

Congress of the United States
Washington, DC 20515

September 6, 2023

The Honorable Patrizia Cavazzoni, M.D.
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Drugs
10903 New Hampshire Avenue WO22 Stop 5411
Silver Spring, MD 20993

Dear Dr. Cavazzoni:

Recently, after almost a decade, the Food and Drug Administration (FDA) released a proposed rule on Prescription (Rx)-to-Over-the-Counter (OTC) Switch, known as Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU).

While we support FDA's efforts to improve public health through increased access to nonprescription drugs, we are concerned one key element of the rule may create a disincentive to switch medicines to nonprescription status, thus undermining public health goals.

The reason for this concern is the proposed concept of simultaneous marketing of both prescription and nonprescription versions of the same drug. This flies in the face of a decades-old law to prevent this from occurring: When two products are used for the same condition, with the same indication, same dose, same strength, same form, and same route of administration, they ought to have the same legal classification. That provision in law has served its intended function for decades: Reduce the possibilities for confusion, and not allow two companies making the same thing to arbitrarily decide whether they are going to sell it with or without a prescription. As proposed, the rule departs from the law.

Simultaneous marketing of the same Rx and OTC product with an ACNU would ultimately limit rather than expand access for underserved communities, while also undermining the rule's anticipated favorable economic impacts. For decades, Rx-to-OTC switches have proven to increase access to safe and effective self-treatment options, and we should be extremely cautious of any actions that could disincentivize manufacturers from pursuing this pathway that benefits consumers and the healthcare system.

Ultimately, we want to be able to deliver on what the Office of Management and Budget (OMB) estimated: that further OTC Switches can lead to, on average, a \$26.70 savings per transaction. Removing the simultaneous marketing provision of the proposed rule will help.

We look forward to hearing back from you in advance of the final rule.

Sincerely,



Robert E. Latta
United States Representative



Debbie Dingell
United States Representative



Dan Crenshaw
Member of Congress