁴ <https://www.nejm.org/doi/full/10.1056/NEJMp2301700>

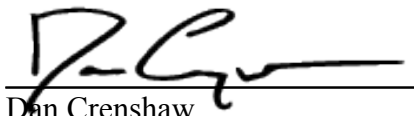
We also request a staff-level briefing for the Members signed onto this letter outlining actions the Administration will take to modernize the regulatory approach to smoking cessation therapies within six months of receipt of this letter.

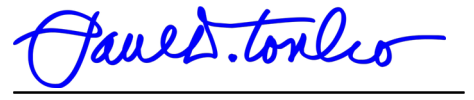
Thank you for your consideration of our concerns and request regarding actions the Department can take to improve the Framework and better support Americans seeking to quit smoking. We share your commitment to ensuring the health and well-being of all Americans and look forward to working with you on this and other public health priorities.

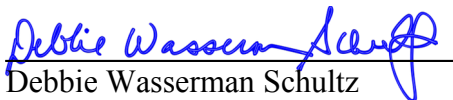
Sincerely,



Ann McLane Kuster
Member of Congress

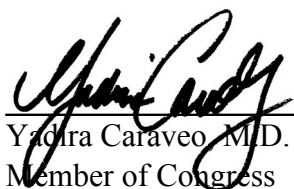

Larry Bucshon, M.D.
Member of Congress

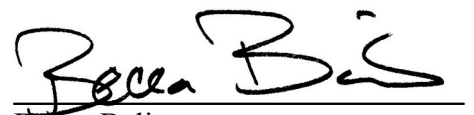

Dan Crenshaw
Member of Congress



Paul Tonko
Member of Congress


Debbie Wasserman Schultz
Co-Chair, Democratic Steering &
Policy Committee

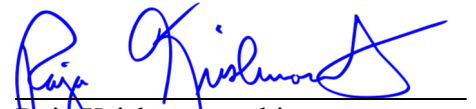

Marcus J. Molinaro
Member of Congress


Ychira Caraveo, M.D.
Member of Congress


Becca Balint
Member of Congress



David J. Trone
Member of Congress



Raja Krishnamoorthi
Member of Congress



Brittany Pettersen
Member of Congress



Diana DeGette
Member of Congress

CC: Dr. Robert Califf, Commissioner of Food and Drugs
Dr. Patrizia Cavazzoni, Director, Center for Drug Evaluation and Research
Dr. Stephen Cha, Counselor to the Secretary, U.S. Department of Health and Human Services