



**FOOD & DRUG
LAW INSTITUTE**

Food and Drug Law Journal 2024 Symposium From Past to Progress: Envisioning the Future of FDA Law and Regulation

November 13, 2024 | In-Person and Virtual Event

Arnold & Porter LLP | 601 Massachusetts Ave NW | Washington, DC 20001

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.

“Defective by Design: A Historical Overview of FDA's Food Defect Regulations”

By **Liam Hospidales**, JD Candidate, Wake Forest University School of Law

This paper provides a comprehensive historical analysis of FDA’s food defect rules and regulations, tracing their evolution from the early 20th century to the present day. The study begins with the examination of the initial establishment of food safety standards in the wake of the Pure Food and Drug Act of 1906, which marked the inception of federal oversight in the food industry. By scrutinizing pivotal legislative milestones such as the Federal Food, Drug, and Cosmetic Act of 1938, the study highlights how FDA developed more stringent regulations to ensure food safety and protect public health.

The paper delves into the creation and implementation of the Food Defect Action Levels (FDAL), which set acceptable limits for natural or unavoidable defects in food products. This period saw significant advancements in food science and a growing public awareness of food safety issues. The FDALs represented a pragmatic approach to balancing food safety with the practicalities of food production, acknowledging that certain levels of contaminants like insect fragments, mold, and rodent hairs were unavoidable despite rigorous quality control measures.



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Through a detailed examination of case studies and historical records, the paper explores how the FDA's food defect rules have been influenced by scientific advancements, consumer advocacy, and industry practices. Notable incidents, such as the cranberry scare of 1959 and the ongoing concerns about pesticide residues, are analyzed to illustrate how specific events have driven regulatory changes and public policy adjustments.

The paper also addresses the role of transparency and consumer trust in the evolution of these regulations. As public access to information has increased, so has the demand for transparency regarding what constitutes acceptable levels of food defects. The study examines how FDA has adapted its communication strategies and regulatory policies in response to these demands, ensuring that consumers are better informed about the safety and quality of their food.

In addition, the paper discusses the impact of globalization on food defect regulations. As the food supply chain has become increasingly global, FDA has had to adapt its regulatory framework to address the complexities of international food production and trade. This section explores how FDA collaborates with international regulatory bodies and aligns its standards with global food safety practices to protect American consumers.

By reflecting on the historical development of the FDA's food defect rules and regulations, this paper provides insights into the ongoing challenges and future directions for ensuring food safety in an ever-evolving landscape. The analysis underscores the importance of continuous adaptation and innovation in regulatory practices to meet the emerging threats and opportunities in food safety and public health.

“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



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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?