The legal history of mifepristone in the United States of America. How medical abortion is (partially) filling in the gaps lacking protection after the Supreme Court's overturn of Roe

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ABSTRACT: After the Dobbs landmark decision restored the power to regulate and ban abortion to individual states in 2022, the Supreme Court was called to address reproductive rights once again in 2024. In Food and Drugs Administration v. Alliance for Hippocratic Medicine, anti-abortion groups and some medical professionals demanded a declaration of illegitimacy for mifepristone, the drug used for medication abortions, along with the regulatory framework of the drug, established and updated through time by the Food and Drug Administration (FDA). Although the Justices recognized that the plaintiffs lacked standing without delving into the case's merits, the importance of scientific evaluations in judicial reasoning is an increasingly relevant matter.

KEYWORDS: Reproductive rights; medical abortion; mifepristone; Supreme Court; judicial review

SUMMARY: 1. Introduction – 2. The origins of medication abortion – 3. The approval process for mifepristone in the United States – 4. Mifeprex's restrictive regimen and the phenomenon of abortion exceptionalism – 5. *Food and Drug Administration v. Alliance for Hippocratic Medicine*: a Supreme Court's ruling with no rule – 6. The role of science in judicial reasoning.

1. Introduction

In 1973, the Supreme Court delivered a landmark decision recognizing that the Constitution of the United States protected the right to access abortion.[1] Thirty years later, the Food and Drugs Administration approved mifepristone as a safe and effective nonsurgical method for terminating early pregnancies, [2] introducing a brand-new, less invasive way of getting an abortion.

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[1] *Roe v. Wade*, 410 US 113 (1973). The Supreme Court derives the constitutional protection of a woman's decision whether to terminate her pregnancy by recognizing it as encompassed in the broader right to privacy, which is itself a penumbra of the Fourteenth or the Ninth Amendment depending on the interpretation. The fact that the right to abortion cannot find direct expression in the constitutional text is the reason no consensus could ever form on the matter. It also gave ground for the Justices to overturn the precedent in 2022, as they followed a more originalistic approach.

[2] E. PINHO, *The Story of RU-486 in the United States*, in *Harvard Library,* 2001.

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Since then, the tenuous and consistently under-assault right to terminate a pregnancy has been believed by most to encompass the right to obtain medical abortion services. Nevertheless, the two received a rather different treatment when their legitimacy was questioned in front of the Justices of the Supreme Court.

In the ruling of *Dobbs v. Jackson Women's Health Organization,* delivered in June of 2022, the Supreme Court found that the federal protection of the right to abortion had no constitutional ground, overturning the precedent *Roe v. Wade* after fifty years.[3] Two years later, in March 2024, neither the legitimacy of medical abortion nor the drug used for it were addressed in the judgment of the case *Food and Drugs Administration v. Alliance for Hippocratic Medicine.* Instead, the Court recognized the plaintiffs' lack of standing without weighing in on the case's merits.[4]

In the absence of an adjudication of the factual issues presented, today medication abortion remains accessible throughout the United States. Surgical abortions, instead, have been banned in any circumstance by twelve States ever since the right to abortion lost its federal protection two years ago.[5] Nevertheless, limitations to the drug's availability are consistently being pushed forward by anti-abortion groups, threatening to worsen the public healthcare crisis initiated by *Dobbs.*

This paper's objective is to discuss how interdisciplinary concepts are increasingly influencing both the legislative and judicial branches of government, as continual advancements in medicine and technology are progressively shaping the creation and interpretation of laws. To do so, the paper first examines the scientific and technological revolution that led to the discovery of mifepristone. Secondly, the legislative developments following the scientific progress findings are analysed to determine whether the Food and Drug Administration properly relied on widely approved evidence when evaluating the safety of medical abortion. Thirdly and lastly, the paper discusses the Supreme Court's ruling on the matter in the judgement concerning mifepristone, or lack thereof, and how the ruling fits in the discussion concerning the role of science in judicial reasoning.

2. The origins of medication abortion

In the complaint presented for the case *Food and Drugs Administration v. Alliance for Hippocratic Medicine* by four anti-abortion medical associations and doctors, the chemical abortion regimen is described as being able to "block the action of the hormone progesterone, chemically destroy the baby's environment in the uterus, block nutrition to the baby, and ultimately starve the baby to death in the mother's womb".[6] Despite being impactful, the rather graphic description and the depiction of a fertilized egg as a "baby" do not align with scientific literature and research papers on the matter, which provide a more factually accurate understanding of the process.

According to scientifically based sources, as the hormone progesterone is secreted during a woman's natural reproductive cycle, the uterine wall thickens, creating a suitable environment for a fertilized

[3] *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022).
[4] *Food and Drug Administration v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024).
[5] *State Bans on Abortion Throughout Pregnancy*, in *Guttmacher Institute*, July 29, 2024, updated as of March 11, 2025.
[6] Complaint in the United States District Court for The Northern District of Texas Amarillo Division, *Food and Drug Administration v. Alliance for Hippocratic Medicine*, filed November 18, 2022, 17.

egg to implant and develop in the womb. The consistent production of progesterone is necessary until the placenta is formed.[7]

In 1970, French researchers found that mifepristone was able to block the action of progesterone by acting as a progesterone impostor, thereby preventing the real hormone from attaching to the uterine wall.[8] In the absence of real progesterone, the uterine lining would break down, similarly to the menstrual cycle's process and, ultimately, uterine contractions would take place, causing the expulsion of the detached ovum.[9]

A decade after the discovery, the French pharmaceutical company Roussel-Uclaf invented the synthetic drug labelled Roussel-Uclaf 38486, more commonly known as RU-486. In 1987, the drug was approved for distribution as an abortifacient in France, and other European countries quickly followed.[10] Overseas, by contrast, the approval process was not as smooth and rapid, because the Republican-oriented Reagan and Bush administrations strongly opposed the introduction of RU-486 into the United States on the grounds that it morally diluted the act of abortion.[11]

3. The approval process for mifepristone in the United States

In 1988, the Food and Drugs Administration began a program allowing the importation by mail of small doses of untested and unapproved drugs in response to the needs of AIDS and cancer patients. As the regulation imposed that the importation could only be for personal use under the supervision of a legitimate physician and if the drug did not pose an unacceptable threat to the patient's health, the RU-486 pill was assumed to be included in the exception. However, the FDA quickly issued Import Alert 66-813 to specifically state the exclusion of medication abortion in the scope of the regulation. The following Import Alert 66-47, issued a month later, stated that the abortion pills would be subjected to automatic detention and detainment.[12]

The reversal introduced by the agency in Import Alert 66-47, with no notice or comment, became the object of contention in 1992. More precisely, the District Court for the Eastern District of New York stated in its judgment for the case *Benten v. Kessler* that the FDA's actions and behaviour were grounded on political considerations, rather than on the concern for the safety and health of the users of the drug as it should have been.[13]

[7] S.L. Nene, *Will Freedom Ring Soon for the Reproductive Rights Movement*, in *UCLA Women's Law Journal*, 3, 1993, 113-114.

[8] E. Pinho, *The Story of RU-486 in the United States*, cit., 6.

[9] S.L. Nene, *Will Freedom Ring Soon for the Reproductive Rights Movement*, cit., 113-114.

[10] E. Pinho, *The Story of RU-486 in the United States*, cit., 6.

[11] E. Pinho, *The Story of RU-486 in the United States*, cit., 9. The Reagan and Bush Administrations opposed RU-486 and overturned many federally financed abortion programs. They banned federal support for fertility research, stopped funding international family planning organizations, and prohibited counseling about abortion in federally financed clinics. Both Presidents' opposition to abortion and related services made it difficult for RU-486 to be approved in the United States, as they had the authority to appoint Commissioners who shared their views and could control FDA policy direction.

[12] S.L. Nene, *Will Freedom Ring Soon for the Reproductive Rights Movement*, cit., 114.

[13] *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992).

In the case, Leona Benten had filed a lawsuit to compel the FDA to return her RU-486 pills, which FDA agents had seized under Import Alert 66-47. Ms. Benten claimed that the importation ban on abortion pills had been implemented by the administration illegally because the agency had not adhered to the required notice and comment procedure.[14]

The District Court approved the preliminary relief in the form of an order directing the return of the drug to Ms. Benten so that she could use it, under the supervision of her personal physician, to terminate her pregnancy before the date the drug could no longer be employed.[15] However, the Second Circuit Court of Appeal granted a stay pending appeal, which allowed the FDA to keep the confiscated pills for the duration of the second-degree trial.[16]

In an emergency proceeding, the United States Supreme Court voted to uphold the stay;[17] consequently, Ms. Benten had to end her pregnancy through a surgical abortion.[18] The interpretation that determined the resolution of this case represented a fundamental step in the unfolding access to medication abortion.

On the one hand, in the first encounter between the Supreme Court and mifepristone, the scientific relevance of medication abortion's safety had no bearing, as the question pertained to the administrative misconduct of the FDA's regulation and its consequences. In truth, regardless of both the scientific and administrative relevance of the matter, the seven Justices who joined in the decision plainly argued that "the petitioners ha[d] failed to demonstrate a substantial likelihood of success on the merits of [the] claims", expressing no view on the assertion that the holding of the drug constituted an undue burden, as contended by Justice Stevens in his dissenting opinion.[19]

On the other hand, there was no denying that the right to access abortion through mifepristone was interwoven with the broader right to abortion, as Justice Stevens' reference to the undue burden criteria clearly hinted to the ruling of *Planned Parenthood v. Casey*, delivered by the Supreme Court in the same year.[20]

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[14] *Benten v. Kessler,* 799 F. Supp. 281 (E.D.N.Y. 1992).

[15] *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992). The Court makes a compelling argument highlighting, on the one hand, that the ruling at hand should not work as a precedent ("Women tempted to follow Ms. Benten's path are forewarned that they have no assurance that they will have her success. Even assuming the agency in the future exercises its discretion under the personal use policy with respect to RU486, women importing the drug in the future must recognize that that discretion may be exercised against them and that that exercise is in large part unreviewable by the courts.") but reminding the defendant, on the other hand, that democracy draws its legitimacy also from the diligence of respecting procedures ("It may well be that the comments on any procedure whether to change the rules or leave them as they are will be raucous and emotional, but in a democracy the best results over the long run flow from adhering to the democratic procedures set forth in the country's laws. Attempts to avoid those procedures, even when engaged in the best of intentions, do not, in the long run, further the interests of anyone.").

[16] S.L. Nene, *Will Freedom Ring Soon for the Reproductive Rights Movement*, cit., 115.

[17] *Benten v. Kessler*, 505 U.S. 1084 (1992).

[18] S.L. Nene, *Will Freedom Ring Soon for the Reproductive Rights Movement*, cit., 115.

[19] *Benten v. Kessler*, 505 U.S. 1084 (1992).

[20] *Benten v. Kessler*, 505 U.S. 1084 (1992). Justice Stevens' dissenting opinion states: "In this case, applicant Benten's constitutionally protected interest in liberty has two components—her decision to terminate the pregnancy and her decision concerning the method of doing so. The Government does not assert any interest in, or right to, burden the former decision. The Government does, however, assert an interest in the latter by protecting Benten from taking medication under the supervision of her doctor instead of undergoing an invasive surgical

A year after the *Benten* case, in 1993, a study published in the New England Journal of Medicine confirmed that mifepristone was a strong antiprogestin, although not strong enough: only 20% of early pregnancies would be terminated when the drug was administered in the early stages of conception. The proposed solution, then, was to opt for a sequential administration of two drugs: first, mifepristone to inhibit progesterone production, and, secondly, a prostaglandin-E derivative to increase uterine contractility and complete the interruption of the pregnancy.[21]

In France and Great Britain, the prostaglandin-E derivate was either administered intramuscularly or intravaginally, resulting in a rather cumbersome process. The aforementioned study, instead, suggested the use of misoprostol, which was to be administered orally. It found that the combination of mifepristone followed 48 hours later by misoprostol proved to be a safe, convenient, and potentially private successful method of abortion. Nonetheless, the possibility of rare accidents could not be excluded and caution had to be exercised.[22]

In the same year, on his second full day in office, President Clinton signed an executive order allowing the importation of RU-486 for personal use. This move, a departure from the previous administration's stance, also called for a review of the FDA's ban on private importation. Influenced by the case *Benten v. Kessler*, the order enabled women like Ms. Benten to exercise their right to privacy and obtain non-surgical abortions.[23]

Coherently with this turn of the tide in the abortion matter, in the years that followed other studies ensued, eventually all agreeing with the safety of the two-drug regimen.

In 1994, following extensive negotiations with the Clinton administration, Roussel Uclaf donated the rights to sell mifepristone in the United States to the Population Council, a non-profit, non-governmental research organization.[24] The Population Council submitted a New Drug Application (NDA) to the FDA, and in the years that followed the efficacy and safety of mifepristone were evaluated in 17 centres in a clinical trial that needed to assess how the regimen would operate in the American health care system. Out of 2,121 patients, 259 had a failed medical abortion, a percentage similar to the one of the French clinical trials.[25] The most commonly reported adverse episodes were abdominal pain and uterine cramping followed by nausea, vomiting, headache, dizziness, and diarrhoea, although only 23% of those adverse events were judged to be severe.[26]

procedure. In view of the Government's "personal use exception" policy, expressed in the Federal Drug Administration's February 1, 1989, revision of its Regulatory Procedures Manual, the only legitimate governmental interest that is now relevant is the interest in avoiding any "significant health risk" associated with the use of this medication when prescribed by a competent physician. There is no evidence in this record that Benten faces any such risk; indeed, on the specific facts of this case, the Government's purported interest actually supports her position."

[21] R. Peyron, E. Aubeny, V. Targosz, L. Silvestre, M. Renault, F. Elkik, P. Leclerc, A. Ulmann, E.E. Baulieu, *Early termination of pregnancy with mifepristone (RU 486) and the orally active prostaglandin misoprostol*, in *New England Journal of Medicine*, 328, 21, 1993, 1509 – 1513.

[22] *Ibidem.*

[23] S.L. Nene, *Will Freedom Ring Soon for the Reproductive Rights Movement*, cit., 113.

[24] G. Donley, *Medication abortion exceptionalism*, in *Cornell Law Review*, 107, 2021, 637.

[25] E. Pinho, *The Story of RU-486 in the United States*, cit., 19.

[26] *Ivi,* 30.

Despite these challenging consequences, the Population Council concluded, based on a study of acceptability and feasibility, that the oral mifepristone and misoprostol treatment regimen was acceptable for administration to women in the United States and feasible for ongoing clinical practice. In September of 1996, the FDA granted conditional approval to RU-486. The conditions that the administration imposed on the Population Council in order for it to obtain approval for abortion pills included the obligation to monitor the adequacy of the drug's distribution and credentialing system and the duty to follow up on the outcome of a representative sample of mifepristone-treated women who had had surgical abortions after the drugs had failed.[27]

Eventually, the Population Council licensed the rights to produce and distribute mifepristone to Danco Laboratories, LLC, in 1997, but manufacturing issues delayed marketing for a couple of years.[28] In February of 2000, the FDA issued a second approval letter, recalling the conditions stated in the first, adding ulterior requirements for the physicians prescribing the drug,[29] and specifying that endorsement would be granted only in application of the restrictions imposed under Subpart H of the Code of Federal Regulations. Subpart H regulated the accelerated approval of new drugs for serious or life-threatening illnesses and imposed that the restrictions were statutorily required rather than voluntarily undertaken by the manufacturer. [30]

The Population Council opposed such a condition, arguing that pregnancy did not fall in the category of a "serious life-threatening condition". Additionally, under Subpart H, mifepristone would have been stigmatized as a high-risk drug, ultimately deterring users. Besides, restrictions on the use and distribution had already been adopted regardless.[31]

However, the organization ultimately had to consent to the administration's imposition and on September 28th, 2000, RU-486 secured FDA approval under Subsection H to produce and distribute the mifepristone and misoprostol regimen. [32]

Access to medication abortion was now legal, but greatly constrained.

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[27] *Ivi.,* 35.

[28] G. DONLEY, *Medication abortion exceptionalism*, cit., 637.

[29] Population Council to Center for Drug Evaluation and Research, *Approval Letter for Mifeprex (mifepristone) tablets, 200mg*, NDA 20-687, 28 September, 2000. "Mifeprex must be provided by or under supervision of a physician who meets the following qualifications: Ability to assess the duration of pregnancy accurately; Ability to diagnose ectopic pregnancies; Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary; Has read and understood the prescribing information of Mifeprex; Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well; Must notify sponsor or its designate in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an ongoing pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure, Must report any hospitalization, transfusion or other serious events to the sponsor or its designate; Must record the Mifeprex package serial number in each patient's record".

[30] J.J. SERPICO, *Abortion exceptionalism and the mifepristone REMS*, in *Contraception*, 104, 1, 2021, 8-11.

[31] *Ibidem.*

[32] E. PINHO, *The Story of RU-486 in the United States,* cit., 43.

4. Mifeprex's restrictive regimen and the phenomenon of abortion exceptionalism

In its second approval letter, the FDA stated that, because adequate information had been presented to approve mifepristone, it could now be introduced into the market under the trade name of Mifeprex in the form of 200 mg tablets. The regimen for the medical termination of intrauterine pregnancy prescribed the use of Mifeprex followed by misoprostol in the ensuing 24 – 48 hours, but only throughout the first 49 days of pregnancy.[33] As mentioned above, the letter also imposed that the physician providing the drug possessed certain qualifications, in addition to describing specific procedures for storage, dosage tracking, and damaged product returns. Finally, the program required in-person ingestion in the presence of a physician.[34]

If such requirements may have seemed slightly disproportionate compared to the research results of efficacy and safety even back then, as time went on the regulation program defined for mifepristone was perceived by many as a clear expression of the abortion exceptionalism phenomenon, in which abortion care is treated differently under the law than other comparable healthcare concerns.[35]

In 2007, Subpart H was absorbed by the Amendments to the Food, Drug, and Cosmetic Act, which formally established the Risk and Evaluation Mitigation Strategy (REMS) program. Under this new program, the FDA would institute a REMS only in exceptional circumstances, specifically when a drug would be potentially highly beneficial but carried serious risks of side effects.[36] More specifically, the administration was required by law to consider six factors when determining if a REMS had to be considered necessary: the size of the target population, the seriousness of the condition, the expected benefit, duration of treatment, the seriousness and the incidence of known or potential adverse events and whether the drug was a new molecular entity. The new REMS program could also require additional impositions on healthcare providers, demanding them to take specific actions, called Elements to Assure Safe Use (ETASU).[37]

As mifepristone was on the list of the FDA's identification of drug and biological products deemed to have REMS, its manufacturer Danco Laboratories submitted a proposition for the regulatory system, which was approved by the FDA in 2011. In the first mifepristone REMS, the original requirements for safe use were incorporated, joined by the additional condition of three necessary visits. The first visit was to receive the medication, as only physicians could provide the drug; the second, on the 3rd day, determined whether the termination was complete, and physicians could also provide misoprostol if it had not been fully successful; lastly, on the 14th day, a check-up was imposed to confirm whether the medical abortion had occurred.[38] The REMS also required that mifepristone only be dispensed in "clinics, medical offices, and hospitals" specifically forbidding access through pharmacies.[39]

[33] Population Council to Center for Drug Evaluation and Research, *Approval Letter for Mifeprex (mifepristone) tablets, 200mg*, 28 September, 2000.
[34] *Ibidem.*
[35] J.J. SERPICO, *Abortion exceptionalism and the mifepristone REMS,* cit.
[36] *Ibidem.*
[37] *Ibidem.*
[38] P.J. ZETTLER, A. BECKMEYER, B.L. BROWN, A. SARPATWARI, *Mifepristone, preemption, and public health federalism*, in *Journal of Law and the Biosciences,* 2022, 9.
[39] J.J. SERPICO, *Abortion exceptionalism and the mifepristone REMS,* cit.

In May 2015, Mifeprex's sponsor Danco Laboratories submitted a Supplementary New Drug Application to make changes to the REMS, as well as the indications and dosing, based on new clinical best practices that had emerged from studies over the years.[40] During its review, the FDA received numerous letters from academics and professional organizations requesting the elimination of the REMS, but, although it concluded that no new safety concerns had arisen in recent years and that the known serious risks occurred infrequently, the REMS were not removed. Instead, they were only modified. [41] The purpose of the introduction of the REMS program was to ensure that the benefits of certain dangerous medications outweighed their risks, so doubts arose when the administration decided to keep in place the REMS regime for mifepristone even though it had found that the numbers of adverse events had appeared to be stable or decreased over time, indicating that serious adverse events would likely remain acceptably low.[42]

Nonetheless, the FDA approved the changes in 2016. As part of the innovations, any healthcare provider, instead of just licensed physicians, could become a certified prescriber. Additionally, the in-person visit requirement was reduced to only the initial visit to obtain the entire medication regimen. Lastly, the gestational age approved for use was extended from 49 to 70 days, and the dose regimen for mifepristone and misoprostol was modified based on research demonstrating improved safety and effectiveness with an altered dose. [43]

Only a year after introducing the new REMS, an article from the New England Journal of Medicine argued that the remaining in-person requirement and physician certification were medically unnecessary.[44] Following the change in administration, the FDA announced its intention to exercise enforcement discretion regarding mifepristone for the duration of the COVID-19 public health emergency. Additionally, a pending lawsuit from the American Civil Liberties Union claimed the unconstitutionality of the drug's REMS. In such a scenario, the FDA agreed to make a comprehensive review of the regulatory system in place for medication abortion.[45]

Consequently, the FDA updated mifepristone REMS once more in January 2023, defining it as a permanent rule the one temporarily introduced during the pandemic that allowed patients to receive their pills through telemedicine instead of travelling to a medical facility. However, it maintained requirements for prescribers, pharmacies, and patients,[46] a choice conflicting with the proven safeness and efficacy of medication abortion.

After an extensive review, the administration would have had the opportunity to finally eliminate the burdensome application of REMS regulation for medication abortion and introduce a more practicable set of rules for access and distribution, especially in light of the increasing challenges in obtaining sur-

[40] *Ibidem.*
[41] G. Donley, *Medication abortion exceptionalism*, *op. cit.*, 641.
[42] *Ibidem*.
[43] *Ivi,* 642.
[44] R. Peyron *et al.*, *Early termination of pregnancy with mifepristone (RU 486) and the orally active prostaglandin misoprostol*, in *New England Journal of Medicine*, 328, 21, 1993, 1509-1513.
[45] P.T. Kim, T. Papagiannopoulos, *FDA's Liberalization of Mifepristone Dispensing: Securing The Future of Access to Medical Abortion*, in *Health Affairs Forefront*, 2023.
[46] *Purcell v. Becerra (formerly Chelius v. Becerra*), in *ACLU*, https://www.aclu.org/cases/chelius-v-becerra.

gical abortions after *Dobbs*. Multiple organizations and associations, such as the World Health Organization, the American College of Obstetricians and Gynaecologists, the American Medical Association, and many others, have attested repeatedly that mifepristone is a safe medication, that the requirements still in place for it do not benefit patients and they disproportionately burden certain communities.[47]

Yet, today, obtaining abortion pills is only partially filling in the gaps left by the overturn of *Roe*.

5. Food and Drug Administration v. Alliance for Hippocratic Medicine: a Supreme Court's ruling with no rule

In November 2022, anti-abortion advocates filed a lawsuit against the Food and Drug Administration and the Health and Human Service, claiming that the initial approval of the drug and the following review of the regulations of 2016 and 2019 were not in accordance with law. Consequently, the plaintiffs requested that these measures be held unlawful, set aside, and preliminary and permanently enjoined.[48]

Nevertheless, the research evidence of the last twenty years greatly confuted these statements, as the FDA itself had acknowledged in 2016 that Mifeprex had been "increasingly used [because] its efficacy and safety [had] become well-established by both research and experience, and serious complications [had been] proven to be extremely rare."[49]

When the Supreme Court agreed to hear the case, it was presented with a clear opportunity to definitively confirm the safety and effectiveness of the abortion pill as a non-invasive option for terminating a pregnancy. Given the unique nature of this issue, it was essential to adhere to strict, science-based criteria in order to deliver the most effective and compelling judicial reasoning. However, since the Justices sitting on the Supreme Court bench were the same ones who had denied federal protection to the right to abortion only two years prior, recognizing the value of the right to medical abortion would have been a significant contradiction with the recent jurisprudence – although that is a limit that did not stop them from overturning *Roe* in 2022.

On June 13th, 2024, the Supreme Court, in delivering its ruling on the case concerning mifepristone, gave no space for discussion on the merits of the case, and more specifically the legitimacy of the FDA's regulation on medication abortion. Instead, the Supreme Court's unanimous opinion, authored by Justice Kavanaugh, held that plaintiffs did not have Article III standing to challenge the FDA's actions concerning the regulation of mifepristone.

To establish standing, a plaintiff must show (i) that they have suffered or are likely to suffer an injury in fact, (ii) that the injury was likely caused or will be caused by the defendant, and (iii) that the injury is likely to be redressed by the judicial relief sought. Thus, the existence of a personal interest in the

[47] *Fact sheet – The safety of medication abortion,* in *Expanding Medication Abortion Access Project,* https://emaaproject.org/wp-content/uploads/2022/02/Fact-Sheet_Safety-of-Medication-Abortion-Care_2-24-22.pdf .

[48] Complaint in the United States District Court for the Northern District of Texas Amarillo Division, *Food and Drug Administration v. Alliance for Hippocratic Medicine*, cit.

[49] P.T. KIM, T. PAPAGIANNOPOULOS, *FDA's Liberalization Of Mifepristone Dispensing: Securing The Future Of Access To Medical Abortion*, cit.

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case is required to obtain a judicial ruling. In its analysis, the Court argued that the plaintiffs lacked standing because of the absence of a causal link between the damages sustained by the plaintiffs and the actions of the defendant's administration.[50]

In their more than hundred-page complaint, the Alliance for Hippocratic Medicine and the other fellow plaintiffs profusely but unsuccessfully argued the correctness of their request.

Firstly, they argued that the relaxation of the FDA's restrictions on the use and distribution of mifepristone could have caused pregnant women to experience an increase in complications from the use of the drug, which in turn would have led to an increase in the number of emergency abortion procedures required. As a result, the plaintiffs concluded, doctors would have been forced to offer emergency treatments to complete or provide abortions, in contrast with their conscience's beliefs.[51]

However, conscientious objection is protected at the federal level both by *ad hoc* laws that have been in force since the first approval of Mifepristone in 2000, and by the more recent federal Emergency Medical Treatment and Labor Act. Moreover, the Court pointed out that the plaintiffs had failed to identify any concrete case in which a doctor had been forced, despite his conscientious objection, to perform an abortion or provide other abortion-related treatment that violated his morality.[52]

In addition to alleging a possible violation of their right to conscientious objection, the plaintiff doctors cited various monetary and related damages that they would have allegedly suffered because of the FDA's actions. More specifically, they mentioned: the possibility of having to divert resources and time away from other patients to treat patients with complications from mifepristone; the increased risk of liability suits for treating such patients; and the potential increase in insurance costs. However, again, the Court found that the causal link between the FDA's regulatory actions and the alleged damages was too speculative or otherwise attenuated to establish standing.[53]

Thirdly, the plaintiff medical associations claimed that the Food and Drug Administration had compromised their ability to provide services and fulfill their organizational missions. The associations stated that they had been forced to spend a considerable amount of time, energy, and resources to conduct their own studies on mifepristone in order to learn more about the risks of the drug, to draft citizens' petitions against the FDA, and to engage in public advocacy and education, all at the expense of other spending priorities. Yet, once again, the mere fact that an organization had spent money to gather information to support the plaintiff's lawsuit did not prove legal standing, as these considerations did not demonstrate that the plaintiffs, for that reason alone, had suffered a direct injury. Therefore, causation was found to be lacking in this instance as well.[54]

Finally, the Court additionally rejected the "if not us, then who?" argument that contented that plaintiffs had to have standing to act only because if they did not, then no one could, and therefore no one could have ever challenged the FDA's actions.[55]

Even if the plaintiffs' argument for associational standing was not satisfactory in this case, it does not mean that other plaintiffs in different cases cannot pursue this avenue. As Justice Thomas noted in his

[50] *Food and Drug Administration v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024).
[51] *Ivi,* 14.
[52] *Ivi,* 15.
[53] *Ivi,* 18.
[54] *Ivi,* 21.
[55] *Ivi,* 23-24.

concurring opinion, the Court should eventually examine whether this type of standing can be reconciled with the requirements of Article III of the Constitution. [56]

On one hand, the ruling of the Supreme Court offered no real and concrete resolution for the questions concerning the regulation of medication abortion, but, on the other, although it is in the FDA's prerogative to determine pharmaceutical regulations to protect public health, it has become clear that the disputes surrounding the REMS on mifepristone highlight the complex intersection of public health, scientific evidence, and governmental authority.

There are diverse perspectives on the issue, with many arguing that the regulations are excessive, as scientific evidence has repeatedly proved that medication abortion is safe and effective, [57] while others, like the plaintiffs of the case at hand, believe they are too lenient. [58]

The lower courts' decisions on the merits of the case, by partially granting the motions, were part of a trend in which judges hold the belief that they are more capable than public health agencies in addressing scientific questions. [59]

More specifically, District Judge Matthew Kacsmaryk, by refusing to defer agency findings and conclusions unless "capricious and arbitrary" as he should have, acted in such a way that could be defined as *ultra vires* – beyond his authority – seriously compromising the stability of the separation of powers in the American administrative and judicial system. [60]

The Fifth Circuit Court of Appeals supported Judge Kacsmaryk's position, expanding on his criticism of the FDA by describing the halt in collecting nonfatal adverse events data as an "ostrich's-head-in-the-sand" approach. However, it is important to note that the FDA had determined that this data collection was unnecessary based on 15 years of adverse event reports, and the Court's presumption to approximate the administration's extensive expertise and scientific knowledge seemed entirely inappropriate. [61]

Conclusively, while the Supreme Court's dismissal of the case for lack of standing maintained the possibility of accessing mifepristone unvaried, it did not fully criticize or reverse the lower courts' rulings. As the debate continues, finding a balance that prioritizes public health and safety while respecting the authority of governmental agencies remains a significant challenge.

5. The role of science in judicial reasoning

The case at hand is peculiar due to the complexity of the intertwined questions at play. The primary point of contention is the legality of the regulations imposed on the use and access of mifepristone.

[56] *Ivi,* Justice Thomas concurring.

[57] L. SAXE, *No Longer Viable: The Push for the FDA's Removal of Mifepristone from the Rems Program under Dobbs*, in *Administrative Law Review Accord*, 8, 2022, 107.

[58] Complaint in the United States District Court for the Northern District of Texas Amarillo Division, *Food and Drug Administration v. Alliance for Hippocratic Medicine*, cit.

[59] D.G. AARON *et al.*, *Court Intrusion into Science and Medicine—The Mifepristone Decisions*, in *JAMA*, 329, 20, 2023, 1735-1737.

[60] *Ibidem.*

[61] *Ibidem.*

This issue is in turn part of a larger discussion about the legitimacy of the right to abortion, which is itself situated within the broader context of reproductive rights.

Additionally, the common thread connecting the judgments of the lower and higher courts is the methodology and legitimacy of judicial rulings in cases involving laws purportedly based on scientific evidence. In this context, the distinction between the judicial and executive branches of government can blur, making it difficult to define their boundaries clearly.[62]

With reference to this latter matter concerning the relationship between the courts and administrative agencies, the *Chevron v. Natural Resources Defense Council, Inc*. ruling used to represent the fundamental precedent to refer to. The 1984 landmark decision introduced a two-step test articulated to identify when U.S. federal courts should have to defer to a government agency's interpretation of a law or statute. The *Chevron* doctrine of deference stipulated that when courts were faced with regulatory issues, they first had to determine whether Congress had already directly addressed the matter. If Congress's intent was not clear, only then should the court consider whether the agency's interpretation of the statute was based on a permissible construction.[63]

In other words, the administrative principle that descended from the *Chevron* doctrine commanded courts to defer to agencies' interpretations of statutes they administered so long as the statute's provision was ambiguous and the agency's interpretation was reasonable. This reasoning was considered coherent with the judicial review's goal: it was deemed to be the court's duty to interpret the law, in which they are experts, and defer to other subjects' interpretations for the facts and policy-making, assuming the matter corresponded with their area of expertise.

Originally, the *Chevron* deference doctrine was celebrated by the right, as it was seen as a way to limit the illegitimate exercise of policy-making authority by unelected judges. However, over the years, the left began to embrace the principles of the ruling, while conservatives started to view the decision as a means of increasing the power and discretion of government agencies.[64]

As the tide changed, the foundations on which *Chevron* stood also started to tremble, and, after forty years of validity, on June 28th, 2024, the precedent was overturned by *Loper Bright Enterprises v. Raimondo.*

Before the overrule, those who endorsed the *Chevron* doctrine of deference, especially in connection to the FDA authority and the reproduction healthcare issues discussed above, believed that the agency had to be responsible for keeping mifepristone on the market, or exploring alternative ways to preserve the abortion medication, because the experts' opinions on abortion scientific development, public health, and safety had to prevail over the judges' intent to dictate agency direction.[65]

Yet, the Supreme Court leaned for the opposite direction, overturning *Chevron* by analyzing the quality of the reasoning and the workability of the precedent in accordance with the principle for which the *stare decisis* doctrine should not be forcefully imposed as an "inexorable command".[66]

[62] *Ibidem.*
[63] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984).
[64] C.R. SUNSTEIN, *Chevron as law*, in *The Georgetown Law Journal*,107, 2018, 1618.
[65] E. SELTZER, *Not So Juris-prudent: The Misguided Movement to Abandon Chevron Deference Through the Lens of Mifepristone and the Attacks on FDA Autonomy*, in *American University Washington College of Law*, 2023, 6-7.
[66] *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), 29.

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In the Court's analysis, only a few words were spent on the reasoning aspect: the precedent was deemed as "fundamentally misguided", arguing the existence of flaws in the doctrine from its origins, which, on one side, determined a continuous effort of the Court to revise and limit its application, and, on the other, gathered a plethora of dissenters from Members of the Court, such as Justices Kennedy, Thomas, Gorsuch and Scalia.[67]

The aspect of workability was analyzed in greater depth. Specifically, the first step of the two-step test was deemed "unworkable" because it required the identification of ambiguity in the text of the law. However, according to the Court, ambiguity had proven to be a vague concept, heavily influenced by individual interpretation. As a result, *Chevron* was described by the Court's majority as essentially subject to the personal sensibilities of judges, making it a highly uncertain standard of deference.[68] Therefore, the Opinion of the Court sharply concluded that "courts need not and, under the APA, may not defer to an agency interpretation of the law simply because a statute is ambiguous".[69]

Given the radicality of the statement, it is crucial to highlight that although the overturn defined in *Loper Bright* primarily dealt with administrative issues its consequences may have a significant impact on the Food and Drug Administration's (FDA) ability to enforce its regulations, especially in the context of access to reproductive healthcare.

On the one hand, it should be reiterated that the FDA has faced criticism for its history of bias and political involvement in reproductive health decisions, deviating from its own standards for classifying mifepristone under the Risk Evaluation and Mitigation Strategies (REMS) program without adequately explaining why the drug should be considered an exception to the general regulatory rules.[70] A study from 2022 indicates that even family physicians oppose the significant barriers that mifepristone REMS entail, as the regulation impedes their ability to provide medication abortion in primary care settings.[71]

On the other hand, to maintain a proper separation of powers, the relationship between the courts and administrative agencies should be collaborative. However, the recent shift in the authority to interpret statutes, which moved from the administration to the judiciary with the *Loper Bright* ruling, has altered the balance between these two branches.

Given these considerations, it becomes clear that the *Alliance for Hippocratic Medicine v. FDA* judgement did not determine a definite end to the mifepristone dispute.

Firstly, because in the future similar cases to the *Alliance for Hippocratic Medicine v. FDA* ruling will be read under the lens of the *Chevron* overturn, it is not certain that they will be resolved in the same manner, given the changed interpretative context.

[67] *Ivi*, 30.

[68] G. Romeo, *Statutory stare decisis e tenuta del precedente wrongly decided: una lettura di Loper Bright Enterprises v. Raimondo*, in *DPCE online,* 65, 3, 2024, 2137.

[69] *Loper Bright Enterprises v. Raimondo*, 35.

[70] L. Saxe, *No Longer Viable: The Push for the FDA's Removal of Mifepristone from the Rems Program under Dobbs*, cit., 108.

[71] S. Wulf, C. Perez, S. Mcneil, L. Maldonado, A.B. Fields, D. Carvajal *et al., Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, in *Contraception*, 109, 2022, 19-24.

In this scenario, States might attempt to raise broader *Chevron*-related claims by arguing that the FDA's interpretation of Subpart H, which includes mifepristone, is incorrect and should not be given any deference. In this hypothetical challenge, the Court would not have to defer to the agency's interpretation, although it could still arrive at the same conclusion as the agency.[72]

Secondly, the fact that the Court did not grant standing to the anti-abortion medical association Alliance for Hippocratic Medicine and to the doctors who filed the case does not mean that it cannot grant standing in the future. The concept of standing is closely linked to the principle of separation of powers, which ensures that the different branches of government do not infringe upon one another. What the concept does not determine is how the powers should be allocated.[73] Given the broad nature of the concept of standing, and the repercussions of such vagueness, some have pointed out that, today, it has become a tool for the Court to decide whether it wants to reach or avoid the merits of a certain case.[74] In this scenario, the procedural decision made in *Alliance for Hippocratic Medicine v. FDA*, while it appeared to be a victory for the abortion rights movement, did not in fact resolve the conflict but rather only postponed it. This judgement's conclusion seemed more like a manipulation of the standing doctrine by the Court to avoid concretely taking a stance, reflecting a strategic choice by the Justices rather than a simple adherence to procedural rules regarding the requirements for legal action.[75]

In addition, it is important to recognize that these matters are necessarily politically influenced. It is of course not irrelevant to note that most of the Justices currently sitting at the Supreme Court have Republican-oriented views, or that the vast majority of States where abortion access is denied or restricted are usually red states. A relevant instance is represented by a recent piece of legislation introduced in Wyoming, a state with strong Republican traditions, that, in addition to introducing a total (surgical) abortion ban, also prohibited "prescrib[ing], dispens[ing], distribut[ing], sell[ing] or us[ing] any drug for the purpose of procuring or performing an abortion."[76]

The law had the clear intent of prohibiting access to abortion overall, both surgically and through the two-drug regimen, but its efficacy has been blocked by a temporary restraining order. Nevertheless, the intent remains obvious: fighting for the implementation of the most researched and evidence-based arguments is futile if it must be measured against values and morals. The legitimacy of regulations surrounding medication abortion does not matter when the political agenda seeks to deny any access to the procedure based on ethical principles.

The considerations regarding potential future litigation related to mifepristone, including varying interpretations of standing and the new interpretative administrative context established after *Loper Bright*, should not lead pro-choice advocates to despair. There are still several options to explore for the upcoming mifepristone cases, from references to the equal protection clause to preemption arguments that would require states to ensure legal access to mifepristone based on federal regulation.[77]

Ultimately, it is clear that while judicial solutions exist, legislative action would be a more effective option. However, considering the outcomes of the recent US presidential elections and the subsequent

[72] *FDA v. Alliance for Hippocratic Medicine,* in *Harvard Law Review*, 138, 1, 2024.
[73] F.A. Hessick, *The Separation-of-Powers Theory of Standing*, in *North Carolina Law Review*, 95, 3, 2016, 684.
[74] *FDA v. Alliance for Hippocratic Medicine,* cit.
[75] *Ibidem.*
[76] *Johnson v. State of Wyoming II*, Wyoming State Trial Court, 18853-2023.
[77] *FDA v. Alliance for Hippocratic Medicine,* cit.

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nomination of President Trump, it seems unlikely that this option will occur, at least in the next four years.