Abstract:
This chapter examines both parties' arguments in the Alliance for Hippocratic Medicine v. the Food and Drug Administration in the North District Court of Texas. The chapter discusses how interest groups and Christian Conservative Legal Organizations, such as the AHM forum, shop when filing cases in federal court to get a judge they feel is more ideologically aligned with their organization to hear their case. This chapter uncovers the consequences of forum shopping through a brief case study of Judge Matthew Kacsmaryk, who first listened to this case in federal court, holding that the FDA's approval of mifepristone was unlawful. The chapter also discusses the FDA's emergency relief petition to the United States Supreme Court and concludes with an overview of the lobbying efforts over chemical abortion.

Chapter 2: Pro-Life Religious Interest Groups & the Regulatory Authority Over Reproductive Rights

On Tuesday, November 8, 2022, the day of the midterm election, the back lash against the Biden Administration, dubbed the "red wave" by political analysts did not hit the shores of voting precincts, despite the President's approval rating hovering at 40% (Cillizza, 2022). Voters in critical states, like Michigan and Pennsylvania, ranked *abortion*, not inflation or crime as the most important issue of the election. And though they lost the House of Representatives, Democrats gained a seat in the Senate, held onto several governorships, took away two legislative chambers from Republicans in Michigan and Minnesota, and gained complete control of state capitols in Maryland and Massachusetts (Schneider and Otterbein, 2022). It was clear that in the wake of the *Dobbs* decision, abortion was a top electoral issue, especially for women, where a gender gap emerged, suggesting both younger and older women favored Democratic candidates (Kurtzleben, 2022). For example, in the weeks following the landmark *Dobbs* decision, more than 70% of newly registered voters in Kansas were female. Though percentages vary, this emerging pattern continued with an increase of female voter registration numbers across multiple states, such as Pennsylvania, Ohio, Oklahoma, Florida, North Carolina, Idaho, Alabama, New Mexico, and Maine, which worked to the advantage of Democrats (Paris and Cohn, 2022).

Yet, despite election results showing that 61% of Americans believe abortion should be legal, the Christian Legal Movement took the opportunity to launch another attack on reproductive rights by targeting the Food and Drug Administration's regulatory authority over the abortion pill (Hartig, 2022). Just days after the midterm election, the Alliance for Hippocratic Medicine (AHM) filed a lawsuit against the executive regulatory agency in the United States District Court for the Northern District of Texas, located in Amarillo (NARAL, 2023). In the lawsuit, the AHM looked the court to revoke the FDA's approval of mifepristone, a drug that blocks the needed hormone progesterone to sustain a pregnancy, which is used in a regimen with misoprostol to form the "abortion pill." This regimen is used to terminate pregnancy that is less than 70 days in duration (Mayo Clinic, 2023; FDA, 2023). In the complaint, the AHM, represented by the Christian Conservative Legal Organization (CCLO), Alliance Defending Freedom (ADF) questioned the FDA's accelerated approval of chemical abortion drugs, which the plaintiffs argue the agency could only do by labeling pregnancy an "illness." The AHM argued that the pregnancy is not an "illness" or "serious" nor "life-threatening"

condition and the FDA's decision was political, not scientific (*Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 2022, 2).

However, before delving further into the AHM's and Biden Administration's arguments over the FDA's regulatory authority on chemical abortion, it is important to first take a closer look at who the AHM is, why it was established in Amarillo, TX, and filed its original complaint with the Northern District Court.

The Alliance for Hippocratic Medicine

The AHM is an interest group of pro-life medical professionals (Bourkland, 2023). The AHM consist of five partnering organizations: the Catholic Medical Association, the Coptic Medical Association, the American Association of Pro-Life Obstetricians and Gynecologists (APPLOG), and the Christian and Dental Association (Alliance for Hippocratic Medicine, 2023a). The AHM is incorporated in Tennessee as a non-profit organization, but as of August 5, 2022, they registered an agency in Amarillo, Texas, just three months before they filed their lawsuit against the FDA (Hammonds, 2023). The AHM's mission is to "uphold and promote the fundamental principles of Hippocratic medicine," which includes, "protecting the vulnerable at the beginning and end of life." Although the AHM's presence is relatively new in Texas, members of this organization have been challenging the FDA's approval of the abortion pill since August 2002 (Alliance Defending Freedom, 2023b). In March 2016, the FDA denied the citizen petition filed by these members. During the COVID pandemic, the FDA loosened some regulation on the abortion pill by temporarily removing the in-person dispensing requirement and in December 2021, the FDA denied another citizen petition by members of the AHM. Subsequently, the FDA permanently removed the in-person dispensing requirement, opening the opportunity for the abortion pill to be accessible via telemedicine and mail (Alliance for Defending, 2023b). Some argue these developments, along with the appointment of the Honorable, Judge Matthew Kacsmaryk to the United States District Court for the North District of Texas is what spurred the AHM to locate to Amarillo and file suit there (NARAL, 2023; Wheeler, 2023).

Forum & Judge Shopping

In the last several years, federal courts have seen cases challenging a variety of government actions. Plaintiffs in these cases often look for flexibility in selecting the court to file their case. Acting as strategic actors, plaintiffs sometimes calculate where to file their suit based on their perception of how certain legal rules in a jurisdiction may or may not favorably apply to their claims (Lampe, 2022). This practice is known as "forum shopping." Though forum shopping is limited in the federal court system by things such as the *Erie Doctrine*, which holds that a federal court sitting in diversity jurisdiction must apply the substantive law of the state in which it sits, it still can occur (Cornell Law School, 2023). Additionally, some parties may also try to bring their claim before a specific judge, a practice known as "judge shopping" (Lampe, 2022).

Keeping the above in mind, we can now assess a plausible reason or argument for why the AHM filed their suit against the FDA in United States District Court for the North District of Texas. First, it is important to understand that the claim the AHM filed with the court is regarding a question over the FDA's regulatory authority, which is a matter of federal question

jurisdiction. There are two main factors that determine where a claim can proceed: jurisdiction and venue. Jurisdiction deals with the power of a court to rule on a case. For a court to have the authority over a case it must have personal jurisdiction over the parties and subject matter jurisdiction, meaning it can decide on the legal issued presented. Federal courts have both diversity and subject matter jurisdiction. Subject matter jurisdiction deals with the court being able to hear a specific type of claim. In the case of the AHM against the FDA, the plaintiff's claim deals with a federal question, therefore, it was appropriate for a federal district court to hear the case (Lampe, 2022).

Now, why did the AHM choose to file their suit in the district court in Amarillo, Texas? The answer lies in the issue of venue, again, this refers to the court location where it is proper for a case to proceed. Venue will occur in a court close to the geographic area of where one or more of the parties are located (Lampe, 2022). As discussed above, the AHM registered itself in Amarillo, Texas just three months before it filed its suit against the FDA; therefore, the North District of Texas was the appropriate venue for the case (Hammonds, 2023). However, there is the argument that judge shopping was also part of the AHM's legal strategy. For instance, there are ninety-four federal district courts throughout the United States, with each district divided into divisions. In Texas, there are four federal district courts with twenty-seven divisions. Eight of these divisions only has one judge; therefore, any case filed in these respective divisions will automatically go to that one judge, so parties are aware of who will preside over their case. Judge Matthew Kacsmaryk, a Trump appointee, is the only federal judge in the Amarillo division of the U.S. District Court for the Northern District of Texas (Chemerinsky, 2023). Judge Kacsmaryk is a former lawyer who served as Deputy General Counsel for First Liberty Institute and Assistant United States Attorney for the Northern District of Texas (The Federalist Society, 2023). The First Liberty Institute is a Christian Conservative Legal Organization, dedicated to defending religious freedom (First Liberty Institute, 2023). Some, such as legal scholar, Erwin Chemerinsky, argue that the AHM's move to file in this division was intentional because, "Conservative litigators know if they file their case in federal court in Amarillo, their judge will be Kacsmaryk" (2023).

So, beyond Kacsmaryk being a judicial nominee by a president who promised to appoint "pro-life" judges to the federal judiciary, what other factors could've led the AHM to "shop" for this judge when filing their case against the FDA (NBC News, 2016)? Well, some point to Kacsmaryk's family history as a factor. According to the *Washington Post*, when Kacsmaryk was a young law student, his seventeen year old sister gave birth to his nephew at a maternity center. Kacsmaryk traveled to see his nephew at the center before he was given up for adoption. Kacsmaryk later became a board member of Christian Homes and Family Services, the organization that took his sister in when she decided adoption or over abortion (2023). Although judicial officers are supposed to be independent and impartial, some argue that Judge Kacsmaryk's conservative background, may have pushed the AHM to hedge their bets when filing their suit in Amarillo, where he was sure to get the case. For example, Wheeler (2023) notes that key Biden Administration cases involving immigration, reproductive health, and LGBTQ rights have all been before Judge Kacsmaryk and hit roadblocks, as seen in his decision to halt federal protection for asylum seekers, eliminating rules expanding teen access to birth control, as well as rejecting a policy that stopped doctors from discrimination against patients based on their gender identity or sexual orientation.

Since the *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration* (2023) was filed in the Northern District of Texas, the federal Judicial Conference, the judiciary's administrative unit, has approved a new policy to combat forum shopping. As discussed above, this issue has come up with particular attention to federal districts in Texas, where one judge is automatically assigned cases and interest groups file their petitions there in hope of a getting a decision in their favor based on the judicial officers' ideological background. On March 12, 2024, the Conference stated that a civil claim looking to bar or implement a state or federal action would now be randomly assigned to judges throughout federal judicial districts and that the policy overrides local orders allowing for only one judge to hear all cases filed at their courthouse. The policy change comes as claims for national injunctions are on the rise (Thomsen and Wheeler, 2024). However, U.S. Senate Republican leaders, such as Senators Mitch McConnell (Republican from Kentucky), John Cornyn (Republican from Texas), and Thom Tillis (Republican from North Carolina) stated in a March 14, 2024 letter, directed to the chief judges of U.S. District Courts throughout the country, that the Conference's policy was not legislation and therefore, it was not up to this body but Congress to decide how cases should be assigned to lower courts (Monyah and Wheeler, 2024). This move by the Conference and rebuke by Republican leaders will keep forum shopping a contested issues as the interest groups and government officials keep navigating the court system in filing their claims.

The Arguments by the Alliance for Hippocratic Medicine

Now that the parties and selection of where the AHM's case against the FDA was originally heard has been discussed, it is important to look at the arguments and case timeline. Starting with the plaintiffs, the Alliance for Hippocratic Medicine, made several key arguments in their original complaint relating to their position that the United States Food and Drug Administration "chose politics over science," by failing to live up to its mission of protecting the health, safety, and welfare of Americans by rejecting or limiting the use of dangerous drugs, like mifepristone (*Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 2022, 2). The AHM argued for a preliminary and permanent injunction ordering the FDA to withdraw mifepristone and misoprostol as an approved form of chemical abortion (*Id*. at p. 110-111).

Again, mifepristone is a drug that blocks the hormone, progesterone, which is needed to sustain pregnancy. Mifepristone, when used with misoprostol, a medication prescribed to prevent stomach ulcers, can end pregnancy within seventy days or less since the first day of a woman's last menstrual period (FDA, 2023a; Krugh and Manni, 2023). This drug combination works by the mifepristone causing the embryo to separate from the uterine lining, while the misoprostol induces abortion by causing contractions and expelling the embryo (National Library of Medicine, 2000). The AHM argues the process to make chemical abortion accessible in the United States began under the Clinton Administration when they encouraged the French manufacturer of the abortion pill, RU-486, to donate their patent rights to a nonprofit group, the Population Council (*Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 2022, 2). News outlets during this time noted the unconventional approach efforted by the Clinton Administration to work around obstacles, so that RU-486 could be available for use in the United States, since it was banned by the previous President, George H.W. Bush. As a result, in 1992, manufacturers of the RU-486 refused to market the drug in the United States; however, this began to change a year later under the Clinton Administration (Eaton, 1994). In

their complaint, the AHM argues that after Population Council received the patent rights to mifepristone, they submitted a new drug application for chemical abortion and worked alongside the FDA during the drug's review process which was approved in 2000. The AHM claims this process was rushed, arguing that in order to approve the chemical abortion drug, the FDA had to look to the Code of Federal Regulations, § 314 Subpart H, which gives the agency the ability to grant an "accelerated approval" of "certain new drug products that have been studied for their safety and effectiveness in treating serious or life threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments."

However, the AHM states that pregnancy is not a life threatening illness and it "rarely leads to complications that threaten the life of the mother or child" (*Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 2022, 15). The AHM further argues that the FDA has increased the gestational age for which pregnant women or adolescence can take the chemical abortion drug from seven to ten weeks, despite claims that increased risk is in involved in doing so. The AHM also finds it problematic that in 2016, the FDA changed the dosage for chemical abortion, decreased the required number of in-person office visits from three to one, expanded who could prescribe the drugs, and discontinued the requirement of abortion providers to report non-fatal complications from chemical abortion drugs. Furthermore, the AHM argued that in 2019, the FDA approved a generic of mifepristone without imposing up-to-date clinic investigations on this new version, skirting requirements under the Federal Food, Drug, and Cosmetic Act, as well as the Pediatric Research and Equity Act (*Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 2022, p. 3-5).

Another point of interest the AHM raised in its original complaint to the District Court in Amarillo is that the chemical abortion regimen has adverse health effects. The AHM claims that by blocking a woman's progesterone receptors in the uterus, which is necessary for the growth of a fetus, mifepristone begins to block the natural hormone and "chemically destroys the baby's environment in the uterus, blocks nutrition to the baby, and ultimately starves the baby to death in the mother's womb" (*Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 2022, 17). And, because mifepristone alone only works about 25% of the time to terminate pregnancy, the AHM argues that the FDA's chemical drug abortion regimen calls for the use of misoprostol, which induces cramps and contractions "in an attempt to expel the baby from the mother's womb" (*Id.* at p. 18) Furthermore, the FDA argues under this regimen 10% of women need follow up medical treatment for incomplete or failed chemical abortion attempts, with over a third requiring surgery if the drugs are taken in the second trimesters (*Ibid*.) Essentially, the AHM argues that chemical abortion is not more safe than surgical abortion, as they claim 20% of females will have adverse effects after taking chemical abortion pills and that the regime increases abortion-related emergency room visits. The AHM also addresses potentially adverse mental health effects for undergoing chemical abortion (*Id*. at p. 21).

Furthermore, the AHM complaint argues against the FDA's 2021 "Non-Enforcement Decision" on mifepristone, which stopped the agency from requiring abortion practitioners to provide in-person dispensing of the drug and allowed for mail-order prescriptions of the chemical abortion pill. The FDA argued that this action was taken because of the COVID-19 public health emergency; however, the AHM argues this was a way to circumvent safety protocols and further relax the conditions under which the drug is prescribed. In December of

2021, two and half years after the AHM filed a citizens petition requesting the FDA restore the pre-2016 conditions to the drug regimen, the agency rejected their request, and the Biden Administration announced it would permanently allow the chemical abortion pill to be sent via mail (*Id*. at p.5-6).

Ultimately, the AHM's complaint centers around their effort to stop the increased access to abortion that the chemical abortion pill provides, particularly because it no longer requires multiple doctor's visits and has been approved to be distributed via mail by the FDA since December 2021. This goal is evidenced via the points in their complaint noted above and the argument that easy access to chemical abortion pills aids sex traffickers and abusers because their victims do not have to enter an actual facility to undergo termination of their pregnancy but instead can be forced to take the medication without this step. As a result, their abuse is not detected by professionals trained to identify and assist victims of sex trafficking (*Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 2022, p. 6).

The FDA's Opposition to AHM's Motion for a Preliminary Injunction

As much as the AHM's argues that the Food and Drug Administration based their approval of the chemical abortion drug on politics, the defendants claim the plaintiffs' arguments are speculative at best, as well as untimely, unexhausted, and without merit (*Defendants' Opposition to the Plaintiffs' Motion for a Preliminary Injunction*, 2023, 1).

In their complaint, the government argues that the FDA is responsible to ensure that new drugs it authorizes are safe and effective for their intended use and rebuts allegations by the AHM that their approval of the chemical abortion drug fell below or outside necessary standards. The FDA derives part of this authority from the Federal Food, Drug, and Cosmetic Act, which prohibits the interstate distribution of new drugs that have not gone through formal FDA approval. The FDA argues that all their approvals are based on scientific evidence that the drug being considered is safe and effective for its intended purposes. The FDA argues that whenever a drug's sponsors submit a supplemental new drug application these same standards apply. Furthermore, when a generic version is being considered, the FDA states that their review ensures it is materially the same as the approved drug (*Id*. at p.1-2).

The FDA explains that in the original approval process from 1996 to 2000 of the chemical abortion drug, that they determined through multiple studies, that all evidence showed the use of the drug was safe and effective for its intended purposes and its distribution outweighed any risks. The FDA also affirmed that in using Subpart H, they were able to place restrictions on in person dispensing requirements and agreed prescriptions for the drug would be given by or under the supervision of a physician that could accurately date pregnancy and diagnosis ectopic pregnancies. This is why in 2002, when the plaintiffs, the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and the Christian Medical Association (CMA) submitted a citizens petition (which is required before asking a court to invalidate the FDA's authorization of a drug), the FDA rejected it on March 29, 2016 (*Id*. at p.4-6)

However, in 2016, in relying on more studies on the chemical abortion drug, the FDA increased the gestational age limit from 49 to 70 days, reduced the numbers of visits from one to three, and recognized at home distribution as safe because research showed mifepristone was associated with an "exceedingly low rates of serious adverse events," and that there was

no significant difference among patients who followed up on the phone with their healthcare provider when being distributed the drug versus those who did so in person (*Id*. at p. 5). However, during this time, the FDA also expanded the healthcare providers who could distribute the drug outside of physicians if they were also certified under the agency's Risk Evaluation and Mitigation Strategy (REMS) process, which is required for certain medications with any serious safety concerns to ensure the benefits of the therapeutic outweigh risks (FDA 2023b). Furthermore, the FDA explains that in 2019, when the agency approved the generic version of the chemical abortion drug it was deemed to be materially same as the originally approved drug, so there was nothing that the organization did to breach protocol (*Defendants' Opposition to the Plaintiffs' Motion for a Preliminary Injunction*, 2023, 5-6).

In 2019, the plaintiffs, APPLOG and the American College of Pediatricians (ACP) submitted a second citizen petition, challenging the 2016 changes to the conditions of the approval, including REMS; however, this petition did not ask the agency to withdraw approval of mifepristone. Instead, the petition requested the FDA to retain the REMS and in-person dispensing of the drug and return to the approval requirements of 2000, such as limiting mifepristone's use to a forty-nine day gestation period, requiring the medication to only be given by or under the supervision of a physically present, certified physician, require the original three office visits, supply a contraindication for patients without regular access to emergency medical care, mandate reporting of adverse effects, and continue additional studies on the regimen (*Id*. at p. 6-7). However, the FDA continued to relax restrictions on the drug in April 2021 during the COVID-19 pandemic by permitting it to be mailed and took note of a six month evaluation period where no evidence of serious safety concerns developed. On January 3, 2023, the FDA removed the in person dispensing requirement completely (*Id*. at p. 6).

In the original compliant, the FDA argues that the plaintiffs have shown little likelihood of success on the merits and their claims are speculative. The FDA also argues the plaintiff do not show injury, which is a key element to stand before a court and present a case and that therefore, they are outside of the proper zone of interests and are not cognizable under Article III. However, the FDA does concede that the only possible issue with merit that the plaintiffs have in their complaint to be heard by the Court are those in their 2019 citizen petition (*Id*. at p.1, 9). Other than this issue, opposition holds that the plaintiff's arguments are likely to fail on their merits, the studies they present do not undermine the authority of the FDA, and their request for a preliminary injunction would not only harm the public interests by withdrawing a safe and effective drug, but comprise state healthcare systems, disrupt businesses in the sale and distribution of mifepristone, and interfere with Congress' ability to entrust the FDA to guarantee the safety and efficacy of approving drugs (*Id*. at p. 20-22, 34-40).

Judge Kacsmaryk District Court Order and Opinion

On April 7, 2023, Judge Matthew Kacsmaryk granted the plaintiff's (the Alliance for Hippocratic Medicine et al.), motion in part by staying the FDA's approval of mifepristone. Judge Kacsmaryk stayed the applicability of the order for seven days to permit the federal government time to seek immediate relief from the United States Court of Appeals for the Fifth Circuit (*Alliance for Hippocratic Medicine et al* v*. U.S. Food and Drug Administration et al.,* 2023, 67).

In his opinion, Judge Kacmaryk addressed several key issues. Kacmaryk immediately accused the FDA of ignoring the plaintiff's 2002 citizens petition where they requested the agency to stay the approval of Mifeprex (mifepristone) and halt all distribution and marketing of the drug pending the final action on the petition because the FDA had used the Subpart H process to expedite the drug's approval by categorizing it as treatment for a serious or life-threatening illness (*Id.* at p. 1-2). Judge Kacmaryk added that in 2006, the House of Representatives' Subcommittee on Criminal Justice, Drug Policy, and Human Resources expressed similar concerns and investigated the FDA's handling of mifepristone, finding it was associated with "the death of eight women, nine life-threatening incidents, two hundred and thirty-two hospitalization, a hundred sixteen blood transfusions, and eighty-eight cases of infection" (*Id*. at p. 4).

Kacmaryk also attacked arguments made by the FDA against the AHM in their response to the plaintiff's complaint. For instance, Kacmaryk argued that the plaintiffs can stand before the court because they have associational standing due to the AHM's members ability to claim adverse events can occur because of chemical abortion drugs overwhelming the medical system and putting "enormous pressure and stress" on physician during emergencies, which can consume crucial and scarce resources, particularly in areas where there is limited doctor availability (*Id*. at p. 7). Kacmaryk also agreed with the plaintiffs that the medical associations that are party to their claim have standing since they are "opposed to being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion" (*Id*. at p. 8). Furthermore, Kacmaryk said that the plaintiffs have organizational standing by showing the defendant's actions drain their organizations' resources and cause them adverse effects. He further held that the affiliated medical associations to the plaintiff's claim also have organizational standing due to the FDA's failure to require the reporting of adverse events from those taking the abortion pill and that this comprises these groups ability to educate and inform their member physicians, patients, and the public of the dangers the drug poses (*Id.* at p. 11-12).

Furthermore, Kacmaryk held that the FDA's 2016 and 2021 changes significantly departed from the original approved drug scheme. And, that the agency's review of the plaintiff's 2019 petition, which was completed in 2021, essentially reaffirmed their substantive reconsideration of the abortion pill and its potential dangers. Therefore, Kacmaryk held any statute of limitations period for the plaintiffs to contest the FDA's authorization of the abortion pill begins in 2021 and the AHM is not time barred in bringing the case to the court under the principle of equitable tolling, which gives the court discretion to extend a deadline due to extraordinary circumstances that inhibited an individual's timely action (Cornell Legal Information Institute, 2023; *United States v. Patterson* (5th Cir. 2000)). Kacmaryk argued that because of the FDA's "unreasonable delay" in responding to both the plaintiffs 2002 and 2019 petitions, equitable tolling was appropriate in terms of the AHM ability to stand before the court on their claim (*Alliance for Hippocratic Medicine et al* v. *U.S. Food and Drug Administration et al.,* 2023, 24).

Regarding the FDA's 2021 changes removing the in-person dispensing requirement of the chemical abortion pill, Kacmaryk argued that the agency did not have the authority for such action. Kacmaryk held that under *Heckler v. Chaney* (1985), the FDA may have discretion in "one-off" decision, but it does not have the authority to "suspend entire statues" and

therefore, any exception to judicial review is very narrow (*Id.* at p. 26). Additionally, the AHM argued that the FDA's 2021 decision to dispense mifepristone via mail did not address federal criminal laws prohibiting such distribution. The FDA countered that the AHM did not exhaust its arguments on this issue because they did not present the matter at any stage of the administrative proceedings on the dispensing of the drug via mail. Kacmaryk held that the AHM's failure to exhaust claims through the administrative process did not preclude judicial review because exhaustion is not required where an agency is found to act in excess of its authority. Therefore, a court will review "a particular challenge to an agency's decision which was not raised during the agency proceedings" (*Myron v. Martin* (5th Cir. 1982); *Id*. at p. 27).

In his opinion, Kacmaryk went on to address several other issues in favor of the plaintiffs, such as public policy concerns surrounding the applicability of the Comstock Act, originally enacted in 1873 and which currently includes section 1462, prohibiting the mailing of obscene or crime-inciting matter, including "every article or thing designed, adapted, or intended for producing abortion…" (18 USC 1461). Kacmaryk held that along with the concerns over individual injury and injustice that may result from use of mifepristone, that the FDA's administrative procedures were inadequate as evidenced by their slow response time to the plaintiffs' petitions and suspending the requirement of abortion practitioners to report non-fatal adverse events. He further stated that the plaintiffs will be successful on the merits due to the FDA violating federal law on mail dispensing, categorizing pregnancy as an illness and thus violating Subpart H for the Accelerated Approval of New Drugs for Serious or Life-Threatening Illness (*Alliance for Hippocratic Medicine et al* v*. U.S. Food and Drug Administration et al.,* 2023, 29-50).

The Aftermath of the District Court Ruling

Within a week of the District Court's decision, the FDA applied for a stay of Judge Kacmaryk's ruling. However, on April 12, 2023, the United States Court of Appeals for the Fifth Circuit issued a ruling refusing to block Judge Kacmaryk's decision at the District Court and attempted to reinstate pre-2016 restrictions on the chemical abortion pill. As a result on April 14, 2023, the FDA filed an application for emergency relief from the United States Supreme Court (Center for Reproductive Rights, 2023; SCOTUSblog.com, 2023a). By this time Danco Laboratories, LLC, a pharmaceutical corporation that solely distributes Mifeprex, intervened in the case on side of the Food and Drug Administration (*Food and Drug Administration, et al. v. Alliance for Hippocratic Medicine, et al.*, 2023; Rutherford 2023). On April 21, 2023, the FDA's application for a stay was granted by the Supreme Court, "pending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for writ of certiorari, if such a writ is timely sought" (*Food and Drug Administration, et al. v. Alliance for Hippocratic Medicine, et al.*, 2023, 1).

The case was then filed before the Fifth Circuit. On August 16, 2023, after officially hearing the appeal, the court vacated in part and affirmed in part the District Court's stay order. Specifically, the appellate court held that the medical organizations and doctor's concerns regarding the accelerated approval process of mifepristone was likely barred by the statute of limitations, keeping the drug available to public under 2016 conditions. The Fifth Circuit also vacated the part of the district court's order on the 2019 generic approval because the medical organizations and doctors who were party to the claim did not show how the generic version of

mifepristone caused them injury. However, the court of appeal affirmed the portions of the stay order concerning the 2016 Amendments to the drug protocol (i.e., the change in dosage, decreased number of required visits for medical consultation, exceptions to who could prescribe the drug, and the removal of reporting non-fatal complications from the medications use) affirmed, along with the district court's ruling on the 2021 Non-Enforcement Decision permitting mifepristone to be distributed by mail (*Alliance for Hippocratic Medicine et al. v. U.S. Food & Drug Administration et al. and Danco Laboratories, LLC*. (5th Cir. 2023)). However, the Supreme Cour of the United States April 21, 2023, stay, pending a final disposition on appeal superseded this decision.

Also following the Fifth Circuit's ruling, on September 8, 2023, both the Food and Drug Administration and Danco Laboratories, LLC. filed a petition for writ of certiorari to the United States Supreme Court to formally hear their case against the Alliance for Hippocratic Medicine. On December 13, 2023, the Supreme Court announced the cases were consolidated and the petitions for certiorari were granted, meaning the Court would officially hear and rule on the case during its 2023-2024 calendar (SCOTUSblog.com, 2023b).

On March 26, 2024, the Supreme Court of the United States heard arguments in *U.S. Food & Drug Administration v. Alliance for Hippocratic*. The main issues evaluated before the Supreme Court during oral arguments centered on: (1) whether the respondents, Alliance for Hippocratic Medicine, et al. have Article III standing to challenge the FDA's 2016 and 2021 actions easing access to mifepristone; (2) if the FDA's actions in 2016 and 2021 were arbitrary and capricious; and (3) if the lower district court properly granted preliminary relief. During oral arguments, the government claimed that millions of Americans have safely used mifepristone, the Alliance does not have proper standing, and therefore, cannot rely on the theory of injury pronounced by the District Court. The government also argued that the AHM's position relies on too many "remote contingencies," as only an exceptionally small number of women have experienced serious side effects from the drug and their arguments on harmfulness are "speculative" (*Id*. at p. 5). The government also argued that the FDA decision to ease access to mifepristone was based on dozens of studies and that granting the respondents relief would cause major disruption to the federal system of both developing and approving drugs, causing harm to not only the FDA but the pharmaceutical industry. Furthermore, the government argued the agency conducts routine surveillance of drugs, adjusting regulatory schemes if safety concerns emerge and that the liability for harm to patients always rests with drug sponsors. When challenged by the justices on the respondent's arguments that mifepristone by mail saw an increase in emergency room visits by patients, the government rebutted that these trips did not equate to serious adverse events for women. Danco Laboratories, manufacturers of mifepristone, also argued that the changes in access to the drug resulted in more reporting to the FDA on adverse reactions.

The respondents, the AHM, countered the FDA in oral arguments by claiming that the FDA's approval of mifepristone by mail was based on inadequate data, so the district court's decision simply restored critical protections to women using the drug. The AHM also argued that by not giving the Alliance standing, health care practitioners would be forced to violate their consciences by being put in a position to manage abortions in the event of a woman's adverse reaction to mifepristone, causing the doctor professional harm without judicial recourse. Essentially, the AHM argued that doctors and healthcare professionals they represent

should receive a form of third party standing, which allows another person or entity to assert the rights of individuals when their interest are closely aligned, and it is difficult for that person to assert their own rights. What is interesting is that third party standing has usually been invoked by doctors in abortion cases challenging the constitutionality of restrictions on the procedure. However, here, the AHM attempted to use the principle to argue that to prevent standing denies these healthcare practitioners individual recourse or rights (Reingold, 2020; *U.S. Food & Drug Administration v. Alliance for Hippocratic*, 2024a). Again, this approach is aligned with Lewis' (2017) claims that conservatives are beginning to use an individual rights based approach when fighting progressive abortion policies, to secure their rights to things like conscience protection, religious liberty, and access to the courts.

During oral arguments, the justices seemed to be concerned if the Alliance for Hippocratic Medicine and the doctors they represented had proper standing to bring a lawsuit against the FDA. The Supreme Court also appeared to have concerns about whether the lower courts decisions on the case went too far in scrutinizing the FDA and if the courts have the proper knowledge to make determinations on the agency's regulation of drugs, such as mifepristone. (Suhasini and Reingold, 2024). On June 13, 2024, the Supreme Court issued its official decision in the case, ruling in favor of the FDA. The Supreme Court came to its decision by holding that the Alliance for Hippocratic Medicine did not have proper standing to sue the Food and Drug Administration because the lack the ability to demonstrate that injury was done to the doctors and medical organizations the AHM represented (*Food and Drug Administration et al. v. Alliance for Hippocratic Medicine et al*. (2024b)). This case will be further discussed in Chapter 4.

Lobbying Over Chemical Abortion

In evaluating how access to the abortion pill is now at the Supreme Court, it is important to understand some of the first ideas behind the population control movement in the United States, as well as efforts to bring RU 486 to the market, and how the COVID-19 pandemic ushered in an era of lobbying on the topic of self-managed abortion. These underlying dynamics provide additional context for where and why the United States is on access to mifepristone.

As previously mentioned, Roussel-Uclaf, the French manufacturer of the chemical abortion pill, RU-486, was lobbied by the Clinton Administration to give their patent rights to the nonprofit group, the Population Council, so the medication could be distributed in the United States. The Population Council would eventually grant Danco Laborites an "exclusive license to manufacture and distribute Mifeprex in the United States" (*Alliance for Hippocratic Medicine et al. v. U.S. Food & Drug Administration et al. and Danco Laboratories, LLC*. (5th Cir. 2023), 5). So, who is the Population Council and why were they selected as the organization to contract with Roussel-Uclaf? Well, the Population Council was first founded through the Rockefeller Brothers Fund in 1952 with an interest in global population growth, family planning, and the health and development of nations. Trustee, John D. Rockefeller III, began to work on population control efforts from the standpoint of human fertility and contraception research, which included access to affordable birth control. The Council funded research on increasing access to contraception among racial minorities and the poor, while some members also focused on controlling the population growth among white and economically well-off families. (The Population Council, 2023; Ziegler 2013).

The population-control movement, which the Council played an influential role in, began to develop after World War II as concerns with overpopulation gained traction and the United States government engaged in family planning policy under the Social Security Act, opened foreign aid on the issue to developing country. And, under President Nixon, the National Center for Population and Family Planning was created within the Department of Health, Education, and Welfare. The Population Movement was both influential and diverse, as evidenced by Nixon receiving bipartisan support for the Family Planning Services and Population Research Act of 1970 (Ziegler, 2013). As the Population Movement continued to grow, there was a split among some who did and did not support legalize abortion. Members that endorsed the legalization of abortion were linked to issues such as the sexual revolution, women's movement, and environmental stewardship. However, there was no formal position among the Population Council endorsing legal abortion pre-*Roe* (Ziegler, 2013). Yet, once *Roe v. Wade* (1973) appeared before the Supreme Court, concerns over population control began to change and the focus turned to issues of privacy and their relation to procreation, marriage, and contraception in deciding that women had a constitutional right to terminate their pregnancies up to the point of viability (Ziegler, 2013; *Roe v. Wade* 1973).

In the aftermath of *Roe*, the pro-Choice movement stepped away from arguments surrounding population in advocating for abortion. Arguments among pro-choice circles began focusing more women's bodily autonomy, societal equality, and increased access to reproductive rights and healthcare (Ziegler, 2013). In the 1980s, U.S. feminist groups, such as the Feminist Majority Foundation (FMF), Reproductive Health and Technology Project (RHTP), Abortion Rights Mobilization (ARM), Planned Parenthood (PP), and the National Abortion and Reproductive Rights Action League (NARAL) had been paying attention to the development of RU-486 in France and urged the French manufacturer to bring it to U.S. markets (Jackman, 2002). However, Roussell Uclaf was hesitant to bring mifepristone to the United States due to fear of anti-abortion boycotts, hostility towards the medication by the Bush Administration, and concerns about anti-abortion violence (Jackman, 2002; Dorozynski, 1997). At first the pressure from anti-abortion activist, such as the National Right to Life Committee, Catholic hospitals, and conservative members of Congress were successful in getting the FDA's then-Commissioner, Frank Young in 1989 to issue a ban on RU-486 being brought into the United States (Jackman, 2002). Jackman (2002) argues this is the point when the strategy to bring mifepristone to the United States shifted from solely a traditional governmental lobbying standpoint to oe that included a strategy of independent campaigns among feminist social groups. Some of these efforts included the Feminist Majority Foundation (FMF) launching a national education initiative on mifepristone. The FMF also led a delegation of medical practitioners and researchers that met with officials of Roussel Uclaf, signaling the American scientific community's support of the drug. From this point, the FMF engaged state legislatures to pass resolutions in support of making RU-486 available in the United States. Other groups, such as the RHTP worked with NARAL, Population Crisis Committee, the Population Council, and the National Women's Health Network to survey politicians on their positions, develop media campaigns, and promote research on the mifepristone. For example, between October of 1989 and April 1994, the FMF and their network mailed eight million letters and petitions to women's rights supporters containing educational information about mifepristone. These materials were sent to both Hoechst AG (former German parent company of Roussel Uclaf) and

Roussel Uclaf to show these companies that public support for mifepristone was surpassing the opposition in the United States.

As part of a multi-pronged approach to bring attention to and overturn the FDA's import ban on mifepristone, Abortion Rights Mobilization challenged the policy by having a pregnant woman, Leona Benten, bring the drug through U.S. customs on a flight from London to New York's John F. Kennedy International Airport. As part of the plan, Lawrence Lader, an abortions rights leader, organized the trip and notified authorities in advance of what Benten was doing (Bella, 2023; Jackman, 2008; *Benten v. Kessler*, 1992, 1085-1086). A legal battle ensued, with the District Court granting a preliminary injunction compelling the drug be returned to Benten. The Court of Appeals stayed the District Court's decision, pending an appeal. Finally, the Supreme Court of the United States in a 7 to 2 decision denied the application to vacate the stay, stating that the applicant (Benten) did not demonstrate a substantial likelihood of her claim on the merits and the drug was not approved by the FDA. Jackman (2002) argues that though this case was not successful in terms of lifting the FDA's ban, it succeeded in garnering wide media coverage and by the time Roussel Uclaf announced it was donating its patent rights to the nonprofit, Population Council in 1994, most all the country's major newspapers published editorials supporting the drug's availability in the United States. Overtime, feminist organizations turned the anti-abortion threats of violence on their head by pushing RU-486 to be made available in the United States through doctors' offices because it would cut down on pro-life extremists protesting outside of clinics. This argument was also picked up by media outlets.

Yet, one of the biggest challenges of getting RU-486 accessible to U.S. markets was the Bush Administration. Again, to work around the Bush Administration, the Feminist Majority Foundation launched a national campaign to get state and local municipalities, as well as Congress to pass resolutions supporting the accessibility of RU-486. States such as New Hampshire, California, Hawaii, and Maine participated in this effort, as well as New York City. Members of Congress, such as Representatives Ron Wyden (Democrat or Oregon), Patricia Schroeder (Democrat of Colorado), and Senator Paul Wellstone (Democrat of Minnesota), called for hearings on the drug and sponsored legislation to remove the Food and Drug Administration's import alert on the medication and call for clinic testing (Jackman, 2002).

Finally, the election of President Bill Clinton in 1992 provided the final round of pressure on Roussel Uclaf to apply to the FDA for the approval of RU-486 (Thoss, 1993). And, within the first days of Clinton's inauguration, the President issued an executive order revoking the prohibitions on the importation of RU-486 (Tumulty and Cimons, 1993). By 1994, Roussel Uclaf had agreed to donate its patent on the drug to the Population Council. By 2000, the medicated abortion become available under the FDA's approval in the United States (Saul, 1999).

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