SPECIAL REPORT

FDA v. Alliance for Hippocratic Medicine: Conscience Rights Implications for Healthcare Providers

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McDermott Will & Emery

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TABLE OF CONTENTS

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INTRODUCTION

The Supreme Court of the United States's (SCOTUS's) unanimous decision in *Food and Drug Administration v. Alliance for Hippocratic Medicine* (*FDA v. AHM*) on June 13, 2024, articulated a much more absolute view of the protections federal law affords to individual healthcare provider personnel to refuse to participate in the provision of certain healthcare for personal conscience reasons than has ever previously been articulated in the text, legislative history or judicial interpretation of the relevant federal statutes. That aspect of SCOTUS's decision may lead to a significant uptick in the number of conscience-based opt-out requests that healthcare provider organizations receive from members of their workforces (*e.g.*, physicians, nurses), while simultaneously making each such request more difficult to address without significant cost or liability exposure.

All organizations that employ, or independently contract with, individual workers to provide any type of healthcare services that are likely to generate conscience-based objections should become familiar with this new articulation of the scope of individual conscience-based opt-out rights and work together with knowledgeable counsel on how to handle such requests when they arise. As detailed below, it remains to be seen how this recent articulation will interact with more established federal laws that address the balance between individual rights and employer burdens.

THE *FDA V. AHM* SCOTUS DECISION

On June 13, 2024, SCOTUS unanimously rejected a challenge to the US Food and Drug Administration's (FDA's) approval of the medication mifepristone, which is commonly used to conduct medical (as opposed to surgical) abortions. *See Food and Drug Administration v. Alliance for Hippocratic Medicine*, No. 23-235 (June 13, 2024). Most of the widespread publicity about this decision has understandably focused on its implications for abortion access in the wake of SCOTUS's prior decision in *Dobbs v. Jackson Women's Health Organization*, which overturned *Roe v. Wade*.

But the federal government's legal position in *FDA v. AHM*, and SCOTUS's unanimous adoption of aspects of that position, may have substantial unexpected impacts on all organizations that employ or independently contract with physicians, nurses and other individual healthcare provider personnel to provide patient care. Such impacts may arise from an unprecedented and seemingly expansive characterization of such individuals' rights under federal law to refuse to participate in care to which they personally object on religious, moral or conscience-based grounds.

In a nutshell, SCOTUS rejected the petitioners' claim in *FDA v. AHM* that the FDA's regulation of mifepristone causes conscience injuries because the petitioners did not show that the FDA's decisions caused any such injuries. Justice Kavanaugh wrote, for the unanimous SCOTUS, that "federal conscience laws definitively protect doctors from being required to perform abortions or to provide other treatment that violates their consciences."[1] He wrote this as part of SCOTUS's reasoning as to why the petitioners (AHM) lacked standing to challenge the FDA's approval of the medication in question – reasoning that SCOTUS drew explicitly (and pointedly) from the solicitor general's briefing and oral argument on the FDA's behalf.

[1] *Food and Drug Administration et al. v. Alliance for Hippocratic Medicine et al.*, 602 U.S. 1, __ at slip op. p. 14 (2024).

For the proposition quoted above, SCOTUS's opinion cited the Church Amendments, 50-year-old federal appropriations language codified at 42 U.S.C. § 300a–7. The opinion states that such laws "allow doctors and other healthcare personnel to 'refus[e] to perform or assist' an abortion without punishment or discrimination from their employers . . . [and] . . . more broadly provide that doctors shall not be required to provide treatment or assistance that would violate the doctors' religious beliefs or moral convictions."[2]

The opinion adds that such "strong protection for conscience remains true even in a so-called healthcare desert, where other doctors are not readily available" to provide needed care and that the Emergency Medical Treatment and Labor Act (EMTALA) doesn't change that calculus "because EMTALA does not impose obligations on individual doctors."[3] The opinion further states that "doctors need not follow a time-intensive procedure to invoke federal conscience protections . . . A doctor may simply refuse; federal law protects doctors from repercussions when they have 'refused' to participate in an abortion. . . . '[h]ospitals must accommodate doctors in emergency rooms no less than in other contexts.'"[4] SCOTUS did not elaborate on whether, and if so to what extent, an employer could require at least some advance notice of workforce member objections to ensure the organization's ability to provide timely patient care.

The unanimous opinion summed up the discussion of certain standing arguments by calling federal conscience protections "broad and comprehensive," adding that "Federal law fully protects doctors against being required to provide abortions or other medical treatment against their consciences."[5] As noted above, for all of these propositions, SCOTUS explicitly relied on and adopted positions taken by the solicitor general in briefing and oral argument on behalf of the FDA, aiming to show that petitioners challenging FDA approval lacked standing.

HISTORICAL CONTEXT AND ANALYSIS

These sweeping statements by a unanimous SCOTUS about the nature and scope of federal conscience protections are unprecedented. The statutory provisions on which they rest have been in place for roughly 50 years, and no court (as far as we know) has previously interpreted them in such a broad, absolute manner – although US Department of Health and Human Services (HHS) Office for Civil Rights (OCR) leadership during the Trump administration tried unsuccessfully to do so through rulemaking that ultimately was enjoined by multiple courts before being abandoned upon the start of the Biden administration. In many cases, the statutory text itself, or its legislative history, clearly indicates a much more limited scope than the unanimous SCOTUS opinion seemingly announces.

For example, the Church Amendments' primary anti-discrimination provision (42 U.S.C. § 300a–7(c)), which SCOTUS repeatedly cited for its sweeping statements quoted above, expressly applies only to any entity that either:

- (Group 1) "receives a grant, contract, loan, or loan guarantee under the Public Health Service Act [42 U.S.C. § 201 *et seq*.], the Community Mental Health Centers Act [42 U.S.C. § 2689 *et seq*.], or the

[2] *Id*. at 15.
[3] *Id*. at 15, 16.
[4] *Id*. at 17.
[5] *Id*.

Developmental Disabilities Services and Facilities Construction Act [42 U.S.C. § 6000 *et seq*.] after June 18, 1973," or

- (Group 2) "receives after July 12, 1974, a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services."

Notably, none of the referenced statutes for either Group 1 or Group 2 encompass the most common sources of federal funding and reimbursement to healthcare providers, such as Medicare, Medicaid, the Children's Health Insurance Program, TRICARE or the Federal Employees Health Benefits program. By the statute's express terms, only a smaller subset of entities that receive very specific types of federal funding are covered.

For entities in Group 1, as defined in the prior paragraph, the statute prohibits "(A) discriminat[ion] in the employment, promotion, or termination of employment of any physician or other health care personnel, [and] (B) discriminat[ion] in the extension of staff or other privileges to any physician or other health care personnel . . . because he performed or assisted in the performance of a lawful sterilization procedure or abortion, because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting sterilization procedures or abortions."

For entities in Group 2, the statute prohibits "(A) discriminat[ion] in the employment, promotion, or termination of employment of any physician or other health care personnel, [and] (B) discriminat[ion] in the extension of staff or other privileges to any physician or other health care personnel . . . because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity."

The statute does not define "discrimination," so the very small number of courts that have had to apply it have had to supply such a definition from other sources. The primary (and, in our view, most logical) source has been Title VII's framework for employee religious discrimination claims, which Congress enacted just a year before the first Church Amendment provision. *See, e.g., New York v. United States Dep't of Health & Hum. Servs.*, 414 F. Supp. 3d 475, 513–14, 523–24 (S.D.N.Y. 2019) (citing *Shelton v. Univ. of Med. & Dentistry of N.J.*, 223 F.3d 220, 222–23, 224–28 (3d Cir. 2000)). Under that familiar balancing test, an employer is required to reasonably accommodate an employee's religious beliefs through modification of job expectations and duties as agreed upon between the employee and employer, but only to the extent that can be done without undue hardship to the employer.[6] In short, the Church Amendments' protection for a healthcare workforce member's conscience-based

[6] Note that SCOTUS reinterpreted Title VII's "undue hardship" standard last year in *Groff v. DeJoy*. For the prior 45 years, since a 7 – 2 decision in *Trans World Airlines, Inc. v. Hardison*, courts had found undue hardship to employers whenever a requested accommodation of employee religious beliefs or practices would require the employer to bear "more than a *de minimis* cost." *See* 432 U.S. 63 (1977). Last year, in *Groff*, SCOTUS changed the standard to one more demanding of employers, now defining "undue hardship" to require a showing that the requested accommodation would result in "substantial increased costs in relation to the conduct of [the employer]'s particular business." 143 S.Ct. 2287-97 (2023). But even this new interpretation of Title VII maintains the basic concept of balancing employer and employee rights and needs – very different from an absolute (or near-absolute) employee right to opt out of participation in work activities (*e.g.*, provision of patient care) to which the employee objects on conscience grounds, regardless of employer impact.

refusal rights (within the statutorily defined scope of coverage, based on receipt of specific funding streams) has been treated as real and meaningful, but far from absolute, over the 50-year history of those amendments.

The legislative history of the Church Amendments supports this nuanced and careful interpretation. For example, another Church provision cited by SCOTUS in *FDA v. AHM* (42 U.S.C. § 300a–7(d)) seems on its face to be worded very broadly and absolutely: "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions." SCOTUS's opinion characterizes that statutory language in seemingly absolute terms: "And the Church Amendments more broadly provide that doctors shall not be required to provide treatment or assistance that would violate the doctors' religious beliefs or moral convictions."[7]

But when Senator Church introduced this statutory language in 1973, in the wake of *Roe v. Wade*, he was clear that its purpose was limited to ensuring that the *federal government* would not use funding streams to force, through funding conditions, private sector organizations and individuals to provide care (such as abortion care) that they otherwise would decline to provide for conscience reasons. He explained during Senate floor debate that:

> [T]his amendment addresses itself to a distinct minority of our hospitals. One thousand one hundred and eighty-six is the total figure [of religiously affiliated hospitals]. Most of our hospitals are not church owned, and this amendment would not in any way affect sterilizations or abortions in publicly owned hospitals . . . *This amendment does not lay down any requirement on any hospital as to what it may or may not do. This amendment is directed at what the Federal Government may or may not do.* It clears up an ambiguity in the present law by making it explicitly clear that it is not the intention of Congress to mandate religious hospitals to perform operations that are contrary to deeply held religious beliefs . . . *This amendment does not impose any requirements on the hospital. It merely says that the Government does not impose a new requirement conditioning the acceptance of Federal money upon the performing of certain operations that are contrary to religious beliefs, or deeply held moral conviction.*

199 Cong. Rec. 9600–01 (1973) (emphases added).

In in the unanimous *FDA v. AHM* opinion, SCOTUS mentioned none of this important scope-limiting statutory language, legislative history or history of judicial interpretation. Instead, it merely adopted (without analysis) the solicitor general's litigation position that the plaintiffs challenging the FDA's approval of mifepristone lacked standing because (among other reasons) the individual conscience protections already enshrined in federal law such as the Church Amendments were broad and robust enough to protect the plaintiffs from being forced to participate in providing care that violated their individual consciences.

Going forward, the opinion likely will be cited as a unanimous SCOTUS declaration of such broad and near-absolute conscience-based opt-out rights, despite the fact that its statements on this topic appear not to have been informed by any of the 50 years of history of the relevant statutory provisions. Organizations seeking to restrict access to abortion or other medical treatments to which they morally object, or at least to broaden individual

[7] Slip Op. at 15.

healthcare workers' abilities to refuse participation in such care, already are lauding the *FDA v. AHM* decision as a victory for individual conscience rights.

PRACTICAL IMPLICATIONS FOR HEALTHCARE PROVIDER EMPLOYERS

Organizations that employ, or independently contract with, individuals to provide healthcare to patients should expect an increase in the frequency, breadth and potentially last-minute timing of individual workforce member attempts to opt out of participation in certain types of care to which some people might object on individual religious or moral grounds. Abortion, contraception, sterilization, *in vitro* fertilization and other reproductive technology, gender dysphoria care, gender affirming care, vaccination, forced hospitalization, end of life treatment/hospice, assisted dying, withdrawal of nutrition and fluids, blood transfusions, organ transplantation, routine autopsies, and prescription of pre-exposure (PrEP) and post-exposure (PEP) prophylaxis are just some examples of the many types of care likely to be the subject of such requests.

Organizations should be prepared for conscience-based opt-out requests or refusals to come not only from core provider personnel assigned to provide such care hands-on (*e.g.*, physicians, nurses, technicians) but also from workforce members whose involvement is more removed (*e.g.*, schedulers, housekeeping staff, patient transportation staff). Such opt-out requests or refusals may also now more frequently arise in the heat of the moment (*i.e.*, only when a need for an objected-to intervention presents itself) rather than in advance, when reasonable accommodations can more easily be planned. This is expected to further exacerbate an already challenging set of circumstances involved in maintaining an adequate and efficient workforce to provide a full scope of appropriate medical care needed to meet patient expectations and legal and accreditation requirements.

These potentially challenging circumstances will be due in no small part to updated rules implementing Section 1557 of the Affordable Care Act, which go into effect beginning July 5, 2024. Under Section 1557, providers may, but are not required to, notify HHS OCR regarding a view that the provider is exempt from performing certain services due to conscience or religious freedom law protections. If a provider chooses to refuse to provide such notice and nevertheless denies services to a patient because of a perceived exemption, and if a complaint is subsequently made that the refusal was discriminatory, OCR will not seek backward-looking relief against the offending behavior – only future discriminatory refusals by that provider will experience enforcement.

While most such refusals are likely to be made in good faith by workforce members, some may be more calculated or strategic (potentially with advocacy organizations backing them), seeking not only to distance the objecting individual from participation in a procedure of concern but also to make it more difficult for the organization to provide the objected-to care at all. Provider organizations should prepare to be targeted by such efforts.

EMTALA may present a notable challenge for organizations subject to it, namely hospitals and stand-alone emergency departments. Adopting the solicitor general's position, SCOTUS in *FDA v. AHM* dismissed the petitioners' EMTALA-based arguments by confirming that individual providers are not subject to EMTALA, so EMTALA could not possibly conflict with those individual providers' conscience-based opt-out rights. But that does not let EMTALA-covered *organizations* off the hook. To the contrary, it presents such organizations with the potentially directly competing federal legal duties of:

- Providing appropriate emergency care and stabilization to patients who present, in order to comply with EMTALA, while also
- Honoring individual workforce members' purported rights to refuse to participate in such care (possibly even if such refusals arise only in real-time, rather than in advance).

For example, suppose a patient presents with a rupturing ectopic pregnancy to the only operating emergency department in a region, and the sole attending physician on duty in that emergency department announces that, for conscience reasons, she will not participate in care that results in termination of that pregnancy, not even a procedure that is standard of care and necessary to protect the presenting patient's life or health. Taking SCOTUS at its recent unanimous word, the organization operating that emergency department must be prepared somehow to both comply with EMTALA and honor the provider's conscience rights. Doing so seemingly would require redundant staffing or on-call backup coverage by another attending physician whom the organization somehow is reasonably sure does not share the same conscience-based objection as the on-duty attending physician. Such a situation could easily become untenable in practice, but both the solicitor general and SCOTUS glossed over this possibility as if it would not present any problem.

If the November 2024 federal election were to result in a change of party control of the White House, provider organizations should also expect an emboldened HHS leadership in the next administration to take an aggressive stance concerning investigations, potential civil penalties and attempted termination of federal funding streams over individual workforce member conscience issues and how organizations handle them. For example, Roger Severino, the director of OCR during the Trump administration, wrote the following in his chapter of the Heritage Foundation's 2025 "playbook" for a new Republican administration:

> **OCR should return to Trump Administration policies that initiated robust enforcement of these conscience laws.** It should restore and fully fund the Office of the Deputy Director for the Conscience and Religious Freedom Division (CRFD) and ensure that it has the necessary delegations from the Secretary to enforce these laws. The Secretary should give adequate delegations to OCR to pursue enforcement of conscience laws, including [the Religious Freedom Restoration Act], and require all HHS components that provide funding or grants to cooperate with OCR CRFD investigations . . . . HHS should withdraw funding from any violating entities that refuse to correct their behavior, and OCR CRFD should work with [the assistant secretary of HHS for financial resources] to ensure that all grant announcements and instruments inform grantees and applicants of their obligations to comply with federal health care conscience laws specifically as a condition of obtaining or maintaining their funding.

CONCLUSION

Until June 2024, courts have consistently treated individual physicians' and other healthcare workers' rights to refuse to participate in certain patient care for personal conscience reasons as real and important, but far from absolute. They have required that such interests be balanced against the rights of employers to avoid undue hardship (including increased cost and/or decreased workplace efficiency) and the rights of patients to access appropriate care. In its unanimous *FDA v. AHM* decision this month, SCOTUS (without analysis) characterized such conscience-based opt-out rights in much broader and more absolute terms. Healthcare provider organizations should prepare for an increased number and intensity of employee refusals on conscience grounds, including

refusals that may arise at the last minute. Such organizations should familiarize themselves with the *FDA v. AHM* decision and consult with counsel knowledgeable in this area about options, preparation steps, and risk mitigation strategies going forward.

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