IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his Patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA**, in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. 2:22-cv-00223-z

AMICUS BRIEF ON BEHALF OF THE CHATTANOOGA NATIONAL MEMORIAL FOR THE UNBORN

Now comes the Chattanooga National Memorial for the Unborn ("NMU") and files this Amicus Brief in support of Plaintiffs' Complaint (Doc. 1) and Plaintiffs' Motion for Preliminary Injunction (Doc. 6). The NMU is a Tennessee nonprofit corporation located in Chattanooga, Tennessee which is dedicated to healing pain associated with the loss of aborted children and providing education and information about the abortion process and its consequences.

As detailed below, undersigned counsel's law firm[1] also represented the Estate of Brenda Vise with respect to the claim outlined below, all of which is directly relevant to the issues in this pending case relating to protocols relating to Mifeprex.

The Volunteer Women's Medical Clinic, LLC ("Clinic") was located in Knoxville, Tennessee and actively solicited patients for abortion services including chemical abortions.

Brenda C. Vise was born on June 24, 1963 and was 38 years of age when she learned that she was pregnant in September, 2001. In reliance upon marketing materials provided by the Clinic, Ms. Vise made an appointment with the Clinic for Friday, September 7, 2001.

While at the clinic on September 7, 2001, Ms. Vise was administered a pregnancy test which confirmed her pregnancy and was also given an ultrasound examination. Ms. Vise was advised that the ultrasound showed no fetus in the uterus. Clinic personal explained that this was because the fetus was "too small to be seen." It was estimated that Ms. Vise was approximately 6 weeks pregnant. By such point in her pregnancy, a fetus in the uterus would have been easily seen with a proper ultrasound examination.

[1] Attorneys Hoyt O. Samples and Michael S. Jennings represented the Estate of Brenda Vise. Hoyt. O. Samples retired from the practice of law at the end of 2022.

The Clinic then advised Ms. Vise to have a chemical abortion which would avoid a surgical abortion procedure. Ms. Vise was advised that two different medications were required to complete a chemical abortion. While at the Clinic on or about September 7, 2001, Clinic personnel described Mifeprex to Ms. Vise. Mifeprex is also known as RU-486 and is commonly referred to as the "abortion pill."

At that time, Mifeprex was not to be administered if it had been more than 49 days since a woman's last menstrual period began. Mifeprex was also not to be administered if there was a suspicion that the pregnancy was outside the uterus. Such condition is commonly referred to as an ectopic or tubal pregnancy.

Anywhere from one-half to one percent of all pregnancies are ectopic and an untreated ectopic pregnancy is usually fatal. It is therefore extremely important to determine if an ectopic pregnancy is present. If so, immediate action needs to be taken and in no event should Mifeprex be administered.

Ms. Vise was advised by the Clinic that the side effects of Mifeprex were mild and short-lived. Mifeprex operates by blocking a hormone needed for a woman's pregnancy to continue.

Mifeprex can, in and of itself, cause an abortion, but normally it is required that a second drug be administered approximately 48 hours after the administration of Mifeprex.

Prior to administering the second chemical, a patient should be checked to see if she is still pregnant. If so, then two additional tablets were to be administered at that time. If the woman was not pregnant, no additional medication was to be given.

The Clinic instructed Ms. Vise to take the second medication at her home with no follow up examination to determine if she was still pregnant after taking the first medication.

Contrary to information disseminated by the Clinic, nearly all women who receive Mifeprex will report adverse reactions.

Mifeprex should only be administered by or under the supervision of a physician who is able to assess the duration of the pregnancy accurately and who is able to diagnose ectopic pregnancies. Such physician should also have the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding or have plans to provide such care through other qualified physicians.

Because Mifeprex in and of itself does not regularly result in a chemical abortion, the Clinic then required Ms. Vise to take a second drug known as Cytotec.

Cytotec was originally developed by G.D. Searle & Co. to prevent gastric ulcers in people who take anti-inflammatory drugs for conditions such as arthritis. The drug was approved by the FDA solely for such use in 1988. At the time that Ms. Vise received her treatment, the federal government had never approved Cytotec for use in pregnant women and specifically had not approved it for use in pregnant women for the use of inducing an abortion and in fact, had warned against such use.

The manufacturer of Cytotec in August, 2000, specifically issued a letter to healthcare providers that Cytotec was contraindicated in women who are pregnant and that Cytotec was not approved for the induction of labor or abortion and should not be used in an abortion.

After receiving the Mifeprex in Knoxville, Ms. Vise returned to her home where she began experiencing significant and continuing problems. The Clinic was contacted and Ms. Vise was advised that all of her symptoms were "normal and routine." This continued even though multiple calls were placed to the Clinic and as Ms. Vise's symptoms worsened.

The Clinic had issued a directive that Ms. Vise was to take the Cytotec approximately 48 hours after the Mifeprex had been administered.

Ms. Vise's medical condition continued to worsen and the Clinic advised her to take different medications for pain and for nausea. She was never referred to a physician.

On Monday, September 10, 2001, Ms. Vise's medical condition continued to deteriorate and the Clinic continued to advise that all of her symptoms were "to be expected."

Ms. Vise was eventually transported to a hospital in Chattanooga by ambulance where exploratory surgery would reveal that she had had an ectopic (tubal) pregnancy which had ruptured. Such rupture led to massive infection and a collapse of her vital systems.

Ms. Vise's representatives later learned that the ultrasound of Ms. Vise's uterus in Knoxville was not even that of a uterus but was of a bladder. This was because no qualified person was reading the ultrasounds.

The current FDA has now removed even the minimal safeguards that required a woman to be under a physician's care who was capable of diagnosing and ectopic pregnancy and of requiring that there should be an ultrasound positively showing the existence of a fetus in the uterus. The failure to do so can result in an undiagnosed ectopic pregnancy which is invariably extremely serious or fatal.

Under the current regimen proposed by the FDA, there is **ABSOLUTELY NO** requirement that any procedure be done to rule out an ectopic pregnancy. Because anywhere from one-half to one percent of all pregnancies are ectopic, women will die because of this failure.

Based on recent statistics, the pregnancy rate for women in the United States was 102.1 per thousand women. This means of all women who are prescribed the abortion pill that roughly one percent of them will have ectopic pregnancies. Given the FDA's refusal to take steps to protect

against ectopic pregnancies, this means that as many as one in one hundred pregnant women may die who take the abortion pill.

Such should be totally unacceptable to a civilized society.

Plaintiffs in the underlying case have pointed out this and many other reasons why the FDA's current approach to the abortion bill and its regime are not only legally wrong but morally and medically reprehensible.

NMU therefore strongly supports Plaintiffs' Complaint and Plaintiffs' Motion for Preliminary Injunction.

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CERTIFICATE OF SERVICE

I certify that this document will be served on all defendants via ECF and via first class United States mail and email to:

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This 9th day of January, 2023

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