Another Failure at the FDA?

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- If the mission of the FDA is to protect the public health by ensuring the safety and effectiveness of drugs and medical products, has it done a good job?
- With all shortcuts and criminal violations the FDA took with the COVID “vaccines”, it is the first time they’ve done this, right?
- Will the lawsuit filed by the Alliance for Hippocratic Medicine finally expose the criminal enterprise known as the Food and Drug Administration?

With its failure to properly test the so-called COVID-19 ‘vaccines’, the FDA lost a lot of peoples’ trust, but this may not be the first time the FDA criminally approved a dangerous drug.

The Alliance for Hippocratic Medicine, along with others, have filed suit against the Food and Drug Administration regarding its approval of the abortion drug Mifeprex. Their complaint claims that the FDA violated multiple federal laws and its own regulations when it first approved the drug, then again over the next three decades when it expanded its use.

This case has not been heard by a court yet, but I want to take some time and evaluate the specifics in the complaint to see if they pass constitutional muster. This will also give us a framework by which to evaluate the court’s decision when it’s published.

The Alliance for Hippocratic Medicine's complaint is lengthy, so I will focus on the parts of the complaint I think are most relevant. Let's start with the very first item in the complaint.

The U.S. Food and Drug Administration (FDA) must protect the health, safety, and welfare of all Americans by rejecting or limiting the use of dangerous drugs.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

Don't you love it when a legal complaint starts with an unconstitutional assertion? Public safety is not a power delegated to the United States and neither is regulating drug safety. Since Congress is only authorized to create laws necessary and proper for putting into execution the powers delegated to it, drug safety is not a power delegated to the United States. It is unnecessary or improper for Congress to create it by legislation. Also, according to the Supreme Court in Norton v. Shelby County:

An unconstitutional act is not a law; it confers no rights; it imposes no duties; it affords no protection; it creates no office; it is in legal contemplation as inoperative as though it had never been passed.

Norton v. Shelby County

Since the act that created the FDA was unconstitutional, the FDA does not legally exist. The complaint then goes into some history of the illegal acts behind the approval of Mifeprex.

Beginning in January 1993, on his second full day in office, President Bill Clinton directed his cabinet to legalize chemical abortion drugs in the United States.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

It appears that, from the beginning, the push for chemical abortions was more political than medical.

President Clinton and his agency officials then pressured the French manufacturer of the key chemical abortion drug, mifepristone (also known as "RU- 486" and "Mifeprex"), to donate for free the U.S. patent rights of the drug to the Population Council—as its name suggests, an entity focused on population control.

After receiving the patent rights to mifepristone, the Population Council submitted a new drug application, worked closely with the Clinton FDA during the review process, and, not surprisingly, obtained the agency's approval on September 28, 2000—just over one month before the closely contested 2000 U.S. presidential election.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

That's political extortion to get the patent for a drug, turning it over to a politically aligned third-party, and then rushing it through the approval process. Sounds like an organized crime operation to me.

Alliance for Hippocratic Medicine then claims that the FDA not only had no cause to rush Mifeprex through the accelerated approval process, but doing so violated their own regulations.

The only way the FDA could have approved chemical abortion drugs was to use its accelerated drug approval authority, necessitating the FDA to call pregnancy an "illness" and argue that these dangerous drugs provide a "meaningful therapeutic benefit" over existing treatments.

But pregnancy is not an illness, nor do chemical abortion drugs provide a therapeutic benefit over surgical abortion. In asserting these transparently false conclusions, the FDA exceeded its regulatory authority to approve the drugs.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

According to the FDA's own accelerated drug approval

procedures, there must be reason to rush the process, and political pandering is not a valid reason.

In some cases, the approval of a new drug is expedited. Accelerated Approval can be applied to promising therapies that treat a serious or life-threatening condition and provide therapeutic benefit over available therapies.

FDA Development & Approval Process | Drugs

As the complaint points out, pregnancy is not an illness, and in the vast majority of instances it's not life threatening. And without a therapeutic benefit of chemical abortion over a surgical one, there was absolutely no reason for the accelerated approval process. Of course, why let the rules get in the way of a political agenda?

At least the FDA used a scientific process to make sure Mifeprex was safe and effective though, right? Tell me if you've heard this before: The FDA used an accelerated process to approve a drug for something that was not a generally life-threatening illness, then failed to perform the required safety testing, all while disregarding the evidence of complications?

What's more, the FDA needed to disavow science and the law because the FDA never studied the safety of the drugs under the labeled conditions of use despite being required to do so by the Federal Food, Drug, and Cosmetic Act (FFDCA). The agency also ignored the potential impacts of the hormone-blocking regimen on the developing bodies of adolescent girls in violation of the Pediatric Research and Equity Act (PREA). And the FDA disregarded the substantial evidence that chemical abortion drugs cause more complications than even surgical abortions.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

It seems to be a recurring theme from our "friends" at the

Food and Drug Administration. If the FDA is using the same playbook for COVID as they did for chemical abortions, what can we expect in the future?

Since then, the FDA has not followed the science, reversed course, or fixed its mistakes—all to the detriment of women and girls. Instead, the FDA has doubled down on its actions and removed the few safeguards that were in place.

In March 2016—fourteen years after two Plaintiffs filed a citizen petition with the FDA asking the agency to withdraw its approval of chemical abortion drugs—the FDA rejected these Plaintiffs' petition despite their explanations that the agency violated federal laws by approving these drugs and ignoring the substantial evidence that these drugs harm women and girls.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

Ignoring science, ignoring the law, and ignoring both pleas and evidence that the drug should be pulled? Yep, that sounds like the same playbook the FDA is following for COVID. The FDA would not abuse its authority for political purposes, would it?

On the same day that the FDA rejected the citizen petition and mere months before another U.S. presidential election, the FDA also made "major changes" to the chemical abortion drug regimen, eliminating crucial safeguards for pregnant women and girls.

For example, the FDA extended the permissible gestational age of the baby for which a pregnant woman or girl may take chemical abortion drugs—from seven weeks to ten weeks.

Numerous studies have demonstrated that there is an increased risk from chemical abortion drugs to pregnant women and girls as the baby's age advances from seven weeks to ten weeks because the surface area of the placenta as well as the size

of the baby significantly grow during these three weeks.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

Wait, the FDA would change the acceptable use for an untested drug in the face of evidence of the dangers of such a move? They only did that once, right?

Also in 2016, the FDA changed the dosage and route of administration for the chemical abortion drugs, reduced the number of required in-person office visits from three to one, expanded who could prescribe and administer chemical abortion drugs beyond medical doctors, and eliminated the requirement for abortionists to report non-fatal complications from chemical abortion drugs— without requiring any objective clinical investigations or studies that evaluated the safety and effectiveness of this new chemical abortion regimen or any safety assessment of its effects on the developing bodies of girls under 18 years of age.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

Now, after all of this, the Alliance for Hippocratic Medicine is asking the court to do what the FDA should have done from the beginning.

After two decades of engaging the FDA to no avail, Plaintiffs now ask this Court to do what the FDA was and is legally required to do: protect women and girls by holding unlawful, setting aside, and vacating the FDA's actions to approve chemical abortion drugs and eviscerate crucial safeguards for those who undergo this dangerous drug regimen.

ALLIANCE FOR HIPPOCRATIC MEDICINE v. FDA

What I've covered so far is just the tip of the iceberg.

Conclusion

Let's put the constitutionality of the FDA aside and ask the

two very important questions we need answered. First, did the FDA fulfill its mission?

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA Mission

Did the FDA protect the public health, ensure the safety, efficacy, and security of drugs and other products? Obviously no. The FDA has shown a repeated history of not following the law or their own policies, of rushing approval of drugs that have political support, and not doing the safety and efficacy testing needed to determine if a drug is both safe and effective.

The second question, did the FDA violate the law by these actions? The simple answer is yes. The FDA is required by law to approve a drug before it enters interstate commerce:

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

21 U.S.C. §355

The approval of a drug can be expedited, but only in certain situations.

The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the

drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

21 U.S.C. §366

Since pregnancy, in general, is not a life-threatening condition, and the accelerated approval was not limited to life-threatening situations, this approval violated federal law. Furthermore, there appears to be no evidence that a chemical abortion is a demonstrably substantial improvement over a surgical one.

In short, the Food and Drug Administration's flagrant disregard for the law and the public health they were tasked to protect shows it to be an utter failure. Add to that the fact that the act that created the FDA was unconstitutional when it was passed, and what do we have? We have an illegitimate agency, with an annual budget of $8.4 billion, that has shown a disturbing tendency to violate the law and ignore their own regulations and policies, most likely either in pursuit of political ends or under political pressure.

Based on these facts, the Food and Drug Administration should be immediately defunded, shut down, and those who violated the law or used this agency for their own political ends, should be prosecuted to the full extent of the law. Do I expect that to happen? I would be pleasantly shocked if it did.

What about Alliance for Hippocratic Medicine's lawsuit? I plan to follow it closely. While justice for all of the Americans who have been injured or killed by the FDA's malfeasance can never be truly attained, it would be good to see this dictatorial and despotic agency taken down a few notches. I can only hope that doing so will be a step in rescuing the American people from this bureaucratic monstrosity.

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