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FDA's Race to Defend Women From Dangerous Drugs

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Abortion advocates—seeking to exploit the COVID-19 crisis to advance unfettered access to abortion-inducing drugs—found a friend in federal court. In mid-July, Judge Theodore D. Chuang issued a preliminary injunction prohibiting the Food and Drug Administration (FDA) from enforcing certain health and safety practices that abortion providers are required to follow when prescribing the only FDA-approved abortion drug regimen. The judge's injunction will supposedly end after the COVID-19 public health emergency ends; however, the judge's Memorandum Opinion explicitly invites abortion providers to provide a "public health justification" to continue to block these important protections for women and girls when that time arrives.

The FDA is not planning to let that happen. FDA fired back with a Motion to Stay the Preliminary Injunction pending appeal. In other words, FDA asked the judge to permit these safeguards to remain in effect until the Fourth Circuit Court of Appeals reviews the injunction. Judge Chuang, however, waited less than a week to deny FDA's motion.

Next stop—the appellate court. FDA's arguments before the Fourth Circuit will likely mirror those they made in their motions before the trial court. In their Motion to Stay, FDA argued that the Plaintiffs lacked the third-party standing necessary to bring the lawsuit on behalf of women seeking mifepristone, the first drug in the two-drug regimen, and have failed to show that these requirements pose a substantial obstacle to abortion for their members' patients during the pandemic. FDA also stated that they will suffer irreparable harm from the injunction because "they will be unable to enforce requirements that FDA has determined, based on its experience and scientific expertise, are necessary to ensure the safe use of Mifeprex."[1]

Background

The Plaintiffs in this case—organizations that promote abortion and an abortion provider—are challenging an FDA requirement that the abortion drug mifepristone (sold under the brand name Mifeprex or as a generic)[2] may only be dispensed at certain healthcare settings by or under the supervision of a certified Mifeprex provider.[3] They are also challenging the requirement that a patient sign a Patient Agreement Form in person. Instead, they want abortion providers to have the authority to mail mifepristone to a woman after consulting with her through

[1] Defendants' Memorandum in Support of Their Motion to Stay Preliminary Injunction Pending Appeal (Motion to Stay Memo), Doc. 104-1, p. 2.
[2] Under the FDA-approved drug-induced abortion regimen, mifepristone is used in combination with another drug, misoprostol.
[3] This requirement is part of a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU). *See* 21 U.S.C. § 355-1(f)(A).

telemedicine and receiving her informed consent online or through the mail.

While abortion advocates have long argued that FDA health and safety requirements for the use of mifepristone should be eliminated entirely and permanently,[4] the Plaintiffs in this case are more narrowly attacking the heart of these requirements for a limited time—as long as the COVID-19 pandemic lasts. Their proffered rationale is that women will risk exposure to the virus if they must enter an abortion facility to obtain the drug, and they face increased obstacles that are the result of the pandemic (*e.g.*, limited transportation and childcare).

The Plaintiffs' true agenda is transparent, however. After months, or even years (there is presently no end in sight for the pandemic) of distributing drugs through the mail (or a pharmacy),[5] abortion advocates will argue that this practice "works" and FDA restrictions are medically unnecessary. The courts will then need to decide how many women's deaths or other serious adverse reactions to the drugs are acceptable before permanently eliminating these critically important protections. More on that topic later.

FDA's Legal Argument: Standing

FDA correctly argued that the Plaintiffs should not be permitted to bring this lawsuit because they "failed to meet the ordinary standard for asserting the rights of their third-party patients, which requires showing a close relationship between Plaintiffs and their patients and that the patients are hindered from bringing suit on their own. … [I]n fact, the entire point of this suit is to *reduce* Plaintiffs' relationship with their patients."[6] Further, FDA asserted that the Plaintiffs failed to "show that they are directly regulated by the in-person requirements such that they are entitled to assert their patients' rights."[7]

FDA explained that "evidence of a single physician's relationship with her patients does not establish that the thousands of physicians who are members of the

[4] Another lawsuit challenging the mifepristone REMS with ETASU is pending in a federal court in Hawaii. The Plaintiffs in *Chelius v. Azar* are seeking a declaration that the Mifeprex REMS in its entirety violates the Fifth Amendment and the Administrative Procedure Act (APA), and a remand to FDA with instructions to remove the Mifeprex REMS within ninety (90) days, or another certain time period. CIV. NO. 1:17-cv-00493-JAO-RT.

[5] The Plaintiffs have filed a "Motion for Clarification" "that, under the Injunction, clinicians may dispense mifepristone through a supervised delivery service agreement with one of a very limited number of mail-order pharmacies (likely one or two) that will contract to stock the medication and deliver it directly to patients only at the direction and under the supervision of a clinician prescribing mifepristone pursuant to a REMS certification agreement. Plaintiffs seek this clarification because there is a potential discrepancy between the Injunction (which permits this delivery model) and three phrases in the Court's Opinion (which seemingly would not)." Doc.109, p. 2.

[6] Motion to Stay Memo at 4.

[7] *Id.*

Plaintiff organizations *generally* have close relationships with their own patients who seek a Mifeprex prescription, and may seek to assert not only the rights of long-time patients, but of *all* patients seeking Mifeprex prescriptions."[8] Regarding alleged hindrances preventing women from bringing lawsuits on their own, FDA explained "many of these alleged challenges existed prior to the pandemic and did not prevent patients in other cases from vindicating their own rights in recent decades."[9]

FDA's Legal Argument: Due Process

FDA next dismantled the court's holding that Plaintiffs are likely to succeed on their due process claim that these in-person requirements impose an undue burden on the right to abortion. The court wrongly concluded that it was permitted to balance the mifepristone requirements' burdens and benefits, regardless of whether Plaintiffs showed a substantial obstacle, based on the Supreme Court's decision in *Whole Woman's Health v. Hellerstedt*.[10] FDA correctly stated that under *Planned Parenthood v. Casey*, "an abortion regulation does not impose an undue burden unless it 'has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.'"[11] Further, in the recent case *June Medical Services v. Russo*,[12] "[a]ll nine Justices [] emphasized the importance of demonstrating that a law poses a substantial obstacle to abortion access in order to obtain relief … and at least five justices (a majority of the Court) explicitly *rejected* the sort of free-floating cost-benefit test applied by the Court in this case."[13]

The court also wrongly concluded that, because of challenges arising out of or exacerbated by the pandemic, these in-person requirements pose a substantial obstacle to women seeking abortion. FDA quoted the holding in *Casey* that "[t]he fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it."[14] The requirements at issue in this case serve the valid purpose of protecting women's health and clearly do not strike at a "right" to abortion when they regulate only one abortion method; what's more, these requirements do nothing to prohibit drug-induced abortion. FDA succinctly stated that:

[a] one-time trip to obtain Mifeprex at a clinic is at most a minimal burden,

[8] *Id.*
[9] *Id.* at 5.
[10] 136 S. Ct. 2292 (2016).
[11] Motion to Stay Memo at 6; 505 U.S. 833, 877 (1992).
[12] No. 18-1323, 2020 WL 3492640 (2020).
[13] Motion to Stay Memo at 6.
[14] Motion to Stay memo at 6-7, citing *Casey*, 505 U.S. at 874 (plurality).

> and the current COVID-19 pandemic does not transform a one-time trip into a substantial obstacle to abortion access. … the same or similar "risk" of exposure to COVID-19 arises *whenever* a patient travels outside the home, whether to go to the store, the park, or any other location. And CDC guidelines provide numerous steps patients and medical professionals can take to mitigate patient safety concerns in light of COVID-19.[15]

FDA also argued that "[i]f an in-person surgical abortion is not an undue burden for women seeking abortions after ten weeks, it cannot be an undue burden for women seeking earlier-term abortions simply because Plaintiffs would prefer another alternative."[16] The "right to abortion" does not include the right to a particular procedure or method; therefore, the in-person requirements do not deprive a woman of the ability to choose to have an abortion.

The FDA clarified that even if patients had a right to a particular procedure, the "[p]laintiffs provide no evidence that the Mifeprex in-person requirements have caused patients to forgo a medication abortion altogether or undergo a riskier procedure because of delays during the pandemic." Further, women may experience delays from waiting to receive the drugs in the mail or from a courier. Regardless, under *Casey*, "the possibility that a law may cause some delay in obtaining an abortion does not mean that it constitutes a substantial obstacle."[17]

FDA also explained how the court's comparison of the in-person requirement to the regulations struck down in *Whole Woman's Health* and *June Medical*, where the regulations would have led to a reduction in abortion providers and clinics, actually demonstrates "the lack of a substantial obstacle" in this case: "there is *no* evidence that the in-person requirements have caused, or would cause, a comparable reduction in the number of Mifeprex clinics or prescribers."[18]

Critically, FDA addressed the court's error in not deferring to FDA's scientific judgment. The court should have required only a "rational basis" for the in-person requirements, "in furtherance of its legitimate interests" in protecting women.[19] Instead the court "erroneously reasoned that in order to survive review, the benefits of the in-person requirements had to outweigh their (alleged) burdens, and that the benefits failed to do so."[20] FDA explained that the court failed to correctly examine FDA's purposes for the in-person dispensing requirements, which are to ensure

[15] Motion to Stay Memo at 7.
[16] *Id.*
[17] *Id.* at 8-9.
[18] *Id.* at 9.
[19] Motion to Stay Memo at 10, citing *Gonzalez v. Carhart*, 550 U.S. 124, 158 (2007) and *June Medical*, 2020 WL 3492640, at 25 (Roberts, C.J., concurring in the judgment).
[20] Motion to Stay Memo at 10.

that:

(1) at the time of dispensing, the patient has the opportunity to receive counseling about the risk of serious complications associated with Mifeprex and what to do should they arise; and

(2) there is no delay in the patient receiving their Mifeprex prescription, which could increase the risks of serious bleeding or infection.[21]

It is entirely appropriate for FDA to make this determination— "FDA's evaluation of a drug's risks to determine the appropriate restrictions necessary for safe use is a matter quintessentially within FDA's expert scientific judgment. Given this background, the court should not substitute its own judgment for that of FDA, even in the context of a constitutional question."[22] Specifically, "FDA determined during its 2013 Review, based on its experience and scientific expertise, that the in-person dispensing requirement is necessary to mitigate the serious risks associated with Mifeprex—a decision FDA reaffirmed in 2016 when it concluded that the 'safety profile of Mifeprex ha[d] not substantially changed.'"[23]

FDA explained that the court also incorrectly applied the "large fraction" standard established in *Casey*. The court applied this test to the "narrow subset of women who seek a medication abortion during the pandemic bud do not 'actually require an in-person visit with their healthcare provider in order to be properly assessed and counseled.'"[24] FDA correctly states that the women who *should* be considered "at a minimum include all women impacted by the in-person requirements, which includes all women seeking a medication abortion."[25] This is the group of women for whom the law is a restriction, which should be considered under *Casey.*

In fact, abortion providers cannot truly know which women should be seen in person prior to obtaining abortion-inducing drugs, because contraindications to drug-induced abortion are often not evident without an ultrasound and physical exam. Tragically, women with these contraindications, such as ectopic pregnancy, may suffer serious complications that could have been avoided if they had been appropriately examined.

[21] *Id.*
[22] Motion to Stay Memo at 11.
[23] *Id*. at 12.
[24] Motion to Stay Memo at 13 (quoting Mem. Op. at 40-41).
[25] Motion to Stay Memo at 13.

FDA: Irreparable Harm

FDA also argues that the agency and the public "will be irreparably harmed if the preliminary injunction is not stayed. The federal government is irreparably harmed whenever it is enjoined from enforcing its public health and safety regulations."

The concern that women will be negatively impacted when they no longer have any in-person contact with healthcare professionals is far from theoretical. In late March, the United Kingdom began permitting mifepristone and misoprostol to be delivered by mail without an in-person appointment because of the pandemic. A leaked email to the British National Health Service from a Regional Chief Midwife revealed that women are suffering and even dying because of the reduction in care:

> … [T]he [Care Quality Commission] indicated that they are aware of 13 [adverse] incidents related to [abortion pills through the mail]….[redacted] herself had been made aware of 10 incidents across 6 organisations …there have been **2 maternal deaths** linked to this issue also. One case where **a woman was found at home** the morning after starting the process and the second where **a woman presented with sepsis** and died very quickly in the [emergency] dept. … The incidents in [redacted] range between women attending ED with **significant pain and bleeding related to the process through to ruptured ectopics, major resuscitation for major haemorrhage and the delivery of infants who are up to 30 weeks gestation.** There was also a near miss where a woman had received the pills by post and then wished for a scan so attended a trust and was found to be 32 weeks. There are 3 police investigations in [redacted] linked to these incidents and one of those is currently a **murder investigation as there is a concern that the baby was live born**" (emphasis added).

It is only a matter of time before these tragic stories begin to surface in the United States, now that abortion drugs will be delivered through the mail to women who have not been properly examined. Hopefully the Fourth Circuit will quickly reverse Judge Chuang's decision and permit FDA to enforce these important protections. Otherwise "safe," first-trimester abortions in this country will increasingly lead to not one, but two tragedies—the deaths of unborn children *and* their mothers.

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