Congress of the United States

Washington, DC 20515

April 11, 2025

VIA ELECTRONIC SUBMISSION

Martin Makary M.D., M.P.H.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

Dear Commissioner Makary:

In September 2023, a number of Members of Congress wrote the Food and Drug Administration (FDA) expressing a concern with one element within the agency's then-proposed rule on Additional Conditions of Nonprescription Use, which would cover prescription-to-nonprescription switches with added technology. That element: Simultaneous marketing of the otherwise same prescription drug after approval of a nonprescription drug with an additional condition of nonprescription use.

Despite these concerns, the simultaneous marketing provision was included in the final rule published in the last few weeks of the Biden Administration (December 26, 2024). The rule is currently under the President's executive order to delay implementation dates to consider questions of fact, law, and policy. With the rule now issued, we do not believe it would be time- or cost-effective to withdraw it, given it was many years in the making, with its first appearance on President Trump's semi-annual regulatory agenda in 2018. A full-on withdrawal, re-proposal, and finalization would take years to fix.

But the final rule made matters worse: Perhaps recognizing that the simultaneous marketing provision is unlawful, they included a significant and objectionable poison pill discussion in the preamble to the rule that was never signaled in the proposed rule and appears to have been inserted in the final days of the previous administration. The preamble states that the entire rule should be stricken if the simultaneous marketing provision (21 CFR § 314.56(d)) is invalidated and claims that this provision is fundamental to the rule. This is a frank attempt to insulate a portion of the rule that stretches a plain reading of the statute from judicial review: If a sponsor were to have a product with an additional condition of nonprescription use approved and then challenged FDA's position on simultaneous marketing, it would risk eliminating the very rule on which its product approval was based.

Historically, when all uses of a product are switched to nonprescription use, FDA has, as required by statute, determined that the prescription product must no longer be available. Of course, different formulations of the same drug active ingredient might be available for prescription use – for example –

intravenous acetaminophen is marketed as a prescription drug because it is a different formulation. However, this statutory requirement avoids confusion that would result if both prescription and nonprescription version of a product for the same conditions of use were marketed. The historic ban on simultaneous marketing is further beneficial because it allows a drug sponsor who undertakes the significant expense of demonstrating that a drug can be switched to nonprescription use to benefit from a limited period of exclusivity. The provision of the rule that purports to allow simultaneous marketing of defunct prescription versions of a switched drug, notwithstanding the law and FDA's past position, threatens to undermine these benefits.

We repeat that we do not believe the rule should be withdrawn. But FDA can and should eliminate the poison pill language in the preamble to the rule that seeks to insulate the simultaneous marketing provision of the rule from future challenge. The agency could either publish an advisory opinion to amend the preamble to revise this advisory opinion, or reissue just the with that portion withdrawn and rest of the preamble otherwise unchanged.

We want to see sponsors be able to deliver on FDA's and the Office of Management and Budget's (OMB) impact analysis benefit estimate supporting the rule: Further prescription-to-nonprescription switches can lead to an average of $26.70 savings per transaction. Withdrawing the over-reaching portion of the preamble will help.

We look forward to hearing from you on this important matter.

Sincerely,

Robert E. Latta
Member of Congress

Dan Crenshaw
Member of Congress

Mariannette J. Miller-Meeks, M.D.
Member of Congress