



## BREAKING NEWS! 5th Circuit Court Hands Down Decision on the FDA's Approval of the Abortion Pill

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Aug 18 2023

It's been a long, hot summer, and are you as thirsty as I am for some good news? Well, we got it this week. Wednesday, August 16, 2023—The 5<sup>th</sup> Circuit Court has finally released its decision on the case *Hippocratic Alliance vs. FDA and Danco Labs*. Spoiler alert: pro-life progress was made! Let's stop to thank God for this victory for the unborn and for the women and men who are harmed by abortion!

Let me bring you up to speed on this latest court decision about the future of mifepristone in America. As you may recall, this all began back in November 2022 when the Alliance Defending Freedom (ADF) submitted the lawsuit on behalf of AAPLOG, CMDA, ACP, and the Hippocratic Alliance.

I read (most of) the 96-page court decision, and I realized something: I'm not a lawyer! I was grateful that the author included enough common language that helped in the translation.

I'll start with the bottom line: NOTHING changes for the time being while the Supreme Court allows time for a challenge.

**If you're like me, you've lost some of the details over the last few months. This will bring you up to speed:**

The essence of the lawsuit boils down to this: the FDA violated the Administrative Procedure Act. This act basically requires agencies (like the FDA) to function in accordance with laws and charges federal courts to hold agencies accountable whose actions are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."\*\*\* Specifically, the 2016 label changes (allowing use up to 10 weeks, only requiring one visit, allowing other prescribers, not only physicians), and the 2021 removal of the in-person requirement were determined by the 5<sup>th</sup> circuit court to be unlawful.

Their violation of the law has harmed thousands of women and shown their disregard for the health and welfare of women.

Here is a summary of the case as it makes its way through the courts:

1. NOVEMBER 2022--Four physicians and the Hippocratic Alliance filed a lawsuit against the FDA and Danco Labs (manufacturer of Mifepristone) making a series of claims about how the original approval of Mifeprex and the subsequent changes the FDA has made in the ensuing years violated the law and requested that Mifeprex be taken off the market.
2. APRIL 2023--The U.S. District Court in Amarillo, TX, heard the case and agreed with the claims, ordering that Mifepristone be pulled from the market
3. APRIL 2023--The U.S. Department of Justice (i.e. President Biden) issued an appeal to the 5<sup>th</sup> Circuit Court, putting the implementation of the ruling on hold.

4. APRIL 2023--The 5<sup>th</sup> Circuit Court upheld the District Court's ruling in part, allowing the continued distribution of Mifeprex, but under the original 2000 rules
5. APRIL 2023--This decision was paused, pending a request from the DOJ for "emergency relief" by the Supreme Court (SCOTUS)
6. APRIL 2023--SCOTUS granted emergency relief pending the Appeals Court Decision: nothing changed with the distribution of the abortion pill
7. MAY 2023--5<sup>th</sup> Circuit Court heard the entire case, soup to nuts
8. AUGUST 2023--5<sup>th</sup> Circuit handed down its decision

### What did the 5th Circuit Court decide?

They decided that Mifepristone and its generic may remain on the market, but may only be used under the 2011 FDA-approved package labeling.

#### This means that Mifeprex (or the generic):

- Approved for use up to 49 days (7 weeks) from the LMP
- May only be prescribed by physicians IN PERSON
- 3 office visits required
- May NOT be prescribed via telehealth modalities
- May NOT be sent through the mail, or picked up at pharmacies

In addition, it restores the ability of anyone to submit ALL adverse events to the FDA, not just when a woman dies.

#### This is FANTASTIC news!

BUT...yes, you knew there would be one—all of these changes are on hold under the previous SCOTUS ruling, while the court waits to see if the FDA or Danco petitions the court for *certiorari*. *Certiorari* is a Latin legal term meaning "more fully informed." It is used when a certain party wants a case to be heard by a higher court, usually SCOTUS.

It is highly likely that that is exactly what will happen in this case. It is expected that this holding pattern will last anywhere from months to more than a year. The wheels of justice move slowly.

Read the press release from the Alliance Defending Freedom [here](#).

#### What Does This Mean for Pregnancy Centers?

Nothing changes for the foreseeable future. Continue to do what you do best: extend compassion, hope, and help to women and men facing difficult pregnancy decisions. Pray for justice to prevail and for the 5<sup>th</sup> court's ruling to go into effect. Pray for protection for our centers, and all who are working to advance the cause of life.

To access my previous blog posts on this court battle and access a handout on Misoprostol Information to further inform your staff & clients, visit [this link](#).

**\*\*5 U.S.C. § 706(2)(A).**