

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>

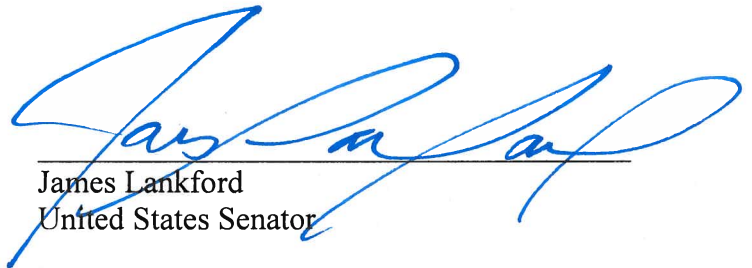
5. A copy of any transcripts or notes from consideration of Danco applications by the Bone, Reproductive and Urologic Drugs Advisory Committee.
6. The locations where mifepristone is manufactured and/or packaged and a list of all FDA safety reviews of these locations in the past 15 years including any 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



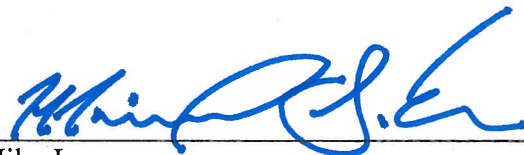
Virginia Foxx
Member of Congress



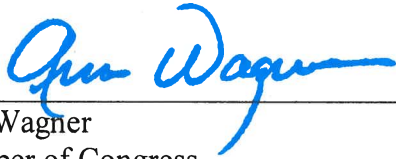
Ted Cruz
United States Senator



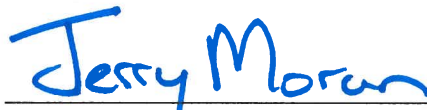
Vicky Hartzler
Member of Congress



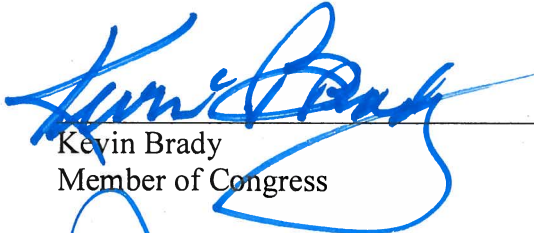
Mike Lee
United States Senator



Ann Wagner
Member of Congress



Jerry Moran
United States Senator



Kevin Brady
Member of Congress



David Vitter
United States Senator



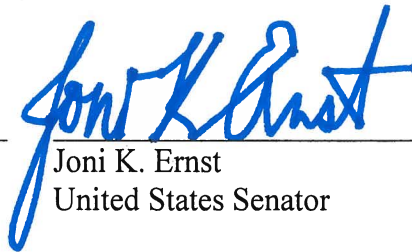
Tom Cole
Member of Congress



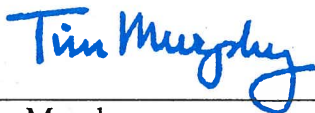
James E. Risch
United States Senator



Daniel Lipinski
Member of Congress



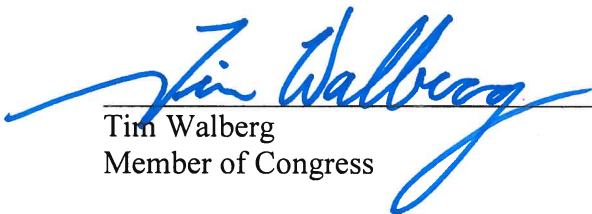
Joni K. Ernst
United States Senator



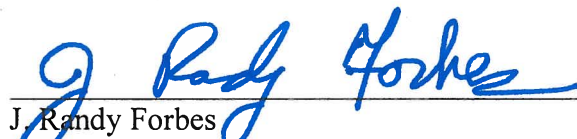
Tim Murphy
Member of Congress



Steve Daines
United States Senator



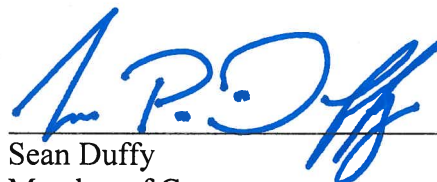
Tim Walberg
Member of Congress



J. Randy Forbes
Member of Congress



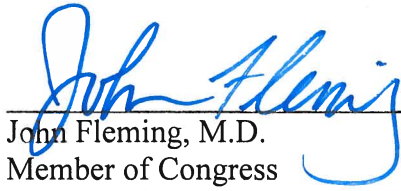
Pete Olson
Member of Congress



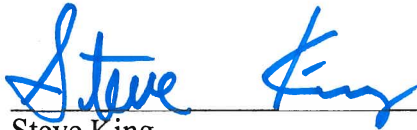
Sean Duffy
Member of Congress



Todd Rokita
Member of Congress



John Fleming, M.D.
Member of Congress



Steve King
Member of Congress



Jeb Hensarling
Member of Congress



Sam Johnson
Member of Congress



Bob Goodlatte
Member of Congress



Walter B. Jones
Member of Congress



Matt Salmon
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Steve Chabot
Member of Congress



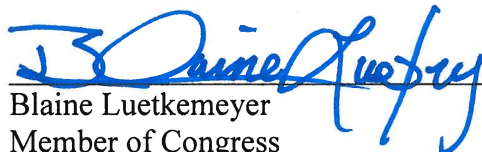
Doug Lamborn
Member of Congress



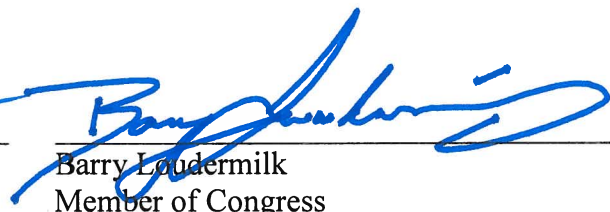
Steve Pearce
Member of Congress



Trent Franks
Member of Congress



Blaine Luetkemeyer
Member of Congress



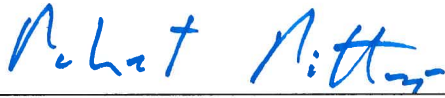
Barry Loudermilk
Member of Congress



Jeff Duncan
Member of Congress



Steve Russell
Member of Congress



Robert Pittenger
Member of Congress



Gregg Harper
Member of Congress



Brian Babin
Member of Congress



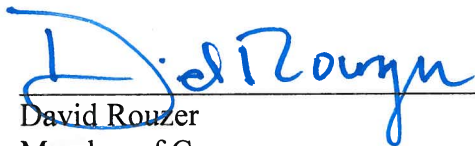
Doug LaMalfa
Member of Congress



Jeff Miller
Member of Congress



Phil Roe, M.D.
Member of Congress



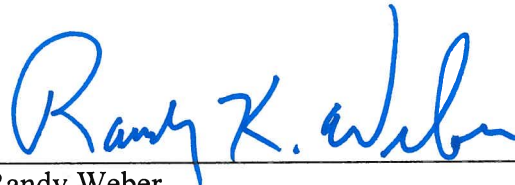
David Rouzer
Member of Congress



Richard Hudson
Member of Congress



Earl L. 'Buddy' Carter
Member of Congress



Randy Weber
Member of Congress



Rick Allen
Member of Congress



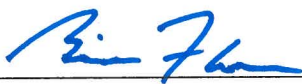
Dan Benishek, M.D.
Member of Congress



Mark Meadows
Member of Congress



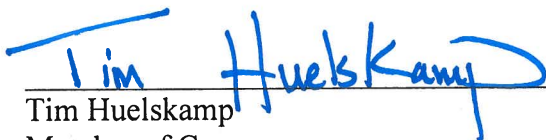
Blake Farenthold
Member of Congress



Bill Flores
Member of Congress



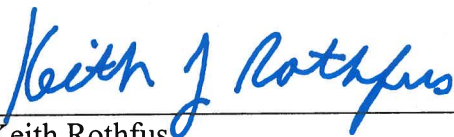
Daniel Webster
Member of Congress



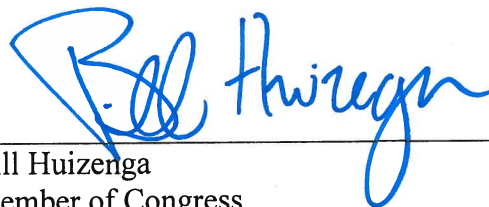
Tim Huelskamp
Member of Congress



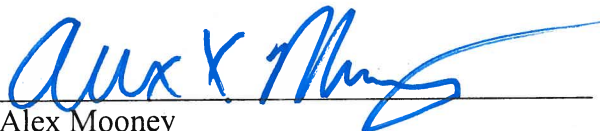
Markwayne Mullin
Member of Congress



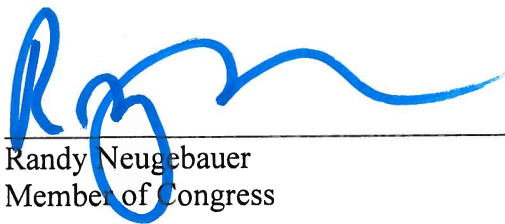
Keith Rothfus
Member of Congress



Bill Huizenga
Member of Congress



Alex Mooney
Member of Congress



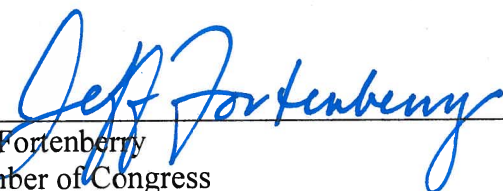
Randy Neugebauer
Member of Congress



Trent Kelly
Member of Congress



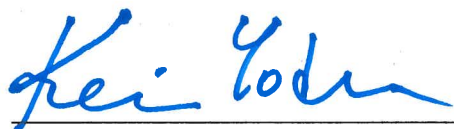
Charles W. Boustany, Jr. M.D.
Member of Congress



Jeff Fortenberry
Member of Congress



Bill Johnson
Member of Congress



Kevin Yoder
Member of Congress



Mark Walker
Member of Congress



Chris Stewart
Member of Congress



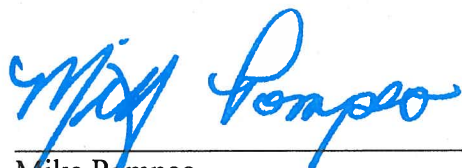
John Ratcliffe
Member of Congress



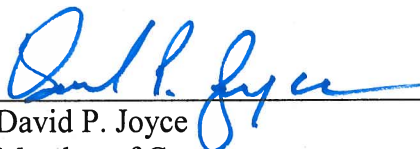
Bob Gibbs
Member of Congress



David Brat
Member of Congress



Mike Pompeo
Member of Congress



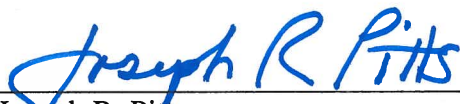
David P. Joyce
Member of Congress



Jody Hice
Member of Congress



Mike Kelly
Member of Congress



Joseph R. Pitts
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