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Abstracts

"How Courts Reviewed FDA Action Before *Chevron* and May Again After *Loper Bright*"

By **Eva F. Yin**, Partner; **Daniel Orr**, Senior Counsel; and **Jonathan Trinh**, Associate, Wilson Sonsini Goodrich & Rosati

The Supreme Court's recent decision *Loper Bright Enterprises v. Raimondo* is a paradigm shift in administrative law. Overruling *Chevron USA Inc. v. Natural Resources Defense Council*, *Loper Bright* abolished the Chevron doctrine that—for over 40 years—directed courts to defer to an agency's reasonable interpretation of a statute that the agency enforces.

Loper Bright directs lower courts to exercise their "independent judgment" instead, but provides little guidance as to what standards should apply in place of *Chevron*. This article examines the interpretive tools that federal courts used to review FDA action before *Chevron* and that they are likely to return to now.

Looking at the 100 most cited decisions that interpreted the Federal Food, Drug, and Cosmetic Act before 1984, we examine: Skidmore deference, primary jurisdiction, procedural due process, rational basis scrutiny, and other interpretive tools that federal courts will likely use to review FDA action in the future.

"The Challenges of Regulating Information as Medicine"

By **Barbara J. Evans**, Professor of Law and Stephen C. O'Connell Chair, University of Florida Levin College of Law; **Azra Bihorac**, Senior Associate Dean for Research, University of Florida; and **Eric S. Rosenthal**, Associate Professor of Neurology, Harvard Medical School

The race to regulate AI is as heated as the race to develop it. Many scholars and policymakers embrace "AI exceptionalism," the view that artificial intelligence/machine learning (AI/ML) algorithms pose unique, novel risks requiring urgent regulatory intervention to avert catastrophic harms. The presumed urgency justifies sweeping grabs for regulatory jurisdiction, forcing old regulations into new uses for which they may be poorly tailored, in a rush of legal corner-cutting that offends both statutory and constitutional limits on agency authority. Both the risks and benefits of AI tools are highly context-dependent and require close point-of-use oversight that centralized, 20th century regulatory agencies are ill-equipped to provide.

This article brings together three leading scholars from the fields of medicine, AI-enabled health care, and law to argue against AI exceptionalism. The article positions the challenge FDA faces in regulating

AI/ML clinical decision support software within a longer, ongoing struggle for epistemic control over the medical knowledge base: Who—a federal agency or medical professionals—should decide whether a specific piece of information has sufficient quality and reliability to be suitable for physicians to use to inform patient care? After 1990, advances in pharmacogenomics, diagnostics, and medical AI created a world where information, in a very real sense, is medicine. FDA faces five challenges in defining its role in regulating information as medicine.

First, there are constitutional constraints on FDA's power to regulate information and information flows. FDA cannot brush these aside simply by conceptualizing information as a product or by dismissing *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) as "inapposite," as the agency did in the preamble to its recent lab-developed test final rule. First Amendment constraints are real, but there are ways the agency can oversee medical software effectively within those constraints. Doing so entails delineating oversight authority between FDA and the medical profession. Congress outlined a workable and, seemingly, constitutional division of responsibilities in 21st Century Cures Act, from which FDA deviated in its 2022 final Guidance on Clinical Decision Support Software.

To make Congress's scheme work, a second challenge is to enunciate criteria for assessing whether AI/ML tools are sufficiently explainable that a healthcare professional using the software would be able to independently review the basis for its decisions and not be forced to rely on the software as the sole basis for decision-making. 21 U.S.C. § 360j(o)((1)(E)(iii). This is a key jurisdictional criterion under the 21st Century Cures Act, yet wielding it presents tough challenges with which FDA has not successfully grappled.

A third challenge is for FDA to define its role in addressing algorithmic bias, which is both a civil rights/equity concern and a safety/effectiveness issue. The fourth challenge is to navigate broader (and often hidden) impacts that FDA's policies can have on reimbursement, commercialization, and clinical translation of medical software. A final challenge is to recognize the radical individualization of AI/ML tools, which may perform quite differently processing your data than when processing mine. Are they custom devices?