

Congress of the United States
Washington, DC 20515

January 31, 2023

The Honorable Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street NW
Washington, D.C. 20548

Dear Comptroller General Dodaro:

On January 3, 2023, the U.S. Food & Drug Administration (FDA) posted a new policy that increases access and consumption of mifepristone. We write to seek your review of whether the January 2023 REMS Modification for mifepristone, issued by the FDA, constitutes a “rule” for purposes of the Congressional Review Act (CRA).

With limited exceptions, the CRA defines a “rule” as follows:

‘[R]ule’ means the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing.”

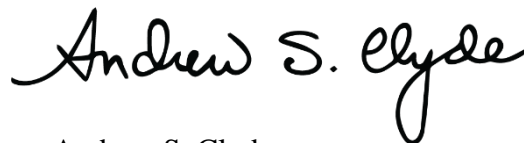
Based upon this broad definition, the Government Accountability Office has rightly pointed out that “agency pronouncements may be rules within the definition of 5 U.S.C. § 551 and the CRA, even if they are not subject to notice and comment rulemaking requirements under section 553.”

The FDA’s update appears to prescribe detailed policy. For these reasons, we respectfully request a determination as to whether or not this “rule” is applicable under the CRA. Please respond with your determination by February 14, 2023.

Sincerely,



Marco Rubio
U.S. Senator



Andrew S. Clyde
Member of Congress



Cindy Hyde-Smith
U.S. Senator



Christopher H. Smith
Member of Congress



Michael S. Lee
U.S. Senator



Mary E. Miller
Member of Congress



Thom Tillis
U.S. Senator



Andy Biggs
Member of Congress



Roger Marshall, M.D.
U.S. Senator



Debbie Lesko
Member of Congress



Mike Braun
U.S. Senator



Barry Loudermilk
Member of Congress



Rick Scott
U.S. Senator



Doug Lamborn
Member of Congress

Roger F. Wicker
U.S. Senator

Bill Johnson
Member of Congress

Ben Cline
Member of Congress

Paul A. Gosar, D.D.S.
Member of Congress

Troy Balderson
Member of Congress

Randy K. Weber
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Josh Brecheen
Member of Congress

Jeff Duncan
Member of Congress

Mike Bost
Member of Congress

Jefferson Van Drew
Member of Congress

Mike Ezell
Member of Congress

Jim Banks
Member of Congress



Andy Ogles
Member of Congress



Marjorie Taylor Greene
Member of Congress



Alex X. Mooney
Member of Congress



Diana Harshbarger
Member of Congress



Lance Gooden
Member of Congress



Bob Good
Member of Congress



Trent Kelly
Member of Congress



Michael Guest
Member of Congress



Russ Fulcher
Member of Congress



Daniel Webster
Member of Congress