

Congress of the United States
Washington, DC 20515

April 25, 2016

Dr. Robert M. Califf, M.D.
Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf,

We are deeply disappointed to learn that you have loosened FDA standards governing use of the abortion drug mifepristone, also referred to as Mifeprex or RU-486. This powerful abortion drug has been associated with serious adverse events including hemorrhaging, severe infections and even deaths of mothers who have taken it.

Furthermore, the drug's original approval process was extremely controversial. At the start of the Clinton Administration, President Clinton issued an Executive Order instructing the FDA to reevaluate the status of the abortion drug. Then-FDA Commissioner Kessler even urged the European patent-holder, Roussel Uclaf, to submit an application for approval of mifepristone. When mainstream drug manufacturers refused to bring this baby-killing drug to the United States, abortion proponents created Danco Laboratories for the sole purpose of distributing the abortion drug in the United States. Finally, the drug was pushed through the approval process in the final months of the Clinton administration.

In light of this history, we are concerned about the recent changes to the FDA-Approved Regimen and the Risk Evaluation and Mitigation Strategy (REMS) for Mifeprex (mifepristone) announced on March 30, 2016. We respectfully request that you provide the following information within a month (no later than May 20, 2016):

1. A thoroughly updated "Postmarketing Adverse Events Summary" including any reported deaths associated with mifepristone through December 2015. The current available data on Adverse Events¹ has only been updated through April 2011.
2. A list of all applications submitted to the FDA since 2000 by Danco Laboratories, including but not limited to the recently approved application to loosen standards governing the use of the abortion drug, Mifeprex (mifepristone).
3. A timeline of FDA actions associated with Danco's application to loosen standards governing the use of the abortion drug, Mifeprex (mifepristone) including any review by the Bone, Reproductive and Urologic Drugs Advisory Committee (formerly the Reproductive Health Drugs Advisory Committee.)
4. A copy of all documents, studies and other evidence used to assess the safety and efficacy of the Mifeprex (mifepristone) changes announced on March 30, 2016.

¹<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf>

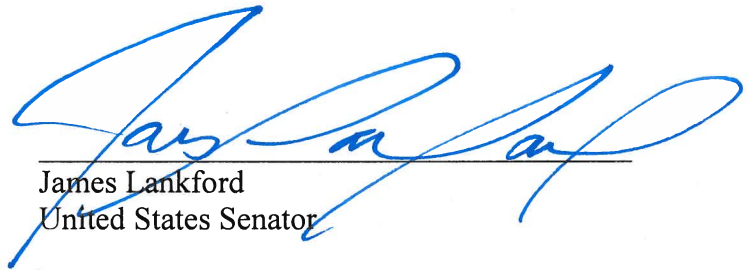
5. A copy of any transcripts or notes from consideration of Danco applications by the Bone, Reproductive and Urologic Drugs Advisory Committee.
6. The locations where mifepristone is manufactured and/or packaged and a list of all FDA safety reviews of these locations in the past 15 years including any site visits conducted by the FDA or at the request of the FDA.
7. A copy of all communications between you, or any member of the FDA staff, and the White House and/or the Office of the Secretary of HHS, regarding mifepristone, Mifeprex, RU-486 or "medication abortion."
8. A copy of all communications between you, or any member of the FDA staff, and any nongovernmental entity (such as Planned Parenthood, ACOG, Gynuity) regarding mifepristone, Mifeprex, RU-486 or "medication abortion."

Thank you for your prompt response to these requests within a month (no later than May 20, 2016). In addition please provide documents as they become available, rather than holding all responses until all documents are collected. If you have any questions about this request, please contact Autumn Christensen with Rep. Chris Smith at 202-225-3765.

Sincerely,



Christopher H. Smith
Member of Congress



James Lankford
United States Senator



Diane Black
Member of Congress



Roy Blunt
United States Senator



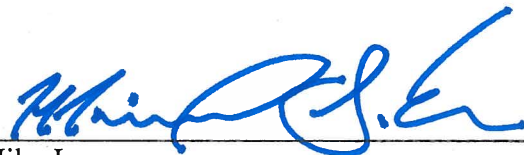
Virginia Foxx
Member of Congress



Ted Cruz
United States Senator

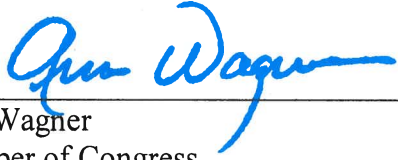


Vicky Hartzler
Member of Congress

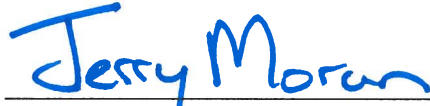


Mike Lee
United States Senator

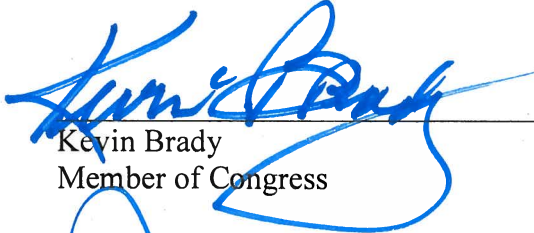




Ann Wagner
Member of Congress



Jerry Moran
United States Senator



Kevin Brady
Member of Congress



David Vitter
United States Senator



Tom Cole
Member of Congress



James E. Risch
United States Senator



Daniel Lipinski
Member of Congress



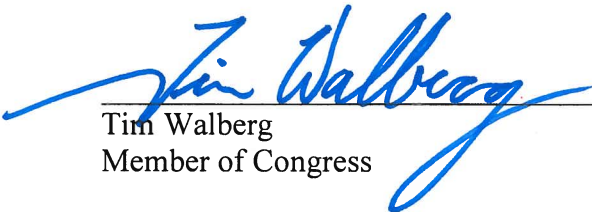
Joni K. Ernst
United States Senator



Tim Murphy
Member of Congress



Steve Daines
United States Senator



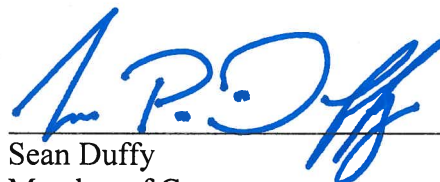
Tim Walberg
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J. Randy Forbes
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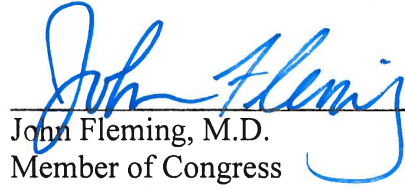
Pete Olson
Member of Congress




Sean Duffy
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Todd Rokita
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John Fleming, M.D.
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Steve King
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Jeb Hensarling
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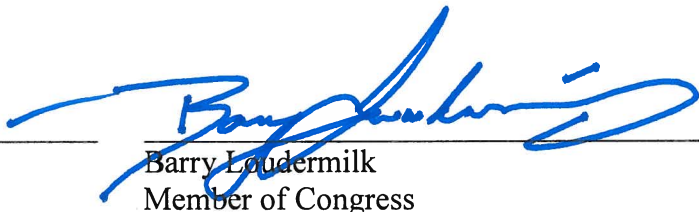
Steve Pearce
Member of Congress



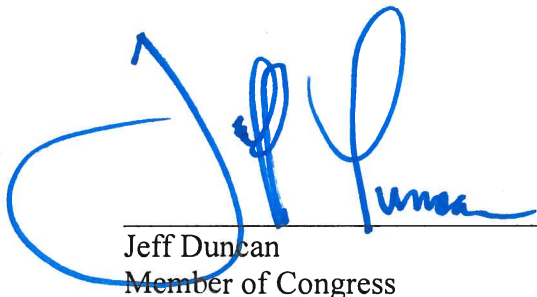
Trent Franks
Member of Congress



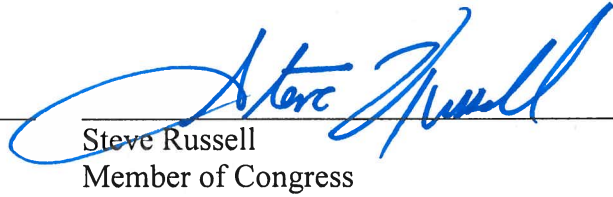
Blaine Luetkemeyer
Member of Congress



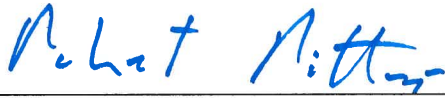
Barry Loudermilk
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Jeff Duncan
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Steve Russell
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Robert Pittenger
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Gregg Harper
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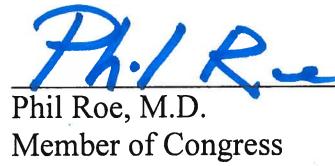
Brian Babin
Member of Congress



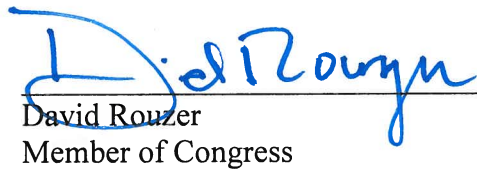
Doug LaMalfa
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Jeff Miller
Member of Congress



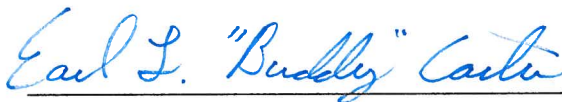
Phil Roe, M.D.
Member of Congress



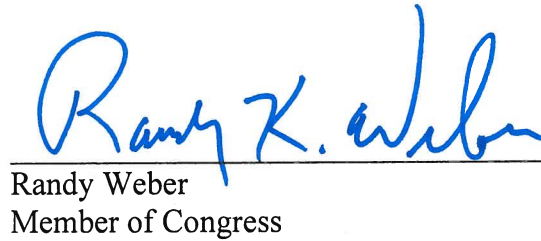
David Rouzer
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Richard Hudson
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Earl L. 'Buddy' Carter
Member of Congress



Randy Weber
Member of Congress



Rick Allen
Member of Congress



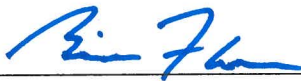
Dan Benishek, M.D.
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Mark Meadows
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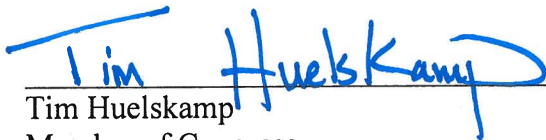
Blake Farenthold
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Bill Flores
Member of Congress



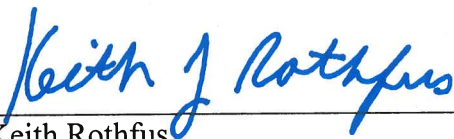
Daniel Webster
Member of Congress



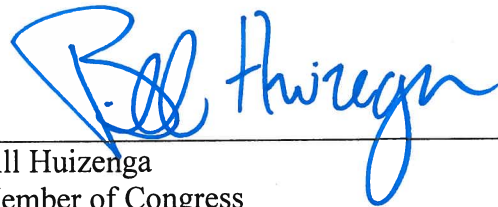
Tim Huelskamp
Member of Congress



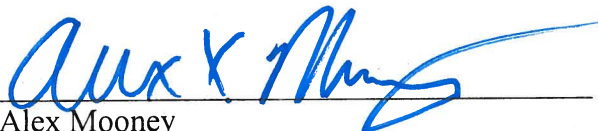
Markwayne Mullin
Member of Congress



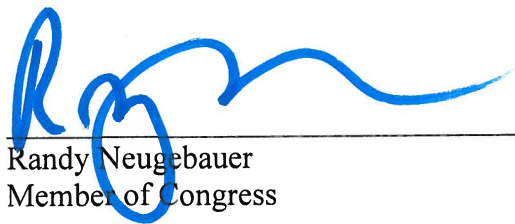
Keith Rothfus
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Bill Huizenga
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Alex Mooney
Member of Congress



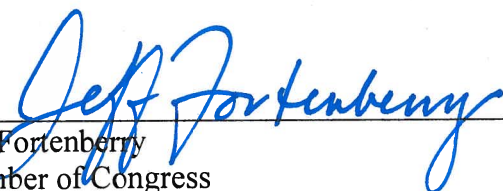
Randy Neugebauer
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Trent Kelly
Member of Congress



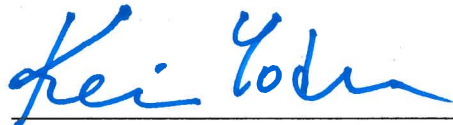
Charles W. Boustany, Jr. M.D.
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Jeff Fortenberry
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Bill Johnson
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Mark Walker
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Chris Stewart
Member of Congress



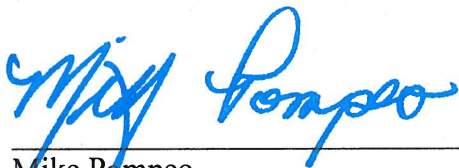
John Ratcliffe
Member of Congress



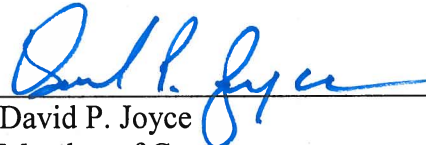
Bob Gibbs
Member of Congress



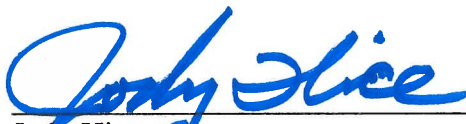
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Mike Pompeo
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David P. Joyce
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Jody Hice
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Mike Kelly
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Joseph R. Pitts
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