Nos. 23-235 & 23-236

In the

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF DR. ALLAN SAWYER AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

MICHAEL S. OVERING
Counsel of Record
EDWARD C. WILDE
790 E. Colorado Blvd., #320
Pasadena, CA 91101
Tel: (626) 564-8600
movering@digitalmedialaw.com
ewilde@digitalmedialaw.com

Counsel for Amicus Curiae

February 26, 2024

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Other Authorities

INTEREST IN THE CASE[1]

Amicus Curiae, Dr. Allan Sawyer is the former President of The American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG"), which is the largest non-sectarian, pro-life physician organization in the world, with over 4,000 members across the United States and associate members on every continent. AAPLOG exists to equip its members and other concerned medical practitioners with an evidence-based rationale for defending the lives of both the pregnant mother and her unborn child.

Dr. Sawyer believes that physicians and medical practitioners are responsible for the care and well-being of both the pregnant woman and her unborn child; that the unborn child is a human being from the time of fertilization; that elective abortion of human life at any time from fertilization onward constitutes the willful destruction of an innocent human being; and that, consistent with the Hippocratic Oath, this procedure should have no place in the practice of the healing arts.

Dr. Sawyer has spent his career committed to educate abortion-vulnerable patients, the general public, lawmakers, pregnancy care center counselors, and medical colleagues regarding the medical and psychological complications associated with induced abortion, as evidenced in the peer-reviewed scientific literature.

Dr. Sawyer brings a wealth of education, experience, and credentials, including a Master of Science in Molecular Genetics/Biological Sciences from

---

[1] No counsel for a party authored the brief in whole or in part, and no counsel or a party made a monetary contribution intended to fund the preparation or submission of this brief.

Stanford University, a fellowship of the American College of Obstetrics and Gynecologists (ACOG) from 1995 to 2017, and service as chair of several committees when he was active in ACOG.

SUMMARY OF ARGUMENT

The recent changes in the FDA recommendations for use of Mifeprex were not the result of a change in the medicine. The drug still entails the risk of dangerous complications for the mother. Those risks were managed in the previous FDA guidelines by requiring the continual oversight of a physician.

The FDA has used the effective risk management of the previous system as evidence that substantially less risk management is needed now. This would be akin to the Department of Transportation using evidence of fewer people dying from accidents after the imposition of seat-beat regulations as proof that seat beats were no longer needed.

The FDA's change in recommendations is plainly popular with certain political constituencies. Supporters of this move, including some participating in this litigation, may have the money and sophistication to obtain proper medical oversight and care regardless of whether it is required by law. In contrast, the women most likely affected by the agency's actions are precisely those most likely to need medical supervision in the first place.

The risks resulting from the change in the FDA recommendations will be borne by the most isolated and vulnerable among us. Thus, the wealthy will continue grandstand with their banner of "women's health" and at the same time force greater danger onto the poor. And when a poor woman dies from

complications caused by an out-of-state doctor sending her drugs in the mail, the story will not even make the local news.

It would be the perfect crime, so to speak, but for the inevitable complications caused by an unsupervised drug regimen that will often only partially effectuate the termination of a pregnancy. In those cases, women will often need to seek the intervention of medical personnel—including ones who do not perform abortions (and oppose them)—in order to conclude the abortion surgically.

In short, the FDA's decision does not give evidence that it was driven by the "science." It is contrary to medical ethics and experience. It reflects a kind of "luxury belief" propagated to confer social status on those who will not suffer the consequences if their beliefs are societally accepted. The instant *amicus* strongly urges the Court to uphold the decision below.

ARGUMENT

I. THE FDA MADE ITS DECISION BASED UPON POLITICAL CALCULATION, NOT MEDICAL WISDOM.

The controversy of abortion drives passionate claims. The arguments advanced by the conflicting parties here do rightly raise fundamental concerns: control over one's body, on the one hand, and the protection of innocent life, on the other. The positions are firmly held by the conflicting parties.

This brief does not seek to balance the scales, but rather to note another problem which arises from such a profound and deep conflict. The sides not only fail to feel the weight of the primary argument

advanced by the other; their passion may cause them to overlook other concerns entirely.

The drugs at issue cause the human body to prohibit the fetus to continue to mature and then cause the body to evacuate the fetus. The combination of drugs terminates the pregnancy. At present, the legal decisions as to whether and when one may terminate a pregnancy will vary from state to state.

On the FDA's webpage "What we do," the agency sets out its mission. In part it reads:

> FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

(https://www.fda.gov/about-fda/what-we-do#mission). The instant amicus contends that the FDA has, in this instance, abandoned its purpose to protect health and instead regulated to achieve the political aims of the current administration. While the Executive Branch is free to advocate and use its political influence to motivate Congress to make certain policy decisions, the FDA should remain free from such pressure. Reducing its "science-based" decision-making to mere politics erodes the credibility of the agency and the public trust in it.

Case in point: the FDA's *amici* here have presented briefs that urge this Court to ignore the warnings on the label required by the FDA. For example, *amicus* brief dismisses the warning for the medication at issue with a handwave: "These are not

'complications,'" writes the American College of Obstetricians. *Amici* Br. at 5, Nos. 23-245 & 23-236 (filed Oct. 12, 2023). It is remarkable how one's political position can influence one's attention to the labels. And it is all the more saddening that such contortions appear in a brief backed by medical professionals.

The FDA's label for Mifeprex speaks for itself. It, reads, in part:

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

(https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf). The label then lists a bevy of other warnings and contraindications, including the following:

> MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies [see (4)]. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX.

(https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf). It is critical that a

woman with an ectopic pregnancy seek medical advice and attention, yet the FDA's allowance for Mifeprex by mail ignores its own mandatory warning on this drug. And, it should go without saying that a doctor cannot perform magic by telephone and diagnose an ectopic pregnancy.

According to the FDA, the previous label gave these instructions:

> Required three office visits by the patient:
>
> (1) 600 mg of Mifeprex administered to the patient by the physician or under the supervision of the physician in a clinic, medical office, or hospital.
>
> (2) Patient returns on day three for examination with physician; if termination of pregnancy is not complete, physician administers 400 mcg of misoprostol for patient to take orally.
>
> (3) Patient returns to physician for follow-up visit approximately 14 days after administration of Mifeprex to confirm complete termination of the pregnancy occurred.

(United States Government Accountability Office, Report to Congressional Requesters (March, 2018) https://www.gao.gov/assets/gao-18-292.pdf) The FDA has now reduced the recommendation to "you might want to see someone after this is over":

> Patient should follow up with healthcare provider who prescribes approximately 7 to 14 days after Mifeprex administration to confirm complete termination of pregnancy has occurred and to evaluate the degree of bleeding.

(United States Government Accountability Office, Report to Congressional Requesters (March, 2018) https://www.gao.gov/assets/gao-18-292.pdf).

Estimates are up to 20,000 women per year may suffer serious "side effects" as result of this medication. Without a physician overseeing the patient, bad things can and will happen. There is simply no medical rationale for the agency's action; driven by politics, not science, it was an arbitrary and dangerous decision, and the judgment below should be affirmed.

II. IT IS ALWAYS THE POOR WHO WILL SUFFER UNDER THE FDA'S NEW RULE.

Putting aside the important moral questions, the drugs at issue have profound and often serious side effects upon women. These side effects can be managed (in most cases) by means of a trained and attentive physician who first performs a physical examination of the woman and then monitors her during and after the use of the drugs.

Women from wealthier backgrounds can obtain adequate care even if not monitored. Indeed, the careless attitude of certain *amici* and the parties supporting the FDA's change in "recommendations" is itself evidence that the change will not affect them. These are lawyers, activists, and organizations with the sophistication and resources to appear before this Court—resources that suggest they and the women they represent are not among the most vulnerable, the most likely affected by the FDA's relaxed requirements. They will have an attending physician and access to medical care.

In contrast, the poor quite often do not have the same options. They may receive only telemedicine, and even traveling across state lines for access does not guarantee proper medical monitoring or assistance. The women who will be utilizing a phone call across state lines will be disproportionately (if not solely) those women most vulnerable and least politically important. They are not the people before this Court. They have not retained attorneys. They will not know the procedure for making an *amicus* argument.

But such women will pay the price when a doctor sitting comfortably in California guesses wrong. When a doctor makes a decision about a woman whom he hasn't seen or treated, that woman may need real medical attention, not a political prescription.

Respectfully, the Court has received a blinkered view of the risks. Properly understood, the effects of the FDA's decision are perverse. The most politically active and powerful will applaud the decision to make these drugs available across state lines with only a phone call. However, the same people who can reward their favorite politicians will not be the people who have to pay the cost of this change in policy with their lives.

III. THE FDA'S DECISION AND SUPPORT FOR IT ARE PREMISED ON MISTAKEN "LUXURY BELIEFS."

Writer Rob Henderson (PhD, Cambridge) has discussed and developed the concept of "Luxury Beliefs," which he defines as "ideas and opinions that confer status on the upper class, while often inflicting costs on the lower classes." (Rob Henderson, Luxury Beliefs are Status Symbols, Rob Henderson's

Newsletter, June 12, 2022, https://www.robkhenderson.com/p/status-symbols-and-the-struggle-for). Participation in the instant lawsuit—arguing that these drugs should be prescribed without an in-person doctor's visit—is a politically advantageous position. It is also effectively free to those making the political argument. *See supra* § I. Thus, this is an exemplar of a luxury belief, which serves primarily "to indicate evidence of the believer's social class and education." *Id.* "Members of the luxury belief class promote these ideas because it advances their social standing and because they know that the adoption of these policies or beliefs will cost them less than others." *Id.* The Court ought not join the petitioners in their reality-free luxury delusion.

In one of the unfortunate ironies of the FDA's change in position, it will be the doctors in more "protective" or "restrictive" jurisdictions who will find themselves forced into concluding an abortion surgically where the medication has been unsuccessful. The conscience protections of medical staff in a state which limits abortions will be shoved aside when the medication from a permissive state cruelly does just "half the job."

Thus, those who bask in the glow of their luxury belief not only off-load the danger to the poor; they offload the blood and gore and mess to nurses and doctors whom they need never meet. The pharmaceutical companies and the prescribing doctors can say that mifepristone will be "safe and effective," Pet.App.62a, knowing they won't face the consequences. After all, they complied with the FDA's instructions (or lack thereof). But they're not the ones the FDA is obligated to protect.

It really is a perfect crime. A manufacturer promotes 'FDA-approved' abortion by mail. A doctor in one state collects the fee for prescribing a pill—without the work of actually seeing the patient. A poor woman in another state suffers the damage of the drug. A medical staff who is abhorred at abortion cleans up the mess.

Our Nation and this Court should not tolerate this mess, one driven by politics, not medicine or science or any other legitimate end of agency decision-making. Thus, the evidence shows the FDA's change in policy was arbitrary and capricious, and the decision below should be affirmed.

CONCLUSION

It is respectfully requested that this Court leave in place the decision of the lower court.

Respectfully Submitted,

MICHAEL S. OVERING
Counsel of Record
EDWARD C. WILDE
790 E. Colorado Blvd., #320
Pasadena, CA 91101
Tel: (626) 564-8600
movering@digitalmedialaw.com
ewilde@digitalmedialaw.com

Counsel for Amicus Curiae

February 26, 2024