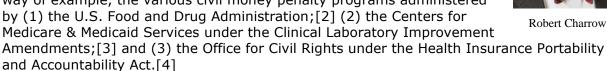
What 5th Circ.'s SEC Ruling Means For HHS Programs

By Robert Charrow (June 9, 2022)

The U.S. Court of Appeals for the Fifth Circuit's recent holding in Jarkesy v. U.S. Securities and Exchange Commission, [1] that the Seventh Amendment's right to trial by jury applies to certain types of administrative enforcement proceedings, calls into question various programs administered by the U.S. Department of Health and Human Services.

Especially at risk are those tethered to the commerce clause, including, by way of example, the various civil money penalty programs administered by (1) the U.S. Food and Drug Administration; [2] (2) the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement



The court's decision also calls into question the propriety of administrative proceedings used to resolve disputes between purely private actors, such as the one created by the No Surprises Act.

By contrast, other programs - especially those under the spending clause where there is some form of quasicontractual relationship between the private actor and government appear to be on more solid footing, even considering the Fifth Circuit decision.

The Seventh Amendment guarantees the right to a trial by jury in any case at law, as opposed to equity, where the amount in controversy exceeds \$20. Under a line of U.S. Supreme Court decisions starting with Dred Scott v. Sandford in 1857,[5] Article III, and arguably by extension the Seventh Amendment, does not apply to matters at law, involving "distinctly public rights," a term with a meaning that is less than clear.

Interestingly, the phrase "public rights" appeared only once in the opinion and was never defined. In Granfinanciera SA v. Nordberg in 1989, the court sought to clarify that Congress "cannot circumvent the Seventh Amendment jury-trial right simply by passing a statute that assigns 'traditional legal claims' to an administrative tribunal."[6]

"Public rights," the court explained, arise when "Congress passes a statute under its constitutional authority that creates a right so closely integrated with a comprehensive regulatory scheme that the right is appropriate for agency resolution."[7]

According to the court:

If a statutory right is not closely intertwined with a federal regulatory program Congress has power to enact, and if that right neither belongs to nor exists against the Federal Government, then it must be adjudicated by an Article III court. If the right is legal in nature, then it carries with it the Seventh Amendment's guarantee of a jury trial.[8]

Paradoxically, according to the Nordberg court, a public right can exist even though the government may not be a party to the action and the Seventh Amendment can apply even if administered by a non-Article III tribunal. Suffice it to say, the court's attempt to define



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the term "public right" is at best muddled.

The Fifth Circuit, perhaps recognizing this lack of clarity, struck out on its own by noting, quite simply,

Securities fraud actions are not new actions unknown to the common law. Jury trials in securities fraud suits would not "dismantle the statutory scheme" addressing securities fraud or "impede swift resolution" of the SEC's fraud prosecutions. And such suits are not uniquely suited for agency adjudication.[9]

The court concluded that the SEC's scheme for administratively resolving these cases violated the Seventh Amendment.

The Fifth Circuit decision, assuming it survives a possible en banc review, places at risk several administrative dispute resolution programs.

This risk increases if one questions the entire "public rights" exception to the Seventh Amendment on purely textual grounds — where in Article III or the Seventh Amendment does one find the phrase "public rights"? Its textual absence has led to what can best be characterized as a remarkably plastic exception to rights that the founding fathers viewed as fundamental.

HHS operates two types of administrative processes — those tethered to the spending clause, such as Medicare and Medicaid, and those tethered to the commerce clause, such as CLIA, HIPAA and the No Surprises Act.

The distinction is potentially critical because a party can waive his or her Seventh Amendment rights as a condition of participating in a federal program, just as those same rights can be waived in the private sector by agreeing to arbitration as a condition of contract, even one for employment.[10]

The No Surprises Act, HIPAA privacy enforcement and CLIA civil money penalty provisions appear to be relatively low-hanging fruit if the Fifth Circuit's reasoning were to be applied.

The No Surprises Act is particularly vulnerable. It establishes compelled private dispute resolution, i.e., arbitration, between a provider, e.g., physician, and the patient's health insurer where the provider is out of network to determine the allowable amount that the physician would receive from the insurer and patient through co-insurance or co-payment.

The dispute between the parties is no different from a traditional contract dispute between a patient and an out-of-network provider where the issue before a court is typically the reasonable amount due for the services.

The fact that the patient is not directly involved does not affect the nature of the dispute. The patient has at least an implied contract with the provider and has an actual contract with the insurer. In the No Surprises Act's dispute resolution system, the patient has effectively assigned, by operation of law, his rights to collect more than the out-of-network amount to the physician.

In such a setting, this is nothing more than a quintessential contract dispute that would trigger a right to a jury trial. There is nothing public or novel about the rights, if any, under the No Surprises Act.

Arguably, these cases could be resolved more expeditiously and at lower cost were they to be litigated by the provider and the insurer in a small claims court, albeit without a jury. Article III does not preclude state court litigation of arguably federal claims using state court procedures.

The viability of HIPAA privacy enforcement through administrative channels is also at risk under the Fifth Circuit's rationale. It has already taken an embarrassing beating in the Fifth Circuit.[11]

The HIPAA privacy rules and its administrative enforcement mechanism, in theory, are designed to protect the privacy rights of patients, most of whom are not beneficiaries of federal health care programs.

The statutory provisions not only authorize imposition of penalties on those who violate those rights, but require the agency to dole out a portion of what it receives in penalties to recompense those who have been injured as result of the unlawful disclosure of their protected health information.[12]

The cause of action created by HIPAA is no different from the causes of actions under state law and the Restatement (Second) of Torts Section 652B, for invasion of privacy, e.g., intrusion upon seclusion, and the fact that a portion of the recoveries must be shared with the injured patients strongly suggests that the HIPAA scheme is designed to vindicate private, as opposed to public rights.[13]

It is hard to envision anything public about an individual's private affairs. In short, under the Fifth Circuit rationale, the HHS Office for Civil Rights' administrative enforcement scheme for privacy is, at best, on life support.

Some administrative enforcement schemes of the FDA and CMS for CLIA appear to be on somewhat sounder grounds than the OCR's, but others may be just as vulnerable.

The FDA civil money penalty scheme was originally applied only to generic drugs in response to the generic drug scandal of the late 1980s,[14] but as with most government programs, it has ballooned over the years and now encompasses foods, medical devices, drugs and biologics.

The civil money penalty for false advertising[15] is likely the most vulnerable since it mirrors the common law tort of unfair competition that dates back to the early 15th century in England.[16]

This claim would be actionable under common law and under the consumer laws of various states.[17] Under the Fifth Circuit rationale, Seventh Amendment rights would apply to actions seeking civil money penalties for violating the advertising provisions of the Food, Drug and Cosmetic Act.

Under CLIA, CMS administers a certification, inspection and proficiency testing program for laboratories testing human specimens for diagnostic or treatment purposes.

CLIA also authorizes the secretary to impose penalties for various misconduct, including fraudulently obtaining certification. "Fraud on CMS" appears similar to stock fraud, at issue in Jarkesy and therefore, potentially susceptible to Seventh Amendment challenge. Other civil money penalty causes of action, such as failure to allow inspection, may be at less risk.

If the Jarkesy rationale is adopted by the Supreme Court, many HHS administrative enforcement proceedings will come under further legal scrutiny.

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[1] Jarkesy v. Securities and Exchange Comm'n, No. 20-61007 (5th Cir. May 18, 2022) (split decision).

[2] See 21 U.S.C. § 333(f) & (g).

[3] See 42 U.S.C. § 263a(h) & (i).

[4] See 42 U.S.C. § 1320d-5.

[5] The doctrine first emerged in Murray's Lessee v. Hoboken Land & Improvement Co., 59 U.S. 272 (1856), where a government tax collector, who had been accused of embezzling more than \$1.3 million (about \$42 million in 2022 dollars) from the federal fisc, fled the country. Using a "distress warrant," the government seized and sold the embezzler's property to the defendant. However, after the distress warrant had issued but before the sale, plaintiff had obtained a judgment and executed on the same property. In resolving the ownership dispute the Court held

there are matters, involving public rights, which may be presented in such form that the judicial power is capable of acting on them, and which are susceptible of judicial determination, but which Congress may or may not bring within the cognizance of the courts of the United States, as it may deem proper.

- [6] Nordberg at 492 U.S. at 52.
- [7] Jarkesy, Slip. Op. at 7 (paraphrasing Nordberg).

[8] Granfinanciera, S.A. v. Nordberg, 492 U.S. 54-55.

[9] Slip Op. at 11.

[10] See Circuit City Stores, Inc. v. Adams, 532 U.S. 105 (2001).

[11] See University of Texas M.D. Anderson Cancer Center v. U.S. Dep't of Health and Human Servs., No. 19-60226 (Jan. 14, 2021).

[12] See Health Information Technology for Economic and Clinical Health Act § 13410(c)(3).

[13] Although the right of privacy traces its origins to the article by Warren and Brandeis, Samuel Warren & Louis Brandeis, The Right to Privacy, 4 HARV. L. REV. 193 (1890), other,

much older torts, such as defamation, were a form of breach of privacy, albeit requiring publication and falsity.

[14] The scandal involved payments to FDA officials by two generic manufacturers to have their applications moved to the head of the line to be reviewed at FDA. See The Generic Drug Scandal, NEW YORK TIMES, Sec. A18 (Oct. 2, 1989).

[15] See 21 U.S.C. § 333(g).

[16] See The Schoolmaster's Case, Y.B. Hilary 11 Hen. 4 (1410).

[17] See, e.g., Calif. Bus. & Prof. Code § 17200; POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102 (2014).