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## **'Is pregnancy a serious illness?' Circuit judges question FDA's abortion pill approval and safety**

**By Carole Novielli**

The case *Alliance for Hippocratic Medicine (AHM) v. Food and Drug Administration (FDA)*, regarding the status of the abortion pill, was argued May 17 before the United States Court of Appeals for the Fifth Circuit. The lawsuit challenged the legitimacy of the drug's 2000 approval—and at least one of the judges pushed back on the narrative that the FDA could 'do no wrong,' even suggesting the move to weaken the REMS for mifepristone and remove required reporting of non-fatal adverse events was not "very pro-science, pro-information, pro-intellectual curiosity" of the agency.



Tension arose when Circuit Court Judges Jennifer Walker Elrod, James Ho, and Cory Wilson grilled opposing counsel about disparaging remarks the abortion pill manufacturer (Danco Laboratories) made in its motion for a stay against the previous District Court's ruling. That ruling was issued by U.S. District Court Judge Matthew J. Kacsmaryk, who suspended the FDA's 2000 approval of the abortion pill mifepristone and all FDA abortion pill decisions made thereafter. A temporary stay was later issued by the Supreme Court until the case could be heard on appeal.

Arguing on behalf of the plaintiffs, Alliance Defending Freedom (ADF) attorney Erin Hawley told the Court, "This case isn't about ending abortion, it's about challenging a particularly dangerous type of abortion."

### **Danco Called Out for 'Unusual Remarks'**

Opposing counsel Jessica Lynn Ellsworth (representing abortion pill manufacturer Danco Laboratories) and Deputy Assistant Attorney General Sarah Harrington (representing the FDA) were argumentative at times, prompting the Circuit Judges to lecture the pro-abortion attorneys.

### **Is Pregnancy an 'Illness?'**

Tension could also be heard during discussion over whether pregnancy was an "illness," a classification allegedly used to "fast-track approval authority" of the drug—according to plaintiffs.

"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," pro-life plaintiffs wrote in their initial complaint.

"But pregnancy is not an illness, nor do chemical abortion drugs provide a therapeutic benefit over surgical abortion," they added.

Judge Ho then asked opposing counsel, "When we celebrate Mother's Day—are we celebrating illness?"

### **Debating the Issue of Standing**

AHM's lawsuit also alleged that the FDA's lax requirements have essentially violated the conscience rights of pro-life emergency room physicians or OBGYNs who are treating abortion pill complications.

Opposing attorneys disputed the claim and in return they argued that AHM did not have standing to bring the case. "There must be a specific doctor with a specific injury from the regulation," Ellsworth claimed, suggesting no link was evident with these plaintiffs.

*continued on page 2*

# Michigan Nurses For Life



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...To raise the consciousness of the nursing profession to protect all human life from conception until natural death

...To form an educated core of nurses who can speak for their profession by acting as a community resource for life issues

...To promote public education and awareness about life issues on both ends of the spectrum, from abortion to euthanasia

...To uphold and defend human life in all stages and conditions of development

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## FROM THE PRESIDENT

Dear Colleagues,

The summer months generally mean a time to lay back a little, relax, enjoy the sun, and warm temperatures. Unfortunately, the assault on human life never seems to take a holiday.

More and more efforts are being made to find more and more ways to take the life of unborn children and the fragile elderly and handicapped.

Abortion pills by mail with no physical examination of the patient; hospice patients slowly, but surely, being sedated to death, laws to provide for employer payment for travel to abortion centers outside of the city of residence of the woman so inclined; provisions to provide abortion as a "health care benefit" being required in employee health policies; in Maine a school board refused to allow a Christian church to rent one of their properties because they did not support abortion; physical attacks on people offering pro-life information in colleges and universities—and the list goes on.

This could be downright discouraging to those of us who have been in the pro-life movement for years, some for decades. But—I know something that those who hold life in low regard and think they have won the war don't know. I know what I see in high school-aged youngsters and dedicated college students. They don't listen to the death promoters. They seek answers that provide protection for human life. They help at pro-life events, they participate in marches and rallies, they learn, and they share what they have learned, they help at pregnancy care centers, they know—yes, they KNOW—that there are better answers to human problems. They are Young! They are Strong! They are not angry or bitter—they are kind and compassionate and, in the end, they will PREVAIL.

So, don't be discouraged, continue your pro-life efforts—we have reinforcements behind us.



Love Life! Diane

### "Is Pregnancy a Serious Illness?"

*continued from front page*

The judges appeared to push back, citing multiple places in the plaintiff's declarations where the pro-life doctors testified they had to complete abortions on women who presented for emergency situations after a chemical abortion.

In arguing on behalf of AHM, ADF attorney Erin Hawley told the Court that "There is no question there is a substantial risk of harm. Plaintiff-doctors have been forced to participate in and perform abortions." Hawley even pointed to mifepristone's drug label, which clearly tells women to present to the ER if experiencing complications.

### Abortion Pill Mifepristone Black Box Warning on March 2023 label

On behalf of the FDA, attorney Harrington disputed that under FDA's requirement, which allows for mail order abortion pills and no in-person visit with a health care provider, women will present to an ER.

"It's extremely, statistically unlikely that any woman will need to go to the emergency room to seek care after taking mifepristone," Harrington claimed, later alleging that this amounted to less than one percent of all women who take mifepristone.

But ADF attorney Erin Hawley pushed back during her argument, directing the Justices to the March 2023 mifepristone label which shows that between 2.9% and 4.6% of women will likely present to the ER.

On this matter Circuit Judge Cory Wilson weighed in:

*It just strikes me that what the FDA has done in making this more*

available and doing it by mail order and removing the doctor visits as well as the requirement that the prescriber be a doctor, is you've made it much more likely that patients are going to go to emergency care or a medical clinic where one of these [pro-life] doctors is a member. I don't see how you square that circle.

### Judge Reacts to 'FDA Can Do No Wrong' Theme

The Government's counsel called the District Court's decision which led to the appeal "unprecedented," and claimed that the plaintiffs were "unlikely" to succeed in their claims.

The judges immediately responded and pointed out throughout the hearing that the FDA was not off limits to judicial scrutiny and even cited multiple examples where the FDA's initial drug approval process for dispensing of a drug was called into question.

Ho also pointed to criticisms of the FDA over unacceptable "food safety failures" and then claimed that the "FDA is being blamed for the opioid crisis."

### FDA rushed drug for preterm births NYTs

In response, Danco's attorney suggested that courts should not "second guess the FDA."

But, "FDA approved this drug [mifepristone] in 2000," Judge Ho said, before proceeding to read an excerpt from the *AMA Journal*. "Of all the novel therapeutics approved by the FDA that decade, one-third of them have had safety issues," Judge Ho claimed.

In a press conference following arguments in the case, Hawley referred to the FDA's "unprecedented and unlawful actions to approve chemical abortion drugs" and to "later remove those crucial safe guards" as political, claiming the FDA "placed politics ahead of women."

"Now, we are asking the...Court to restore public safety and trust by demanding that the FDA follow proper science not politics...our women and our girls deserve better," Hawley stated.

A decision in the case is expected within a few months.

—Excerpt from *LiveAction*, May 18, 2023



### Is Hospice an Antidote to Assisted Suicide?

*continued from back page*

It is significant that the American Academy of Hospice and Palliative Medicine (AAHPM) "takes a position of studied neutrality on the subject of whether PAD [physician-assisted death] should be legally permitted or prohibited." Neutrality gives the green light to assisted suicide as surely as support does.

Also, there is more than one way to assist a suicide. For instance, some hospices facilitate Voluntary Stopping Eating and Drinking (VSED), particularly in states that do not permit physicians to prescribe drugs for patients to commit suicide. VSED means that a patient, who is capable of eating and drinking, chooses to refuse food and fluids with the intention to cause death. This is suicide. When a hospice supports this decision by providing palliative care as the patient starves and dehydrates to death, the suicide is assisted—not prevented—by the hospice.

The only real antidote to assisted suicide is to make it illegal everywhere, in all circumstances, and by any means. The law is a great teacher.

*For information on end-of-life care, visit HALO's site at halo-voice.org.*

—American Life League, May 22, 2023

## Upcoming Events

### NATIONAL RTL CONVENTION – PITTSBURGH

June 23-24

For information, visit: [nrlconvention.com](http://nrlconvention.com)

### ANNUAL MOTOR CITY CARAVAN FOR LIFE

Saturday, June 24 - 11:00 a.m.

For details, call RTL-LIFESPAN 734-422-6230

### NATIONAL DAY OF REMEMBRANCE FOR ABORTED CHILDREN - RTL-LIFESPAN

Saturday, September 9

For information, call 734-524-0162

### 40 DAYS FOR LIFE, FALL CAMPAIGN

September 27 – November 5

Find a location, visit: [40daysforlife.com](http://40daysforlife.com)

### MICHIGAN NURSES FOR LIFE 25TH ANNIVERSARY FALL CONFERENCE

Saturday, October 21 – Save the Date!

### RTL – LIFESPAN LEGISLATIVE LUNCHEON

Saturday, October 28

Keynote Speaker: Frank Pavone, President, Priests for Life  
For details, call 734-422-6230



## Is Hospice an Antidote to Assisted Suicide?

By Julie Grimstad

The goal of palliative care is to relieve symptoms—including pain and stress—at any stage in a serious illness. Palliative care can be provided in conjunction with curative or life-prolonging treatment. Hospice is a subset of palliative care. Hospice provides comfort care when a person no longer has curative options or has chosen to forgo treatment because the burdens of treatment outweigh the benefits. The founding principles of hospice were to maintain dignity, to increase quality of life, and to provide comfort and pain control. When these principles are followed and staff members are trained in proper pain management, hospice can be a blessing for people in need of expert end-of-life care.



Unfortunately, there is a growing trend to misapply palliative medications to make people die, particularly in the hospice care setting.

Because people who are receiving hospice care have a limited life-expectancy, it is the “ideal” setting for stealth euthanasia. The term “stealth euthanasia” means to cause a patient’s death while pretending to provide appropriate end-of-life care. Patients and families must be vigilant.

“Numerous reports from families of hospice and palliative care patients indicate that a one-size-fits-

all pattern of administering a combination of opioids and anti-anxiety drugs has emerged. Whether or not patients have pain and/or agitation, they may begin to receive these drugs upon admission.” [Quote from “Drugs Commonly Used in Hospice and Palliative Care,” Making a Difference, A Guide for Defending the Medically Vulnerable, [www.halovoice.org](http://www.halovoice.org)]

Here is a typical report that HALO receives from grieving family members. Their loved one was alert and not complaining of pain. After admission to hospice, increasingly frequent and larger doses of pain medications, anti-anxiety drugs, and sedatives were administered to the point where he or she was sleeping all the time and could not eat or drink. Some reported that patients were denied usual medications to control blood pressure, diabetes, heart disease, infections, etc.

Is hospice an antidote to assisted suicide?

Sometimes, hospice is promoted as an antidote to assisted suicide. There is merit in the argument that we should ensure patients don’t commit suicide because they are not receiving adequate treatment to manage pain and other symptoms. However, Oregon’s experience suggests that hospice care is not an antidote to assisted suicide. In 2020, it was officially reported that 95% of patients who killed themselves using Oregon’s so-called “death with dignity” law were enrolled in hospice at the time of death.

*continued on page 3*