RO KHANNA
17TH DISTRICT, CALIFORNIA

COMMITTEE ON OVERSIGHT AND REFORM
Chairman of the Subcommittee on Environment
Subcommittee on Government Operations

COMMITTEE ON ARMED SERVICES
Subcommittee on Cyber, Innovative Technologies and Information Systems
Subcommittee on Strategic Forces

COMMITTEE ON AGRICULTURE
Subcommittee on Commodity Exchanges, Energy and Credit
Subcommittee on Livestock and Foreign Agriculture

Congress of the United States
House of Representatives
Washington, DC 20515-0517

306 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2631
(202) 225-2699 (F)

DISTRICT OFFICE:
3150 DE LA CRUZ BLVD, SUITE 240
SANTA CLARA, CA 95054
(408) 436-2720
(408) 436-2721 (F)

khanna.house.gov

September 3rd, 2021

Commissioner Janet Woodcock
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Woodcock,

Thank you for your ongoing efforts to protect public health, particularly during this critical stage of the COVID-19 pandemic. We are writing about the draft guidance on drug products labeled as homeopathic as issued by the Food and Drug Administration (FDA or Agency) in 2017 and revised in 2019. We understand that the FDA is concerned about products labeled as homeopathic that push the envelope, prompting the Agency to reevaluate its regulatory approach to keep them within the appropriate guardrails of traditional homeopathic drugs. Unfortunately, the guidance has disproportionately impacted manufacturers who produce safe, genuine homeopathic products, which in turn has made a growing number of these medicines less accessible, if not entirely unavailable, to consumers who rely on them.

Since 1938 until 2017, the FDA consistently recognized the distinction between pharmaceutical and homeopathic drugs, and Congress has repeatedly reaffirmed this distinction as set forth in the Food, Drug, and Cosmetic Act. Most recently in 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which exempts homeopathic drugs from review under its provisions regarding pharmaceutical drugs. In 1938, the FDA supported the decision to recognize the Homeopathic Pharmacopoeia of the United States and its supplements as the official compendium of standards and monographs for homeopathic drug ingredients giving the Agency the tools to regulate homeopathic drugs as a unique and separate category of drugs. On several occasions the FDA has commented on this distinction as set forth by Congress, and the Agency's policies have been in adherence with the law which, as the FDA stated in 1988, "gives no premarket review of true homeopathic dilutions."

This distinction has previously allowed the FDA to enforce standards that separate and safeguard legitimate homeopathic products while permitting swift action against products that are adulterated, misbranded, or improperly labeled as homeopathic. It helps to protect consumers, provides manufacturers with a clear pathway to market their products, and ensures access to products which meet homeopathic standards for quality and purity.

However, the draft guidance outlines enforcement priorities that do not distinguish between products that meet homeopathic standards and those that are adulterated, misbranded, or improperly labeled as homeopathic. Under this guidance, manufacturers who comply with standards for quality, purity, and proper dilution are subject to enforcement action for products

which are nontoxic by their very nature when made according to those standards. Additionally, the draft guidance no longer references the framework by which homeopathic manufacturers can legally market their products without risk of enforcement action, raising concerns about the stability of the market and the availability of homeopathic drug products among our constituents.

In congruence with both the 2021 and 2022 Appropriations report in which Congress "urges FDA to consider the views of patients in finalizing its draft guidance," we are writing to understand how the FDA intends to utilize and adhere to the framework established by Congress as well as the Agency in order to protect consumers and ensure access to the products that meet homeopathic standards for quality and purity. Thank you again for your ongoing work to improve access to safe and affordable healthcare and thank you for your full and fair consideration of this inquiry.

Sincerely,

Ro Khanna
Member of Congress

Martin Heinrich
United States Senator

Dwight Evans
Member of Congress

Lisa McClain
Member of Congress

Mike Lee
United States Senator

Brian Fitzpatrick
Member of Congress

Joe Neguse
Member of Congress

Andy Biggs
Member of Congress

Paul Gosar
Member of Congress

Ralph Norman
Member of Congress

Gus Bilirakis
Member of Congress

Glenn Grothman
Member of Congress

Chellie Pingree
Member of Congress

Jamaal Bowman
Member of Congress

Diana Harshbarger
Member of Congress

Jamie Raskin
Member of Congress

Tony Cárdenas
Member of Congress

Jaime Herrera Beutler
Member of Congress

Matt Rosendale
Member of Congress

John Carter
Member of Congress

Andy Levin
Member of Congress

Thomas R. Suozzi
Member of Congress

Antonio Delgado
Member of Congress

Nicole Malliotakis
Member of Congress

John Yarmuth
Member of Congress