



## Perspective

### The Supreme Court's Abortion Exceptionalism — Judicial Deference, Medical Science, and Mifepristone Access

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**O**n April 12, 2021, the Food and Drug Administration (FDA) temporarily lifted its decades-long restriction on access to medication abortion, which accounts for two in five abortions

in the United States.<sup>1</sup> The agency's action nullifies a Supreme Court order, 3 months earlier in *Food and Drug Administration v. American College of Obstetricians and Gynecologists (FDA v. ACOG)*, requiring that patients prescribed the abortion pill mifepristone pick it up in person, even during the pandemic. Although the direct ruling in *FDA v. ACOG* is now moot, we believe that its stealth logic still has troubling implications beyond medical care and public health. The case betrays a blind deference to regulators who ignore scientific facts in the name of politics.

Medication abortion uses two drugs to end a pregnancy without surgery or anesthesia. The first drug, a prescription hormone blocker called mifepristone, was first approved by the FDA in 2000. Studies show that mifepristone is as safe as aspirin and no less safe when it is available over the coun-

ter.<sup>2</sup> Yet the FDA had always required patients to obtain the pill in person at a hospital or health clinic, a rule it is supposed to reserve for drugs such as opioids and antipsychotics that pose a substantial risk of dangerous side effects, abuse, or overdose. As the Covid-19 pandemic worsened in March 2020, viral-transmission risks led the FDA to broadly waive in-person pickup requirements for medications, including controlled substances such as methadone and fentanyl — but not mifepristone, which made it the only self-administered drug that patients couldn't get by mail or at a pharmacy drive-through window.

In July 2020, a federal court ordered the FDA to exempt mifepristone, too. It found that the in-person mandate forced “patients to decide between forgoing or substantially delaying abortion care, or risking exposure to Covid-19

for themselves, their children, and family members.”<sup>3</sup> The FDA appealed this injunction to the Supreme Court, which instructed the FDA to go back to the lower court with more facts and ask it to reconsider. The lower court denied the FDA's request in December 2020, reasoning that pandemic-related risks associated with in-person visits had, by that point, only increased. The FDA appealed to the Supreme Court again. By this time, Justice Amy Coney Barrett had replaced Justice Ruth Bader Ginsburg on the nine-member court; Barrett was President Donald Trump's third appointee after he had promised to nominate only justices who would overturn *Roe v. Wade*. On January 12, 2021, the Court reinstated the FDA's selective restriction on mifepristone access by emergency order.

The order in *FDA v. ACOG* was part of the Court's “shadow docket,” a narrow class of fast-tracked rulings for which the Court rarely spells out its reasoning. Of the six justices who ruled in the FDA's favor — including the three

Trump appointees — only Chief Justice John Roberts gave a reason. In his view, the in-person mandate didn't trigger the judicial scrutiny that usually applies to government restrictions on the right to abortion. This standard analysis determines whether regulatory obstacles to abortion access are outweighed by benefits such as patient safety or women's health. Roberts set this constitutional balancing test aside. He argued that the case boiled down to whether the lower court had overreached in second-guessing the FDA, even in the absence of evidence that mifepristone posed special risks. The chief justice concluded that the lower court should have deferred to the agency's "background, competence, and expertise to assess public health" — and to its assurance that women who couldn't obtain mifepristone in time to undergo medication abortion could undergo surgical abortion instead.<sup>4</sup>

"What a callous response," Justices Sonia Sotomayor and Elena Kagan countered in their dissent, citing the invasiveness of surgical abortion and its associated risks. The FDA restriction "treats abortion exceptionally" and "imposes an unnecessary, irrational, and unjustifiable undue burden on women seeking to exercise their right to choose."<sup>4</sup> Social-distancing policies have substantially reduced patient capacity for many abortion providers. Clinic closures and shortened hours can make it difficult to get an appointment during the 10-week window in early pregnancy when mifepristone is most effective. Access limits fall hardest on low-income women, who struggle to take time off from work, and on women living in rural areas where abortion clinics were already scarce before the pandemic.

The scant reasoning in this shadow-docket decision also leaves doctors without guidance about why the Court voted to reinstate the FDA restrictions on mifepristone and how it might rule under similar circumstances moving forward. Such ambiguity risks chilling medical practice if clinicians avoid treating patients according to patients' best interests for fear of potential legal backlash.<sup>5</sup> The only available explanation is the chief justice's solo opinion that courts should abandon judicial review of the unsubstantiated reasons regulators give for constraining access to certain fundamental liberties.

The Roberts Court has bowed to dubious defenses for abortion restrictions before. In 2003, President George W. Bush signed a nationwide ban on a late-term procedure, intact dilation and extraction, which was deemed the safest way to end certain pregnancies. After three federal appeals courts struck down the law, the Supreme Court upheld it in *Gonzales v. Carhart* (2007), citing Congress's "discretion to pass legislation in areas where there is medical and scientific uncertainty."

The FDA's action under President Joe Biden permits patients to get mifepristone by mail for the duration of the pandemic. But after the pandemic, the original in-person requirements for medication abortion are on track to be restored. A federal court in Hawaii is slated to revisit these underlying restrictions in a pending case, *Chelius v. Azar*. Initially filed in 2017, *Chelius* had been put on hold pending the Supreme Court's decision in *FDA v. ACOG*. That ruling and the FDA's latest action were about the pandemic-era decision not to exempt mifepristone from in-person pickup requirements. *Chelius* addresses a differ-

ent issue: whether the pickup requirement for mifepristone lacks medical justification in the first place, pandemic aside. If it does, the requirement would be an "arbitrary and capricious" abuse of the FDA's discretion under the Administrative Procedure Act — in this case, an abuse of its discretion to set rules for dispensing drugs.

The biggest question that *FDA v. ACOG* raises — about the proper scope of judicial deference — goes beyond telemedicine, public health, or abortion access. Federal judges are charged with smoking out illegitimate grounds for impeding constitutional rights. Doing so requires taking a hard look at the reasons agencies and legislatures give to justify restrictions on such rights. We believe the Supreme Court abdicates its duty when it outsources this critical appraisal to regulators themselves.

Disclosure forms provided by the authors are available at NEJM.org.

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