DEMOCRACY FORWARD

Summary of Key Points in *FDA v. AHM* Oral Arguments

On March 26, the United States Supreme Court heard oral arguments in *U.S. Food and Drug Administration v. Alliance for Hippocratic Medicine* (*FDA v. AHM*), which could have wide-sweeping implications for access to medication abortion and judicial deference to FDA's expertise.

Solicitor General Elizabeth Prelogar represented the FDA. Danco Laboratories, the branded maker of mifepristone, was represented by Jessica Ellsworth of Hogan Lovells. Erin Hawley — an attorney at the Alliance Defending Freedom, an SPLC-identified hate group — represented AHM.

Below is a summary of key points raised in these oral arguments, prepared by Democracy Forward, which represented GenBioPro, the nation's only manufacturer of generic mifepristone, in amicus briefs submitted in this case:

Justices questioned whether AHM had standing (i.e. whether AHM had been harmed such that it could have its case heard in court).

- Justice Kagan questioned whether AHM had any standing by inquiring whether any of their member doctors had been required to participate in an emergency procedure that they objected to: "What actual emergency treatment has she participated in that she objects to and that she has stated that she objects to?"
- Justice Sotomayor was also skeptical that AHM has standing to bring this case, noting that the organization's claims of harm were mostly hypothetical and speculative instead of having occurred. She also called the chance of any of the harms AHM described as possibilities as "infinitesimally small."
- Justice Thomas responded to concerns that AHM lacks standing to bring this case by asking the Solicitor General if AHM doesn't have standing, who might? The Solicitor General replied that someone like a prescribing physician would have standing and later on in arguments that "federal conscience protections are specifically designed to deal with this issue."
- Finally, the attorneys representing the government and Danco Laboratories took serious issue with AHM's standing claims.
    - Danco's attorney said that "respondents lack standing under every prong…"
    - The Solicitor General noted that "the fact they don't have a doctor who's willing to make that kind of sworn declaration [of when their ability to make a conscience objection was violated] in court shows they don't have a past harm."

Other Background: In addition to a questionable standing argument, one plaintiff organization (AHM) appears to have been established exclusively for the purpose of bringing this case. The same anti-abortion groups that created AHM had previously tried to challenge the FDA's actions

by filing citizens' petitions. When that failed, they artificially created a new organization, AHM. These extremist anti-abortion activists intentionally based the organization in Amarillo, TX – despite having a mailing address in Tennessee and no members in Amarillo – in order to get assigned to Judge Matthew J. Kacsmaryk, whose record demonstrates a willingness to accept extreme, unprecedented legal theories.

Attorneys representing the FDA and Danco Laboratories reiterated how mifepristone is essential, lifesaving care – and the devastating impacts of restricting access to it.

- The Solicitor General highlighted the safety and efficacy of medication abortion throughout her arguments. The FDA approved mifepristone in 2000 and has "maintained that judgment across five presidential administrations," per the Solicitor General.
- Restricting mifepristone would cause "profound harm," according to the government. That harm, the Solicitor General said, includes harm to the health care system (which would be overloaded with people needing more intensive medical procedures), harm to the drug regulation and approval process (which could face dueling decisions by the FDA and the courts), and the millions of people who could no longer access mifepristone.

Other Background: Medication abortion is an incredibly common and safe form of abortion care: it accounted for 63 percent of all abortion care in 2023. If medication abortion is not available, people seeking an abortion may have to use more invasive methods that can be difficult to access amidst the panoply of abortion restrictions across many states and can often be more expensive.

Extremist far-right activists are trying to revive a nearly century-old, unenforced law, known as the Comstock Act, to ban abortion – and only Justices Thomas and Alito expressed openness to that theory.

- Justice Thomas seemed keen to bring the widely abrogated law back to life, asking the branded maker of mifepristone, Danco Laboratories, how it would respond to an argument that mailing mifepristone violates the Comstock Act. Danco's attorney replied that the statute "has not been enforced for nearly 100 years."
- Justice Thomas similarly asked for AHM's views on the Comstock Act, tacking on an additional question about whether or not AHM could raise a Comstock Act claim and if the ability to raise a Comstock Act claim had been exhausted. AHM's attorney replied that AHM's position is that the Comstock Act applies and that it can be used in this case. In particular, AHM is claiming that it would have been futile to raise this argument earlier given FDA's reliance on a legal opinion from the Department of Justice's (DOJ) Office of Legal Counsel that suggests Comstock does not apply; AHM also asserted that the exhaustion standard should not apply to the circumstances of this case.
- Justice Gorsuch asked the Solicitor General if the FDA should have considered the Comstock Act in its 2021 decision to approve mifepristone being available via telehealth. The Solicitor General replied that the FDA should not have considered the Act and that,

in fact, it may have been impermissible to do so. "I don't think it would have even been permissible for FDA to consider [Comstock]…The only thing FDA can take into account for restrictions is safety and efficacy…"

Other Background: The Comstock Act is a law from the 1870s that has not been enforced for nearly 100 years. The law bans "obscene" materials from being sent through the mail or via common carriers. DOJ has already determined that the Comstock Act does not apply to lawful abortions. However, extremists are using any loophole they can find – including reviving this vestigial law – to ban abortion nation-wide.

A broad range of unlikely allies are opposing extremists' claims in this case because of how dangerous the precedent set would be and the scope of possible disruption to the drug regulation and innovation system in the U.S.

Background: Groups submitting amicus briefs on behalf of the FDA include organizations representing doctors who provide abortion, patients, academics, former FDA commissioners, pharmaceutical companies and executives, legal experts, medical experts, former military officials and national security leaders, disability rights advocates, the faith community, municipalities around the country, local elected leaders, 263 members of Congress, and more.

- Danco's attorney underscored that if the Court adopted AHM's argument on the Food, Drug, and Cosmetic Act (the FDA's authorizing statute) – namely, that judges could overrule the agency's expertise – medication abortion would be far from the only drug impacted. Calling AHM's interpretation of the law "inflexible," Danco's attorney emphasized that if judges were to second-guess the FDA in this case, the entire drug regulation system in the U.S. could be upended.

Justice Jackson led questioning regarding the wisdom of substituting generalist judges' opinions for the opinions of experts at administrative agencies such as the FDA.

- Throughout oral argument, Justice Jackson appeared skeptical of transferring authority from the experts at the FDA to less specialized judges. She noted that the lower court's ruling on this case "relied on studies that have since been discredited and removed," implying courts may lack familiarity with interpreting complex scientific information.
- Justice Jackson asked Danco's attorney: "Do you think that courts have specialized scientific knowledge when it comes to pharmaceuticals?" She also inquired whether the pharmaceutical company had "concerns" about judges parsing scientific research and information into sound decisions. Posing a similar question to AHM's attorney, Justice Jackson asked "what deference if any" courts owe the expert agency's assessment concerning the efficacy and safety of drugs.
- Justice Alito asked rhetorically whether the FDA was infallible and if the FDA had ever had to pull a drug. Justice Sotomayor noted that even when complications with drugs arise, the FDA has a responsibility to step in and handle the issue.

- From FDA's perspective, the Solicitor General said that courts have no reason to make those kinds of complex decisions and that this was, to their knowledge, the first time a court has second-guessed the FDA by restricting access to a drug approved by the agency.

Justices raised concerns that the remedy the anti-abortion groups seek – a nation-wide injunction – is extreme compared to the relatively small scope of harm they allege to have incurred.

- Justice Gorsuch noted the relatively small size of the harm: "We have before us a *handful of individuals* who have asserted a conscience objection" (emphasis added). He also said that recently the country has had "what one might call a rash" of universal injunctions.
- Justice Gorsuch used a historical comparison to underscore his point. He noted: "There are zero universal injunctions during Franklin Delano Roosevelt's 12 years in office, pretty consequential ones, and over the last four years or so the number is something like 60, and maybe more than that."
- Justice Jackson also expressed concern over the extreme nature of the remedy AHM asked for: "I'm worried that there's a significant mismatch in this case between the claimed injury and the remedy that's being sought."
- The Solicitor General agreed with Justice Jackson's assessment, calling it a "profound mismatch." Moreover, in her rebuttal the Solicitor General referred to the nation-wide nature of the remedy sought as a "striking anomaly" relative to the usual determinations of proportionate responses.

Justice Jackson asked about how a ruling in another case the Supreme Court heard this term – *Corner Post v. Board of Governors of the Federal Reserve System* – could interact with this one to undermine government's ability to deliver for people.

- Justice Jackson asked the Solicitor General how *Corner Post* might impact cases like *FDA v. AHM* in the future: "Setting aside standing, have you thought about how a ruling from this court on the statute of limitations in either direction would impact this kind of case and these kinds of challenges?"
- The Solicitor General noted that this highlights the stakes of the *Corner Post* matter and then also said that people across the country have developed "tremendous reliance interests" on having access to mifepristone, which is a factor courts can consider in determining whether to allow a challenge to move forward.

Other Background: Corner Post concerns the statute of limitations under the Administrative Procedure Act (APA), under which litigants generally have six years to facially challenge federal agencies' rule, or policies, in court as unlawful. If the Supreme Court endorses *Corner Post*'s claims, the case could have broad consequences for how the government delivers for people because it would extend the time that litigation can be filed against lonstanding rules and disrupt regulatory stability. Read Democracy Forward's Interested Parties Memo regarding *Corner Post* and other cases regarding agency deference this term as well as a brief from small

business interests concerning the disruptive consequences of what the *Corner Post* petitioners seek.

Justices invoked another key abortion case this term, this one concerning whether states can ban abortion as it applies to emergency care under the longstanding federal law, the Emergency Medical Treatment & Labor Act (EMTALA).

- The Solicitor General explained that EMTALA does not override individual doctors' ability to invoke a conscience objection. Doctors who oppose abortion can still use conscience objections while EMTALA is in place.
- Moreover, the Solicitor General clarified that EMTALA imposes obligations on hospitals – not on individual doctors. This means hospitals must create plans to ensure patients are able to obtain emergency abortion care–like having cross-staffing plans with other hospitals–if an individual doctor at their hospital has a conscience objection and will not perform the care needed.

Other Background: EMTALA is a federal law that for nearly four decades has provided a safety net for patients in emergencies. Hospitals must stabilize patients with emergency medical conditions, regardless of their ability to pay. EMTALA has been supported by lawmakers of diverse ideological perspectives. The Supreme Court will hear arguments on April 24, 2024 concerning whether EMTALA preempts Idaho's near-total abortion ban when an abortion is needed to protect the health of a pregnant person during an emergency. The U.S. Constitution's supremacy clause, which appears in Article VI, is clear that when federal law conflicts with state law, the federal law takes precedence. Democracy Forward is representing the nation's medical experts in this case, including the American College of Emergency Physicians and the American College of Obstetricians and Gynecologists, in supporting the government's preemption position in this case. We will provide background information and resources in advance of the arguments.