SIDLEY

High Court's Healthcare Impact: Fines, FDA Authority, And More Post-*Loper Bright* and *Jarkesy*

August 28, 2024

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TALENT. TEAMWORK. **RESULTS.**

Agenda

- *Loper Bright Enterprises v. Raimondo*
  - Background
  - Implications for Healthcare Companies
- *SEC v. Jarkesy*
  - Background
  - Implications for Healthcare Companies

LOPER BRIGHT ENTERPRISES V. RAIMONDO

The Supreme Court's 2023-2024 *Chevron* Cases

- *Chevron* deference came under attack in two cases:
  - *Loper Bright Enterprises v. Raimondo*, No. 22-451 (D.C. Cir.)
  - *Relentless v. Dep't of Commerce*, No. 22-1219 (1st Cir.)
- Specific dispute: Whether the National Marine Fisheries Service can require certain vessels to pay the cost of onboard third-party monitors.
- Question presented: "Whether this Court should overrule or clarify the *Chevron* doctrine."

Refresher on the *Chevron* Doctrine

- *Chevron* Doctrine's Two-Step Framework:
  - Step One: The court asks whether "Congress has directly spoken to the precise question at issue," or "if the statute is silent or ambiguous with respect to the specific issue."
  - Step Two: If the statute is silent or ambiguous, the court must defer to the agency's interpretation if it is "based on a permissible construction of the statute."

What *Loper Bright* Held

- Historical role of the Court to "to say what the law is"
  - Chief Justice Marshall, *Marbury v. Madison* (1803)
- *Chevron* deference is inconsistent with the APA's requirement to "**decide all relevant questions of law**" and "**interpret … statutory provisions**"
  - 5 U.S.C. § 706: "[T]he reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."
  - The APA mandates judicial deference to agencies on policymaking and factfinding (5 U.S.C. § 706(2)(A), (2)(E)), but not on questions of law.
- Courts must "exercise independent judgment" in statutory interpretation, including interpretative questions that implicate technical matters.
  - "[A]gencies have no special competence in resolving statutory ambiguities. Courts do."

When Agency Views May Still Receive Weight: A Return to *Skidmore*

- Agency views may still receive "weight" or "respect" under *Skidmore v. Swift* (1944)*:*

  Agency interpretations may "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance," based on their "power to persuade."

- Key differences between *Chevron* deference and *Skidmore*:
  - *Chevron* deference is controlling; *Skidmore* "respect" is not.
  - *Chevron* deference applies to changed agency interpretations; *Skidmore* gives weight based, in part, on consistency.

When Agency Views May Still Receive Weight: Policymaking and Factfinding within Delegated Authority

- Under APA, policymaking and factfinding within the agency's delegated authority is still generally subject to "arbitrary and capricious" review and "substantial evidence" standards.
- *Loper Bright* recognizes that, in some cases, the statute expressly delegates authority to the agency, or the best reading of the statute is that it confers discretion to the agency.

- In those case, the court's role involves:
  - "Fixing the boundaries of the delegated authority" and
  - "Ensuring the agency has engaged in reasoned decisionmaking within those bounds."

Am. Clinical Lab. Assoc. v. FDA

October 2, 2023 – proposed LDT rule

May 6, 2024 – final LDT rule

Single change to 21 C.F.R. § 809.3(a):

> In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, ***including when the manufacturer of these products is a laboratory***.

Venue: Eastern District of Texas

Plaintiffs: ACLA (based in DC)
HealthTrack Rx (based in Texas)

Complaint supported by declarations from HealthTrack, LabCorp, Quest, ARUP Labs, and the Mayo Clinic

Plaintiff's opening brief due September 3, 2024

Briefing to be completed December 10, 2024

Arguments in the complaint (not exhaustive):

- Violation of the major questions doctrine
- CLIA – no concurrent jurisdiction with CMS
- Abuse of enforcement discretion
- Testing services are not devices

Are LDTs devices?

- Per the complaint, LDTs = “a series of processes and tasks undertaken by trained laboratory professionals using instruments and other tools to derive information that may be useful to a treating physician”
  - Mass spectrometry of a blood sample
  - BRCA1/BRCA2 genomic testing

- Instrument clause – 21 USC 321(h)(1)
  - “The term ‘device’ … means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, **or other similar or related article**, including any component, part, or accessory ….”
    - *See Bacto-Unidisk*, 394 U.S. 784, 799-800 (1969) (device definition should be “confine[d] … as nearly as is possible to the types of items Congress suggested in the debates” which were “items characterized by their purely mechanical nature”)
    - *Genus Medical Tech.*, 994 F.3d 631, 648 (D.C. Cir. 2021) (“the FDA accounts for that clause in classifying as devices all manner of medical products, such as crutches, X-ray machines, and other ‘**things that go clank**’”)
    - Dictionaries define “article” to mean a “material thing”

Device (and Drug) Approval

- To be approvable, a PMA must provide "reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof"
  - Similarly, an NDA must contain "substantial evidence that the drug will have the effect it purports or is represented to have"
- Questions:
  - Does "effectiveness" require statistical significance?
  - Does "an effect" need to be of any particular magnitude?
  - Does "an effect" need to be "clinically significant"?
- FDA's answers were upheld based on *Chevron*
  - *Warner-Lambert*, 787 F. 2d 147, 154-55 (3rd Cir. 1986) ("The Act does not define 'effectiveness,' thus leaving the task of deciding how effective a new drug must be to the agency ….")
  - *E.R. Squibb and Sons*, 870 F.2d 678 (D.C. Cir. 1989) ("we turn directly to the question whether the agency's interpretation, as applied to this case, is permissible under the second step of *Chevron*")

Off-label Promotion

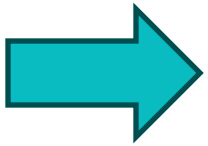
- **Sections 502 and 503 create an apparent contradiction for Rx drugs**
  - A drug is misbranded under section 502(f)(1) unless its labeling bears "adequate directions for use" and FDA interprets "adequate directions for use" to refer to ***lay*** use
  - Section 503(b)(1) defines Rx drugs as those that are "not safe for use except under the supervision" of a licensed provider
  - It would seem to follow that all prescription drugs are necessarily misbranded
- **An obvious way out of the box**
  - Section 503 both created the problem and provided the solution
  - Section 503(b)(2) says an Rx drug "dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of [section 502] except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription."
- **FDA's very different take:**
  - Section 503(b)(2) only applies at the point of dispensing; at all times prior to dispensing, the drug remains subject to all of the misbranding provisions of section 502, including section 502(f)(1)
  - In enacting section 503, Congress relied on FDA to solve the contradiction through its rulemaking authority in section 502(f) ("where any requirement of clause (1) … as applied to [a drug] … is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such [drug] from such requirement")
  - That rulemaking authority allows FDA to impose different requirements ***as a condition*** of the exemption
  - So FDA exempts Rx drugs from the "adequate directions" requirement on the condition that the drug's labeling contains "adequate information" for all the drug's intended uses (potentially including off-label uses)
  - Finally, an intended use can be found based on any relevant source, including oral statements by sales representatives

Potential Vulnerabilities Regarding CMS' Interpretations of Statutory Authorities

In *Loper Bright*, the Court explained that when Congress "expressly delegates" discretion to an agency to resolve an ambiguity or empowers an agency to issue rules to "'fill up the details' of a statutory scheme," agencies will be authorized to exercise that expressly granted discretion.

But even where Congress delegated authority to an agency to engage in gap-filling, courts must still "independently identify and respect such delegations of authority, police the outer statutory boundaries of those delegations, and ensure that agencies exercise their discretion consistent with the APA."

Congress delegated to CMS decisions over whether an item or service is "reasonable and necessary" for the diagnosis or treatment of illness or injury.



Can CMS contradict FDA's decisions on safety and efficacy?

Potential Vulnerabilities Regarding HHS-OIG's Interpretations of the Anti-Kickback Statute

Discount Statutory Exception

"[A] discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program"

42 U.S.C. § 1320a-7b(b)(3)(A)

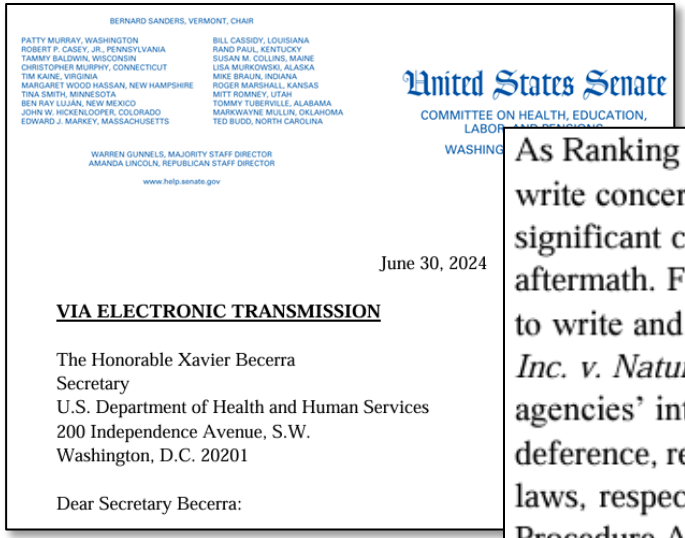
Discount Regulatory Safe Harbor

"(h) Discounts. As used in section 1128B of the Act, 'remuneration' does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section."

(h)(1)(iii) "If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section."

42 C.F.R. § 1001.952(h)

How Does *Loper Bright* Affect March-In Rights?



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June 30, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

As Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, I write concerning the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, and the significant changes that federal agencies will make to their rulemaking and other processes in its aftermath. For 40 years, Congress and federal courts have ceded their respective responsibilities to write and interpret statutes to federal agencies. Under the Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, courts were required to give broad deference to agencies' interpretations of ambiguous provisions in statutes.[1] The Court has now overturned that deference, reinforcing that Congress and the courts are responsible for writing and interpreting the laws, respectively; not agencies.[2] The Court held that such deference defies the Administrative Procedure Act, and that agency interpretations are no longer entitled to deference.[3]

10. Please explain the specific statutory authority that the National Institutes of Health, a sub-agency of HHS, would have to use price as a justification to use march-in rights for drug patents.

"(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention . . . ;" 35 U.S.C. § 203(a)

Statute defines "practical application" as ""available to the public on reasonable terms"—can price justify NIH invoking march-in rights?

SEC V. JARKESY

SEC v. Jarkesy: Right to Jury Trial in Administrative Proceedings

Background: The Dodd-Frank Act granted the SEC discretion to seek civil penalties either before an in-house ALJ or in federal court. Here, the SEC accused an investment adviser with securities fraud. The SEC affirmed the findings of an ALJ and imposed a $300,000 civil monetary penalty.

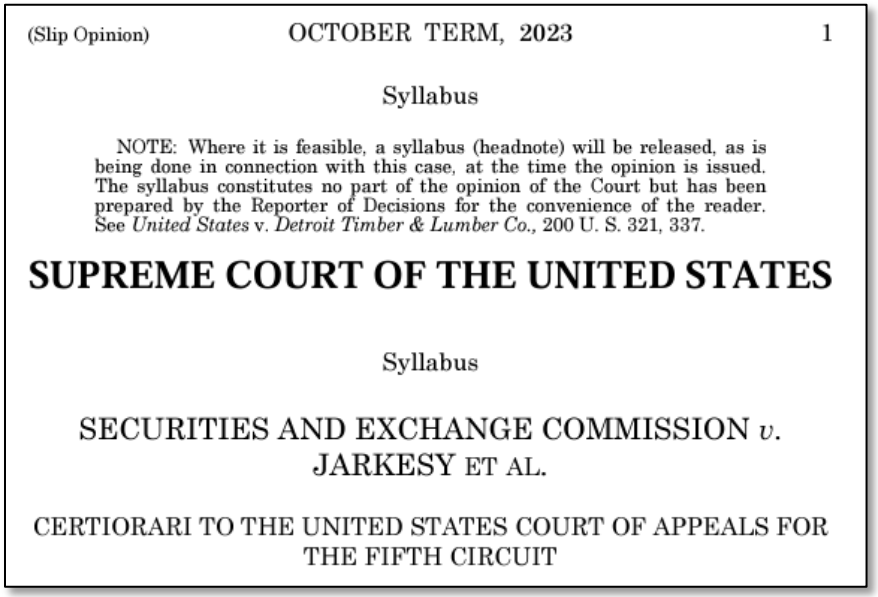
Issue Presented: Whether statutory provisions that empower the Securities and Exchange Commission (SEC) to initiate and adjudicate administrative enforcement proceedings seeking civil penalties violate the Seventh Amendment.

Held: When the SEC seeks civil penalties against a defendant for securities fraud, the Seventh Amendment entitles the defendant to a jury trial.

Jarkesy Majority Opinion

- Does the action implicate the Seventh Amendment, and even if so, does the "public rights" exception to Article III jurisdiction apply?
- The critical first question is whether the action is legal in nature, as opposed to equitable. The Court concluded that civil monetary penalties that are designed at least in part to punish or deter are a remedy that moves an action to one that is legal in nature, and therefore the Seventh Amendment applies.
  - Statutory origins are not dispositive: "[T]he Seventh Amendment does apply to novel statutory regimes, so long as the claims are akin to common law claims."
- The majority and dissent sparred over how broadly to interpret the public rights exception.
  - The government argued that "at a minimum," the exception "allows Congress to create new statutory obligations, impose civil penalties for their violation, and then commit to an administrative agency the function of deciding whether a violation has in fact occurred."
  - The majority disagreed, arguing this exception must be read narrowly, because it has "no textual basis in the Constitution." The Court also reiterated that "effects like increasing efficiency and reducing public costs are not enough to trigger the [public rights] exception."

Forum Matters for Defendants



(Slip Opinion) OCTOBER TERM, 2023 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

SECURITIES AND EXCHANGE COMMISSION *v.* JARKESY ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Procedurally, these forums differ in who presides and makes legal determinations, what evidentiary and discovery rules apply, and who finds facts. Most pertinently, in federal court a jury finds the facts, depending on the nature of the claim. See U. S. Const., Amdt. 7. In addition, a life-tenured, salary-protected Article III judge presides, see Art. III, §1, and the litigation is governed by the Federal Rules of Evidence and the ordinary rules of discovery.

Conversely, when the SEC adjudicates the matter in-house, there are no juries. Instead, the Commission presides and finds facts while its Division of Enforcement prosecutes the case. The Commission may also delegate its role as judge and factfinder to one of its members or to an administrative law judge (ALJ) that it employs. See 15 U. S. C. §78d–1. In these proceedings, the Commission or its delegee decides discovery disputes, see, *e.g.*, 17 CFR §201.232(b), and the SEC's Rules of Practice govern, see 17 CFR §201.100 *et seq*. The Commission or its delegee also determines the scope and form of permissible evidence and may admit hearsay and other testimony that would be inadmissible in federal court. See §§201.320, 201.326.

When a Commission member or an ALJ presides, the full Commission can review that official's findings and conclusions, but it is not obligated to do so. See §201.360; 15 U. S. C. §78d–1. Judicial review is also available once the proceedings have concluded. See §§77i(a), 78y(a)(1), 80b–13(a). But such review is deferential. By law, a reviewing court must treat the agency's factual findings as "conclusive" if sufficiently supported by the record, *e.g.*, §78y(a)(4); see *Richardson* v. *Perales*, 402 U. S. 389, 401 (1971), even when they rest on evidence that could not have been admitted in federal court.

HHS Civil Monetary Penalty Authorities

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 102

RIN 0991–AC34

Annual Civil Monetary Penalties Inflation Adjustment

AGENCY: Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is updating its regulations to reflect required annual inflation-related increases to the civil monetary penalty (CMP) amounts in its regulations, under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and adds references to new penalty authorities.

DATES:

Effective date: This final rule is effective October 6, 2023.

42 CFR 1003.210(a)(3) ...	OIG	Penalty for an excluded party retaining ownership or control interest in a participating entity.
42 CFR 1003.1010	OIG	Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.
42 CFR 1003.210(a)(4) ...	OIG	Penalty for employing or contracting with an excluded individual.
42 CFR 1003.310(a)(3) ...	OIG	Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.
42 CFR 1003.210(a)(1) ...	OIG	Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.
42 CFR 1003.210(a)(6) ...	OIG	Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.
42 CFR 1003.210(a)(8) ...	OIG	Penalty for knowing of an overpayment and failing to report and return.
42 CFR 1003.210(a)(7) ...	OIG	Penalty for making or using a false record or statement that is material to a false or fraudulent claim.
42 CFR 1003.1210	OIG	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.
42 CFR 1003.1210	OIG	Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.
42 CFR 1003.1210	OIG	Penalty for knowing provision of false information by drug manufacturer with rebate agreement.

Jarkesy Open Questions

Will HHS concede that at least certain fraud-based CMP authorities very close to common law fraud trigger the Seventh Amendment?

Will HHS begin to impose (or threaten) more equitable remedies to evade the Seventh Amendment?

Is the 340B arbitration process lawful only if viewed as an optional process?