Top Food and Drug Cases, 2025

Edited by August T. Horvath

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Introduction

AUGUST T. HORVATH*

Once again, it is my privilege to introduce FDLI's Top Food and Drug Cases volume, this time covering significant lawsuits and legal issues from 2025. Our coverage includes government enforcement actions, civil and criminal cases, and significant appeals. The year 2025 was another wild one in the food and drug space. The initials "MAHA" entered our vocabulary with a new set of government agency priorities, and significant court decisions altered the landscape, resolving some long-standing legal questions and raising some new ones.

We typically lead with appellate decisions in this volume because of their great precedential value. This year, we start with a Supreme Court decision, not in the food and drug space, but Dan Logan and Justine Lenehan explain why FDA practitioners nevertheless should know about *FCC v. Consumers' Research*. Mital Patel and Kathy Luo enlighten us about the Ninth Circuit's ruling in *Natural Grocers v. Rollins*, in which the court reviewed the bioengineered-food disclosures of USDA's Agriculture Marketing Service. Ralph Hall describes the Fifth Circuit's ruling in *Zyla Life Sciences v. Wells Pharma*, examining the viability of private litigation based on state statutes mirroring the Federal Food, Drug, and Cosmetic Act. Late in 2025, the Eighth Circuit weighed in on the evidentiary requirements for class certification in food labeling class actions in the *Folgers Marketing Litigation*, reported by Rene Befurt, Sai Sindhura Gundavarapu, and Riddhima Sharma. Sara Koblitz and Anne Walsh cover the D.C. Circuit's ruling in *Novartis Pharmaceuticals v. Kennedy*, a bright spot for FDA in the past year's litigation, as the court validated its approach to so-called "chubby labels."

The federal district courts also have been active in delineating the government's regulatory authority in 2025. We hear from Rebecca Jones McKnight, David Bender, and Lily Barrett about *Wulferic v. FDA*, in which one such court in Texas found that a defendant has a right to a jury trial in an FDA action for civil penalties under the Tobacco Control Act. A court in the Eastern District of California struck the latest blow to the California government's Proposition 65 warning regime in *California Chamber of Commerce v. Bonita*, described for us by Neil Fortin. Andrew Wasson explores a development in the post-*Loper Bright* doctrine of court deference to agencies, or lack thereof, here in the context of defining "biologics," in *Eli Lilly v. Kennedy* in the Southern District of Indiana. An Eastern District of Texas judge in *American Clinical Laboratory Association v. FDA* overturned FDA's new enforcement regime for laboratory-developed tests, as discussed by Tina Papagiannopoulos.

State courts don't get into the action as often in food and drug cases, but Bill Janssen highlights a fascinating 2025 product liability decision from the New York Appellate Division, *Silverstein v. CoolSculpting*.

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The federal government's MAHA campaign to some extent feeds on long-standing government and activist concerns with the ill-defined category of "ultra-processed foods," and this boiled over into litigation late in 2024, with the first decisions on motions to dismiss issued in 2025. Anand Agneshwar and Jocelyn Wiesner analyze these cases and their implications for what undoubtedly will continue to be a growth area for both government enforcement and consumer class litigation.

Finally, Helen Ryan and Laura Schwenderman round out this year's volume with a survey of significant settlements between respondents and a number of agencies with authority in the food and drug spaces.

Several of the cases discussed in this year's book, including *Wulferic v. FDA*, and *Zyla v. Wells Pharma*, are now on appeal, and therefore are cases to watch for the next year or two. Our diligent team of authors will keep the FDLI membership posted on the significant developments that will no doubt occur.

From veteran contributors to first-timers, all of our authors did an excellent job again this year, and I and FDLI extend our sincere appreciation to the group. Nothing is more gratifying to an editor than the enthusiasm and diligence of the contributors who give their time and share their expertise to keep the membership up to date on these important developments. On behalf of the entire crew, we wish our readers a happy and healthy remainder of 2026.

Federal Communications Commission et al. v. Consumers' Research et al.

T. DANIEL LOGAN & JUSTINE E. LENEHAN*

WHY IT MADE THE LIST

"Die Geister, die ich rief," meaning "the spirits I have summoned," is a common German saying reflecting the inability to control those whom one has brought forth. This saying comes from Goethe's poem "The Sorcerer's Apprentice" (Der Zauberlehrling), in which an apprentice sorcerer enchants a broom to fetch water as a substitute for doing the chore himself, but, alas, does not have mastery over the spell to stop it.[1] When the apprentice splits the broom with an ax, both halves continue their tireless work. Only the master can disenchant the errant broom and resolve the quagmire. Here, the nondelegation doctrine is the master's return: Congress may not set its brooms in motion without telling them when to stop. In *FCC v. Consumers' Research*, the Supreme Court confronted the nondelegation doctrine—the constitutional principle that Congress may not cede its legislative power to executive agencies without providing adequate guidance. Given that FDA operates under broad statutory delegations, the potential implications for the agency warranted close attention following the Fifth Circuit's rejection of FCC's Universal Service Fund contribution scheme as unconstitutional. Ultimately, the Court declined to overhaul its nearly century-old framework—and in doing so, it offered important guidance on the boundaries of permissible delegation that has implications for all executive branch agencies.

DISCUSSION

Background: The Nondelegation Doctrine

Article I of the Constitution provides, "All legislative Powers herein granted shall be vested in a Congress of the United States." Courts have long interpreted this provision to prohibit Congress from transferring its legislative power to other branches of government (i.e., "nondelegation"). Nevertheless, from a practical and structural standpoint, Congress must be able to enlist executive agencies to implement the laws it enacts. To reconcile these imperatives, the Supreme Court articulated the "intelligible principle" test as an exception to the nondelegation doctrine: Congress may confer discretion on an agency so long as it provides an intelligible principle to

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[1] Johann Wolfgang von Goethe, *Der Zauberlehrling* (1797). Readers may also be aware of the famous adaptations of this poem, in which the sorcerer's apprentice is portrayed by a cartoon mouse.

guide the agency's exercise of that discretion.[2] To do so, Congress must clearly delineate both the "general policy" and the "boundaries of this delegated authority," with greater specificity needed as the scope of the delegated power increases.[3]

In practice, this intelligible principle standard has proven to be quite permissive. With limited exceptions, the Court has consistently upheld statutory delegations containing broad directives—such as instructing agencies to regulate in the "public interest" or to set "just and reasonable" rates—finding that the surrounding statutory context provided sufficient guidance to satisfy the intelligible principle test.[4] It had become so rarely deployed that it had, at various points, been called "dead," having not been invoked since 1935 (although that was the first and last year in which it was deployed to invalidate a statute).[5]

For proponents of a stricter nondelegation doctrine, *Consumers' Research* presented an appealing vehicle: a federal agency authorized to raise billions in revenue from private carriers, with the assistance of a private corporation, pursuant to a statute containing no numeric limit on the agency's collection authority.

Procedural History

The factual backdrop of *Consumers' Research* centers on the Universal Service Fund (USF), a longstanding program through which FCC subsidizes telecommunications services for underserved populations. The Communications Act of 1934 established FCC and charged it with making communications services available "to all the people of the United States" at "reasonable charges."[6] In 1996, Congress enacted the Telecommunications Act of 1996, which, under Section 254, created an explicit funding mechanism requiring carriers providing interstate telecommunications services to contribute to the USF, with those funds directed to subsidizing services for low-income consumers, rural communities, schools, libraries, and rural hospitals.[7] The statute guides FCC's discretion in selecting which services to subsidize: among other things, the service must be essential to education, public health, or public safety; subscribed to by a substantial majority of residential customers; and available at affordable rates. FCC appointed the Universal Service Administrative Company (USAC), a private, not-for-profit corporation, to manage day-to-day operations of the USF and compile the financial projections used in determining each carrier's required contribution—calculated based on its projected revenue and a "contribution factor" devised by USAC but subject to FCC review and approval.

Consumers' Research, a nonprofit organization, as well as a carrier and several consumers, challenged the contribution scheme in the Fifth Circuit, raising two constitutional objections: first, that Congress had impermissibly delegated its

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2 *See* J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928).

3 American Power & Light Co. v. Securities & Exchange Commission, 329 U.S. 90, 105 (1946); Whitman v. American Trucking Assns., Inc., 531 U.S. 457, 475 (2001).

4 *See, e.g.*, National Broadcasting Co. v. United States, 319 U.S. 190, 225–26 (1943).

5 Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315 (2000).

6 Communications Act of 1934, Pub. L. No. 73-416, § 151, 48 Stat. 1064, 1064 (1934) (codified at 47 U.S.C. § 151).

7 Telecommunications Act of 1996, Pub. L. No. 104-104, § 254, 110 Stat. 56, 71 (1996) (codified at 47 U.S.C. § 254).

legislative—and specifically its taxing—power to FCC without an intelligible principle; and second, that FCC had, in turn, impermissibly subdelegated authority to USAC, a private entity.[8] A three-judge panel rejected both challenges, finding that Section 254 contained an intelligible principle and that USAC operated in a subordinate capacity to FCC.[9] The Fifth Circuit, sitting *en banc*, reversed, holding that the "*combination* of Congress's sweeping delegation to FCC and FCC's unauthorized subdelegation to USAC" was unconstitutional—a theory the court characterized as a "double-layered delegation" with "no foothold in history or tradition" and "incompatible with our constitutional structure."[10] The Fifth Circuit's decision split with the Sixth and Eleventh Circuits, which had rejected substantially identical challenges.[11] The Supreme Court granted certiorari.

The Supreme Court's Analysis

In a 6–3 decision authored by Justice Kagan, the Court reversed the Fifth Circuit and upheld the USF contribution scheme.[12]

The Court rejected the argument, outlined by both respondents and the dissent, that revenue-raising statutes must satisfy a heightened nondelegation standard requiring Congress to specify a numeric cap or fixed rate. In reaching this conclusion, the Court found that existing precedent foreclosed this argument and adopting a proposed numeric-limit requirement would not only lead to absurd results but also imperil numerous existing federal revenue statutes that similarly lack quantitative limits. The Court further declined to distinguish between taxes and fees as a means to limit the reach of such a ruling, finding the line between the two "unbelievably murky in practice" and irrelevant to the nondelegation inquiry.

The Court held that Section 254 adequately constrains FCC's discretion, applying the traditional intelligible principle test to determine that the statutory direction that contributions be "sufficient" to support universal service programs operates as both a floor and a ceiling on the funding Congress authorized FCC to raise. Critically, in the Court's view, the "sufficiency" ceiling is given substantive heft by the statute's detailed provisions defining the scope of universal service—including the designated beneficiaries, the criteria for eligible services (essential, widely used, and affordable), and certain governing principles. Further, the Court found that FCC's ability to update the definition of universal service and articulate additional principles was constrained by the requirement that any additions be "consistent with" the rest of the statute.

The Court also rejected respondents' private nondelegation challenge, holding that FCC's use of USAC did not confer governmental power on a private entity. The Court found that USAC functions subordinately to FCC, subject to its appointment authority, budget approval, and substantive oversight, and makes only non-binding

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[8] A law violates the private nondelegation doctrine when it permits a non-governmental entity to govern without meaningful oversight by a politically accountable agency. *See* FCC v. Consumers' Research, 606 U.S. 656, 692 (2025) (building on Carter v. Carter Coal Co., 298 U.S. 238 (1936), Sunshine Anthracite Coal Co. v. Adkins, 310 U.S. 381 (1940)).

[9] *See* Consumers' Research v. FCC, 63 F.4th 441 (5th Cir. 2023).

[10] *See* Consumers' Research v. FCC, 109 F.4th 743, 778, 782 (5th Cir. 2024) (*en banc*) (emphasis in original, internal quotations omitted).

[11] *See* Consumers' Research v. FCC, 67 F.4th 773 (6th Cir. 2023); Consumers' Research v. FCC, 88 F.4th 917 (11th Cir. 2023).

[12] FCC v. Consumers' Research, 606 U.S. 656 (2025).

recommendations that FCC retains full authority to revise. The Court likewise dispatched the Fifth Circuit's "combination theory" of "dual-layered delegation," reasoning that the public and private nondelegation doctrines "do not operate on the same axis" and therefore a measure implicating but not violating each does not compound to create a constitutional violation.

Concurring and dissenting opinions add important texture. Justice Kavanaugh concurred to emphasize that the intelligible principle test's "staying power" may reflect both the difficulty of devising a workable alternative and concerns that a stricter test could diminish the President's Article II authority to implement legislation. He also suggested that concerns about expansive delegations have been "substantially mitigated" by other recent developments in administrative law—namely, the elimination of *Chevron* deference in *Loper Bright* and the rise of the major questions doctrine. In a potentially notable signal, Justice Kavanaugh separately argued that delegations to independent agencies headed by officers who are not subject to at-will removal by the President (as compared to agencies under an Executive department) may raise distinct constitutional concerns.

Justice Jackson wrote a brief concurrence to question whether the private nondelegation doctrine is a constitutionally grounded doctrine at all.

Justice Gorsuch penned a dissent, joined by Justices Thomas and Alito. He characterized universal service contributions as taxes and maintained that the Constitution requires Congress to specify a tax rate or cap before authorizing an agency to collect revenue. Moreover, the dissent found Section 254's qualitative standards too indeterminate to constrain FCC's discretion, accused the majority of reading the statutory criteria more narrowly than either the text or FCC's own past practice would support, and criticized the Court's continued reluctance to enforce the nondelegation doctrine with the vigor it applies to other constitutional principles.

IMPACT OF THE DECISION

Consumers' Research will not be remembered as the watershed moment in the nondelegation story that some anticipated after *Gundy v. United States*. In that 2019 case, four Justices appeared to signal a willingness to revisit the intelligible principle framework. Justice Gorsuch, in dissent, suggested replacing the principle with a significantly more stringent standard that would have permitted delegations of power to agencies solely to: (1) "fill up the details" of an already decided scheme; (2) to make fact findings triggering a congressionally defined consequence; or (3) exercise genuinely executive functions.[13] Indeed, *Consumers' Research* suggests that, at least for the foreseeable future, the Court is unwilling to revisit the nondelegation doctrine. As signaled by Justice Kavanaugh in his concurrence in *Consumers' Research*, this may be due, at least in part, to the absence of a viable replacement framework that is both more stringent and administrable, as well as the Court's recent jurisprudence constraining and narrowing broad congressional delegations.

The overruling of *Chevron* deference in *Loper Bright* means that courts now exercise greater independent judgment in determining the reach of agency authority under a statute, rather than deferring to the agency's own interpretation of ambiguous text. And the major questions doctrine, as articulated in *West Virginia v. EPA*, requires

[13] See Gundy v. United States, 588 U.S. 128, 148–49 (Alito, J., concurring in the judgment), 157–59 (Gorsuch, J., dissenting).

agencies to point to clear congressional authorization before asserting authority over matters of vast economic or political significance. Together, these doctrines arguably accomplish indirectly what a reinvigorated nondelegation doctrine would do directly: they cabin agency authority not by invalidating the underlying statutory grant, but by constraining the scope of discretion the agency may claim under it. Justice Kavanaugh suggested that these developments have, collectively, addressed the structural concerns that might otherwise warrant tightening the nondelegation standard.

For agencies such as FDA, a practical consequence of the Court's preservation of the intelligible principle test is that the status quo remains: the primary battleground will concern interpretation of the scope of statutory delegations, rather than their constitutionality. The intelligible principle test remains intact and forgiving, but courts are now more willing to read delegating statutes narrowly to avoid constitutional concerns.

For the food and drug bar specifically, several aspects of the decision merit attention. FDA operates under broad delegations from Congress in the Federal Food, Drug, and Cosmetic Act—the kind of expansive grants of authority that, as the Court emphasized, require proportionally greater specificity from the delegating statute.

The Court's treatment of the revenue-raising question may bear on FDA's user fee programs. PDUFA, MDUFA, GDUFA, and related statutes each authorize FDA to collect fees from industry to support review activities, and like the contribution scheme at issue in *Consumers' Research*, these statutes rely on qualitative criteria to channel agency discretion. Moreover, private industry negotiates directly with FDA to determine the amount of revenue raised under user fee programs. Had the Court adopted the respondents' proposed rule requiring a numeric cap or fixed rate for any revenue-raising delegation, these programs could have faced novel constitutional challenges. But unlike the USF contribution scheme—which lacked any numeric constraint—the user fee statutes contain quantitative guardrails of their own. Each program includes statutory "trigger" conditions requiring that FDA's non-user-fee appropriations meet certain thresholds before the agency may collect or obligate user fee revenue. These triggers arguably function as a sort of numeric constraint, suggesting that even under a stricter nondelegation framework, the user fee programs may rest on solid constitutional ground. Indeed, the Gorsuch dissent's own tax-versus-fee distinction reinforces this conclusion. The dissent recognized that fees carry a "built-in intelligible principle" because they compensate for a specific government service—precisely the relationship between FDA user fees and the cost of review activities.

The resolution of the private nondelegation claim likewise has implications for FDA. The agency regularly delegates its authorities to carry out aspects of its statutory mission, some of which do not appear to comport with the Court's guidance regarding acceptable private nondelegations. For example, it is difficult to square the generally recognized as safe (GRAS) self-determination pathway with the private nondelegation doctrine. Unlike assistance by a private entity in the form of "non-binding" advice, such as that provided by USAC, GRAS self-determinations empower private entities to make a substantive determination regarding the permissibility of food ingredients under the Federal Food, Drug, and Cosmetic Act (FDCA). Similarly, the FDCA's incorporation by reference of the United States Pharmacopeia (USP) into the definition of "drug" and the drug adulteration and misbranding provisions has been argued to be

an impermissible delegation to a private entity.[14] Under *Consumers' Research*, the key question is whether the agency retains genuine decision-making authority—it is unclear whether FDA retains that authority in the above examples.

In sum, *Consumers' Research* suggests that the master has already returned to the workshop. *Loper Bright* and the major questions doctrine may supply courts with tools adequate to scrutinize agency action and constrain statutory authorities, leaving the nondelegation doctrine, for now, an incantation that need not be spoken.

[14] Anne Stark, *Is the Incorporation of the United States Pharmacopeia into the Food, Drug, and Cosmetic Act an Unconstitutional Delegation of Legislative Power?*, 73 Food & Drug L.J. 134, 134 (2018) (citing to 21 U.S.C. §§ 321(g), 351(b), 352(e)(3)).

Natural Grocers v. Rollins

MITAL PATEL & KATHERINE LUO*

WHY IT MADE THE LIST

The law governing the disclosure of bioengineered food has continued to develop since the U.S. Department of Agriculture (USDA) established national uniform regulations under the National Bioengineered Food Disclosure Standard in 2018. The standard became fully mandatory in 2022, and three years later, the Ninth Circuit's decision in *Natural Grocers v. Rollins*[1] stands as one of the most consequential appellate rulings interpreting the new framework. While the court upheld the status quo as to the required use of the statutory term "bioengineered," it reversed the district court on the scope of bioengineered ingredients that must be disclosed and the methods by which those disclosures may be made.

The decision is already prompting labeling changes for consumer products on shelves, and the remand for the Agricultural Marketing Service (AMS) to revisit the proper detectability standard signals that the disclosure law will continue to be refined in the years ahead. For consumers, manufacturers, and retailers alike, *Natural Grocers* reflects courts' willingness to scrutinize these standards in their early years—both to sharpen their present clarity and to anticipate more advanced technology for processing and detecting bioengineered ingredients in the future.

DECISION AND BACKGROUND

In 2016, Congress enacted Public Law No. 114-216, which amended the Agricultural Marketing Act of 1946 (AMA) and directed the USDA to establish a "national mandatory bioengineered food disclosure standard." The Secretary of Agriculture delegated that authority to AMS, which promulgated its final regulations in 2018 under the National Bioengineered Food Disclosure Standard. The standard became fully mandatory on January 1, 2022, and generally requires covered foods to disclose whether they are "bioengineered" or contain a "bioengineered" ingredient. While the statute does not define "bioengineered" itself, it defines "bioengineering" with respect to a food as referring to a food that (1) "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques," and (2) for which "the modification could not otherwise be obtained through conventional breeding or found in nature."

In July 2020, a group of grocery retailers and public interest organizations sued AMS in the Northern District of California, alleging under the Administrative Procedure Act (APA) that three aspects of the disclosure standard were unlawful or

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[1] Nat. Grocers v. Rollins, 157 F.4th 1143 (9th Cir. 2025).

arbitrary and capricious. First, plaintiffs challenged the regulation's exclusion from the disclosure requirements of foods containing bioengineered material that was "not detectable" under the agency's detectability standards. Plaintiffs argued that this exemption was improper and that AMS was required to mandate disclosure for *all* foods—including highly refined foods—that might contain "undetectable" bioengineered ingredients. Second, plaintiffs asserted that AMS should have permitted the use of more familiar terms in disclosures, such as "GMO" or "genetically engineered," rather than mandating the term "bioengineered." Third, plaintiffs challenged the regulatory provisions allowing manufacturers to satisfy their disclosure obligations through QR codes or text messaging, rather than through more conventional on-package statements or symbols.

In September 2022, the district court granted summary judgment to plaintiffs on the third claim concerning disclosure methods, but denied summary judgment on the other two claims. The court remanded the two challenged disclosure-format provisions to AMS without vacating them, effectively leaving the allegedly deficient provisions in place. Plaintiffs appealed, and on October 31, 2025, a unanimous Ninth Circuit panel reversed in part, affirmed in part, and remanded. The court held that AMS had committed legal error in excluding from the disclosure requirement foods with "undetectable" bioengineered material; that the agency's mandated use of the term "bioengineered" in disclosures was reasonable and lawful; and that the district court abused its discretion by declining to vacate the unlawful QR-code and text-message disclosure provisions.

The Detectability Standard for Highly Refined Foods

The central issue in the case was whether AMS could properly exempt from disclosure certain highly processed foods that may contain "undetectable" bioengineered ingredients. In many of these products—such as refined oils, sugars, and corn syrup—bioengineered ingredients undergo such substantial processing that any modified genetic material is rendered "undetectable" under the regulation's standards. Specifically, the regulation provides that a food does not "contain" modified genetic material if that material is "not detectable," and that material is "not detectable" if either "the food had been subjected to a refinement process validated to make the modified genetic material in the food undetectable" or "analysis or testing appropriate to the specific food confirms the absence of modified genetic material." A manufacturer who could establish either condition was, therefore, exempt from the disclosure requirement.

The Ninth Circuit held that AMS committed legal error in categorically excluding highly refined foods from the definition of "bioengineered foods." The court reasoned that whether a food actually *contains* bioengineered material is conceptually distinct from whether such material can be *detected* using a particular method. It accordingly rejected AMS's position that non-detectability under the regulation's described methods was legally equivalent to non-presence. AMS's own regulations, the court observed, undermined that premise. The regulation itself acknowledged that a particular detection technique might not be "sufficiently sensitive" to identify modified genetic material that is, in fact, present, and AMS expressly recognized in its analysis accompanying the final rule that future detection methods may be more accurate than earlier ones, such that foods presently exempt from disclosure could later fall within the standard. Yet, the regulation simultaneously permitted manufacturers to continue relying on previously "validated" refining processes without further

testing, even if subsequently developed tests could detect modified genetic material in the resulting product.

AMS sought to defend the regulation on the alternative ground that § 293(b)(2)(B) of the AMA granted it discretion to set "amounts" of bioengineered substances below which their potential presence could be disregarded. The court rejected this argument under *SEC v. Chenery Corp.*, which permits a reviewing court to uphold an exercise of agency discretion only on the same basis articulated by the agency itself. AMS, the court observed, had never invoked this discretionary authority in justifying its detectability standard. Instead, the agency had rested entirely on what the court characterized as its "flawed legal premise" that non-detectability was equivalent to non-presence.

On remand, however, the court left the proper detectability standard to AMS's further consideration. Contrary to plaintiffs' position, AMS was not required to impose a universal disclosure requirement on every highly processed food. Rather, the agency's authority under § 293(b)(2)(B) to set "amounts" of bioengineered substances directly empowered it to establish the threshold levels at which a food would qualify as "bioengineered." Although the particular detectability standard adopted by AMS was contrary to law, the court emphasized that "it remains open to the agency to address the subject of detectability by a proper exercise of that authority on remand."

"Bioengineered" Terminology

In contrast, the court ruled in favor of AMS on the use of the term "bioengineered," as opposed to purportedly more familiar alternatives such as "genetically modified" or "GMO." Affirming the district court, the Ninth Circuit held that the agency's terminology choice was neither arbitrary nor capricious. AMS had reasonably concluded that a single, uniform term would "ensur[e] disclosure consistency and minimiz[e] marketplace confusion." Moreover, "bioengineered" was the very term Congress had used in the AMA, and broader alternatives such as "genetically engineered" could capture more than Congress intended. The court observed, for example, that the AMA's disclosure provision uses the term "bioengineered," while its preemption provision uses the broader phrase "genetically engineered"—a textual distinction supporting the agency's conclusion that the two terms have different scopes. Finally, the court accepted AMS's view that any consumer unfamiliarity with the term "bioengineered" could be addressed through outreach and education rather than through the wholesale adoption of additional and potentially conflicting terminology.

Disclosure Via QR Codes and Text Messaging

Finally, the Ninth Circuit held that the district court abused its discretion by declining to vacate the regulatory provisions governing QR-code and text-message disclosures after concluding that those provisions violated the AMA. Although the district court had granted summary judgment to plaintiffs on this claim, it remanded the two provisions to AMS without vacatur, effectively leaving the unlawful disclosure options in place. The Ninth Circuit emphasized that vacatur is the "default remedy" under the APA when agency action is found unlawful, subject only to limited exceptions. The district court had been concerned that vacatur would "disrupt consumer access to bioengineering disclosures," but the panel was unpersuaded—precisely because the disclosure options at issue had already been deemed inadequate. As the court explained, "[a]llowing an inadequate disclosure option to

continue throughout the entirety of the administrative process for amending the regulations would *itself* perpetuate a disruption." While industry reliance on existing labels was a legitimate concern, the court concluded that any transitional disruption could be addressed through prospective vacatur with appropriate transition periods, rather than by leaving unlawful disclosure methods in effect indefinitely.

IMPLICATIONS AND IMPACT

Natural Grocers will require AMS to undertake significant revisions of the National Bioengineered Food Disclosure Standard on remand. First, and most significantly, the decision reopens the question of which highly refined foods must bear bioengineering disclosures—now and in the future. Although a revised detectability standard could ultimately produce results similar to those under the current rule, AMS must arrive at any such standard through evidence-based analysis and the express exercise of its discretionary authority under § 293(b)(2)(B), rather than through the flawed legal premise that non-detectability equals non-presence.

The timing of any such revisions will be shaped in the first instance by proceedings in the Northern District of California, to which the Ninth Circuit remanded the case.

If, by contrast, the revised standard moves toward stricter detection thresholds, the universe of foods subject to bioengineering disclosure could materially expand. Manufacturers that currently market products without disclosures in reliance on the "undetectable" exemption should monitor these developments closely, as more demanding detection standards could substantially alter their labeling obligations.

Regarding terminology, the court's affirmance of AMS's choice of "bioengineered" as the uniform disclosure term anchors the statutory vocabulary around a single phrase, reducing uncertainty as to how labeling claims should be framed. The decision's issue-by-issue approach reflects a judicial goal of long-term clarity. Against the backdrop of varied food claims and labeling requirements, the move toward a single statutory term offers a welcome point of consensus that will help consumers and producers align in their understanding of when bioengineered materials are present in food.

Food manufacturers currently relying on QR codes or text messaging as their primary method of bioengineered food disclosure face the most immediate practical uncertainty. Although the prospective vacatur contemplated by the court will afford some runway, manufacturers should anticipate that these methods will eventually be prohibited. Companies that depend solely on QR codes or text messaging should accordingly begin transitioning to traditional on-package disclosures, and should evaluate any alternative disclosure methods that AMS may develop in the interim. Notably, AMS solicited public comment on these disclosure options in April 2024, following the district court's ruling, suggesting that the agency was already alert to the need for regulatory revision well before the Ninth Circuit's opinion issued.

Beyond its immediate effects on the bioengineered food disclosure framework, *Natural Grocers* is significant for its rigorous application of the *Chenery* doctrine in the food regulation context. The court's refusal to uphold AMS's detectability standard reinforces the principle that courts may sustain agency action only on the same basis articulated in the agency's order itself. The holding discourages reliance on post hoc rationales to defend regulations and may embolden future plaintiffs to pursue APA challenges in this space. The decision also underscores the Ninth Circuit's commitment to vacatur as the default APA remedy—a position that gives district

courts a firmer directive to vacate inadequate provisions and that may make agencies more cautious in exercising their delegated authority.

Taken as a whole, *Natural Grocers* is a timely and deliberate ruling aimed at clarifying the law in the consumer food space during these formative years for bioengineered food disclosure. The framework remains in flux, and companies across the food supply chain—from ingredient suppliers to manufacturers to retailers—should watch developments carefully as compliance standards continue to be reshaped in the years to come.

Zyla Life Sciences L.L.C., v Wells Pharma of Houston, L.L.C.[1]

RALPH F. HALL[2]

WHY IT MADE THE LIST

Any case that opens the door to state law oversight of medical products and private entity-based enforcement of FDA-related obligations is worthy of attention.

Over the past century of FDA law, two, often interrelated, questions have arisen, died down, and then reappeared, often with a vengeance. *Zyla* now presents these questions in a way that may dictate a more final resolution.

The first question is what role, if any, does state statutory or state common law have in regulating products and conduct within the scope of the Federal Food, Drug, and Cosmetic Act (FDCA)[3] or otherwise within FDA's jurisdiction.

The second question involves when, how, and even whether private entities or individuals can seek to enforce FDA-related obligations.

These state actions can be direct actions to enforce FDCA-type obligations (often using state statutory structures that mimic or parallel the FDCA). Zyla's lawsuit against Wells for marketing a product without the necessary FDA approval and the recent action brought by Texas against the makers of Tylenol for allegedly inadequate warnings are examples of this type of case. A private action such as a product liability case to obtain compensation or other redress under state common law or non-FDCA specific statutory systems is an example of this type of case.

Zyla is a 2025 case that directly addresses both of the aforementioned questions. *Zyla* demonstrates the evolving, sometimes seemingly inconsistent, nature of the case law in this area. It also is a fascinating example of the innovative use of state law by a private entity to challenge conduct by a competitor.

Regulated industry, patients, other stakeholders, and practitioners need to understand this evolving landscape both for offensive uses and to be prepared defensively if a client is subject to some litigation based on state law claims.

The importance of this issue is underscored by the fact that the Supreme Court is currently considering a petition for a writ of certiorari in this exact case[4] and has

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[1] Zyla Life Sciences v. Wells Pharma ("*Zyla*"), No. 23-20533 (5th Cir. 2025).

[2] Professor of Practice (retired), University of Minnesota Law School; Hall Strategies, LLC

[3] 21 U.S.C. § 201 et seq. We recognize that FDA also has responsibility for certain statutes not technically part of the FDCA. For convenience, these will be combined with references to the FDCA.

[4] Petition for Writ of Certiorari, *Zyla*, No. 25-257.

invited the Solicitor General to file a brief expressing the views of the United States on this question.[56]

DISCUSSION

Facts and Case Status

In this case, Zyla sued Wells in federal court (under diversity jurisdiction) for allegedly selling a "new drug" (as defined in 21 U.S.C. § 321(p)) without having an approved New Drug Application (or other equivalent marketing authorization). Wells was selling a compounded version of a drug for which Zyla had FDA marketing authorization.[7] Zyla asserted that this conduct violated the laws of six states that have state statutory systems that parallel the FDCA.[8] Wells filed a motion to dismiss under FRCP 12(b)(6) asserting that Zyla's claims were barred by preemption and the FDCA. The District Court agreed and granted the motion to dismiss.

Zyla appealed and the Fifth Circuit reversed. The Fifth Circuit ruled that the claims presented by Zyla were not precluded by the terms of FDCA and were not preempted. Wells has filed a (still pending) petition for a writ of certiorari.[9]

Role of State Law

Analysis of State Law Claims

To understand *Zyla* and its importance (and implications) one needs to understand the environment within which this recent case exists.

Many practitioners have long believed that only the federal government has the authority to enforce FDCA obligations or requirements. (Product liability cases are efforts to enforce non-FDCA based claims.)

The obvious basis for this belief starts with the FDCA itself. 21 U.S.C. § 337 specifically states that all actions to enforce the FDCA must be brought "in the name of the United States."[10] (The Supremacy Clause and the Interstate Commerce Clause are the foundational constitutional provisions upon which § 337 is based.) A plain reading of this section is that the power to enforce the FDCA is reserved solely to the federal government (i.e., the Department of Justice) and not to states or private litigants.

The statutory language reserving to the federal government the sole right to bring enforcement actions for violations of FDCA obligations is supported by the Supreme

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[5] As of the date of writing this article, the Supreme Court has not ruled on the petition for a writ of certiorari. It may well be that this case is the subject of another article next year if the Supreme Court acts.

[6] In addition to judicial activity, Congress and state legislators may be asked to consider how to address these claims. Congress might want to consider changes to the FDCA to clarify what roles states and private parties should have in enforcing claims within the scope of the FDCA and the jurisdiction of FDA.

[7] The specific issues around compounding drugs are not the subject of this article.

[8] States with such parallel state provisions are: California, Colorado, Connecticut, Florida, South Carolina, and Tennessee.

[9] Wells has been supported in this petition by the Americans for Access to Compounded Medication.

[10] Section 337(b) sets forth some limited situations in which a state may bring actions in its name under a limited number of food-related obligations. There is a process for prior notice to FDA of such an intent. It seems that this exception is limited to actions brought by the state. In any event, this provision is not relevant to the facts in this case.

Court in the well-known decision in *Buckman*.[11] In *Buckman*, the Supreme Court prevented a private party from bringing a case asserting that the defendant had committed fraud on FDA.

Various cases following *Buckman* have supported this interpretation. In *Nexus Pharmaceuticals, Inc., v. Central Administrative Pharmacy Services, Inc.* ("*Nexus*"),[12] the Ninth Circuit upheld the dismissal of claims that the defendants were illegally marketing a new "drug" in violation of FDCA requirements. While *Buckman* involved allegations that the defendant had violated the federal statute (the FDCA), the plaintiff in *Nexus* asserted that the defendants had violated various state laws that prohibited the sale of an unapproved new drug (essentially state law provisions that were parallel to, or identical to, the FDCA).[13] The *Nexus* court utilized a preemption analysis to justify the dismissal of the case.

However, the case law is open to different interpretations. In *Bubak v. Golo*,[14] the Ninth Circuit permitted a state law-based claim to proceed. The *Bubak* court distinguished this case from *Nexus* because the state statute at issue in *Bubak* did not explicitly incorporate the FDCA. The plaintiff in *Bubak* asserted its claims under the California Unfair Competition Law,[15] while the claims in *Nexus* were state statutes that explicitly incorporated the FDCA. Interestingly, the court focused on the legal basis for the cause of action and not on the factual basis. In many ways, the same type of conduct existed in both cases with the difference being the legal basis for the plaintiff's claims.

There is also a plethora of product liability cases addressing preemption (in all of the different forms or types of preemption). Product liability cases almost universally involve state law-based claims (generally, negligence, failure to warn, manufacturing defect, or state-specific product liability statutes). Absent express or conflict preemption, many of these cases are permitted to proceed. *See, e.g.*, *Medtronic v. Lohr,* 518 U.S. 470 (1996); *Wyeth v. Levine,* 555 U.S. 555 (2009).

In *Nexus*, the court utilized a classic preemption analysis. Using § 337, *Buckman*, and the Supremacy Clause, the court concluded that the state law-based cause of action intruded into the federal realm. The same type of conduct was addressed in both statutory systems.

However, in *Zyla* (and *Bubak*), the court concluded that § 337, *Buckman*, and its progeny did not apply to bar the application of state laws that are parallel to, and consistent with, the FDCA. The defendant's reliance on § 337, *Buckman*, *Nexus* and similar cases to argue for preemption was to no avail.

The *Zyla* court concluded that the preemption or overbreadth doctrine was not applicable to this case. To win on preemption, the defendant would need to establish that the state law in question imposed new or additional requirements on the defendant.

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[11] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)

[12] 48 F.4th 1040 (9th Cir. 2022). The Ninth Circuit muddied up these waters in Davidson v. Sprout Foods, Inc.,106 F.4th 849 (9th Cir. 2024), in finding certain food labeling claims not preempted.

[13] While *Zyla* listed six states with laws identical o the FDCA, the court in *Nexus* also listed Arizona and Pennsylvania as states prohibiting the sale of an unapproved new drug. *Nexus*, at 9.

[14] Bubak v. Golo., No. 24-492, (9th Cir. October 9, 2025). It is critical to note that this case is "Not for Publication." As such, its use as precedent in limited. The case is included here as an example of a case permitting a state law cause of action to be prosecuted.

[15] Cal. Bus. & Prof. Code §§ 17200, 17204.

In conducting its analysis along these lines, the court relied on cases such as *Kansas v. Garcia*, 589 U.S. 191 (2020), which help define the federal/state relationship.

The court in *Zyla* determined that the state statute in question was identical to, and incorporated, the FDCA, and thus found that it was not preempted. The court did not conduct a detailed analysis of the "sole power" language in § 337 once it found as such.

The court relied particularly on *California v. Zook*, 336 U.S. 725 (1949). *Zook* involved a question of whether certain conduct was permitted under the Interstate Commerce Clause and does not directly involve the FDCA. The Supreme Court in *Zook* held that the California law at issue in that case was not preempted. Using *Zook*, the *Zyla* court held that the mere "fact of identity" between the federal and state statutory schemas did "not mean the automatic invalidity of the state measures. . . ."[16] The *Zyla* court reinforced the interest the state has in addressing violative conduct even if the federal system also prohibits such conduct.

In addition to the classic preemption and statutory interpretation arguments, the defendant in *Zyla* argued that permitting a state law-based cause of action would effectively negate the congressional intent expressed in § 337 that the federal government (and only the federal government) be the enforcement mechanism for FDCA claims. The *Zyla* court rejected this argument (which the court in *Nexus* seemingly accepted). The *Zyla* court had no problem with both federal law and (parallel) state law being the basis for enforcement actions. The court emphasized federalism, the historical role of states in protecting its citizens, the benefit of leveraging federal enforcement resources and cases such as *Zook*.

The federal government, the court noted, had also filed a brief supporting such dual enforcement possibilities in another Supreme Court case, *Athena Cosmetics, Inc. v. Allergan, Inc*., 576 U.S. 1054 (2011).

The *Zyla* court explicitly reminded everyone that the federal government has limited resources and that state centric enforcement actions would help address these resource constraints. "Thus it [the federal government] often welcomes state aid in enforcing shared legal norms."[17] The court also was concerned that rejecting state law-based claims would undermine the role of states in protecting its citizens.

It is interesting that the court seemed to accept, without much debate, that the federal government would value or appreciate this state-based enforcement action and that such a state-based action would aid the overall purposes of the FDCA.

Note that in § 337 (b) Congress created an explicit process for states to enforce certain food-centric FDCA provisions but only after prior notice to the United States. The court did not explicitly address whether this provision demonstrated congressional intent to limit state enforcement. Whether adding a provision permitting a state to seek enforcement powers is the right tool for state-based efforts to enforce FDCA provisions is for Congress to decide. And it must be noted that, as currently codified, the § 337(b) requirements apply to FDCA-based causes of action although one can imagine such provisions being expanded to cover parallel state statutory systems.

Zyla involved some complex pharmaceutical compounding questions (often quite fact-specific). Because the case was at the motion to dismiss stage under Rule 12(b)(6) of the Federal Rules of Civil Procedure (FRCP), the court could not conclude or decide

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[16] *Zyla*, at 8.

[17] *Zyla*, at 11.

that the state law in question would, in fact, impose new, additional, or conflicting requirements on the defendant as compared to existing federal requirements.

Analytical Approach

Given this arguably inconsistent, or at least confusing, case law, how should these cases be viewed and analyzed?

It may be helpful to think about this in a three-step approach focusing on the nature of the claim.

- What is the nature of the state law claim being asserted? Is it an FDCA-type provision?
- Is the state law preempted by federal law? Is the state provision inconsistent with, or in addition to, FDCA obligations?
- Does a private person have the authority or right to assert the state law claim?

Step one:

First, an explicit claim of an FDCA violation (a *Buckman* type claim) would seem to fail given § 337 and *Buchman* itself. This is the easiest analytical pathway with highly predictable results given the current state of the law.

Step two:

Assuming the claim satisfies step one, if the claim at issue is explicitly based on a state law equivalent to the FDCA, then the *Nexus* line of analysis would seem to apply and, under § 337, the claim might likely fail. If *Nexus* applies, the claim fails.

The key question asked in step two is whether the state law at issue is preempted under an express preemption analysis, an implied preemption analysis, or a conflict/field preemption analysis. (One can argue that field preemption is included in one of the other types of preemption.) A claim can satisfy step one and still be *excluded* under step two.

The California "Sherman Law"[18] is an example of a state statute that directly incorporates or repeats provisions of the FDCA. Under *Nexus*, state law claims based exclusively on the California Sherman Law may well fail based on a preemption analysis. (This conclusion may be open to debate or further refinement given other recent case law.[19])

The basis for the *Nexus* line of analysis is that if there are state laws identical to the FDCA, then § 337 is directly applicable and Congress, as a policy matter, has vested the United States with the sole right to enforce such provisions. The state requirements being imposed and the interests protected would seem to be the same as the federal requirements and thus would be preempted.[20]

Clearly, if the state law being asserted actually conflicts with, or creates different requirements than, the FDCA in some substantive way, then, under *any* preemption approach, the claim is probably preempted and the case cannot proceed. Remember

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[18] Cal. Health & Safety Code § 110987 et seq.

[19] See *Davidson*, *supra* note 12.

[20] Remember that, in certain circumstances, a state may enforce such provisions if statutorily permitted. *See, e.g.*, § 337.

that in *Zyla* the court proceeded along these lines and determined that, based on the status of the case as being a dismissal under FRCP 12(b)(6), there was no demonstrated conflict and no preemption.

Step three:

Third, if the state law claim is not a direct FDCA-type claim, then the claim could pass steps one and two, and the analysis would move to step three. This is the *Zyla* situation[21] in which the explicit cause of action was based on the state's unfair competition law, not a provision that is exclusive to FDA regulated products or otherwise mimics the FDCA. These types of cases can include the traditional product liability cases as these generally assert non-FDCA state law claims (e.g., failure to warn claims).[22]

A preemption analysis (along the lines of step two) is still critical. If the state law claim is contrary to federal requirements or if there is otherwise express preemption (see, e.g., *Medtronic v Reigel*[23] and § 379a), the case still fails.

Private Causes of Action

The next question is who can bring such an action. Can such an action be brought by a state entity (the Texas Tylenol case, for example) or by a private citizen (the *Zyla* situation)?

If it is a federal law claim, then cases such as *Buckman* and the plain language of § 337 make it clear that actions to directly enforce the FDCA are barred. Only the federal government can enforce the FDCA. So, if the action is an effort by a state entity or a private citizen to enforce the actual FDCA, the result is clear, the case cannot proceed.

Whether a state or private entity can bring a case under state law, regardless of the statutory structure (whether akin to the FDCA, a more general state law, such as the state unfair competition law at issue in *Zyla*, or state common law causes of action), seems a matter of state law.

However, there may be a complexity if the cause of action is a state law parallel to the FDCA. An action to indirectly enforce the FDCA would seem to be a claim in which the rights or responsibilities at issue are based on, or derived from, the provisions in the FDCA (or implementing regulations). In such a case, if a state or private citizen can sue, then the prohibitions in § 337 are bypassed. A state or private citizen may have greater ability to bring an action based on a general state obligation, such as through a general unfair completion law or a product liability claim. Premeption is still an issue. This difference between these types of claims helps explain the different results in *Nexus* and *Zyla.*

If the cause of action is not based on the FDCA, but the defendant raises FDCA compliance as a defense (a common strategy in product liability cases), the case would seem to be best judged under standard preemption law and there would be no limitations outside of general state law on the nature of the plaintiff legally entitled to

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[21] Remember that a petition for a writ of certiorari is pending as of this writing.

[22] Grafting an FDCA claim onto a product liability claim would be covered by *Buckman* and thus not stand. "Fraud on the FDA" directly addresses the interests and prerogatives of the United States. As such, the United States, as the "aggrieved party," should have enforcement rights and responsibilities.

[23] Medtronic v Reigel, 552 U.S. 312 (2008).

sue. Raising FDCA compliance as a defense should not automatically convert the case into a *Buckman* type case.

Assuming that only state law claims are raised, deciding whether a private entity can enforce a state-based FDCA equivalent statute starts with reviewing the actual language of that statute. Does the state statute permit or preclude private enforcement? If the statute (or common law) permits such an entity to bring an action, then the other analytical points discussed above, principally preemption, become relevant as to the viability of the claim, but the legal right to bring the claim has been established.

Open Legal and Policy Issues and Challenges

As evidenced by the pending petition for a writ of certiorari, there are a number of open questions for practitioners and others to ponder.

First, how does one determine whether the claim is an FDCA-centric claim? It is easy if the stated cause of action is based on the FDCA or on interactions with FDA (see *Buckman*). It is also relatively easy if the claim is based on a state statute that is identical to the FDCA. (Often this is done via incorporation of the FDCA into state law.) This is the *Nexus* fact pattern.

The analysis gets more complex if the plaintiff does not directly assert FDCA-type requirements. How central must the FDCA aspects be before the § 337/*Buckman* type of limitations applies?[24]

In *Zyla*, for example, the key to the plaintiff's case is the allegation of marketing of an unapproved product—clearly an FDA question. But the actual legal claim is under a state unfair competition law. If the defendant wins the FDA approval question (the product either was, in fact, approved or did not legally require some FDA approval), the unfair competition claim does not survive. Is this connection to the FDCA so close that the limitation of FDCA enforcement to the federal government applies? The court in *Zyla* did not think so, but we are awaiting possible Supreme Court action.

Contrast this situation with the standard product liability case. In these cases, the FDCA issues are more peripheral to the case. There may be preemption issues but those are more in the nature of a defense. These cases seem to be generally outside of the § 337/*Buckman*/fraud on the FDA type of limitations (recognizing, of course, the case-specific preemption issues that might exist and provide a complete defense).

However, the question about non-federal enforcement of FDCA matters might arise in a product liability case if the plaintiff asserts a negligence per se claim based on assertions that the defendant violated some relevant and material provision of the FDCA.[25] If there has been a final determination that the defendant had, in fact, violated the FDCA, the analysis is easier. If the federal government has not made a legally binding, final determination that the defendant had, in reality, violated a relevant and material provision of the FDCA, we may be back to the situation of mere allegations of FDCA violations and the § 337/*Buckman* type of limitations become more relevant.[26]

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[24] Remember that the "jurisdiction" question—does the plaintiff have the authority or ability to pursue the claim—is related to, but not identical to, preemption issues.

[25] The existence of a negligence per se claim based on a violation of federal law is a matter of state law and there can be differences between the states.

[26] Remember that warning letters, untitled letters, 483s, etc. are not final agency actions. Likewise, guidances are not technically binding.

There are obvious concerns that permitting states or private entities to pursue enforcement of FDCA obligations undercuts the congressional policy that enforcement of FDCA obligations is the sole responsibility of the federal government. For example, an action finding that a particular product violates the laws of six to eight states, including California and Florida, may have the practical impact of being a national determination. Good lawyers likewise can usually find some non-FDCA-specific law such as an unfair competition law to assert claims otherwise falling within the FDA regulatory framework. *Zyla* is such a case. The plaintiff was upset that a competitor was (allegedly) selling a competing product without the needed FDA approval. For whatever reasons, the United States was not addressing this concern. So Zyla sues under state unfair competition law. The § 337/*Buckman* type of limitations are not deemed applicable. As a result, private parties were litigating actual FDCA questions.

The state of Texas' lawsuit against the manufacturers of Tylenol under Texas state law for allegedly false and misleading labeling is, likewise, simply a backdoor way to address specific FDCA labeling issues that FDA has declined to address.

A key issue for litigating these cases is whether a state or private entity should be able to circumvent the § 337/*Buckman* limitations on private causes of action.

Impact on Enforcement Discretion

A core justification used by courts in cases such as *Zyla* is that the federal government has limited resources (certainly true) and that the United States doesn't know about many violations of FDCA-related requirements (also true). The courts conclude that having states or private entities be able to bring enforcement actions (or suits based upon a failure to satisfy FDCA requirements) is simply a tool to fill gaps left by limited FDA/DOJ resources or knowledge.

However, the courts have not analyzed the impact on FDA policy decisions of permitting states and private entities to bring FDCA-related cases. The decision whether to bring an enforcement action is often a policy decision, not just a simple resource question. Vesting enforcement power solely in the federal government preserves the government's ability to control FDCA-related policy.

FDA has on many occasions formally set forth a policy of enforcement discretion applicable to certain matters. There are many examples of the use of enforcement discretion as a policy making tool including:

- Drug importation rules
- Software oversight (particularly wearables and general wellness products)
- Regulatory requirements during drug shortages
- Regulatory oversight of laboratory developed tests.
- Hand sanitizer oversight during COVID
- COVID diagnostic tests
- AI oversight
- Relaxed requirements for access to products treating rare diseases

- Permitting companies to continue marketing products in the face of a warning letter, asserting that the product in question is "adulterated or misbranded" and thus violative

Very recently, FDA announced that it was exercising enforcement discretion for certain aspects of labeling of color additives.

The agency sent a letter to industry providing notice of FDA's intent to exercise enforcement discretion related to these voluntary labeling claims.[27]

What should happen if a state brings an action under an FDCA state law clone seeking to enforce some color additive requirement for which FDA has announced that it will exercise enforcement discretion and not bring any action?

FDA's ability to utilize enforcement discretion is clear. In the face of efforts to mandate enforcement, courts have explicitly recognized the power of FDA to exercise such enforcement discretion. Notably, the Supreme Court in *Heckler v. Chaney*, 470 U.S. 821 (1985) recognized this inherent power. And Congress has explicitly given FDA the authority not to bring enforcement actions for "minor" violations. *See* 21 U.S.C. § 336.

Further, in § 337, Congress has given states a limited role to enforce FDCA requirements, but only after providing prior notification to FDA. One can see litigants arguing that Congress knew how to empower states (and by implication private entities) to enforce FDCA obligations when Congress so desired. As a matter of statutory interpretation, the inclusion of these specific provisions might be the exclusion of state enforcement empowerment in other contexts. [28]

While FDA may formally state that it is going to exercise enforcement discretion, these pronouncements are rarely binding. Does the fact that these pronouncements are non-binding impact these questions? Can there be preemption or a statutory bar based on non-binding FDA pronouncements?

FDA also routinely utilizes enforcement discretion in individual case determinations. These are rarely announced publicly but are important tools for FDA to advance public health and its policy decisions. Again, can a state law-based action brought by a state or private entity be used to override FDA's enforcement discretion? And how would the court and the litigants even know? Can FDA intervene to take control of the litigation?[29] These questions raise statutory authority questions, reliance questions, and preemption questions—all currently without a clear answer.

There is a gray area between some state or private action directly seeking to enforce FDCA obligations (perhaps via a state statute that incorporates the FDCA) and a cause of action such as a product liability case in which the plaintiffs' claims are based on classic state law such as a failure to warn.[30]

One can think of several different fact patterns in which this question may come up:

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[27] *FDA Takes New Approach to "No Artificial Colors" Claims*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2026), https://www.fda.gov/news-events/press-announcements/fda-takes-new-approach-no-artificial-colors-claims.

[28] One can think about analogies to the False Claims Act under which the federal government is given prior notice and the opportunity to intervene.

[29] There is precedent for authorizing the federal government to take control (often via intervention) of litigation if federal interests are involved. *See, e.g.*, the False Claims Act. *See* 31 U.S.C. § 3730.

[30] There also may be some analogies to classic drug product liability cases under a failure to warn cause of action against the pioneer drug in which the defendant asserts that it could not make the proposed label change as FDA had rejected the company's request for such a change.

- FDA has a formal, public enforcement discretion position.
- FDA has knowledge of the specific situation and has knowingly decided not to bring an action for policy reasons.
- FDA has knowledge of the specific situation and has knowingly decided not to bring an action due to resource constraints.
- FDA has no prior knowledge of the specific facts or situation.

Courts have not analyzed these different fact patterns and there may be different results for different situations.

In many cases, permitting a state or private entity to bring an enforcement action targeting conduct for which FDA has exercised enforcement discretion will undercut FDA's policy decisions. Whether and how courts will take this into account is an open question.

Summary

As demonstrated above, there are many different fact patterns presenting differing challenges to FDA's authority.

The analysis of these questions should begin with a straightforward statutory interpretation process applying known rule sets such as using the "plain meaning" of the statute, *Loper Bright*, the "Major Questions Doctrine," and past precedent. Depending on the results of the statutory interpretation process, there might be constitutional questions under the Supremacy Clause and the Interstate Commerce Clause.

Courts will also need to deal with the relationship between the state law-based cause of action to the FDCA. In some cases, this will be through a direct connection such as state statutes that incorporate the FDCA. Other cases have more attenuated connections to the FDCA. Along this spectrum, you have cases such as *Zyla* in which the conduct upon which the state case is directly based on FDCA requirements (in *Zyla* the requirement under the FDCA is to have some premarket approval). The actual cause of action, however, sounds in state unfair competition law. Further along the spectrum, one finds cases based on classic state laws such as product liability law.[31] Here, FDA's oversight role may be relevant as a defense, thus triggering preemption questions.

Courts will need to address the authority question, preemption, and, in some cases, the right of a private entity to bring suit. As part of this assessment, courts should consider the impact on FDA policy making of permitting state law-based claims to be pursued by the state or by private entities.

IMPACT

The law on state-based causes of action is clearly still evolving. The robustness of the case law varies across areas with product liability case law being the most

[31] Cases such as *Buckman* (fraud on the FDA) or cases asserting a negligence per se claim based on violations of the FDCA seem closer to the *Nexus* type of claim.

developed. Cases such as *Lohr*, *Levine*, *Mensing*, and *Reigel* provide a level of certainty. (Recognizing, of course, that there are specific factual and legal questions in each case and potential judicial and statutory changes.)

Cases such as *Zyla*, *Bubok*, and *Nexus* demonstrate that in other types of cases such certainty does not exist. Here we see some important differences between the cases. *Nexus* provides insights into situations involving state law provisions incorporating the FDCA. *Zyla* involves FDCA-centric issues (premarket approvals), but the actual cause of action is a non-FDCA-specific state law such as the California Unfair Competition Statute.

Practitioners need to be alert to these key factual and legal differences in both the underlying conduct and in the specific basis for the cause of action being asserted.

Importantly, *Zyla* also opens the door for private litigants to use FDCA-related requirements to advance commercial or policy objectives.

Until the Supreme Court (perhaps in *Zyla*) or Congress definitively resolve these questions, stakeholders and practitioners will need to consider the possible offensive use of state laws to address perceived FDCA violations not otherwise addressed by FDA. For example, companies could use state laws to challenge competitors if the plaintiff believes that the defendant's FDCA compliance (or lack thereof) has given the defendant some material competitive advantage.

States or private litigants may also consider using state law to address what they perceive to be mistaken government policy decisions or priorities. The Texas Tylenol lawsuit is such an example. These cases could seek to challenge product approvals, indications for use, warnings, or whatever.

Conversely, industry and other potential defendants need to be prepared to face state law-based claims (asserted either by the state itself or by private litigants) challenging their actions. While industry has long faced such claims in the product liability context, these new claims could directly attack the product, the company's compliance, and regulatory decisions. In the past, a company might just complain to FDA or Congress about the premarket approval (or lack thereof) of a competitor's product. Now, if *Zyla* is the law, rather than just complaining, the company could sue the competitor for its failure to have the proper premarket approval using one of a number of state law-based claims. And this risk is not limited to just premarket approval issues. Such claims could arise from alleged failures to file adverse event reports, not doing recalls, lack of proper quality systems, or conducting improper/inadequate clinical studies.

Finally, FDA should consider how it should address such cases. Will such cases undercut FDA's policy? How should FDA address such challenges? Will FDA seek to intervene in cases or seek congressional clarity?

Time will tell the development of the law in this area and its impact on stakeholders. Practitioners should be monitoring this development, considering how to best use the evolving law offensively and defensively and addressing the policy issues raised by these cases.

In re Folgers Marketing Litigation

RENE BEFURT, SAI SINDHURA GUNDAVARAPU & RIDDHIMA SHARMA*

WHY IT MADE THE LIST

Class litigation related to food labeling continues to be the focus of many lawsuits in recent years. Decisions regarding if a class should be certified in these cases often hinge on whether common issues outweigh individual issues among proposed class members. When assessing this question, courts may consider a variety of evidence, including survey evidence. In the matter discussed herein, *In re Folgers Marketing Litigation*, the district and appellate courts disagreed on whether the evidence presented by Plaintiff sufficiently demonstrated that individual issues would not outweigh common issues and that proposed class members similarly relied on the at-issue claim.[1] While the district court found that certain survey evidence presented by Plaintiff's experts demonstrated evidence of common traits and harm among proposed class members, the appellate court took a different stance and overturned the district court's decision to certify the proposed class.[2]

The appellate court's decision to overturn the class certification ruling stated that Plaintiff "had to prove a causal connection between the deceptive act and a harm they suffered."[3] The court emphasized that "for many people in [the] proposed class, the representations on the containers would not have caused them any ascertainable loss," as "a significant proportion of the proposed class did not read those representations or, if they did, did not care about them one way or the other."[4] In its decision, the appellate

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[1] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification); Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830 (8th Cir. Nov. 26, 2025) (Opinion).

[2] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 10 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification); Sorin v. Folger Coffee Co. (*In re Folger* Coffee Marketing), No. 24-2830 (8th Cir. Nov. 26, 2025) (Opinion).

[3] Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830, at 4 (8th Cir. Nov. 26, 2025) (Opinion). (citing *In re* St. Jude Med., Inc., 522 F.3d 836, 838 (8th Cir. 2008) and Owen v. Gen. Motors Corp., 533 F.3d 913, 922 (8th Cir. 2008)).

[4] *Id.* at 4.

court highlighted deposition testimony as evidence that individual inquiry would be necessary, and a class should therefore not be certified.[5] Additionally, the appellate court dismissed Plaintiff's arguments that "every member of the class suffered an ascertainable loss," regardless of their reliance on the representations, because "the representations thus spurred increased demand," resulting in all consumers of the products paying higher prices than they would have otherwise.[6] While the district court pointed to survey evidence offered by Plaintiff as evidence supportive of class certification, the appellate court did not reach the same conclusion.[7] The district and appellate courts' opinions in this matter highlight the role that certain evidence, including survey and deposition evidence, can play in demonstrating whether or not common issues outweigh individual issues among proposed class members and influence courts' decision to certify a class.

DISCUSSION

Procedural Background and Ruling of the District Court

In February 2023, Plaintiffs Shelley Ashton, Ellen Moser, Geoff Thomson, Federick Tan, Marcia Sorin, A. Kevin Fahey, Mark Smith, and Trina Green filed a Third Amended Complaint in a class action lawsuit against The J.M. Smucker Company and The Folger Coffee Company relating to Folgers ground coffee products.[8] Plaintiffs alleged that representations that each of the Folgers ground coffee products "MAKES UP TO" a certain quantity of coffee were deceptive because the products "do not produce the number of cups claimed when one follows the brewing instructions provided on the back label."[9]

Plaintiffs further stated that they "and other consumers purchased the Products relying on Defendants' serving amount representations on the Products' packaging" and alleged "that the Products' labeling vastly overstates the number of cups of coffee they are able to make."[10] Plaintiffs also argued that "a reasonable consumer cannot measure or calculate how many servings the Products can make. Nor are reasonable consumers expected to keep track of the precise number of cups of coffee they make over a period of time."[11] Based on these allegations, Plaintiffs claimed they "would have paid significantly less for the Products, or would not have purchased them at all."[12]

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[5] *Id.* at 5.

[6] *Id.* at 5.

[7] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 9–10 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification); Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830, at 5 (8th Cir. Nov. 26, 2025) (Opinion).

[8] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 1 (W.D. Mis. Feb. 27, 2023) (Dkt. 240, Third Amended Consolidated Class Action Complaint).

[9] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 3 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification).

[10] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 18 (W.D. Mis. Feb. 27, 2023) (Dkt. 240, Third Amended Consolidated Class Action Complaint).

[11] *Id.* at 18.

[12] *Id.* at 19.

Plaintiffs filed "a suggestion in support of their motion for class certification" in March 2023.[13] Folgers filed an opposition to Plaintiffs' motion for class certification in July 2023.[14] Plaintiffs sought certification of six statewide classes, but the district court opted to evaluate issues specifically related to the Missouri class first.[15] Plaintiff Mark Smith filed a supplemental brief in support of his motion for class certification for the Missouri class in January 2024.[16] Folgers filed a response to Plaintiff's supplemental brief in early February 2024.[17] Plaintiff filed a supplemental reply brief in support of his motion for class certification in late February 2024.[18]

In July 2024, the district court sided with Plaintiff and granted Plaintiff's motion for class certification for the Missouri class.[19] The court ruled that, "with respect to Missouri Class members, the injury alleged is—at the least—substantially similar" and that "[t]he fact that *some* class members did not care about or were not deceived by the misrepresentation is better addressed in the context of the merits of the claim. (emphasis added)."[20] In its opinion, the court highlighted evidence offered by Plaintiff's experts, Dr. J. Michael Dennis and Dr. Samantha Iyengar.[21] According to the district court, Dr. Dennis' consumer perception survey supported Plaintiff's theory that "consumers believe the Up To Claim will be met under both the Single-Serving [brewing] Method and the Pot [brewing] Method."[22] With respect to Dr. Iyengar's choice-based conjoint survey, the court determined that the study "provide[d] common evidence on the question of whether the inflated Up To Claim impacted a consumer's decision to purchase a Product."[23] The court emphasized that "the Up To Claim was contained on the front of all Products" and that Dr. Iyengar's survey found that "the inflated Up To Claim 'had a significant and positive impact on consumers' preferences."[24]

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[13] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 1 (W.D. Mis. Mar. 22, 2023) (Dkt. 301, Suggestions in Support of Plaintiffs' Motion for Class Certification).

[14] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP (W.D. Mis. Jul. 17, 2023) (Dkt. 316 Defendants' Suggestions in Opposition to Plaintiffs' Motion for Class Certification).

[15] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 3 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification).

[16] *In re* Folgers Coffee Marketing Litigation, No. 21-MD-02984-BP (W.D. Mis. Jan. 26, 2024) (Dkt. 395 Plaintiffs' Supplemental Brief Pursuant to ECF No. 391).

[17] *In re* Folgers Coffee Marketing Litigation, No. 21-MD-02984-MD-C-BP (W.D. Mis. Feb. 9, 2024) (Dkt. 404 Defendants' Response to Plaintiffs' Supplemental Brief Pursuant to Doc. 391).

[18] *In re* Folgers Coffee Marketing Litigation, No. 21-MD-02984-BP (W.D. Mis. Feb. 23, 2024) (Dkt. 406 Plaintiffs' Supplemental Reply Brief Pursuant to ECF No. 391).

[19] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 2 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification).

[20] *Id.* at 5, 6.

[21] *Id.* at 9–10.

[22] *Id.* at 10.

[23] *Id.* at 10.

[24] *Id.* at 11.

Ruling and Reasoning of the Appellate Court

Folgers appealed the district court's decision to certify the class at the U.S. Court of Appeals for the Eighth Circuit.[25] In November 2025, the appellate court reversed the district court's decision and reversed certification of the class.[26] In its opinion, the appellate court noted that "fraud cases are typically unsuitable for class treatment [. . .] because the proof required in such cases often varies with respect to what representations consumers received and whether those consumers relied on those representations."[27] The court found that, "for many people in [the] proposed class, the representations on the containers would not have caused them any ascertainable loss" as "a significant proportion of the proposed class did not read those representations or, if they did, did not care about them one way or the other."[28] Notably, neither of Plaintiff's survey experts offered surveys that employed an experimental design that could have assessed proposed class members' reliance on the at-issue claim.[29] The court went on to state that "[w]hat matters is that many class members weren't deceived, and figuring out who was and who wasn't will require consumer-by-consumer inquiries into each class member's individual tastes, interpretations, and circumstances."[30]

In forming its judgment, the court also addressed Plaintiff's argument concerning consumer's reliance on the product label. Counsel for Plaintiffs stated that "'[Missouri's Merchandising Practices Act (MMPA)] does not require individualized proof of reliance in order to state a claim,' and since all containers of the relevant Folgers products included the representations, individualized showings are unnecessary." However, the court referenced *In re St. Jude Med., Inc.* to emphasize that Plaintiffs "had to prove a causal connection between the deceptive act and a harm they suffered," and further referenced *Owen v. Gen. Motors* to note that "'there is no denying that causation is a necessary element of an MMPA claim.'"[31] The surveys offered by Plaintiff's experts did not employ an experimental design that would have isolated the causal impact of the at-issue claim on proposed class members' purchasing decisions.[32]

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[25] *In re* Folgers Coffee Marketing Litigation, No. 24-2830 (8th Cir. Dec. 3, 2024) (Brief of Appellants The J.M. Smucker Company and The Folger Coffee Company); *In re* Folgers Coffee Marketing Litigation, No. 24-2830 (8th Cir. Feb. 6, 2025) (Brief of Appellees); *In re* Folgers Coffee Marketing Litigation, No. 24-2830 (8th Cir. Mar. 31, 2025) (Reply Brief of Appellants The J.M. Smucker Company and The Folger Coffee Company).

[26] Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830 (8th Cir. Nov. 26, 2025) (Opinion).

[27] *Id.* at 3 (citing *In re* St. Jude Med., Inc., 522 F.3d 836, 838 (8th Cir. 2008)).

[28] *Id.* at 4.

[29] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Declaration and Expert Report of J. Michael Dennis, Ph.D); *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Expert Report of Samantha Iyengar, Ph.D.).

[30] *Id.* at 4–5.

[31] *Id.* at 4 (citing *In re* St. Jude Med., Inc., 522 F.3d 836, 838 (8th Cir. 2008) and Owen v. Gen. Motors Corp., 533 F.3d 913, 922 (8th Cir. 2008)).

[32] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Declaration and Expert Report of J. Michael Dennis, Ph.D); *In re* Folgers Coffee Marketing

Weighing both sides' arguments, the court ultimately pointed to consumer evidence rooted in the testimony of proposed class representatives, who indicated on the record that the at-issue "MAKES UP TO" claim did not impact their purchasing decisions.[33] In its opinion, the court highlighted one example in which a proposed class representative explained why she continued to purchase the at-issue products even after she had sued Folgers, stating concisely: "I like my coffee."[34] Last but not least, the court addressed Plaintiff's price premium argument and reacted to Plaintiff's expert's theory that, "[t]o the extent that the alleged misconduct in this case artificially inflated market demand, then each consumer who purchased a Contested Product paid a higher price."[35] The court expressed that it rejected the notion that, "because some buyers did not receive the benefit of the bargain, all buyers should have paid less," as this approach "would allow those who suffered no ascertainable loss from Folgers' representations to piggyback on the injuries of others to pursue a remedy."[36]

IMPACT

Both the district and appellate courts focused on the relationship between common and individual questions in assessing whether the class should be certified in this matter.[37] But, notably, the courts reached different conclusions as to whether questions affecting only individual proposed class members overwhelmed questions common to the proposed class and whether class certification would be appropriate. While the district court's opinion appeared to accept the survey evidence offered by Plaintiff's experts as evidence of a common theory of harm, the appellate court seemed to find this evidence unconvincing and lacking a causal nexus. Instead of the provided survey evidence, the court considered statements from Named Plaintiff Depositions pertaining to reasons behind purchases, as well as comments regarding whether consumers paid attention to or relied on the allegedly misleading statements when considering their purchase.[38]

We agree that the survey evidence offered by Plaintiff's experts did not establish that proposed class members similarly relied on the at-issue "MAKES UP TO" claim when considering their ground coffee purchase. Specifically, the survey evidence offered did not establish that consumers would have made different purchasing decisions in a but-for world where the allegedly misleading claim was not present or otherwise amended on the packaging. At most, the surveys offered by Plaintiff's experts provide some evidence that (1) some consumers may perceive the "MAKES

Litigation, No. 21-2984-MD-C-BP (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Expert Report of Samantha Iyengar, Ph.D.).

[33] *Id.* at 5.

[34] *Id.* at 5., referencing Hudock v. LG Elecs. U.S.A., Inc., 12 F.4th 773, 777 (8th Cir. 2021).

[35] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP, at 21 (W.D. Mis. Mar. 22, 2023) (Dkt. 262 Expert report of Daniel P. Werner, Ph.D., CPA).

[36] *Id.* at 5 (citing Johannessohn v. Polaris Indus. Inc., 9 F.4th 981, 987–88 (8th Cir. 2021)).

[37] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification); Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830 (8th Cir. Nov. 26, 2025) (Opinion).

[38] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 9-10 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification); Sorin v. Folger Coffee Co. (*In re Folger* Coffee Marketing), No. 24-2830, at 5 (8th Cir. Nov. 26, 2025) (Opinion).

UP TO" claim to imply that both brewing methods will make the same total number of cups of coffee, and (2) consumers are more likely to select products with more servings than fewer servings, all else equal.[39] Notably, the "materiality" survey offered by Dr. Dennis, which was not referenced in either the district or appellate court opinions, utilized a flawed "referendum" approach that did not reflect a real-world purchasing scenario or account for other factors that may have influenced consumers' purchasing decisions outside of the at-issue claim.[40] While the district court declined to exclude Dr. Dennis' testimony, the court did state that, compared to Dr. Dennis's approach, "the materiality inquiry is more nuanced, and [Named Plaintiff] Smith will need additional proof to prevail."[41]

In addition to discounting the survey evidence provided by the Plaintiff, the appellate court's opinion sheds light on the appellate court's willingness (or lack thereof) to accept arguments that all consumers, regardless of reliance on at-issue representations, could be damaged by them. The appellate court appeared reluctant to accept any claims of class-wide harm on the basis that the alleged deceptive representation enabled Folgers to command a market price higher than they would have otherwise, causing all consumers to pay more for the product than they would have in a but-for world.[42] The appellate court's dismissal of this "price-premium" theory emphasizes once again the court's expectation that Plaintiff must establish a clear, common relationship between consumers' exposure to, perceptions of, and reliance on the allegedly misleading claim and the alleged harm.

Does the Allegedly Deceptive Representation Impact Proposed Class Members' Purchasing Decisions Similarly?

An initial consideration for the courts was determining whether proposed class members were similarly exposed to the allegedly deceptive representations. In its order, the district court noted that "Defendants' Up To Claim appeared on each Product and differed only in the quantity of servings it represented [. . .] providing evidence the Missouri Class members were exposed to the Up To Claim."[43] While the appellate court acknowledged that proposed class members were similarly exposed to the allegedly deceptive representations, it found this evidence insufficient and, referencing *In re St. Jude Med., Inc.*, asserted that, even with similar exposure, it was

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[39] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Declaration and Expert Report of J. Michael Dennis, Ph.D); *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Expert Report of Samantha Iyengar, Ph.D.).

[40] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP, at 16-19 (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Declaration and Expert Report of J. Michael Dennis, Ph.D).

[41] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 9 (W.D. Mis. Jul. 31, 2024) (Dkt. 428 Order Denying Defendants' Motions to Exclude or Strike Opinions Offered by Dr. J. Michael Dennis).

[42] Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830, at 5 (8th Cir. Nov. 26, 2025) (Opinion).

[43] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 9 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification).

still necessary for Plaintiff "to prove a causal connection between the deceptive act and a harm they suffered."[44]

On the question of causality, the district court found that Plaintiff offered "common evidence on both the nature of the misrepresentation and the impact the misrepresentation had on consumers' purchasing decisions."[45] The district court referenced Plaintiff's experts' survey evidence, particularly a choice-based conjoint survey offered by Plaintiff's expert Dr. Iyengar to support this finding.[46] Dr. Iyengar's survey measured consumers' preference for ground coffee products that contain more versus fewer than six fluid ounce servings relative to five other product attributes, all else equal.[47] Dr. Iyengar's survey does not examine whether the at-issue claim impacted consumers' decisions to purchase the at-issue products or investigate proposed class members' purchase drivers related to the at-issue products.[48] To answer these questions, the appellate court relied on deposition testimony offered by Named Plaintiffs in the other statewide classes. Specifically, the appellate court cited testimony from Plaintiffs in the other statewide classes who indicated on the record that the at-issue "MAKES UP TO" claim did not impact their purchasing decisions.[49] The appellate court's elevation of deposition testimony in its decision highlights the influence that "real-world" testimony and data can have on the question of common versus individual issues. The appellate court's decision is a reminder that the choice of survey, and the specific questions a survey seeks to address, can be crucial for either side's success in making an argument. Here, surveys that directly addressed the question of causality—that is, whether proposed class members noticed, processed, and relied on the allegedly misleading information when considering a purchase of the at-issue products—and an investigation into consumers' purchase drivers could have helped the court to understand consumer behavior in this matter.

Overall, this case presents an interesting insight into the facets that drive consumer decision-making, including the extent to which consumers pay attention to, process, and rely on certain packaging information. In answering each of these questions, a researcher may consider the extent to which consumers may vary in any or all of these aspects.

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[44] Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830, at 4 (8th Cir. Nov. 26, 2025) (Opinion) (citing *In re* St. Jude Med., Inc., 522 F.3d 836, 838 (8th Cir. 2008)).

[45] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-W-BP, at 11 (W.D. Mis. Jul. 31, 2024) (Order Granting in Part Plaintiffs' Motion for Class Certification).

[46] *Id.* at 10.

[47] *In re* Folgers Coffee Marketing Litigation, No. 21-2984-MD-C-BP (W.D. Mis. Mar. 22, 2023) (Dkt. 259 Expert Report of Samantha Iyengar, Ph.D.).

[48] *Id.*

[49] Sorin v. Folger Coffee Co. (*In re* Folger Coffee Marketing), No. 24-2830, at 5 (8th Cir. Nov. 26, 2025) (Opinion).

Novartis Pharms. Corp. v. Kennedy

SARA W. KOBLITZ & ANNE K. WALSH*

WHY THIS CASE MADE THE LIST

FDA has long permitted Abbreviated New Drug Application (ANDA) applicants to "carve-out" patent-protected uses from product labeling, resulting in differences between the Reference Listed Drug (RLD) and the ANDA, but *Novartis v. Kennedy* explores what happens when an ANDA sponsor attempts to ***add*** language to its labeling.[1] This is significant because the statute only speaks to the "omission" of language from labeling, without reference to a potential addition of language, leaving to the courts to decide whether any deviation from the original labeling is appropriate. In one of the first cases on appeal challenging FDA's authority under the Administrative Procedure Act (APA) since the landmark decision in *Loper Bright v. Raimondo*,[2] the D.C. Circuit deferred to FDA's scientific expertise in this case, showing that deference to Agency interpretation is not dead.

DISCUSSION

Legal Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), initially enacted in 1938, FDA has the statutory authority to oversee the safety of food, drugs, medical devices, and cosmetics.[3] To do so, the FDCA since 1962 has required FDA to review and approve all new drugs for safety and efficacy prior to introduction into interstate commerce.[4] FDA authorizes the sale of new drugs through a New Drug Application (NDA), which requires the submission of clinical trial data establishing the proposed new drug's safety and efficacy for its intended use under the conditions of its proposed labeling.[5]

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1 Novartis Pharms. Corp. v. Kennedy, 156 F.4th 626, 629 (D.C. Cir. 2025).

2 Administrative Procedure Act, Pub. L. 79–404, 60 Stat. 237 (1946); Loper Bright Enters. v. Raimondo, 603 U.S. 369 (2024).

3 Kefauver Harris Drug Amendments Act of 1962, Pub. L. No. 87–781, 76 Stat. 780 (1962); Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75–717, 52 Stat. 1040 (1938).

4 *See* 21 U.S.C. § 355.

5 *Id.*

When a drug is approved, the FDCA requires the drug's sponsor to file with FDA "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug . . . ."[6] The statute then obligates FDA to "publish" a list of all such patent data,[7] which it does in FDA's Orange Book.

The FDCA also provides an "abbreviated" pathway to market for "follow-on" or generic versions of previously approved drug products. Specifically, the FDCA authorizes FDA to approve an ANDA if a sponsor demonstrates that the proposed generic drug contains the same active ingredient(s) in the same dosage form, using the same route of administration, in identical strength or concentration, and is bioequivalent to the previously approved drug that FDA already has found to be safe and effective for its intended use, called the reference listed drug (RLD).[8] In other words, an ANDA must be "pharmaceutically equivalent" and "therapeutically equivalent" to its RLD. "Pharmaceutical[ly] equivalent" drugs contain identical amounts of the identical active drug ingredients, defined for these purposes as "the same salt or ester of the same therapeutic moiety."[9] The therapeutic or "active moiety" is "the molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance."[10] "Therapeutic equivalents" are bioequivalent pharmaceutical equivalents that "can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling."[11]

Typically, ANDAs must have the same labeling as the RLD.[12] However, the statute allows "changes required . . . because the new drug and the listed drug are produced or distributed by different manufacturers."[13] Such changes include "omission of an indication or other aspect of labeling protected by patent."[14] Those changes may not "render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use."[15]

ANDA applicants may duplicate the RLD, but not without addressing the patents listed in the Orange Book for the RLD it is referencing.[16] Indeed, an ANDA applicant may rely on FDA's findings of safety or efficacy for an approved product as long as the ANDA applicant certifies to such patents in one of the following ways:

(i) the required patent information has not been filed;

(ii) the listed patent has expired;

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6 21 U.S.C. § 355(b)(1)(viii); *see also* 21 C.F.R. § 314.50(h).

7 21 U.S.C. § 355(j)(7)(A)(i)-(iii); *see also id*. § 355(c)(2).

8 *Id*. § 355(j)(2)(A).

9 21 C.F.R. § 314.3(b).

10 *Id*.

11 *Id.*

12 21 U.S.C. § 355(j)(2)(A)(v).

13 *Id.*

14 21 C.F.R. § 314.94(a)(8)(iv)

15 *Id.* § 314.127(a)(7).

16 21 U.S.C. § 355(b)(2)(A); *id.* § 355(j)(2)(A)(vii).

> (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or
>
> (iv) the listed patent is invalid or will not be infringed by the new product.

If a Paragraph IV certification is selected (i.e., the applicant asserts that the RLD patent is invalid or will not be infringed), the ANDA applicant must provide notice of the application and patent certification to the RLD holder within 45 days so that the RLD holder has the opportunity to bring patent litigation prior to the approval of the application.[17] If such an infringement suit is filed during the requisite timeline, approval of that ANDA is stayed for 30 months as the patent litigation is resolved.[18]

Importantly, however, not all patents listed in the Orange Book require a certification. "Method of use" patents might instead trigger a "section viii statement," which informs FDA that the proposed ANDA does not seek approval for the use covered by a listed method-of-use patent, as detailed in the "use code" selected by the RLD sponsor.[19] In that situation, the ANDA applicant "carves-out" from its product labeling the language that the NDA sponsor lists in the "use code" for that patent, resulting in labeling for the RLD and the ANDA that are not identical. An applicant adding language to its labeling to effectuate a carve-out, however, is not anticipated by the statute or implementing regulations.

Factual Background

Novartis' Entresto (sacubitril; valsartan), marketed since July 2015, "contains a complex comprised of anionic forms of sacubitril and valsartan, sodium cations, and water molecules."[20] At approval, Entresto was indicated "to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction."[21] Novartis performed additional studies with Entresto, which resulted in updates to the product labeling. In 2019, for example, Novartis added to the labeling a modified dosing regimen for patients not taking angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin II receptor blockers (ARBs).[22] Further, Novartis performed studies in patients with preserved ejection fractions, and in 2021 received approval for chronic heart failure more generally.[23] Specifically, the indication statement for Entresto was updated to read: "ENTRESTO is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal."[24]

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[17] *Id.* § 355(c)(3)(C); *id.* § 355(j)(5)(B)(iii).

[18] *Id.*

[19] 21 U.S.C. § 355(b)(2)(B), (j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii); 21 C.F.R. § 314.53(f)(1)(i)(B).

[20] *Novartis*, 156 F.4th at 628.

[21] Entresto (sacubitril; valsartan), NDA 207620, Prescribing Information § 1 (July 2015).

[22] Entresto (sacubitril; valsartan), NDA 207620/S-013, Prescribing Information § 1 (Oct. 2019).

[23] *Novartis*, 156 F.4th at 629.

[24] Entresto (sacubitril; valsartan), NDA 207620/S-018, Prescribing Information § 1 (Feb. 2021).

At approval and with each of these changes, Novartis listed patents in the Orange Book, including a formulation patent and five method-of-use patents.[25] These method-of-use patents were associated with two use codes relevant here: "treatment of heart failure with preserved ejection fraction" and "treating chronic heart failure with reduced ejection fraction in patients not taking an ACE inhibitor or an ARB or previously taking low doses of these agents, by titrating up from half the usually recommended starting dose."[26]

By 2019, Entresto had attracted generic competition. In July 2018, 18 sponsors submitted ANDAs to FDA seeking approval to market a generic version of Entresto. Those filers included MSN Pharmaceuticals, whose proposed label omitted Novartis' patented dosing regimen for patients not taking ACE inhibitors or ARBs and chronic heart failure in patients with preserved ejection fraction.[27] Further, the MSN product also stated that the generic drug "contains anionic forms of sacubitril and valsartan, and sodium cations"—omitting the complex including water molecules.[28]

Novartis, however, filed a Citizen Petition in 2019 asking FDA to require any generic version of Entresto to use the same chemical structure as Entresto, and a second Petition in 2022 requesting that FDA refuse to approve "any generic version of Entresto carving out its patented uses from the label."[29] Novartis argued that "carving out the modified dosage for patients not taking ACE inhibitors or ARBs would . . . render the generic version less safe and effective than Entresto" and that "carving out use of Entresto to treat patients with a preserved ejection fraction would require impermissibly adding words to Entresto's existing label."[30] FDA denied both petitions and approved MSN's ANDA in 2024.[31]

Lower Court Decision

Novartis immediately filed suit in the U.S. District Court for the District of Columbia against FDA seeking to set aside the petition denials and the approval of the MSN ANDA.[32] Novartis argued that FDA's approval of the MSN ANDA and denial of the Novartis petitions violated the APA, the FDCA, and the agency's implementing regulations.[33] After cross-motions for summary judgment, the District Court found that "MSN's generic drug is consistent with FDA regulatory and statutory requirements that require a generic drug to have the same label and active ingredients as the reference drug" and that "FDA did not act arbitrarily by excluding part of Entresto's dosing regimen from MSN's generic drug label."[34] Specifically, the court explained, "[i]t cannot be said that the agency applied the wrong standard, inadequately explained

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[25] *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, at ADA 383-84 (U.S. Dept. of Health and Human Servs., 45th ed. 2025).

[26] *Id.* at ADB 182, 186.

[27] *Novartis*, at 156 F.4th at 629.

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*; Novartis Pharms. Corp. v. Becerra, No. 24-cv-02234, 2024 U.S. Dist. LEXIS 186818 (D.D.C. Oct. 15, 2024).

[33] *Novartis*, 2024 U.S. Dist. LEXIS 186818 at *1.

[34] *Id.* at *19.

its decision, or rendered 'a clear error of judgment.'"[35] And "FDA's determination on chemical identity sameness reflects its reasoned 'scientific analysis,' which deserves 'a high level of deference.'"[36] Novartis appealed.

Appellate Court Decision

On appeal, Novartis made two main arguments: that the MSN generic labeling "impermissibly deviates from the Entresto label," and that FDA erred when it concluded that MSN's generic had the same active ingredients as Entresto.[37]

Turning first to the labeling, the D.C. Circuit Court of Appeals explored the differences between the Novartis and MSN labeling. After explaining that the FDCA "permits 'changes required . . . because the new drug and the listed drug are produced or distributed by different manufacturers,'" like MSN made here to avoid Novartis' patents, the court took each labeling difference in turn.[38] First, the court looked at the omission of the modified dosing regimen for patients not taking ACE inhibitors or ARBs.[39] While Novartis claimed that the omission rendered the generic version "less safe or effective" than Entresto in violation of FDA's implementing regulations, the court deferred to FDA's "expertise in evaluating the clinical significance of drug studies," which it would not "lightly second-guess."[40] Because FDA's interpretation of the titration study Novartis used to add the modified dosing regimen to the labeling never changed—FDA was always skeptical—and because FDA's initial finding that Entresto is safe and effective with the modified dosing regimen does not foreclose an interpretation that the generic is not less safe or effective without that dosing regimen, the court rejected Novartis's allegation that FDA impermissibly changed its position without explanation.[41]

Next, the court looked at the indication differences adopted to avoid Novartis's method-of-use patent covering the treatment of heart failure in patients with a preserved ejection fraction. The Entresto label states that the drug "is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal."[42] The MSN label, on the other hand, stated that the drug is "indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure and reduced ejection fraction."[43] Though Novartis contended that the MSN indication "impermissibly tracks the original, superseded Entresto label," which was indicated only for patients with a reduced ejection fraction, the court found that FDA "plainly

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[35] *Id.* at *31 (citing Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

[36] *Id.* at *34 (citing Pharm. Mfg. Rsch. Servs., Inc. v. FDA, 446 U.S. App. D.C. 362, 370 (2020)).

[37] *Novartis*, 156 F.4th at 629.

[38] *Id.* at 630.

[39] *Id.*

[40] *Id.*

[41] *Id.* at 630–31.

[42] *Id.* at 631.

[43] *Id.*

compared it to Entresto's current label."[44] "[I]t is entirely unsurprising that the label for a generic drug would resemble a superseded version of the label," said the court, as it "reflects the intended operation of a scheme that permits the generic's label to contain changes required because the brand-name drug and the generic equivalent are sold 'by different manufacturers'" and "'omit[] . . . an indication . . . protected by patent.'"[45]

Novartis also contended that the addition of words to labeling contradicted FDA's regulations, which allow for only omissions.[46] The court found that that argument puts form over substance. The regulation allows for the omission "of an indication," and the addition of words allowed MSN to omit that indication.[47]

The court next turned to the question of active ingredients sameness. Novartis argued that its product is in a "complex" and a co-crystal while MSN's is not and therefore the active ingredients differ.[48] The court rejected this argument too, explaining that "longstanding FDA regulations and guidance make clear that drugs can have the same active ingredients even if they have different solid-state physical forms or crystal structures."[49] Further, FDA had examined the science and determined that the structure has nothing to do with the product's chemical composition or pharmacological effects. There was, in other words, "no reason to question the FDA's expert judgment . . . ."[50]

IMPACT OF THE DECISION

While the direct impact of this case is fairly limited—it applies in the narrow circumstance in which an ANDA differs from its RLD—this case is significant as a reaffirmation of FDA's scientific authority after the landmark *Loper Bright* case.[51] In *Loper Bright*, the Supreme Court commanded that the courts—not a federal agency—interpret ambiguous statutes, stripping an agency of some of its deference authority.[52] Indeed, after *Loper Bright*, judges now consider—but not necessarily defer to—agency interpretations of their governing statutes. While this case did not directly address *Loper Bright* because neither party argued that this was a case of statutory interpretation, it shows that the absence of broad deference does not inherently doom an agency's position.

In *Novartis v. Kennedy*, the D.C. Circuit unambiguously deferred to FDA's expertise, noting that the case "gives us no reason to question the FDA's expert judgment regarding these scientific issues."[53] This quells fears that courts will substitute their own judgment for an agency's. Even after *Loper Bright*, courts will

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[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *Id.; see also* 21 C.F.R. § 314.94(a)(8)(iv).

[48] *Id.* at 632.

[49] *Id.*

[50] *Id.*

[51] *Loper Bright*, 603 U.S. 369.

[52] *Id.* at 398.

[53] *Novartis*, 156 F.4th at 632.

continue to defer to FDA on matters of science, as the D.C. Circuit did here, recognizing the agency's decades of experience interpreting the relevant active ingredient and the safety and effectiveness of a product after certain changes to labeling.

Also, an important aspect of this case is its preservation of the "chubby label." Legal challenges to "omissions" from labeling—the carve-out—are not new.[54] There has been an increase in the assertion that carve-outs induce infringement, arguing that ANDA manufacturers induce infringement by promoting their carved-out generics as AB-rated or therapeutically-equivalent to the fully-labeled RLDs. The same argument could be made of "chubby labels," where language is added to avoid a patent. But, largely because of the way the case was argued, the D.C. Circuit addressed this from a purely FDA regulatory standpoint, allowing the chubby label to escape the intellectual property-based arguments that may undermine the skinny label's existence.

Another interesting and important aspect of this decision is the reasoning the court gave behind permitting the carve-in. Though the statute is clear that "omissions" are permissible, there is no such language that supports the addition of wording to labeling in order to facilitate that omission. The court had no patience for an argument that puts form over substance. As the court explained, the label may add four words, "but does so to eliminate the patent-protected use of the drug to treat patients with a preserved ejection fraction," which is precisely "how this scheme is supposed to work; an ANDA applicant may 'propose labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use.'"[55]

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[54] *See, e.g.*, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1327 (Fed. Cir. 2021); Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 104 F.4th 1370 (Fed. Cir. 2024).

[55] *Novartis*, 156 F.4th at 631 (citing Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 406 (2012)).

Wulferic, LLC v. FDA

REBECCA JONES MCKNIGHT, DAVID BENDER & LILY BARRETT*

I. WHY IT MADE THE LIST

In 2025, a Texas federal court found in *Wulferic, LLC v. FDA* that the Seventh Amendment right to a jury trial applied to civil money penalties (CMPs) assessed on an FDA-regulated product under the Family Smoking Prevention and Tobacco Control Act (TCA).[1]

Wulferic is noteworthy to a broader audience of FDA-regulated companies as the court, citing the Supreme Court's decision in *SEC v. Jarkesy*, 603 U.S. 109 (2024), analyzed the Seventh Amendment question by opining on the nature of the CMP action sought to be taken by FDA through administrative means, as well as the "public rights" exception in the context of health-related legal and regulatory regimes.

As of this publication, FDA's appeal to the United States Court of Appeals for the Fifth Circuit and additional tobacco-related cases are pending. But regardless of those outcomes, *Wulferic* showcases the after-effects of *Jarkesy* and more broadly the post-*Chevron*[2] environment following *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

Since their issuance, the Supreme Court's decisions in *Loper Bright* and *Jarkesy* have been widely viewed as curbing the roles of administrative agencies, prompting many FDA stakeholders to express concerns that judges would be thrust into rendering decisions without the benefit of the scientific, medical, or other relevant technical

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The authors would also like to thank Matthew Loughran, a health policy analyst at Reed Smith, for his analysis of the legislative history of CMP provisions in the FDA context.

[1] Wulferic, LLC v. U.S. FDA, 793 F. Supp. 3d 830, 835 (N.D. Tex. 2025), *appeal docketed*, No. 25-11112 (5th Cir. Oct. 3, 2025).

[2] Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984).

expertise held by those within FDA. Significant personnel changes at FDA in 2025 may, however, cause stakeholders to consider a different perspective.[3]

Wulferic highlights a time in our history when even those who have traditionally viewed health-related administrative agencies as relatively neutral, science-based safeguards to the public may be more sensitized to the potential for selective agency enforcement or overreach.

II. DISCUSSION

A. Tobacco Civil Money Penalties Under the FDCA

FDA initiated its CMP administrative action against Vapor Lab under its regulations at 21 C.F.R. Part 17, which draw their statutory authority from 21 U.S.C. § 333. Notably, there is variation in the precise statutory provisions applicable across product types and compliance areas, a point to which we will return in our discussion of the impact of *Wulferic.*

The administrative action against Vapor Lab was grounded in the statutory langauge of the Federal Food, Drug, and Cosmetic Act (FDCA) codified in 21 U.S.C. § 333(f)(9). Congress has introduced CMPs under Section 333 for a range of FDA-regulated products and compliance areas since 1988.[4] Some CMPs codified elsewhere in Title 21 predate that section. The CMPs that FDA asserts are subject to administrative proceedings are listed in 21 C.F.R. § 17.1 and summarized below.

Statutory Provision	Topic	Year Enacted
21 U.S.C. § 360pp(b)(1)	Electronic Products	1968
42 U.S.C. § 262(d)(2)	Biologic Recall Orders	1986 (amended 1997)
42 U.S.C. § 300aa–28(b)(1)	Vaccine Manufacturer Records	1986
21 U.S.C. §§ 333(b)(2) and (b)(3)	Prescription Drug Marketing	1988
21 U.S.C. § 333(f)(1)	Medical Devices	1990
21 U.S.C. § 335b	Abbreviated New Drug Application-Related and Debarment-Related Conduct	1992
42 U.S.C. § 263b(h)(3)	Mammography Facility Certificate and Standards	1992 (amended 1998)
21 U.S.C. §§ 333(f)(3) and (f)(4)	Clinicaltrials.gov Registry and Reporting	2007
21 U.S.C. § 333(g)(1)	Direct-to-Consumer Ads for Approved Drugs and Biologics	2007

[3] Lizzy Lawrence, *3 Key Issues to Watch at FDA as Makary Struggles to Stabilize the Agency*, STAT (Dec. 22, 2025), https://www.statnews.com/2025/12/22/fda-2026-outlook-commissioner-makary-future-vaccine-policy-deregulation/ (highlighting "personnel turmoil" at FDA).

[4] 21 U.S.C. §§ 333(b)(2), 333(b)(3).

21 U.S.C. §§ 333(f)(5) and (f)(9)	Tobacco Products (under TCA)	2009

Congress added tobacco products in 2009. In doing so, concurrent with the addition it made at (f)(9) of § 333 (Enhanced Penalties), Congress added a cross-reference in the earlier general CMP portion—(f)(5)(A)—which provides in part: "civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order [present at (f)(8)]."[5]

Senator Mike Enzi (R-WA) added the Enhanced Penalties provision in (f)(9) for violations of the TCA by amendment when the law was in the Senate Health, Education, Labor and Pensions (HELP) Committee. Senator Enzi has stated: "I am pleased I was able to add a measure to the bill that increased civil penalties for violations of the new law and sends a strong message that we are serious about expecting compliance from the tobacco industry."[6] Senator Chris Dodd (D-CT), a key supporter of the legislation, also referenced the stronger penalties in the bill when the it was introduced.

B. Background on the Wulferic Case

In *Wulferic*, the plaintiff was a manufacturer and seller of tobacco products (specifically, e-liquids for use with electronic nicotine delivery systems (ENDS)), doing business as "Vapor Lab."[7] Since the enactment of the TCA in 2009, companies such as Vapor Lab have been subject to a requirement for authorization by FDA prior to sale of their products.[8] With amendments included as part of that legislation, alleged "adulteration" and "misbranding" due to the lack of such authorization could subject companies to CMPs under 21 U.S.C. § 333.[9] The TCA specifically added (f)(9), which states:

> Subject to subparagraph (B) [which provides for enhanced penalties], any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.[10]

The enhanced penalty provisions apply to certain intentional violations of specified tobacco requirements, such as those related to premarket authorization and reporting, and certain repeated or continuing violations after notice.[11] These amounts are adjusted for inflation; as of 2026, the maximum adjusted penalty is $21,903 for a single violation and $1,460,195 for all violations adjudicated in a single proceeding.[12]

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5 21 U.S.C. § 333(f)(5)(A).

6 155 CONG. REC. S6499 (daily ed. June 11, 2009).

7 *Wulferic, LLC*, 793 F. Supp. 3d at 835.

8 *Id.* at 836.

9 *Id.*

10 21 U.S.C. § 333(f)(9)(A).

11 21 U.S.C. § 333(f)(9)(B).

12 45 C.F.R. § 102.3.

Enhanced maximum adjusted penalties increase to $365,050 for a single violation and $14,601,958 for all violations adjudicated in a single proceeding.[13]

On September 16, 2024, FDA filed an administrative complaint with the Department of Health and Human Services (HHS) Departmental Appeals Board (DAB) against Vapor Lab, initiating CMP procedures under 21 C.F.R. Part 17.[14] About three years prior to this action, on October 7, 2021, FDA had issued a Warning Letter to the company.[15] The DAB complaint derived from a June 29, 2024 FDA-commissioned inspection in which FDA identified an e-liquid product that FDA alleged to be adulterated and misbranded due to the lack of premarket authorization.[16]

In Vapor Lab's answer, the company asserted a constitutional right to a jury trial, citing *Jarkesy*.[17] In parallel, it alleged "selective enforcement," given that, upon information and belief, the Center for Tobacco Products (CTP) had not sought to impose CMPs on large, established tobacco companies that Vapor Lab suggested were similarly situated relative to unauthorized tobacco products.[18]

On December 3, 2024, while the administrative proceeding was still pending, Vapor Lab filed suit against FDA in the Northern District of Texas seeking to enjoin FDA's CMP administrative proceedings on constitutional grounds and seeking an order declaring such unconstitutional.[19]

The court first concluded it had jurisdiction to hear the claim—under precedent established by *Axon*, *Free Enterprise*, *Thunder Basin*, and *Elgin*[20]—and then turned to the merits of "whether the FDCA's civil money penalty provision, 21 U.S.C. § 333(f)(9), and FDA's proceeding against Vapor Lab violate the Seventh Amendment."[21]

C. The Court's Analysis of the Merits of Wulferic's Claims

The *Wulferic* court's substantive analysis turned on two main questions:

- First, whether, as a threshold matter, the FDA proceeding at issue implicated the Seventh Amendment; and
- Second, whether the "public rights" exception to Article III jurisdiction applied.[22]

1. The Court's Seventh Amendment Analysis

The Seventh Amendment provides:

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[13] *Id.*

[14] *Wulferic, LLC*, 793 F. Supp. 3d at 837.

[15] Brief in Support of Defendants' Motion for Summary Judgment at 3, Wulferic, LLC v. U.S. FDA, 793 F. Supp. 3d 830 (N.D. Tex. 2025) (No. 4:24-cv-01183-O).

[16] *Id.* at 5.

[17] Complaint Exhibit B at 2, *Wulferic, LLC*, 793 F. Supp. 3d 830 (No. 4:24-cv-01183-O).

[18] *Id*.

[19] Complaint, *Wulferic, LLC*, 793 F. Supp. 3d 830 (No. 4:24-cv-01183-O).

[20] *Wulferic, LLC*, 793 F. Supp. 3d at 839–46 (citing Axon Enter. v. FTC, 598 U.S. 175 (2023), Free Enter. Fund v. Pub. Co. Accounting Oversight Bd., 561 U.S. 477 (2010), Thunder Basin Coal Co. v. Reich, 510 U.S. 200 (1994), and Elgin v. Dep't of the Treasury, 567 U.S. 1 (2012))

[21] *Id.* at 846.

[22] *Id*.

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.[23]

In examining what constitutes a "[s]uit[] at common law," the *Wulferic* court relied primarily on the analyses set forth in *Granfinanciera S.A.*, *Jarkesy*, and *Tull*.[24] The *Wulferic* court first cited *Granfinanciera S.A.* for the principle that the Seventh Amendment applies to suits traditionally decided in English law courts.[25] The *Wulferic* court then turned to *Tull* for instruction on how to analyze the matter further, looking to:

- How the proceeding at issue compares to "18th-century actions brought in the courts of England prior to the merger of the courts of law and equity"; and
- Whether the nature of the remedy sought "is legal or equitable in nature."[26]

The court signaled that the second consideration would weigh more heavily, citing *Jarkesy* for the principle that because some causes of action "sound in both law and equity," the remedy is the "more important" consideration.[27]

As to that, the court in *Wulferic* observed that the CMPs at issue, like those in *Jarkesy*, were penalties with punitive and deterrent objectives and enhanced penalties for intentional violations. The court concluded that the FDCA's CMP remedy is legal in nature, not equitable, as it is not designed in equitable terms (not intended to restore the status quo or provide for restitution of victims).[28]

Although the court observed that Vapor Lab "struggle[d] to identify common law roots for the FDA's cause of action" and offered "no evidence of *English* causes of action decided in courts of law,"[29] it nevertheless determined ("in any event") that the FDCA's CMP provision implicates the Seventh Amendment because under *Tull*

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[23] U.S. CONST. amend. VII.

[24] Granfinanciera, S.A. v. Nordberg, 492 U.S. 33 (1989); Tull v. United States, 481 U.S. 412 (1987).

[25] *Wulferic, LLC*, 793 F. Supp. 3d at 846. The *Jarkesy* court, too, relied heavily on *Granfinanciera S.A.* for its Seventh Amendment analysis. *Jarkesy*, 603 U.S. at 134 (noting "*Granfinanciera* effectively decides this case"). Citing *Granfinanciera S.A.*, the *Jarkesy* court explained that "[e]ven when an action 'originate[s] in a newly fashioned regulatory scheme,' what matters is the substance of the action, not where Congress has assigned it." *Id.* The *Jarkesy* court further cited *Granfinanciera S.A.* in explaining that the SEC actions at issue in *Jarkesy* "target[ed] the same basic conduct as common law fraud, employ[ed] the same terms of art, and operate[d] pursuant to similar legal principles," and "[i]n short [the] action involve[d] a 'matter of private rather than public right.'" *Id.*

[26] *Wulferic, LLC*, 793 F. Supp. 3d at 847–48 (quoting *Tull*, 481 U.S. at 417–18).

[27] *Id.* (quoting *Jarkesy*, 603 U.S. at 123).

[28] *Id.*

[29] Vapor Lab did reach back to identify cases from 1785 and 1787. *Id.* at 847. It posited that these examples presented analogous causes of action to those being pursued by FDA. *Id.* The court, however, noted the examples given involved actions under a criminal statute (penalties under Massachusetts law for selling "diseased, corrupted, contagious, or unwholesome provisions") and admiralty laws (a Pennsylvania case involving forfeiture of a ship due to transporting goods without paying taxes). *Id*.

(quoting *Curtis v. Loether*, 415 U.S. 189 (1974)) the relief sought is more important than "finding a precisely analogous common-law cause of action."[30]

Thus, the court concluded that "Vapor Lab ha[d] the right to a jury trial unless the public rights exception applies."[31]

2. The Court's "Public Rights" Analysis

Having concluded that the facts of *Wulferic* implicated the Seventh Amendment, the court then turned to whether the "public rights" exception applied.[32]

The court began by laying the foundation for the "public rights" exception. As the court explained, under Article III, the judicial power of the United States cannot be shared.[33] An exception has developed in cases involving "public rights," where courts have deemed that administrative adjudication does not infringe on judicial power. The rationale is that certain matters historically could have been decided exclusively by the executive and legislative branches.[34] Revenue collection is likely the least controversial application of this exception, due to an extensive applicable history of revenue collection by sovereigns.[35]

Post-*Jarkesy*, the court recognized a mandate to apply a "narrow and extra-textual '*exception*' to presumptively mandatory Article III jurisdiction,"[36] a position which sits in contrast to the dissent's view that under *Atlas Roofing v. Occupational Safety and Health Review Commission*, 430 U.S. 442 (1977), Congress's creation of a "new regulatory scheme" would justify non-Article III adjudication.[37]

The *Wulferic* court examined whether a "public-health purpose" could equate to a "public right."[38] The court was unconvinced that it could. The *Wulferic* court emphasized the "substance of the *enforcement action*" and not the "object of the regulation" as being the correct point for analysis, to avoid "blow[ing] a hole" in the intended narrow exception with the plethora of laws that could be said to "promote public health."[39]

The court was unpersuaded by the precedents offered by FDA to support its premise: *Crowell v. Benson* and *Houston v. St. Louis*. While "public health" was, in *Crowell*, one of a list of illustrative examples of "matters that may be assigned to the Executive Branch for determination," the *Wulferic* court pointed out that *Crowell* was not actually a case about "public health" (rather, it was about public lands), much less one adopting a public health category of public rights.[40] The court also took issue with the case cited in *Crowell—Houston v. St. Louis Independent Packaging Co.*—as that

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[30] *Id.* at 847–48.

[31] *Id.* at 848.

[32] *Wulferic, LLC*, 793 F. Supp. 3d at 848.

[33] *Id*.

[34] *Id*.

[35] *Jarkesy*, 603 U.S. at 131 (explaining that in Murray's Lessee, 59 U.S. 272 (1855), the court previously "justif[ied] the application of the exception . . . by explaining that it flowed from centuries-old rules concerning revenue collection by a sovereign").

[36] *Wulferic, LLC*, 793 F. Supp. 3d at 849.

[37] *Id.* at 848 (citing *Jarkesy*, 603 U.S. at 180 (Sotomayor, J., dissenting)).

[38] *Id.* at 850.

[39] *Id.* at 849 (emphasis added).

[40] *Id.* (citing Crowell v. Benson, 285 U.S. 22 (1932)).

case involved a meat-labeling regulation and did not involve agency enforcement, the Seventh Amendment, or Article III delegation.[41]

In further support of its ultimate decision, the court noted that FDA's cited cases had not been "revisit[ed]" by the Supreme Court in the context of *Jarkesy*, and that the first case in the Fifth Circuit to apply *Jarkesy* did not include "public health" when that court listed recognized categories of public rights.[42] Further, the power to promote public health is not a "distinctive prerogative" of the federal government; states retain this as a police power under the Tenth Amendment.[43]

The court concluded that the CMP proceedings under the TCA did not, in its view, fall within any of the distinctive areas in which the Supreme Court had concluded "may be resolved outside an Article III court, without a jury," and therefore "the public rights exception does not apply."[44]

The court held that:

- "the FDCA's civil money penalty provisions for tobacco products, 21 U.S.C. § 333(f)(9), violate the Seventh Amendment to the Constitution."[45]
- "the FDA's civil money penalty proceeding against Vapor Lab violates the Seventh Amendment to the Constitution."[46]

The court enjoined HHS to dismiss with prejudice the administrative complaint against Vapor Lab, and enjoined HHS and FDA from adjudicating CMPs against Vapor Lab in an administrative proceeding.[47]

The court declined, however, to issue a nationwide injunction prohibiting HHS and FDA from adjudicating CMPs in administrative proceedings.[48] The court only addressed relief to Vapor Lab, as "the only plaintiff before the Court."[49]

III. IMPACT OF *WULFERIC* AND SIMILAR LITIGATION

The ultimate impact of *Wulferic* is still an open question. Indeed, as we describe more fully below, *Wulferic* is now on appeal and similar cases have been (and are being) litigated across the country. In addition, while this uncertainty plays out relative to tobacco products, stakeholders in other areas of FDA regulation may wonder how they are likely to fare if faced with a CMP proceeding, and whether their situation is likely to track the outcome of *Wulferic.* Below we explore this topic as well.

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[41] *Id.* at 849–50 (citing Houston v. St. Louis Independent Packaging Co., 249 U.S. 479 (1919)).

[42] *Id.* at 850.

[43] *Id.*

[44] *Id.* (internal citations omitted).

[45] *Id*.

[46] *Id.* at 851.

[47] *Id.* at 852.

[48] *Id.* at 851.

[49] *Id.* at 852.

A. Wulferic's Appeal to the Fifth Circuit Stayed

On September 29, 2025, FDA filed a notice of appeal to the Fifth Circuit from the Final Judgment entered by the United States Northern District of Texas on August 1, 2025 in *Wulferic*.[50] Less than two weeks later, on October 9, 2025, FDA filed with the Fifth Circuit an unopposed motion to hold the *Wulferic* appeal in abeyance pending the issuance of the Fifth Circuit's mandate in the related matter of *Texas Tobacco Barn v. U.S. Dep't of Health and Human Services*, No. 25-60200 (5th Cir.), which FDA stated presented a "similar Seventh Amendment challenge to an analogous administrative enforcement action."[51] According to FDA:

> Holding [the *Wulferic* appeal] in abeyance will conserve judicial resources and promote the efficient and orderly disposition of this case. Briefing in this matter has not yet commenced and there is a strong likelihood that the Court's decisions in *Texas Tobacco Barn* will substantially affect the issues raised in this appeal. It is thus in the interest of the parties and the Court to hold this matter in abeyance pending the resolution of that case.[52]

The following day, on October 10, 2025, the Fifth Circuit granted FDA's unopposed motion to hold the *Wulferic* appeal in abeyance until the mandate issues in *Texas Tobacco Barn*.

B. Texas Tobacco Barn v. U.S. Dep't of Health and Human Services, No. 25-60200 (5th Cir.)

Texas Tobacco Barn involved an enforcement action that FDA initiated against Texas Tobacco Barn, a manufacturer and seller of e-cigarette products.[53] According to FDA, Texas Tobacco Barn violated the FDCA by manufacturing and offering for sale an e-cigarette product without prior FDA authorization.[54] FDA served on Texas Tobacco Barn an administrative complaint in August 2023.[55] The matter was heard by an Administrative Law Judge (ALJ), who found Texas Tobacco Barn liable and imposed a monetary penalty in the amount of $19,192.[56] Texas Tobacco Barn sought review of the ALJ's decision before the DAB, which affirmed the ALJ's decision.[57] Texas Tobacco Barn appealed to the United States Court of Appeals for the Fifth Circuit, arguing, among other things, that the Seventh Amendment barred CTP without a jury trial.[58]

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[50] Dkt. 33, *Wulferic, LLC* (No. 4:24-cv-01183-O) (N.D. Tex.).

[51] Dkt. No. 5 at 2., *Wulferic, LLC* (No. 25-11112) (5th Cir.).

[52] *Id.*

[53] *See* Dkt. 30 at 1, No. 25-60200 (5th Cir.).

[54] *See id.*

[55] *See id.* at 9.

[56] *See id.* at 12.

[57] *Id.* at 12–13.

[58] *See id.* at 14.

Wulferic sought and received permission to file an *amicus* brief in *Texas Tobacco Barn* and filed its *amicus* brief on September 3, 2025.[59] In the *amicus* brief, Wulferic argued it was interested in *Texas Tobacco Barn* because it "anticipates FDA may seek to reinstate the administrative complaint against it should [the Fifth Circuit] deny [Texas Tobacco Barn's] Petition for Review."[60] Arguing in support of *Texas Tobacco Barn*, Wulferic contended that: (i) under the Supreme Court's decision in *Jarkesy*, FDA's CMP regime violates the Seventh Amendment right to a jury trial, and (ii) the "public rights" exception does not save FDA's CMP scheme from the Seventh Amendment.[61]

For its part, on the Seventh Amendment issue, FDA argued that executive adjudication had been proper because the TCA implicates public rights, not private ones.[62] According to FDA, "[r]ather than mirroring existing private right claims, the Tobacco Control Act closely parallels the regulatory scheme already established in the rest of the [FDCA], which reflects a substantial innovation on existing protections provided by common-law liability."[63] FDA also contended that "longstanding precedent recognized that the Executive may determine public rights in connection with comprehensive regulatory schemes relates to 'public health.'"[64]

The Fifth Circuit heard oral argument on February 2, 2026.[65] A decision is forthcoming.

C. D and A Business Investments LLC v. FDA, No. 25-01074 (D.C. Cir.)

A similar issue has presented in *D and A Business Investments LLC v. FDA*, No. 25-01074 (D.C. Cir.). The petitioner in *D and A Business Investments, LLC* is the owner and operator of T.H.C. Smokes, a retail shop in Phoenix, Arizona.[66] Based on an FDA inspection of T.H.C. Smokes, FDA's CTP filed an administrative complaint for CMPs against T.H.C. Smokes.[67] CTP alleged that one of the shop's tobacco products was "adulterated" and "misbranded" per FDCA provisions because "there was no marketing granted order authorizing marketing of it nor a substantial equivalent or abbreviated [substantial equivalence] report submitted for the product."[68] Accordingly, the complaint alleged that the shop had "received the adulterated and misbranded ENDS product in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, in violation of 21 U.S.C. 331(c)."[69] The complaint sought a CMP in the amount of $19,192.

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[59] *See* Dkt. 29, No. 25-60200 (5th Cir.).

[60] *Id.*

[61] *Id.* at 5–15.

[62] Dkt. 30 at 18, No. 25-60200 (5th Cir.).

[63] *Id.* at 19.

[64] *Id.* (quoting reference omitted).

[65] *See* Dkt. 58, No. 25-60200 (5th Cir.).

[66] *See* Dkt. 19 at 2, No. 25-01074 (D.C. Cir.).

[67] *See id.* at 3.

[68] *Id.* (citation omitted).

[69] *Id.* (citing complaint).

The dispute went before an ALJ, who found T.H.C. Smokes liable for the alleged violation and affirmed the proposed penalty of $19,192.[70] T.H.C. Smokes appealed to the DAB, which affirmed the ALJ's decision.[71] T.H.C. Smokes petitioned for review in the United States Court of Appeals for the District of Columbia Circuit.

In its opening brief before the D.C. Circuit, T.H.C. Smokes argued, among other things, that it "may not be required to litigate both liability and the amount of a civil money penalty before an ALJ," contending that CMPs are generally "punitive" and therefore "legal" remedies, and that the fact that CMPs are punitive means that the amount must be determined by a jury.[72] Wulferic in turn filed an *amicus* brief in support of T.H.C. Smokes, as in *Texas Tobacco Barn*, in which it contended that: (i) under *Jarkesy*, FDA's CMP regime violates the Seventh Amendment, and (ii) the "public rights" exception does not save FDA's CMP scheme.[73] As in *Texas Tobacco Barn*, FDA argued that the adjudication at issue in *D and A Business Investments* involved a "public health" matter, which implicated public rights, not private ones, determined in connection with "comprehensive regulatory schemes directing executive officials to determine which products are appropriate for public health," and which fit within the public-rights exception to the Seventh Amendment.[74]

The D.C. Circuit heard oral argument on December 8, 2025.[75] A decision is forthcoming.

D. Vaping Dragon LLC v. FDA, No. 25-cv-081 (N.D. Tex. Feb. 2, 2026)

In *Vaping Dragon LLC v. FDA*, the United States District Court for the Northern District of Texas held that FDA's CMP scheme triggers the Seventh Amendment because it is a "suit at common law" and that the scheme does not involve "public rights," which do not require a jury trial.[76]

The case stemmed from an administrative complaint filed by CTP against Vaping Dragon. It alleged that Vaping Dragon had violated the FDCA by receiving and offering for sale an adulterated ENDS product, and sought a CMP in the amount of $21,348.[77] In its answer, Vaping Dragon asserted it had a right to a jury trial on CTP's request. In May 2025, at which point the ALJ had not yet set a hearing, Vaping Dragon filed a lawsuit in federal court, seeking (among other things) a declaratory judgment that FDA's CMP scheme for tobacco products, as well as the accompanying proceedings against Vaping Dragon, violated the Seventh Amendment.[78]

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[70] *Id.* at 8.

[71] *Id.* at 10.

[72] *Id.* at 12.

[73] Dkt. 23 at 5–15, No. 25-01074 (D.C. Cir.).

[74] Dkt. 26 at 14–15, No. 25-01074 (D.C. Cir.).

[75] *See* Dkt. 38, No. 25-01074 (D.C. Cir.).

[76] Vaping Dragon LLC v. FDA, No. 25-cv-081, 2026 U.S. Dist. LEXIS 20806, at *2 (N.D. Tex. Feb. 2, 2026).

[77] *Id.* at *8.

[78] *Id.* at *9.

After determining that it had subject-matter jurisdiction, the court proceeded to the merits of Vaping Dragon's Seventh Amendment claim.[79] First, the court found that FDA's CMP scheme implicates the Seventh Amendment, observing that like the CMP scheme in *Jarkesy*, FDA's CMP scheme is punitive and legal in nature.[80] And although the court acknowledged that "the relationship between the [FDCA] and a common law analogue is not as obvious as it was in *Jarkesy*," the "relief sought is '[m]ore important' than finding a precisely analogous common-law cause of action."[81] Because the court concluded that FDA's CMP scheme is a "textbook legal remedy," the court found that the Seventh Amendment applied.[82]

Next, the court found that the public rights exception did not apply, noting the "presumption in favor of Article III courts, the continued debate over the vitality of the public rights doctrine, and the fact that public health is not an entrenched category of public rights."[83] Accordingly, the court entered judgment in favor of Vaping Dragon, holding that FDA's CMP scheme triggers the Seventh Amendment and that the scheme does not involve "public rights."[84]

On March 31, 2026, FDA noticed an appeal to the Fifth Circuit.[85] On April 7, 2026, FDA filed with the Fifth Circuit an unopposed motion to hold the appeal in abeyance pending the issuance of the Fifth Circuit's mandate in the related matter of *Texas Tobacco Barn v. U.S. Dep't of Health and Human Services*, No. 25-60200 (5th Cir.).[86]

IV. POTENTIAL IMPACT OF COMMONALITIES AND DIFFERENCES ACROSS FDCA CMPS

Given that to date the bulk, by far, of FDA CMP proceedings under Part 17 have been tobacco product related, *Wulferic* and its ultimate resolution will likely be most keenly watched by those involved in this sector.[87] Others, however, may still wonder: "Could this happen to me?"

As noted, CMPs codified in Title 21 of the United States Code were enacted over an extended period of time, and in a piecemeal fashion. Given the piecemeal nature, it is perhaps unsurprising that there is some variation in the statutory language associated with proceedings in which CMPs could be assessed. While *Wulferic* speaks to Seventh Amendment rights in the context of CMPs under current 21 U.S.C. § 333(f), finding Congress's explicit direction of these matters to agency hearings (as is the case for other products and compliance requirements sitting in § 333(f) such as medical devices

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[79] *See id.* at *34.

[80] *Id.* at *37–38.

[81] *Id.* at *42 (quoting references omitted).

[82] *Id.*

[83] *Id.* at *46.

[84] *Id.* at *50.

[85] Dkt. 27, No. 25-cv-00081 (N.D. Tex. Mar. 31, 2026).

[86] Dkt. 4, No. 26-10292 (5th Cir.).

[87] More than 30 DAB decisions involving FDA CMP administrative proceedings for tobacco products are available on the HHS website. *See Board Decisions*, U.S. DEP'T OF HEALTH & HUM. SERVS. DEPARTMENTAL APPEALS BD., https://www.hhs.gov/about/agencies/dab/decisions/board-decisions/ index.html (last visited Apr. 9, 2026). CTP has also indicated that it has brought more than 35,000 CMP actions. *See Wulferic, LLC*, 793 F. Supp. 3d at 844.

and clinicaltrials.gov registry and reporting requirements), there is variation in the language of other statutory provisions which could make attempts by FDA to pursue administrative proceedings in those contexts subject to even greater challenge (e.g., likely challenges on whether Congress even intended such matters to be subject to administrative hearings as opposed to being adjudicated in court).

The history of FDA's implementing regulations for CMP proceedings is illustrative. These regulations first took effect in 1995 and provide the "practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA."[88] At the time the regulations initially took effect, FDA stated: "This rule implements the civil money penalty provisions of several statutes: the National Childhood Vaccine Injury Act of 1986 (NCVIA), the Prescription Drug Marketing Act of 1988 (PDMA), the Safe Medical Devices Act of 1990 (SMDA), the Generic Drug Enforcement Act of 1992 (GDEA), and the Mammography Quality Standards Act of 1992 (MQSA)."[89]

The proposed implementing regulations were not, however, without controversy from industry stakeholders. For example:

- The Pharmaceutical Manufacturers Association (PMA) (later renamed PhRMA) took issue with FDA's proposed *administrative* imposition of CMPs in contrast to seeking such penalties through a judicial proceeding. "Three of the statutes, the SMDA, the GDEA, and the MQSA, specifically authorize the FDA to impose civil monetary penalties administratively, . . . The other two statutes, the PDMA and the NCVIA, . . . do not grant FDA the power to impose those penalties administratively."[90]
- The Administrative Conference of the United States (the "AC," a policy-neutral, independent government agency), while generally advocating for the use of administratively imposed CMPs, noted that it had previously recommended that "agencies undertake to provide for imposing civil money penalties even in the absence of explicit statutory authority, if the relevant statute did 'confer[] *upon the agency* authority to 'assess' or 'mitigate' a penalty, particularly if the agency is required to conduct a 'hearing."[91] The AC stated in its comment letter: "It does not appear [that the PDMA or NCVIA,] the two statutes not expressly authorizing administrative civil money penalties, contain such language." While the AC stated that it believed challenges to FDA's authority to do so "should

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[88] 21 C.F.R. § 17.1.

[89] 60 Fed. Reg. 38,612 (July 27, 1995).

[90] Letter from PMA, *Re: Civil Money Penalties: Biologics, Drugs, and Medical Devices*, Docket No. 91N-0447 (Aug. 25, 1993).

[91] Letter from the Office of the Chairman, Administrative Conference of the United States, *Re: Notice of Proposed Rulemaking by the Food and Drug Administration To Establish Procedures for Administrative Imposition of Civil Penalties*, Docket No. 1N-0447 (July 19, 1993) (citing 1 C.F.R. § 305.79-3 at Para D) (emphasis in original).

> be unsuccessful," it also noted that "the issue has not been resolved definitively."[92]

The relevant statutory language under the PDMA was enacted in 1988, and provides that, in relation to drug sample distribution violations, manufacturers or distributors "shall, upon conviction of [their employed or associated] representative for such violation, be subject to . . . civil penalties."[93] For the NCVIA, the civil penalty language enacted provides simply that a vaccine manufacturer who "intentionally destroys, alters, falsifies, or conceals" required records or reports "shall . . . be subject to a civil penalty."[94]

In the preamble to the final rule, FDA stated simply that it "disagree[d] with the position that civil money penalties in connection with the PDMA and the NCVIA may not be imposed administratively, for the reasons stated in the preamble to the NPRM [Notice of Proposed Rulemaking] (58 FR 30680 through 30681)."[95]

For context on areas in which FDA has, in fact, pursued CMPs through administrative proceedings, as noted FDA has utilized this procedure most frequently in relation to tobacco products. Specifically, "[t]hrough November 30, 2024, CTP has brought 35,883 total civil money penalty actions."[96]

FDA has also pursued some CMP proceedings against mammography facilities under the MQSA, though such proceedings are relatively infrequent compared to tobacco-related actions, most likely due to FDA's alternative enforcement mechanism options such as revocation of accreditation. In terms of CMP proceedings, as an example, in 1998, FDA entered a consent decree with an individual for $25,000 in CMPs after bringing an action for MQSA violations.[97] In 2005, the DAB affirmed an ALJ's decision to uphold the imposition of $1,158,000 in penalties on Korangy Radiology Associates, P.A. and its owner Dr. Korangy for 193 violations of the MQSA.[98] Additionally, in 2014, the HHS DAB upheld the imposition of $2,920,000 in CMPs on Digital Radiology Center, Inc. (DRC), $1,460,000 on Oscar Alzate, DRC's manager, and $83,750 on Brigitte Alzate, an operator and employee of DRC, for violations of the MQSA.[99]

Similarly, in the medical device context, in contrast to administratively imposed CMPs, it is much more common for medical device companies to encounter 483 Observations, Untitled Letters, "It Has Come to Our Attention" Letters, Warning Letters, and the need for (strongly encouraged) voluntary recalls. Medical device stakeholders have, so far, seen only a smattering of CMP administrative proceedings pursued over the years, many of which occurred in the early 2000s. For example, in

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[92] *Id.*

[93] 21 U.S.C. § 333(b)(2).

[94] 42 U.S.C. § 300aa-28(b)(1).

[95] 60 Fed. Reg. at 38613.

[96] *Wulferic, LLC*, 793 F. Supp. 3d at 844.

[97] U.S. FOOD & DRUG ADMIN. CTR. FOR DEVICES & RADIOLOGICAL HEALTH, MAMMOGRAPHY: ADMINISTRATIVE CIVIL MONEY PENALTY (2002), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/enforcement-story-archive/center-devices-and-radiological-health-2002.

[98] *See* Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers, DAB No. 1996 (2005).

[99] *See* Digital Radiology Center, Inc., DAB No. CR3270 (2014); Oscar Alzate, DAB No. CR3396 (2014); and Brigitte Alzate, DAB No. CR3395 (2014).

2001, FDA imposed CMPs against LaserVision Centers and some of its executives for selling an unapproved excimer laser; LaserVision was required to pay $1 million and its executives paid $500,000.[100] FDA also pursued CMP proceedings against Worldwide Medical Corporation and its first president around the same time based upon allegations that Worldwide Medical marketed drug testing kits as over-the-counter products when they had only been approved for professional use in a laboratory setting; in 2002, Worldwide Medical entered a settlement agreement to resolve the allegations for $250,000.[101] In 2003, the LaHaye Center for Advanced Eye Care of Lafayette and Dr. Leon C. LaHaye entered a settlement for $950,000 and $150,000, respectively, after FDA pursued CMP proceedings based on allegations that the parties used a laser to provide laser-assisted in situ keratomileusis (LASIK) without a Pre-Market Approval application or an Investigational Device Exemption approved by FDA.[102] In 2007, FDA ordered TMJ Implants, Inc. (TMJI) and two employees to pay $170,000 in CMPs based on allegations that the parties failed to submit Medical Device Reports for 17 adverse events associated with TMJI's temporomandibular joint (TMJ) implants and accessories.[103]

From publicly available materials, it does not appear that those subject to clinicaltrials.gov have, to date, been subject to CMP proceedings.[104] And while FDA defended, in the preamble to the final rule at Part 17, its authority to bring administrative proceedings relative to the PDMA and NCVIA, we have not yet seen this tested.

So, in many instances FDA has historically relied heavily on the other administrative enforcement tools at its disposal, and the threat of potential CMP proceedings is just one element of the significant leverage it holds over regulated companies (not least of which is the overarching specter of potential *criminal* exposure under the FDCA).

V. CONCLUSION

CMPs have remained present over the years as a potential source of enforcement leverage for FDA, and—regardless of the limited extent of historical use in some areas—remain available as an option the government could seek to utilize against industry stakeholders. As a result, *Wulferic* remains a case of interest across FDA-regulated industries.

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[100] *Enforcement Record Shows New Compliance Approach*, THE GMP LETTER NO. 269 (Wash. Bus. Info., Inc. 2002).

[101] U.S. FOOD & DRUG ADMIN. CTR. FOR DEVICES & RADIOLOGICAL HEALTH, IN VITRO DIAGNOSTIC TEST KITS: CIVIL MONEY PENALTY CASE FOR IN VITRO TEST KIT (2002), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/enforcement-story-archive/center-devices-and-radiological-health-2002.

[102] FDA-2002-H-0065-0035, Settlement Agreement, Oct. 31, 2003.

[103] FDA-2005-H-0506-0110, Order, Sep. 25, 2007.

[104] U.S. FOOD & DRUG ADMIN., CLINICALTRIALS.GOV – NOTICES OF NONCOMPLIANCE AND CIVIL MONEY PENALTY ACTIONS, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/enforcement-story-archive/center-devices-and-radiological-health-2002 (last visited Apr. 10, 2026).

California Chamber of Commerce v. Bonta

NEAL D. FORTIN*

WHY IT MADE THE LIST

On May 2, 2025, the U.S. District Court for the Eastern District of California ruled in *California Chamber of Commerce v. Bonta* that California's warning requirements for dietary acrylamide violate the First Amendment.[1] The court issued a permanent injunction prohibiting enforcement of Proposition 65 (Prop 65) warnings for acrylamide in food.

This case provides landmark relief from Prop 65 enforcement threats, litigation, and forced warning statements to food manufacturers, distributors, and retailers. Prop 65, also known as the Safe Drinking Water and Toxic Enforcement Act, was enacted by California voters as a ballot initiative on November 4, 1986.[2] Among other things, the law requires the Governor of California to publish a "list of those chemicals known to the state to cause cancer or reproductive toxicity. . ." Acrylamide has been on the Prop 65 list of chemicals "known to the state to cause cancer" since 1990.

To avoid litigation and potential penalties of up to $2,500 per day per violation, businesses can display one of the Prop 65 "safe harbor" warnings that advise consumers that "Consuming this product can expose you to acrylamide, which is known to the State of California to cause cancer."[3] Without the warnings, businesses face enforcement actions by the state and private enforcers. Thus, many chose to place warnings on all food products containing acrylamide.

Acrylamide forms naturally during high-temperature baking, roasting, and frying of plant-based foods. Thousands of manufacturers, distributors, and sellers of these foods are now relieved from posting Prop 65 warnings for acrylamide. Likely tens of thousands of food products sold in the United States contain some acrylamide because it forms in all carbohydrate-rich foods cooked at high temperatures, such as French fries, cookies, cereals, bread, potato chips, and crackers.

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1 California Chamber of Commerce v. Bonta, 781 F.Supp.3d 1071 (2025).

2 Cal. Health & Safety Code §§ 25249.5–25249.14.

3 *Id*. at §§ 25249.6, 25249.10.

DISCUSSION

Background

The California Office of Environmental Health Hazard Assessment (OEHHA)[4] is the lead agency designated by the Governor to implement and enforce Prop 65. OEHHA designated five agencies as "authoritative bodies" for carcinogen identification: the United Nations World Health Organization's International Agency for Research on Cancer (IARC), the National Institute for Occupational Safety and Health, the National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA).[5] OEHHA must list a chemical as "known to the state to cause cancer" if one of those authoritative bodies has formally identified the chemical as causing cancer.[6] A chemical must be listed even if it is only known to cause cancer in animals but not humans. Businesses are required to warn before exposing individuals to a listed chemical unless a "no significant risk" exemption applies, which is defined as no more than 1 in 100,000 excess people getting cancer in a lifetime of exposure.[7]

In 1986, IARC determined that acrylamide was "possibly" carcinogenic to humans.[8] In 1988, the EPA classified acrylamide as a probable carcinogen in humans.[9] In 1990, OEHHA listed acrylamide as a chemical "known to the State of California to cause cancer" based on the determinations by IARC and EPA. Based on further evidence in 1994, the IARC classified acrylamide as "probably carcinogenic in humans."[10] Subsequently, the NTP listed acrylamide as "reasonably anticipated to be a human carcinogen." At that time, acrylamide was known as an industrial chemical used in plastics and grouting agents. It had not yet been discovered in food.[11]

However, in 2002, researchers discovered that acrylamide forms in certain plant-based foods during high-temperature cooking processes, such as frying, roasting, and baking. Although the hazard of acrylamide in animal studies was clear, the risk to humans was the subject of considerable scientific debate and uncertainty.

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[4] OEHHA is typically pronounced "oh-EEE-ha."

[5] Cal. Code Regs. tit. 27, § 25306(m).

[6] Cal. Health & Safety Code § 25249.8(b).

[7] Cal. Health & Safety Code § 25249.10(c); Cal. Code Regs. tit. 27, § 25703(b).

[8] Int'l Agency For Rsch. On Cancer, Acrylamide, in Some Chemicals Used in Plastics and Elastomers 233–35 (IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, vol. 39, 1986).

[9] U.S. ENV'T PROT. AGENCY, INTEGRATED RISK INFORMATION SYSTEM (IRIS): ACRYLAMIDE (CASRN 79-06-1) (1988), https://iris.epa.gov/static/pdfs/0286_summary.pdf.

[10] Int'l Agency For Rsch. On Cancer, Acrylamide, in Some Industrial Chemicals (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans vol. 60, 1994) at 425 (inadequate evidence for human but sufficient evidence for animals).

[11] California Chamber of Commerce v. Bonta, 781 F.Supp.3d 1071, 1076–1077 (2025) (undisputed material facts).

Hazard Versus Risk

To paraphrase Paracelsus, the dose makes the poison.[12] IARC, EPA, and NTP determined that acrylamide is a hazard; that is, capable of causing cancer in some circumstances. However, a hazard determination differs from a risk determination. Risk depends on the hazard's potency times the amount of exposure.

The distinction between hazard and risk is critical when issuing a warning statement, such as the Prop 65 acrylamide warnings. A factual statement about a hazard can be perceived as a risk warning, which is misleading. "[T]he Court looks to the meaning of the warning in context, which clearly communicates the message that dietary acrylamide poses a risk of cancer."[13] When examining the warning sentence by sentence, each sentence may be factually accurate, but the overall message conveyed may be misleading. The Ninth Circuit has adopted the approach of considering the overall impression delivered by a compelled warning.[14]

Lack of Scientific Consensus

While IARC, EPA, and NTP found acrylamide to be a "probable" or "likely" carcinogen based on animal studies, the court noted that human epidemiological studies do not support this conclusion. Leading institutions like FDA, the National Cancer Institute, and the American Cancer Society have expressed uncertainty or found no link between dietary acrylamide and cancer in humans.[15] In short, there is no scientific consensus that dietary acrylamide is a carcinogenic risk to humans.

The court found the acrylamide Prop 65 warning to be misleading because it conveys the message that dietary acrylamide increases a consumer's risk of cancer, even though this is an unsettled question in the scientific community.[16] Factually accurate phrases, such as acrylamide being "probably carcinogenic," were deemed misleading in context because they imply a cancer risk from everyday food consumption with insufficient scientific agreement.[17]

The Holding

The court found that Prop 65 compelled businesses to convey acrylamide warnings that are controversial and misleading because they state that dietary acrylamide is carcinogenic to humans despite vigorous scientific debate.[18] Thus, the required warnings are unconstitutional.

The Supreme Court has created two tests to assess the constitutionality of government action regarding commercial speech. The less stringent test, *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, states that the government "may compel commercial speech so long as it is reasonably related to a

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[12] PARACELSUS, *Die dritte Defension wegen des Schreibens der neuen Rezepte* (1538), *reprinted in* 2 WERKE 510 (Darmstadt 1965) ("Alle Dinge sind Gift, und nichts ist ohne Gift; allein die Dosis macht, dass ein Ding kein Gift ist." or "All things are poison, and nothing is without poison; only the dose makes a thing not a poison.")

[13] *Bonta*, 781 F.Supp.3d at 1084.

[14] *Bonta*, 781 F.Supp.3d at 1085.

[15] *Bonta*, 781 F.Supp.3d at 1086.

[16] *Bonta*, 781 F.Supp.3d at 1087.

[17] *Id.*

[18] *Id.* at 1074

substantial governmental interest, and the compelled speech is (1) purely factual, (2) noncontroversial, and (3) not unjustified or unduly burdensome."[19] Applying this test in *Bonta* case, the district court found that the Prop 65 warnings were "neither uncontroversial nor purely factual as the warnings espouse a one-sided view that dietary acrylamide poses a human cancer risk despite a lack of scientific consensus."[20] Thus, the warnings fail to satisfy the *Zauderer* standard.

Under the more stringent test in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, the government may restrict or prohibit commercial speech that is not misleading or related to illegal activity if the restriction or prohibition directly advances a substantial governmental interest and is not more extensive than necessary.[21] As to the acrylamide warnings, the district court concluded that "misleading statements about acrylamide's carcinogenicity do not advance the State's interests in protecting the health of its citizens and that the State has less burdensome alternatives to achieve its goals."[22] California has an interest in preserving its citizens' health; however, providing consumers with misleading or false labels undermines California's interest in accurately informing its citizens about health risks. In addition, California has options for informing consumers about acrylamide in food, such as advertising campaigns or online postings, without burdening businesses' free speech. "[T]he First Amendment does not permit the State to sacrifice speech for efficiency."[23] Accordingly, the court concluded that the Prop 65 warnings failed under the *Central Hudson* test as well.

Because the Prop 65 warnings for dietary acrylamide fail to satisfy either standard, they violate the First Amendment. Therefore, the court granted a permanent injunction prohibiting the enforcement of Prop 65 warnings for acrylamide in food.

IMPACT

OEHHA had set the safe exposure limit of acrylamide at a remarkably low 0.2 µg/day. This is about the amount found in a single French fry or a fragment of a potato chip.[24] Consequently, nearly all carbohydrate-rich foods that are baked, roasted, or fried contain some acrylamide, including cookies, cereals, bread, potato chips, and crackers, as well as coffee and some pasteurized fruit juices. Therefore, tens of thousands of food products were impacted by the acrylamide Prop 65 warning.

The permanent injunction bars California state officials and private parties from enforcing the Prop. 65 warning as it relates to acrylamide in food. Food businesses no longer need to include acrylamide warnings on food products sold in California.

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[19] Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 651 (1985).

[20] *Id.* at 1084.

[21] Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557, 564 (1980).

[22] *Bonta*, 781 F.Supp.3d at 1084.

[23] Nat'l Ass'n Wheat Growers v. Bonta ("NAWG"), 85 F.4th 1263,1283 (9th Cir. 2023).

[24] Cal. Code Regs. tit. 27, § 25705(b)(1). FDA reported an average acrylamide level in French fries of 50 µg/kg. Four grams of French fries, or about one small fry, therefore, would contain 0.2 µg. The FDA data shows potato chips falling within the 700–2500 ppb range (ppb = µg/kg). At 1,000 ppb, 0.1 g of a potato chip would contain 0.2 µg acrylamide, which is about 1/10th of a chip. FDA, *Survey Data on Acrylamide in Food*, https://www.fda.gov/food/process-contaminants-food/survey-data-acrylamide-food (last visited Mar. 17, 2026).

Previously applied warnings may be removed from product packaging, websites, and point-of-sale materials.

The ruling should halt all pending or threatened Prop. 65 lawsuits and notices of violation regarding dietary acrylamide. Any businesses facing Prop. 65 litigation involving acrylamide in food can seek dismissal or withdrawal of the action. Prior consent judgments will not automatically be voided, but they may be eligible for revision based on the ruling.

An earlier decision regarding Prop. 65 warnings for glyphosate also found that the warnings violated the First Amendment.[25] An additional earlier decision granted a regulatory carve-out exempting coffee from Prop 65 acrylamide warning requirements.[26] With close court scrutiny of whether mandated Prop. 65 warnings are "purely factual and uncontroversial," additional warnings may fail to meet the standard. Spurred by these reversals, we can expect more challenges to Prop 65 requirements. Probably wishful thinking, but perhaps going forward, legislatures will be more mindful of the principles of risk communication and the distinction between hazard and risk.

[25] Nat'l Ass'n of Wheat Growers v. Bonta, 85 F.4th 1263, 1266 (9th Cir. 2023).

[26] CERT v. Starbucks Corporation, 300 Cal. Rptr. 3d 729 (Cal Ct. App. 2022).

Eli Lilly & Co. v. Kennedy, 2025 U.S. Dist. LEXIS 196211 (S.D. Ind. 2025).

ANDREW WASSON*

WHY IT MADE THE LIST

The so-called definitional controversies of food and drug law have exercised jurists, litigants, and FDA since the earliest days of food and drug regulation. Along one axis, definitional legal controversies in food and drug law pose difficulties because of the lack of scientific and cultural consensus about the conceptual categorical boundaries for the objects of regulation, like food, drugs, and biological products. In more recent days, these difficult definitional questions are compounded along an additional axis—questions of deference in the context of administrative law. *Eli Lilly & Co. v. Kennedy* is found at the intersection of these axes.

DISCUSSION

Legal Background

FDA's authority to regulate biological products stretches back to 1902, when Congress passed the Biologics Control Act of 1902 in response to the 1901 St. Louis diphtheria tragedy, where diphtheria antitoxin was produced using the blood of a tetanus-infected horse. The Biologics Control Act was eventually superseded by the 1944 Public Health Services Act (PHSA), which attempted to consolidate all of the various laws relating to public health. In its original formulation, the PHSA prohibited introduction of a "virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives" applicable to the prevention, treatment of disease or injury, unless it was produced in an establishment with the appropriate license into interstate commerce.[1] Being many years before the significant advances of the biotechnology revolution, the 1944 PHSA did not contemplate proteins or antibodies.

Incredibly, it was not until the Biologics Price Competition and Innovation Act of 2009 that Congress amended the PHSA to first include "protein (except any chemically synthesized polypeptide)" before the phrase "or analogous product" to bring proteins within the definition of biological product. In October 2010, FDA asked the public to comment on the scientific and technical factors it should consider if it were to develop a regulatory definition of "protein" or "any chemically synthesized polypeptide."[2] In asking for comment, FDA acknowledged the "absence of scientific

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[1] Pub. L. 78-410.

[2] 75 Fed. Reg. 61497 at 61499 (Oct. 5, 2010).

consensus on the distinction between the categories of 'protein' and 'polypeptide' or 'peptide' . . . ."[3]

In a proposed rulemaking, FDA reviewed comments from the public in several dockets following the call for comment and early draft guidance, and also independently reviewed scientific literature and dictionaries.[4] Canvassing the comments, dictionaries, and textbook definitions for protein and polypeptide, FDA observed that there was not a "precise, agreed-upon" definition for protein, polypeptide, and peptide, but that there was agreement on "certain aspects" of the meanings.[5] Notwithstanding—or perhaps because of—the disagreement, FDA explained that it sought to "establish a scientifically reasonable, bright-line rule that provides regulatory clarity and facilitates the implementation of the BPCI Act."[6]

Summarizing its technical analysis, FDA determined that the terms protein, polypeptide, and peptide all referred to amino acid polymers comprising alpha amino acids linked by peptide bonds.[7] FDA observed that peptides were distinguished from proteins as referring to "smaller, simpler" amino acid chains while proteins were "long, complex" polymers.[8] FDA further observed that proteins were characterized by chains with a "specific, defined sequence" of amino acids.[9] FDA proposed defining "protein (except any chemically synthesized polypeptide)" to mean "any alpha amino acid polymer with a specific, defined, sequence that is greater than 40 amino acids in size."[10]

Following public comment, FDA finalized the definition of protein as proposed. Altogether, the final rule defined "protein" as:

> any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer . . . will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence.[11]

In finalizing the definition, FDA rejected concerns about lack of consensus or scientific sufficiency, prioritizing setting a "bright-line rule that provides regulatory certainty."[12]

Notwithstanding FDA's hope of providing regulatory certainty, the line between biological products and drugs has been repeatedly challenged over the last several years. For instance, the D.C. District Court upheld the agency's position that Teva's Copaxone (glatiramer acetate) was not a biological product because it failed to satisfy

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[3] *Id.*

[4] 83 Fed. Reg. 63817 at 63819 (Dec. 12, 2018).

[5] *Id.* at 63820.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *See also* 21 C.F.R. § 600.3(h)(6).

[12] 85 Fed. Reg. 10057 at 10060 (Feb. 21, 2020).

the definitional requirement of a "specific, defined sequence."[13] More recently, the D.C. Circuit upheld FDA's decision that a depot form of octapeptide lanreotide acetate is a drug (and not a biological product).[14]

Factual Background

Eli Lilly is the sponsor of the active retatrutide, which is being studied for the treatment of obesity, obstructive sleep apnea, knee osteoarthritis, and type 2 diabetes.[15] Lilly submitted a Request for Designation in November 2023 asking FDA to classify retatrutide as a biological product.[16] In its Request for Designation, Lilly described retatrutide as:

> an alpha amino acid polymer that contains a specific, defined sequence of 41 amino acids cumulatively, comprising a backbone of 39 alpha amino acids and a second (associated) chain of one residue each of gamma-glutamate and 8-amino-3,6-dioxaoctanoic acid (ADO). The associated chain of two amino acids is covalently bound to the backbone of 39 amino acids through an amide bond between the epsilon-amino group of a lysine residue and the carboxyl group of ADO.[17]

Lilly argued that retatrutide met the definition of protein because it had a "specific, defined sequence," the amino acid chains "are associated with each other in a manner that occurs in nature," and it is an "alpha amino polymer that is greater than 40 amino acids . . . ."[18] Regarding this last point, Lilly argued that FDA should count all of the amino acids in retatrutide—even an amino acid like ADO, which is not an alpha amino acid.[19]

Despite Lilly's arguments, FDA declined to classify retatrutide as a biological product, instead determining that it was a drug.[20] According to FDA, retatrutide was "not an alpha amino acid polymer with a specific defined sequence greater than 40 amino acids in size."[21] In particular, FDA interpreted the definition of protein to require more than 40 alpha amino acids—not just more than 40 amino acids, with at least one being an alpha amino acid. By contrast, FDA found that retatrutide contained 40 alpha amino acids and a single non-alpha amino acid (i.e., ADO).[22] In its letter of classification, FDA stated that it was "common scientific knowledge" that proteins alpha amino acids formed the building blocks of proteins in humans.[23]

FDA also determined that retatrutide did not fall within the definition of biological product by virtue of being "analogous" to a protein.[24] Specifically, FDA found that it

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[13] Teva Pharms. USA, Inc. v. U.S. Food & Drug Admin., 514 F. Supp. 3d 66 (D.D.C. 2020).

[14] Ipsen Biopharmaceuticals, Inc. v. Becerra, 108 F.4th 836 (D.C. Cir. 2024).

[15] *Eli Lilly* at *4.

[16] *Id.* at *4–5.

[17] *Id.* at 5.

[18] *Id.* at *5–6.

[19] *Id.* at *6.

[20] *Id.* at *6.

[21] *Id.*

[22] *Id.*

[23] *Id.* at *6–7.

[24] *Id.* at *7.

would be inappropriate to classify a molecule as a biological product if it was otherwise excluded from the express definition because it failed to meet a fundamental attribute of protein.[25] Here, FDA found that failure to contain more than 40 alpha amino acids was the fundamental defining property.[26] FDA observed that including molecules otherwise excluded in this fashion would "defeat the purpose of the bright line rule . . . ."[27]

Following FDA's letter of designation, Eli Lilly filed a complaint for a declaratory judgment and injunctive relief on September 3, 2024, in United States District Court for the Southern District of Indiana.[28] Lilly asserted that FDA's refusal to designate retatrutide as a biological product exceeded the agency's statutory authority, violated the agency's regulations, and was arbitrary and capricious.[29] Lilly moved for summary judgment on January 28, 2025 and the Defendants cross-moved for summary judgment on March 18, 2025.[30] The court heard oral argument in August 2025.

Decision

The court granted-in-part Lilly's motion for summary judgment with respect to the agency's determination that retatrutide is not "analogous" to a protein, but denied Lilly's motion regarding FDA's decision that retatrutide was not a protein. Correlatively, the district court granted the FDA's motion for summary judgment with respect to FDA's decision that retatrutide was not a protein but denied the motion with respect to FDA's decision that retatrutide was not "analogous" to a protein. The district court vacated and remanded to the agency for further consideration as to whether retatrutide was "analogous" to a protein.

The district court found that FDA did not act arbitrarily and capriciously by finding that retatrutide failed to meet FDA's interpretation of its regulatory definition of "protein." Because the question was about FDA's interpretation of its own regulatory definition, the district court applied the *Kisor*/*Auer* framework of deference.[31] *Kisor/Auer* deference is a three-part test.[32] In the first step, a court must decide whether the regulation is "genuinely ambiguous" by exhausting the "traditional tools of construction."[33] Second, a court must determine whether the agency's interpretation was reasonable in the face of genuine ambiguity.[34] And third, the "'the character and context of the agency interpretation' must entitle it to 'controlling weight.'"[35] Here, the district court determined that "the regulation unambiguously forecloses Lilly's reading" and thus, did not reach the second and third *Kisor* steps.[36]

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[25] *Id.*

[26] *Id.*

[27] *Id.* at *7–8.

[28] *Id.* at *8.

[29] *Id.*

[30] *Id.*

[31] *Id.* at *11.

[32] Auer v. Robbins, 519 U.S. 452 (1997); *see also* Kisor v. Wilkie, 588 U.S. 558 (2019).

[33] *E.g., Kisor*, 519 U.S. at 574.

[34] *Id.*

[35] *Eli Lilly* at *12, quoting *Kisor* at 577–79.

[36] *Eli Lilly* at *12.

The district court found that Lilly's interpretation of the regulatory definition of "protein" was unambiguously foreclosed by the plain language of the regulation. As described above, "protein" is defined as "any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size."[37] The district court reasoned that: "the most natural reading of 'alpha amino acid polymer . . . that is more than 40 amino acids' is a polymer with more than forty *alpha* amino acids. Otherwise, the 'alpha' modifier does no work, and the term becomes superfluous."[38] In addition, the district court credited FDA's contention that it was common knowledge that amino acid "almost always" means an alpha amino acid.[39] The district court also credited scientific textbooks which, in the district court's view, confirmed this position.[40]

While the district court acknowledged that courts often presume that drafters intend meaning by including language in one place and omitting the same language elsewhere, the district court found that such a presumption typically occurs when at least one of the phrases has a consistent meaning throughout the statute or regulation.[41] Here, however, the district court found that "alpha amino acid" did not have a consistent meaning throughout the statute. Because the agency made the "deliberate choice" to limit the definition to alpha amino acids, the district court reasoned that "the most natural reading" of alpha amino acid polymer requires all references to amino acids in the definition to mean alpha amino acids.[42]

Quite differently, the district court rejected FDA's interpretation of the statutory term "analogous" as applied to protein.[43] Unlike for "protein," where FDA applied the *Auer*/*Kisor* framework for agency interpretation of its own regulations, to interpret the statutory term "analogous," the district court applied the Supreme Court's newly landmarked *Loper Bright* decision.[44] As the district court noted, the Supreme Court held in *Loper Bright* that "courts must exercise independent judgment in determining the meaning of statutory provisions."[45] Still, the district court also allowed for some measure of deference to an agency—citing even *Loper Bright*'s acknowledgement that "an agency's interpretation of a statute 'may be especially informative to the extent it rests on factual premises within the agency's expertise.'"[46] Still further, "[e]ven in the wake of *Loper Bright*, courts are permitted to leave those niche factual questions for the agency to decide."[47]

Having said that, the district court called into question FDA's logic and whether FDA's standard was clearly defined and consistently applied. For one, the court questioned FDA's logic that the "fundamental defining property" of a protein was the length of amino acids, in view of FDA's previous position in the Copaxone case that

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[37] 21 C.F.R. § 600.3(h)(6).

[38] *Eli Lilly* at *14.

[39] *Id.* at 15.

[40] *Id.* at *15–16.

[41] *Id.* at 14–15.

[42] *Id.* at 15.

[43] *Eli Lilly* at *18–*23.

[44] *See id.* at *18; *see also* Loper Bright v. Raimondo, 603 U.S. 369 (2024).

[45] *Eli Lilly* at *18, quoting *Loper Bright*, 603 U.S. at 394.

[46] *Id.* quoting *Loper Bright*, 603 U.S. at 402.

[47] *Id.* at *20 (citing Seven Cnty. Infrastructure Coal. v. Eagle Cnty., 605 U.S. 168 (2025)).

the specific, defined sequence was the fundamental defining property of proteins.[48] Moreover, the district court criticized FDA's "bright line" approach to "analogous" products—the district court pointed out "[b]y definition, then, 'analogous products' need not fit into a 'bright line' rule for any category of biological products."[49] As a result, the district court found that, "[b]y requiring 'analogous' products to meet each and every requirement for a 'protein,' FDA effectively reads 'analogous product' out of the statute."[50]

On February 12, 2026, Eli Lilly appealed the district court's decision that retatrutide did not meet the definition of protein.

IMPACT OF THE DECISION

The *Eli Lilly* decision deserves attention for a number of reasons—some quite practical and others increasingly esoteric.

Most practically, the decision provides some clarity, at least provisionally, about whether the definition of protein requires more than 40 alpha amino acids—or, as Lilly contends, whether it requires a total of 40 amino acids, some of which are alpha amino acids. The district court's decision also raises questions about the agency's interpretation of "analogous" here and elsewhere. And if the agency's approach to interpreting "analogous" is untenable, the decision here raises the question of how FDA will structure its analysis regarding this statutory term in the future.

The district court's decision in *Eli Lilly* also provides a data point in the ever-expanding wake of *Loper Bright.* In the *Eli Lilly* decision, we saw an example of a court applying *Loper Bright* (at least with regard to FDA's interpretation of "analogous") to a decision with deep scientific underpinnings. Not only that, we saw a willingness of the district court to still extend some deference to the agency using dicta in *Loper Bright* itself as a basis. Notwithstanding this potential deference, the district court still broadly struck down the agency's interpretation. Thus, while courts may find ways to acknowledge agency expertise, district courts still have substantial leeway to vacate agency decisions.

The district court's opinion into the agency's interpretation of its own regulation defining protein user *Kisor/Auer* deference is another takeaway. While *Loper Bright* did not overrule *Kisor/Auer* deference, after *Loper Bright*, some scholars wondered whether *Kisor/Auer* remained a stable doctrine.[51] Notwithstanding these concerns, we see in *Eli Lilly* an example of a court upholding an agency interpretation using the *Kisor/Auer* framework (although, admittedly not based on any deference due the agency).

And finally, on the spectrum esoteric, the facts of *Eli Lilly* highlight the tensions and difficulties inherent in attempts to provide statutory and regulatory definitions of FDA-regulated products that straddle the line between nature and artifact. Products that are peptides, polypeptides, or proteins carry with them the ontological baggage from long unsettled philosophical disputes that go beyond the typical (and also

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[48] *But see* Teva Pharms. USA, Inc. v. U.S. Food & Drug Admin., 514 F. Supp. 3d 66, 116 (D.D.C. 2020).

[49] *Eli Lilly* at *22.

[50] *Id.*

[51] *See, e.g.*, Notice and Comment Blog, Chad Squitieri, Auer *after* Loper Bright, Yale Journal on Regulation (Oct. 15, 2024).

difficult) vagaries of molding language to fit policy goals. In *Eli Lilly*, these difficulties played out in real time, as we see the parties weighing the benefits of a "bright line rule" against a lack of precise scientific consensus on terminology.

American Clinical Laboratory Association v. U.S. Food and Drug Administration

TINA PAPAGIANNOPOULOS*

WHY IT MADE THE LIST

The regulation of laboratory-developed tests (LDTs) has been one of the most contested and consequential issues in food and drug law for decades. On March 31, 2025, Judge Sean Jordan of the U.S. District Court for the Eastern District of Texas issued a much-anticipated opinion in *ACLA et al. v. FDA*,[1] which vacated the Food and Drug Administration's (FDA's) May 6, 2024 final rule that sought to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA).[2] The decision has sweeping implications for the clinical laboratory industry, for the patients and physicians who depend on laboratory-developed testing services, and for the broader question of how far FDA's regulatory authority extends in the post-*Loper Bright* era.[3] This chapter summarizes the court's opinion, discusses the arguments raised by the parties, and considers the potential impact of the decision on the future of LDT regulation.

BACKGROUND

Historical Regulatory Framework

The regulatory status of LDTs has long been shaped by two overlapping federal regimes: the FDCA, which governs medical devices regulated by FDA, and the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which establishes quality standards for clinical laboratories administered by the Centers for Medicare & Medicaid Services (CMS). Under CLIA, all laboratories that perform clinical tests on human specimens must be certified by CMS or accredited through CMS-approved accreditation organizations.[4] Both CMS and the accreditation organizations issue standards to ensure that laboratory performance is "consistent" and that their tests are "valid and reliable," including quality-control standards and standards for the qualifications of personnel supervising and performing the tests.[5] Laboratories that develop and perform high-complexity tests must be overseen by a laboratory director

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1 Am. Clinical Lab. Ass'n v. U.S. Food & Drug Admin., 776 F. Supp. 3d 554 (E.D. Tex. 2025).

2 Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286 (May 6, 2024).

3 Loper Bright Enters. v. Raimondo, 603 U.S. 369, 144 S. Ct. 2244 (2024).

4 42 U.S.C. § 263a(b); *ACLA*, 776 F.Supp.3d at 562–63.

5 42 U.S.C. § 263a(f)(1); *ACLA*, 776 F.Supp.3d at 563.

who is either a licensed physician or holds a doctoral degree in a relevant science.[6] CLIA further requires strict quality controls, proficiency testing multiple times a year, and regular inspections by the Department of Health and Human Services (HHS), state agencies, and/or authorized accrediting bodies.[7] Laboratory-developed tests have often been responsible for scientific innovations and breakthroughs—for example, testing for the BRCA1/BRCA2 genetic mutations that indicate susceptibility to breast and ovarian cancer—that have become part of the standard of care and, in some cases, have been incorporated into FDA-cleared or approved IVD test kits.[8]

The Medical Device Amendments of 1976 created a comprehensive framework for regulating medical devices under the FDCA, including premarket review, classification into risk-based categories, and post-market controls.[9] However, when FDA began implementing that framework, the agency exercised enforcement discretion with respect to most laboratory-developed tests.[10] At the time, LDTs were typically developed and used within a single hospital laboratory, produced in small volumes, and performed using manual techniques by specialized laboratory personnel.[11] Over time, however, the nature of LDTs changed significantly. Advances in molecular diagnostics, genomics, and automated laboratory instrumentation led to the development of increasingly complex tests performed at scale and marketed nationwide through centralized laboratory networks.[12]

Over the years, FDA from time to time attempted to exercise oversight over certain LDTs, but it generally has not enforced medical device requirements with respect to most LDTs. According to FDA, the agency intended for its enforcement discretion to extend only to LDTs as traditionally defined by the agency, i.e. an *in vitro* diagnostic (IVD) that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing.[13] During this extended period of general FDA enforcement discretion, however, IVDs were offered commercially by laboratories as LDTs, even if they were not designed, manufactured, and used within a single laboratory. FDA referred to such tests in the final rule as "IVDs offered as LDTs."[14] In light of this regulatory history, LDTs have been regulated primarily by CMS at the federal level and by state laboratory regulatory bodies.

FDA's Rationale for the 2024 Final Rule

After decades of enforcement discretion, FDA published a final rule on May 6, 2024, announcing its intent to treat all laboratory-developed tests (including IVDs

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6 42 C.F.R. § 493.1443; *ACLA*, 776 F.Supp.3d at 563.

7 *See* 42 U.S.C. § 263a(f)(3); 42 C.F.R. § 493.801; *ACLA*, 776 F.Supp.3d at 562–63.

8 *See* Complaint ¶¶ 27–31, Am. Clinical Lab. Ass'n v. U.S. Food & Drug Admin., No. 4:24-CV-479-SDJ (E.D. Tex. May 29, 2024), ECF No. 1 [hereinafter ACLA Compl.].

9 Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539.

10 89 Fed. Reg. 37,286, 37,289.

11 *Id.*

12 *Id.*

13 *Id.*

14 *Id.* at 37,286 n.1.

offered as LDTs) as medical devices and to regulate them under the FDCA.[15] Specifically, FDA amended the regulatory definition of "in vitro diagnostic products" in 21 C.F.R. § 809.3(a), which specifies that IVD products are devices, to add the language "including when the manufacturer of these products is a laboratory."[16] The rule established a phased enforcement approach over four years, with reporting, registration, and labeling mandates beginning in years one and two, and enforcement of premarket review requirements beginning in years three and four.[17] At the same time, the final rule created a series of non-binding enforcement discretion carveouts for certain categories of tests, including existing tests (with limited modifications), tests approved by the New York State Department of Health's Clinical Laboratory Evaluation Program, tests manufactured and performed within a healthcare system to meet an unmet need, and "1976-Type LDTs."[18]

FDA explained that the rule was intended to address what it viewed as a growing regulatory gap between laboratory-manufactured tests and other commercially distributed diagnostic devices.[19] The agency emphasized that modern LDTs increasingly rely on complex technologies such as high-throughput sequencing, advanced bioinformatics, and automated instrumentation and are often marketed nationally through centralized laboratory networks rather than confined to a single hospital laboratory.[20] FDA also cited public health concerns, including the possibility that inaccurate or unreliable tests could lead to missed diagnoses, inappropriate treatment decisions, or delayed care.[21]

FDA acknowledged that the costs of the rule would be significant, projecting total costs over the next two decades ranging from $12.57 billion to $78.99 billion, with compliance costs for laboratories exceeding $1 billion per year.[22] The agency conceded that the "increased cost to laboratories" might cause price increases and "reduce the amount of revenue a laboratory can invest in creating and/or modifying" tests.[23] FDA estimated that the rule would initially affect about 79,114 existing tests offered by 1,181 laboratories, and approximately 10,013 new tests every year going forward.[24]

THE PARTIES AND PROCEDURAL HISTORY

The plaintiffs in this consolidated litigation included the American Clinical Laboratory Association (ACLA), a national trade association that represents the clinical laboratory sector; the Association for Molecular Pathology (AMP), a professional society in the field of molecular pathology; infectious disease laboratories

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[15] 89 Fed. Reg. 37,286.

[16] *Id.* at 37,445.

[17] *Id.* at 37,295–311.

[18] *Id.* at 37,296–97.

[19] *Id.* at 37,291–92.

[20] *Id.* at 37,289–90.

[21] *Id.* at 37,291–93.

[22] U.S. FOOD & DRUG ADMIN., LABORATORY DEVELOPED TESTS FINAL RULE, FINAL REGULATORY IMPACT ANALYSIS, Docket No. FDA-2023-N-2177, at 50.

[23] *Id.* at 127.

[24] *Id.* at 49.

HealthTrackRX Indiana, Inc. and HealthTrackRX, Inc.; and Michael Laposata, M.D., a medical doctor and clinical pathologist.[25] ACLA's members include laboratory services providers such as Quest Diagnostics, Labcorp, Mayo Clinic Laboratories, and ARUP Laboratories.[26]

The ACLA plaintiffs filed suit on May 29, 2024, and AMP filed its complaint in the Southern District of Texas on August 19, 2024, which was subsequently transferred to the Eastern District of Texas and consolidated with the ACLA case.[27] ACLA moved for summary judgment on September 3, 2024, and AMP moved for summary judgment on September 27, 2024.[28] FDA filed a cross-motion for summary judgment and opposition brief on October 25, 2024.[29] The court granted the plaintiffs' motions and denied FDA's motion for summary judgment.

SUMMARY AND DISCUSSION

The core dispute centered on a seemingly simple question that carried enormous consequences: Are laboratory-developed tests "devices" within the meaning of the FDCA? The plaintiffs argued that LDTs are professional services performed by highly trained laboratory scientists and are not tangible, manufactured products that can be regulated as "devices."[30] FDA countered that the physical components used to perform laboratory tests—"reagents, instruments, and other articles" that "function together to produce a test result"—constitute "IVD test systems" that are unambiguously "devices" as Congress defined that term, regardless of whether they are manufactured by a laboratory or a non-laboratory manufacturer.[31]

LDTs as Services

As a threshold matter, the court defined "laboratory-developed test services" as in-house diagnostic tests "developed, validated, and performed by trained professionals within a single clinical laboratory."[32] According to the court, the tests are "performed on blood, urine, tissue, or other types of specimens at the request of an individual physician, in the context of a specific doctor-patient relationship."[33] Treating doctors rely on such tests "for patient diagnosis, care, and treatment, ranging from routine tests such as pap smears and gram stains, to sophisticated molecular and genetic sequencing tests for cancer, heart disease, and rare and infectious diseases."[34] The court notably

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[25] *ACLA*, 776 F.Supp.3d 554 at 560–61.

[26] *Id.* at 571–72.

[27] Defendants' Cross-Motion for Summary Judgment at 16–17, Am. Clinical Lab. Ass'n v. U.S. Food & Drug Admin., No. 4:24-CV-479-SDJ (E.D. Tex. Oct. 25, 2024), ECF No. 54 [hereinafter FDA MSJ].

[28] *Id.*

[29] *Id.*

[30] *See* Plaintiffs' Motion for Summary Judgment at 6–7, Am. Clinical Lab. Ass'n v. U.S. Food & Drug Admin., No. 4:24-CV-479-SDJ (E.D. Tex. Sept. 3, 2024), ECF No. 20 [hereinafter ACLA MSJ].

[31] FDA MSJ at 19 (describing the IVD test system as an "apparatus" or "contrivance" composed of "reagents, instruments, and other articles" that "function together to produce a test result").

[32] ACLA v. FDA, 776 F.Supp.3d 554 at 559–60.

[33] *Id.*

[34] *Id.*

framed LDTs as "services," which dovetailed neatly into its analysis of whether LDTs could be a "device" under the FDCA. The court, however, did not elaborate on the "single clinical laboratory" prong of its definition and did not explain how its decision would be affected if a test was developed by more than one entity.

The Definition of "Device"

Central to the court's analysis was the definition of "device" in Section 201(h) of the FDCA, which provides, in relevant part, that a device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory."[35] The court considered the "ordinary, contemporary, common meaning" of these operative terms and applied canons of statutory construction to conclude that "device" refers to tangible, physical products—not professional services.[36] As the court explained, all the terms used in the definition—"instrument," "apparatus," "implement," "machine," "contrivance," "implant," and "in vitro reagent"—refer to tangible, physical objects.[37] The catchall term in the definition "article" likewise "denote[s] 'material things'" rather than intangible services, a reading confirmed by decades of case law, according to the court.[38]

The court rejected FDA's attempt to characterize the collection of physical tools that laboratory professionals use to perform a test as an "IVD test system" that itself constitutes a "device."[39] To illustrate the problem with FDA's reasoning, the court offered a series of analogies. "When a radiologist reads an x-ray, he or she is providing a service that depends on a medical device—the x-ray machine. But the radiologist is rendering a service and is not subject to regulation under the FDCA."[40] Similarly, "when a heart surgeon conducts an operation to repair a valve or insert a pacemaker, the surgical procedure does not become a 'device' merely because it involves the use of surgical instruments, sutures, and other medical equipment."[41] Under FDA's reading, the court reasoned, nearly every medical procedure or examination would constitute "manufacturing" a medical "device," thereby implicating limitless FDA oversight.[42]

The court also criticized FDA's self-created term "IVD test system" and related definitions as "affirmatively work[ing] against the FDCA's limits on FDA's jurisdiction" by improperly conflating two distinct things: "(1) a discrete set of tangible articles packaged as a product for commercial distribution (e.g., a COVID-19 test kit), and (2) an assortment of physical tools that laboratory professionals use in transient relationships to each other to deliver a service."[43] The court emphasized that

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[35] 21 U.S.C. § 321(h)(1).

[36] *ACLA*, 776 F. Supp. 3d at 575, 579–81.

[37] *Id.* at 575–78.

[38] *Id.* at 578–79 (citing ClearCorrect Operating, LLC v. ITC, 810 F.3d 1283, 1290–94 (Fed. Cir. 2015); Kaiser Aluminum & Chem. Corp. v. U.S. Consumer Prod. Safety Comm'n, 574 F.2d 178, 180 (3d Cir. 1978), AMP Inc. v. Gardner, 389 F.2d 825, 826–27 & n.4 (2d Cir. 1968)).

[39] *Id.* at 576–77.

[40] *Id.* at 577.

[41] *Id.*

[42] *Id.* at 577–78.

[43] *Id.* at 576–77.

agencies "can't evade established rules of statutory construction by fabricating their own definitions of commonly used terms, untethered to their ordinary meaning . . . ."[44]

The Broader Statutory Framework: FDCA and CLIA

Beyond the plain text of the device definition, the court found that its interpretation was reinforced by the broader statutory framework, including CLIA.[45] The court observed that the sequence of legislative enactments—the FDCA in 1938, the Clinical Laboratories Improvement Act in 1967, the Medical Device Amendments (MDA) in 1976, and the Clinical Laboratory Improvement Amendments in 1988—"reflects that Congress viewed (1) ensuring medical-device safety and effectiveness, and (2) ensuring laboratory-testing accuracy, as distinct problems requiring different regulatory solutions."[46] Despite this alternating sequence, "Congress never indicated that there was any overlap between these regulatory schemes."[47] On the contrary, "the Senate Report on the 1967 CLIA bill addressed concerns about possible overlap between regulation of clinical laboratories under CLIA and under the Medicare statute, but it did not mention any role for the FDCA in regulating clinical laboratories."[48] Similarly, the House Report on the 1988 CLIA bill "described '[t]he Current Regulatory System' as involving federal regulation of laboratories 'under two programs'—the Clinical Laboratories Improvement Act of 1967 and the Medicare statute—and did not mention regulation under the FDCA."[49] The Report also stated that CLIA's purpose was to ensure that laboratory test services are governed by a single "unified regulatory mechanism."[50]

The court reasoned that if, as FDA asserted, Congress intended the MDA to subject laboratory-developed test services to the FDCA's device regime, then "the enactment of the CLIA Amendments in 1988 makes little sense."[51] Under FDA's theory, by 1988, FDA already had authority to regulate those same tests—"authority that it was simply declining in its discretion to exercise."[52] That theory, the court concluded, "cannot be sustained without rendering CLIA largely, if not entirely, pointless."[53]

FDA's Historical Posture Toward LDTs

The court traced FDA's shifting posture towards regulating laboratory-developed tests over several decades, pointing to inconsistencies between the agency's assertions of jurisdiction and concurrent legislative history.[54] For well over a decade following Congress's enactment of the MDA in 1976 through 1992, "FDA did not claim any

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[44] *Id.* at 576.

[45] *Id.* at 580–84.

[46] *Id.* at 563–64.

[47] *Id.*

[48] *Id.* at 563–64 (citing S. Rep. No. 90-724 (1967), as reprinted in 1967 U.S.C.C.A.N. 2076, 2084).

[49] *Id.* at 564 (citing H.R. Rep. No. 100-899, at 11 (1988), as reprinted in 1988 U.S.C.C.A.N. 3828, 3831).

[50] *Id.* (quoting H.R. Rep. No. 100-899, at 12 (1988)).

[51] *Id.* at 583–84.

[52] *Id.*

[53] *Id.*

[54] *Id.* at 564–69.

authority to regulate laboratory test services as 'devices.'"[55] FDA first suggested it might possess such authority in 1992 in a draft Compliance Policy Guide, but the laboratory profession immediately objected, and FDA declined to finalize the guidance, assuring laboratories that it did "not intend to routinely exercise its authority over home-brew tests."[56] The agency subsequently made tentative claims of jurisdiction in the preamble to a 1996 proposed rule and the 1997 final rule regarding analyte-specific reagents, but each time continued to exercise enforcement discretion rather than actively regulating LDTs.[57]

FDA changed course again in June 2010, suggesting that it was "reconsider[ing] its policy of enforcement discretion" for laboratory-developed test services, and the agency issued draft guidance in 2014 proposing to phase in the regulation of LDTs over nine years.[58] In 2016, the House Appropriations Committee directed FDA to "suspend further efforts to finalize" its guidance and to "continue working with Congress to pass legislation that addresses a new pathway for regulation of [LDTs] in a transparent manner."[59] FDA summarized the comments it received on the 2014 draft guidance in a January 2017 discussion paper and explained that the agency would not be finalizing its guidance at that time "to allow for further public discussion . . . and to give our congressional authorizing committees the opportunity to develop a legislative solution."[60] In 2020, HHS's Office of General Counsel issued a memorandum (the "Charrow Memo") questioning whether FDA had authority to regulate LDTs as devices, observing that LDTs are not "goods or commodities" but rather "clinical laboratory services."[61] Congress, meanwhile, considered but declined to enact several pieces of legislation that would have reshaped the regulatory framework, including the VALID Act and the VITAL Act, neither of which passed in any session.[62]

The Laboratory Plaintiffs argued that FDA's reliance upon a "long-extant statute" to bring about a "transformative expansion in [its] regulatory authority" that "Congress ha[d] conspicuously and repeatedly declined to enact itself" violated the major questions doctrine, which "requires agencies to point to 'clear congressional authorization' for actions of major 'economic and political significance.'"[63] They argued that if Congress had intended to "upend the whole clinical laboratory

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[55] *Id.* at 564–65.

[56] *Id.* at 565–66 (quoting IVD Policy Will Not Include Exemptions for "Standard-of-Care" Tests, The Gray Sheet (Oct. 11, 1993)).

[57] *Id.* at 566; 61 Fed. Reg. 10,484, 10,485 (Mar. 14, 1996); 62 Fed. Reg. 62,243, 62,249 (Nov. 21, 1997).

[58] *ACLA*, 776 F. Supp. 3d at 566; 79 Fed. Reg. 59776 (Oct. 3, 2014); 79 Fed. Reg. 59779 (Oct. 3, 2014).

[59] *ACLA*, 776 F. Supp. 3d at 566–67 (quoting H.R. Rep. No. 114-531, 72–73 (2016)).

[60] *ACLA*, 776 F. Supp. 3d at 567; U.S. FOOD & DRUG ADMIN., Discussion Paper on Laboratory Developed Tests (LDTs) (Jan. 13, 2017), https://www.fda.gov/media/102367/download.

[61] *See* ACLA Compl. Ex. F at 3–4; ACLA MSJ at 13–14.

[62] *See* ACLA MSJ at 14–15; *ACLA*, 776 F. Supp. 3d at 567-68; Verifying Accurate Leading-Edge IVCT Development (VALID) Act of 2020, H.R. 6102, 116th Cong. (2020); VALID Act of 2021, H.R. 4128, 117th Cong. (2021); VALID Act of 2023, H.R. 2369, 118th Cong. (2023); Verified Innovative Testing in American Laboratories (VITAL) Act of 2020, S. 3512, 116th Cong. (2020); VITAL Act of 2021, S. 1666, 117th Cong. (2021).

[63] ACLA MSJ at 32–33 (quoting, Rest. Law Ctr. V. U.S. Dep't of Lab., 2024 WL 3911308, at *8 n.9; West Virginia v. EPA, 597 U.S. 697, 721, 724 (2022)).

profession," it "would have used the appropriate terminology to denote that intent and not hidden it in a statute expressly targeted" at manufactured products.[64]

FDA's Arguments in Defense of the Final Rule

FDA mounted a vigorous defense of its statutory authority. The government argued that the plain text of the FDCA "unambiguously" covers IVD test systems made by laboratories as "devices," emphasizing that the statute has always defined "device" broadly to include any diagnostic "instrument," "apparatus," or "contrivance," together with their "components, parts, and accessories."[65] FDA contended that the fact that an IVD test system is made by a laboratory, or that a laboratory monetizes tests on a fee-for-service basis, does not change the fact that the test system itself is comprised of physical components that function together to produce a test result.[66] The government also argued that CLIA and the FDCA "complement rather than conflict with each other," noting that "regulation under CLIA addresses the proficiency with which laboratories perform tests rather than design them," while "regulation under the FDCA addresses the design of test systems to help ensure that their results are clinically valid."[67]

On the major questions doctrine, FDA argued that this was an "ordinary case of federal regulation pursuant to unambiguous Congressional authorization," not "an extraordinary one presenting major political, economic, or federalism questions."[68] FDA further contended that it had not "newly uncover[ed]" jurisdiction over laboratory-made IVD test systems but had claimed this authority continuously since 1977.[69]

The Court's Ruling

The court rejected FDA's arguments across the board. It found that FDA's expansion of its jurisdiction was "foreclosed by the text, structure, and history of the FDCA and CLIA."[70] The court held that Congress created two separate regulatory frameworks: one vesting authority to regulate tangible devices with FDA, and another vesting authority to regulate laboratory services with CMS.[71] Because the court resolved the case on the ground that the final rule exceeded FDA's statutory authority, it did not need to address the Laboratory Plaintiffs' additional claim that the rule was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[72] The court likewise declined to reach the major questions doctrine, finding that the FDCA's "plain text" was sufficient to resolve the dispute.[73] However, the court acknowledged the doctrine's relevance, observing that it counsels that a "decision of

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[64] *Id.* at 32.

[65] FDA MSJ at 18–20 (citing 21 U.S.C. § 321(h)(1); United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969)).

[66] FDA MSJ at 19.

[67] *Id.* at 3, 36–41.

[68] *Id.* at 3–4.

[69] *Id.* at 21–26.

[70] *ACLA*, 776 F. Supp. 3d at 574.

[71] *Id.* at 574, 585.

[72] *Id.* at 571.

[73] *Id.* at 571 n.10.

such magnitude and consequence on a matter of earnest and profound debate across the country must rest with Congress itself, or an agency acting pursuant to a clear delegation from that representative body."[74]

Criminal Law Implications

The court also highlighted what it described as the "troublesome" and "implausible" consequences of FDA's interpretation.[75] Because FDCA violations can carry criminal penalties, including felony offenses with penalties of years of imprisonment, accepting FDA's reading would mean that "tens of thousands of professionals across the country performing millions of diagnostic testing services every year, working with thousands of doctors and patients, have done so for decades in open and direct violation of the law."[76] According to the court, FDA's theory would mean "that the entire clinical laboratory sector, a significant part of the healthcare system, has been breaking the law for nearly fifty years, and possibly much longer," with its "only protection coming from a policy of enforcement discretion that FDA maintains it is free to revoke at any time."[77]

While the Laboratory Plaintiffs argued that the rule of lenity should be applied given the threat of criminal penalties, the court disagreed, finding the rule inapplicable because there is no "grievous ambiguity" in the statute.[78] Nevertheless, the court noted that "the fallout" from FDA's interpretation "underscores [its] implausibility," and affirms that the agency's "strained reading of the FDCA flouts, rather than effectuates, Congress's intent."[79]

The Remedy

Having concluded that the final rule exceeded FDA's authority, the court turned to the appropriate remedy. Citing binding Fifth Circuit precedent, the court held that "vacatur under § 706 of the Administrative Procedure Act is . . . the 'default' remedy for unlawful agency action" and that "setting aside agency action under § 706 has nationwide effect, is not party-restricted, and affects persons in all judicial districts equally."[80] The court rejected the government's argument that any relief should be limited to the plaintiffs and their members, noting that "it would be impractical, if not impossible, to fashion party-tailored relief here," given the volume and variety of affected trade organizations' members.[81] The court found no basis for the "rare" remedy of remand without vacatur, concluding that "[t]here is no likelihood that FDA can justify its decision on remand, given that the final rule exceeds its authority under the FDCA."[82] Accordingly, the court granted the plaintiffs' motions for summary

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[74] *Id.*

[75] *Id.* at 582–83.

[76] *Id.*

[77] *Id.* at 583.

[78] *Id.* at 583 (quoting Pugin v. Garland, 599 U.S. 600, 610 (2023)).

[79] *Id.* at 583–84 (quoting Van Buren v. United States, 593 U.S. 374, 394 (2021).

[80] *Id.* at 584–85 (quoting Braidwood Mgmt., Inc. v. Becerra, 104 F.4th 930, 951-952 (5th Cir. 2024); Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs., 110 F.4th 762, 789 (5th Cir. 2024)).

[81] *Id.* at 585.

[82] *Id.* at 584–85

judgment, denied the government's cross-motion, and ordered the final rule set aside and vacated.[83]

CURRENT STATUS

The government did not appeal the district court's decision to the Fifth Circuit. Shortly after the opinion was issued, FDA posted a notice on its website confirming that the final rule had been vacated and that the agency would not be pursuing an appeal.[84] Because the court's order vacated the rule with nationwide effect, the phased enforcement timeline that was set to begin in May 2025—including adverse event reporting, registration and listing, labeling requirements, and eventually premarket review— did not occur and was rendered moot.[85]

In September 2025, FDA officially implemented the vacatur and rescinded the final rule.[86] This outcome is consistent with the current administration's broader posture toward regulatory restraint. As noted in the opinion itself, the defendants in the case include officials appointed by President Trump who have demonstrated skepticism toward expansive federal regulation of healthcare services.[87]

IMPACT

The *ACLA* decision represents a decisive, if not necessarily final, resolution of the longstanding debate over FDA's authority to regulate laboratory-developed tests. The decision is significant for several reasons.

First, the opinion provides the most thorough judicial analysis to date of the boundary between FDA's device authority under the FDCA and CMS's oversight of clinical laboratories under CLIA. By holding that LDTs are professional services rather than manufactured devices, the court drew a clear line that requires congressional action before FDA could feasibly reattempt to assert jurisdiction over this sector.[88] Put another way, the court's reasoning effectively forecloses not only the specific regulatory amendment at issue in this case—the addition of "including when the manufacturer of these products is a laboratory" to 21 C.F.R. § 809.3(a)—but also any future attempt by FDA to regulate LDTs as devices through rulemaking, guidance, or enforcement action, absent new legislation. The opinion's sweeping analysis of the FDCA's text, structure, and history leaves little room for FDA to craft an alternative regulatory approach under existing statutory authority.[89] This distinguishes *ACLA* from cases in which vacatur merely requires an agency to correct procedural deficiencies or provide a better explanation for its decision; here, the court concluded that the agency's fundamental jurisdictional claim was "foreclosed" by the statute

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[83] *Id.*

[84] See U.S. Food & Drug Admin., Laboratory Developed Tests, https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests (last visited Mar. 15, 2026).

[85] *See id.* at 570–71.

[86] U.S. Food & Drug Admin., Final Rule, Regulation Identification Number 0910–AJ05 Medical Devices; Laboratory Developed Tests; Implementation of Vacatur, 90 Fed. Reg. 45134 (Sept. 19, 2025).

[87] *ACLA*, 776 F. Supp. 3d at 560 n.1.

[88] *Id.* at 574, 583–85.

[89] *ACLA*, 776 F. Supp. 3d at 574–85.

itself.[90] As explained below, this reading also reinforces the principle, reaffirmed by the Supreme Court in *Loper Bright*, that courts must exercise their "independent judgment in deciding whether an agency has acted within its statutory authority" rather than deferring to the agency's own view of its powers.[91]

Second, the decision highlights the practical consequences of FDA's asserted authority, including the billions of dollars in compliance costs, the vast increase in premarket applications FDA would need to review, and the implication that an entire profession has been engaged in criminal activity for decades under the FDCA's penal provisions.[92] These consequences, the court suggested, only underscore the "implausibility" of FDA's statutory reading.[93]

The *ACLA* decision also has potentially broader implications for the scope of FDA's authority in other contexts. The court's reasoning that FDA may regulate only tangible "devices" and not the professional services that make use of those devices could be relevant to emerging questions about FDA's authority over other technology-enabled healthcare services, including software-based diagnostic tools and artificial intelligence applications in clinical settings. The court's analogies—comparing a laboratory's performance of a test to a radiologist reading an x-ray or a surgeon performing an operation using surgical instruments—suggest a broader principle that the use of regulated devices in the course of delivering a professional service does not convert the service itself into a device subject to FDA jurisdiction.[94] This reasoning could be invoked in future disputes over FDA's authority to regulate clinical decision-support software, telemedicine platforms, or other hybrid products and services that blur the line between tangible devices and professional healthcare activities.

The decision also carries important implications for the "regulatory gap" that now exists with respect to certain categories of laboratory-developed tests. While CLIA establishes standards for laboratory proficiency, quality control, and personnel qualifications, it does not address the clinical validity of tests—that is, the accuracy with which a test identifies, measures, or predicts the presence or absence of a clinical condition. As the government argued in its briefing, "if a laboratory test system lacks clinical validity . . . [it] will not provide meaningful diagnostic information no matter how great the expertise or experience of the professionals performing [it]."[95] FDA's final rule was motivated in part by evidence that some laboratory-developed tests have yielded inaccurate results, potentially causing patient harm.[96] With the final rule vacated, clinical validity remains unregulated at the federal level for most LDTs, and addressing this gap will likely require legislative action. Industry observers have noted that this gap may provide additional impetus for Congress to craft a tailored legislative framework that addresses patient safety concerns without subjecting the entire laboratory testing industry to FDA's device regime.

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[90] *Id.* at 574.

[91] *Loper Bright*, 603 U.S. at 391–92, 395; *ACLA*, 776 F. Supp. 3d at 572–74.

[92] *ACLA*, 776 F. Supp. 3d at 582–85.

[93] *Id.* at 583–84.

[94] *Id.* at 577–78 (analogizing laboratory-developed tests to radiological interpretations and surgical procedures).

[95] FDA MSJ, *supra* note 61, at 39 (quoting 89 Fed. Reg. at 37,340).

[96] *Id.* at 1–2 (describing "numerous examples of potentially inaccurate, unsafe, ineffective, or poor quality IVDs offered as LDTs that have or may have caused patient harm").

Finally, the decision intersects with broader themes in administrative law following the Supreme Court's landmark decisions in *Loper Bright* and *Corner Post*.[97] *Loper Bright* overruled *Chevron* deference and directed courts to find the "best" reading of a statute using traditional tools of statutory interpretation, rather than deferring to an agency's "reasonable" interpretation.[98] The *ACLA* court applied precisely this framework, engaging in a detailed independent analysis of the FDCA's text, structure, and history to reach its conclusion that the statute does not authorize FDA to regulate LDTs as devices.[99] Had *Chevron* still been in effect, the outcome might have been different: FDA's decades-long assertion that laboratory-made IVD test systems fall within its jurisdiction might have been sustained as a "permissible" reading of the statute, even if a court independently analyzing the issue would have reached the opposite conclusion.[100] The *ACLA* decision thus serves as a powerful illustration of *Loper Bright's* practical impact—demonstrating that the demise of *Chevron* deference can produce materially different outcomes in cases where agencies assert regulatory authority at the outer boundaries of their statutory mandates.

In *Corner Post*, the Supreme Court held that a claim under the Administrative Procedure Act (APA) does not accrue, for purposes of 28 U.S.C. § 2401(a)'s six-year statute of limitations, until the plaintiff is injured by final agency action—rather than when the agency action is published or becomes final. The *ACLA* decision did not need to rely on *Corner Post's* statute-of-limitations holding, because the timeliness of the *lawsuit* following the agency's final action was not the issue: the FDA's final rule was published on May 6, 2024, and the plaintiffs challenged it promptly. Instead, the *ACLA* court cited *Corner Post* for a different proposition drawn from Justice Kavanaugh's concurrence: that vacatur is the appropriate APA remedy for unlawful agency action and that it has nationwide effect, i.e. it is not limited to the specific plaintiffs. The court quoted Justice Kavanaugh's observation that the Supreme Court has "affirmed 'countless decisions that vacated agency action, including agency rules,'" and that those decisions "vacated challenged agency rules rather than merely providing injunctive relief that enjoined enforcement of the rules against the specific plaintiffs"[101] Relying on this framework, the *ACLA* court vacated the FDA's final rule in its entirety rather than merely enjoining its enforcement against the Laboratory Plaintiffs.

With the government's decision not to appeal, the *ACLA* decision now stands as the definitive judicial pronouncement on the boundary between FDA's device authority and CMS's oversight of clinical laboratories. Looking ahead, the most straightforward path toward resolving the regulatory status of LDTs is congressional action. Congress has repeatedly considered but failed to pass legislation addressing LDT regulation—including the VALID Act, which would have created a new regulatory pathway separate from both drugs and devices, and the VITAL Act, which would have

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[97] *See Loper Bright*, 603 U.S. 369; Corner Post v. Bd. of Governors of the Fed. Res. Sys., 603 U.S. 799 (2024).

[98] *Loper Bright*, 603 U.S. at 400–403.

[99] *ACLA*, 776 F. Supp. 3d at 572–74 (citing *Loper Bright*, 603 U.S. at 391, 395, 400).

[100] *See* Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843 (1984) (directing courts to defer to an agency's "permissible construction of the statute"); *Loper Bright*, 603 U.S. at 400 (overruling *Chevron* and holding that "a merely 'permissible' reading is not enough").

[101] *ACLA*, 776 F. Supp. 3d at 584 (citing *Corner Post*, 603 U.S. at 830–31).

expressly classified LDTs as professional health care activities regulated under CLIA.[102] New versions of both bills have been introduced in subsequent Congresses without success, and the political dynamics surrounding any such legislation remain complex.

Whether it becomes the catalyst for the kind of comprehensive congressional action that some stakeholders have long sought remains to be seen. In the meantime, the clinical laboratory industry will continue to operate under the existing CLIA framework, and the question of whether that framework adequately protects patients from clinically invalid tests will continue to animate the policy debate.

[102] See ACLA Compl. ¶¶ 86–89 (describing the VALID Act and VITAL Act); *ACLA*, 776 F. Supp. 3d at 567–68.

Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc.

WILLIAM M. JANSSEN*

WHY IT MADE THE LIST

James Barr Ames was Dean of the Harvard Law School until 1910, a devotee of Langdell's casebook method for teaching law,[1] and an intriguing speaker. During a guest lecture one day at Cincinnati's law school, Ames riveted his audience about the law's approach to a "duty to rescue":

> As I am walking over a bridge a man falls into the water. He cannot swim and calls for help. I am strong and a good swimmer, or, if you please, there is a rope on the bridge, and I might easily throw him an end and pull him ashore. I neither jump in nor throw him the rope, but see him drown. . . . Am I guilty of a crime, and must I make compensation to the widow and children of the man drowned . . . ?[2]

Ames then probed his own question: "As the law stands today there would be no legal liability, either civilly or criminally" since "[t]he law does not compel active benevolence between man and man. It is left to one's conscience whether he shall be the good Samaritan or not."[3] But, Ames mused, is this proper? Wouldn't we "all be better satisfied if the man who refuses to throw a rope to a drowning man . . . could be punished and be made to compensate the widow of the man drowned?"[4]

Imposing new legal duties is a controversial (and, often, morally challenging) undertaking. It zeros in on the balance the law must strike between actor autonomy and utilitarianism, or whether, for example, "one human being, seeing a fellow man in dire peril" can "sit on the dock, smoke his cigar, and watch the other drown."[5] The existence of a legal duty to "volunteer" and rescue has been so long debated that it may now be considered a canonical feature of every first-year torts class. And there,

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1 *See* Joseph H. Beale, *James Barr Ames—His Life and Character*, 23 HARV. L. REV. 325, 328 (1910) ("He promised his colleagues again and again to give up the making of case-books and get down to serious work—after just one more.").

2 James Barr Ames, *Law and Morals*, 22 HARV. L. REV. 97, 112 (1908).

3 *Id. See generally* RESTATEMENT (SECOND) OF TORTS § 314 (1965) ("The fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action.").

4 James Barr Ames, *supra* note 2, at 112–13. *See also* RESTATEMENT (SECOND) OF TORTS § 314 cmt c (1965) (though "condemned by legal writers as revolting to any moral sense," such cases "remain the law").

5 *Id.*

it does good service, because novel attempts to recalibrate the law's balance by pronouncing new duties will continue unabated.

In early 2025, the Appellate Division of New York's Supreme Court rebuffed one such request in *Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc.*, where a plaintiff argued that a body-sculpting device's manufacturer owed her a duty to warn about the risks posed by ice pack treatments her providers placed on her body once that treatment had concluded.[6] The duty of one manufacturer to warn about risks posed by another manufacturer's product is a nuanced inquiry. The Appellate Division's crisp navigation of that journey, and the legal standard it applied while doing so, qualifies this decision as one of the top food and drug cases of the year.

DISCUSSION

Plaintiff Liana Silverstein filed a product liability and medical malpractice lawsuit in New York State court seeking compensation for serious burns she sustained to her abdomen following a "CoolSculpting" procedure.[7]

"CoolSculpting" is the patented trade name for cryolipolysis,[8] a non-invasive body contouring technique (commonly known as "fat freezing") that uses cold temperatures to break down "a localized fat bulge that has persisted despite diet and exercise."[9] The procedure draws a "targeted area of pinchable fat" into an applicator device using vacuum pressure, where the pinched area is then cooled for a period of time. "Because fat cells are uniquely sensitive to cold," this "controlled cooling" aims "to kill the fat cells" without freezing the skin.[10] Thereafter, "[t]he fat released from the damaged fat cells is slowly cleared by the body's immune system, usually within two to three months. This causes the fat bulge to become smaller over time."[11] The American Society of Plastic Surgeons ranks cryolipolysis as "one of the most popular nonsurgical fat reduction treatments."[12] According to the manufacturer, "CoolSculpting" is "the leading fat freezing treatment" and the one "doctors use most for fat reduction without surgery," with more than 17 million treatments performed

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[6] Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc., 229 N.Y.S.3d 44, 45 (N.Y. Sup. Ct. App. Div. 2025).

[7] *See* Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc., 2024 WL 3255440, at *1 (N.Y. Sup. Ct. July 1, 2024) [hereinafter, *Silverstein I*], *rev'd*, 229 N.Y.S.3d 44 (N.Y. Sup. Ct. App. Div. 2025).

[8] *See Fat Freezing (Cryolipolysis)*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/treatments/21060-fat-freezing-cryolipolysis (last visited Feb. 25, 2026).

[9] *See Reasons patients want cryolipolysis—Nonsurgical Fat Reduction: Minimally Invasive Procedures*, AM. SOC'Y OF PLASTIC SURGEONS, https://www.plasticsurgery.org/cosmetic-procedures/nonsurgical-fat-reduction/cryolipolysisns (last visited Feb. 25, 2026).

[10] *See Non-Invasive Body Contouring Technologies—Thermal: Cold (Cryolipolysis or Fat Freezing),* FDA, https://www.fda.gov/medical-devices/aesthetic-cosmetic-devices/non-invasive-body-contouring-technologies (last visited Feb. 25, 2026). *See generally* User Manual for CoolSculpting® Elite System, https://www.rxabbvie.com/pdf/coolsculptingelite_manual.pdf.

[11] *Id.*

[12] *See What Is Cryolipolysis—Nonsurgical Fat Reduction: Minimally Invasive Procedures*, AM. SOC'Y OF PLASTIC SURGEONS, https://www.plasticsurgery.org/cosmetic-procedures/nonsurgical-fat-reduction/cryolipolysisns (last visited Feb. 25, 2026).

since 2009.[13] The device is FDA-cleared.[14] The manufacturer lists "typical side effects" from the procedure as including "temporary redness, swelling, blanching, bruising, firmness, stinging, tenderness, cramping, skin inflammation, and aching," as well as "[s]ensory alteration (itching, skin sensitivity, tingling, and numbness) [which] can persist up to several weeks after treatment."[15]

Ms. Silverstein apparently received seventy minutes of CoolSculpting treatment, after which the administering medical staff wrapped four ice packs directly against the skin of her abdomen and sent her home. Once home, Ms. Silverstein claimed that she attempted to remove the ice packs, but "they were stuck to her skin and 'just didn't come off.'"[16] When second degree burns developed, she sued her healthcare providers for medical negligence and, later, the CoolSculpting device manufacturer for product liability.[17]

In pressing her products claim, Ms. Silverstein evidently acknowledged that her injuries were not caused by a malfunction of the CoolSculpting device, nor were they caused during the CoolSculpting treatment or from the device's placement against her body.[18] Rather, Ms. Silverstein's theory was that the device manufacturer breached its duty to warn about the risks of placing ice packs directly on a patient's skin after a CoolSculpting treatment.[19] The ice packs used with Ms. Silverstein were not supplied by the device manufacturer.[20]

The manufacturer moved for summary judgment on Ms. Silverstein's products claim on several grounds. First, it asserted that the risks of prolonged use of ice packs directly on human tissue were commonly known. Second, because those risks were not ones "associated with the use of the Coolsculpting device," the manufacturer insisted they were not risks that gave rise to a duty to warn on its part.[21]

The trial court denied the manufacturer's motion. It began by noting New York's foreboding summary judgment standard: "The drastic remedy of summary judgment, which deprives a party of his day in court, should not be granted where there is any doubt as to the existence of triable issues or the issue is even 'arguable.'"[22] The court then cited to several facts from the summary judgment record that, it ruled, supported a denial of defendant's motion: (a) the device's user manual contained no warnings related to ice packs on bare skin after CoolSculpting treatments; (b) a slide from the manufacturer—entitled "Mitigating Late Onset Pain"—depicted "the use of ice packs

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[13] *See id.*

[14] *See How It Works*, COOLSCULPTING.COM, https://www.coolsculpting.com/how-it-works/faq (last visited Feb. 26, 2026).

[15] *See What are the Side Effects of CoolSculpting?*, COOLSCULPTING.COM, https://www.coolsculpting.com/how-it-works/faq (last visited Feb. 26, 2026).

[16] *See Silverstein I*, 2024 WL 3255440, at *1.

[17] *See* Priscilla DeGregory, *Fat 'Freezing' Procedure Leaves NYC Woman With Third-Degree Burns: Suit*, N.Y. POST (Dec. 18, 2019), *https://nypost.com/2019/12/18/fat-freezing-procedure-leaves-nyc-woman-with-third-degree-burns-suit/* (last visited Feb. 28, 2026).

[18] *Silverstein I*, 2024 WL 3255440, at *1–*2.

[19] *Id.*

[20] *See* Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc., 229 N.Y.S.3d 44, 45 (N.Y. Sup. Ct. App. Div. 2025) [hereinafter *Silverstein II*].

[21] *Id.* at *2.

[22] *Id.* (citation omitted).

to affected areas post treatment"; and (c) testimony by a manufacturer witness created doubt whether the manufacturer "viewed ice packs as contraindicated" or as "a part of its indicated protocol or treatment" for post-administration care.[23]

On appeal, a unanimous five-member panel of the Appellate Division (First Department) reversed, directing that the summary judgment motion be granted and that the complaint be dismissed against the CoolSculpting device manufacturer.[24] The appeals panel rested its decision on three grounds. First, the panel held that the manufacturer had no warning duty to Ms. Silverstein; because the CoolSculpting device was a Class II medical device requiring a prescription, any duty owed would run to prescribers and not to patients directly.[25] Second, under New York tort law, there was no duty to warn of well-known, obvious risks—which Ms. Silverstein's treating physician conceded included the risks of placing ice on bare skin.[26] Third, the panel ruled that the manufacturer would have had no duty to warn of the risks posed by the use of ice packs, as it was a product manufactured by someone else.[27] This third and last ground for reversal merits further discussion.

The appeals panel noted that New York has recognized a duty on the part of a manufacturer to warn about another company's product, but only under certain circumstances. "[T]he manufacturer of a product has a duty to warn of the danger arising from the known and reasonably foreseeable use of its product in combination with a third-party product which, as a matter of design, mechanics, or economic necessity, is necessary to enable the manufacturer's product to function as intended."[28] But that third-party product warning duty did not apply in this dispute, the appeals panel found. Ice packs "were not necessary in any way for the CoolSculpting device to function as intended."[29] Ice packs were not included with the device as supplies (essential or otherwise), were not suggested or recommended by the device's user's manual, and did not produce "any economic benefit" for the manufacturer that had been shown by record evidence.[30] The appeals court discounted the probative value of the "training slide" because it never depicted ice packs being used "simultaneously or in conjunction with" a CoolSculpting treatment, did not offer manufacturer advice but only "recommendations" from "clinicians," and even that advice concerned just "late onset pain" (which occurs not during CoolSculpting treatment, but "develops days or weeks" later).[31] Accordingly, the appeals panel concluded that no duty to warn arose on the part of the CoolSculpting device's manufacturer to caution about ice packs supplied by a different company.

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[23] *Id.* at *3.

[24] *See Silverstein II*, 229 N.Y.S.3d at 45.

[25] *Id.* at 46.

[26] *Id.* (noting that the treating physician "testified that through his education and training, he was aware of and knew of the dangers of placing ice on bare skin, and that those dangers were basic medical knowledge").

[27] *Id.* at 45–46.

[28] *Id.* at 45 (quoting In re New York City Asbestos Litig., 59 N.E.3d 458, 463 (N.Y. 2016)).

[29] *Id.*

[30] *Id.*

[31] *Id.*

IMPACT

Imposing on a manufacturer an additional duty to warn when a consumer uses its product in tandem with another company's product evokes, in some quarters, a visceral sense of injustice—as though the venerable moral/legal joust over a legal duty to rescue or to volunteer has been renewed. On first glance, such a duty seems at odds with settled, foundational products liability theory. The New York Appellate Division's ruling in *Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc.* confronts that impression.

At the very core of products law lies the notion of "defectiveness." It has been that way for millennia—from ancient Roman law, through the ecclesiastical law of the middle ages, then to English law, and on to colonial and post-colonial law in America.[32] "[T]he essence of accountability in products liability law," writes the legendary products scholar Davd G. Owen, "is that the defendant supplied a product that was *deficient* in some respect"; indeed, "[r]egardless of the underlying cause of action, plaintiffs in products liability cases normally must establish that something was *wrong* with the product" that the defendant supplied.[33]

But this attribute is more than just the core of products law: it is also its grounding logic. When Justice Roger Traynor penned his court's pioneering adoption of strict products liability in 1963, he expressed his and his colleagues' reasoning in just these sorts of terms: "Implicit in" a product's "presence on the market" is "a representation that it would safely do the jobs for which it was built."[34] Liability followed when that representation proved to be mistaken: when a product's "own appearance of excellence . . . belied the defect lurking beneath the surface."[35] Or, put another way: "To establish the manufacturer's liability it was sufficient that plaintiff proved that he was injured while using the [product] in a way it was intended to be used as a result of a defect in design and manufacture of which plaintiff was not aware that made the [product] unsafe for its intended use."[36]

The American Law Institute has endorsed the law's emphasis on product "defect" for more than half a century, and continues to endorse it today. Section 2 of the Third Restatement of Torts advises that a product is defective "when, at the time of sale or distribution, it contains . . . inadequate instructions or warnings," and instructions or warnings are inadequate when failing to provide them "renders the product not reasonably safe."[37]

The recurring theme is the defining focus on something wrong with *the product*. It is *the product* that the law is testing for a "defect." *The product* must suffer from some sort of deficiency "lurking beneath the surface" that, when encountered, results in injury to someone while they were in the act of "using" the product "in the way it was intended to be used." If *the product* is not defective, but its use in combination with

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[32] *See generally* DAVID G. OWEN, PRODUCTS LIABILITY LAW 341 (4th ed. 2022).

[33] *Id.* The qualifier "normally" acknowledges compensable claims anchored on attributes such as non-conformity, like breach of warranty or fraud, where a non-defective product might nonetheless still be actionable.

[34] Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 901 (Cal. 1963).

[35] *Id.*

[36] *Id.*

[37] RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(c) (1998).

another product causes an injury, why should there be failure-to-warn liability on the part of the non-defective product's manufacturer?

The appeals panel in *Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc.* decided Ms. Silverstein's case by applying a standard announced a decade earlier by New York's Court of Appeals. In that earlier case, *In re New York City Asbestos Litigation*, the court announced a standard that it had reframed, but its essence had long been applied by the State's appellate courts.[38] In fact, the court wrote, so settled was this existing precedent that the *In re New York City Asbestos Litigation* reframing "adds but a note to a familiar anthem in failure-to-warn jurisprudence."[39] Still, the court's formulation did supply a further bit of precision: "[T]he manufacturer of a product has a duty to warn of the danger arising from the known and reasonably foreseeable use of its product in combination with a third-party product which, as a matter of design, mechanics, or economic necessity, is necessary to enable the manufacturer's product to function as intended."[40]

On closer inspection, this standard does not undermine or contradict core product theory. It aligns with it. The standard supposes a very particular factual setting: that the manufacturer is supplying a product it knows (or could reasonably foresee) cannot function as intended unless and until some third-party's product is added to it. Put another way, in this setting, it is the manufacturer's product that is incomplete, inoperable, nonfunctional without the third-party's add-on. That addition isn't an "extra" in those circumstances; it is essential. It is there, and only there, that this new duty to warn arises.

To be sure, the Court of Appeals carefully cabined its standard. Mere foreseeability of harm is not enough to create this duty, nor is a weighing of equities, symmetry, and sympathy.[41] Instead, courts must assess, on a case-by-case basis, whether the manufacturer in question is in a superior position, when compared to users, "to know of and warn against" the new danger created by the combined use.[42] To users, the court explained, a modern product may often seem to be "a most sophisticated and even mysterious article," well insulated from an ordinary consumer's practical ability to detect dangers—a situation only magnified when two incomprehensibly complex products are combined during a joint use "because he or she rarely has access to sufficient technical information about both products to anticipate the perils of their joint use."[43] This is especially true when the third-party's add-on product is a fungible one that deteriorates and must be replaced; there, users are "more likely to interact with the durable product over an extended period of time, and hence he or she is more likely to inspect warnings on that item or in associated documentation than to review warnings supplied by the maker of the 'wear item.'"[44]

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[38] In re New York City Asbestos Litig., 59 N.E.3d 458, 463 (N.Y. 2016) (the court summarized this settled precedent this way: "a manufacturer has a duty to warn about the dangers resulting from the combined use of its product with another product that is essential to the intended function of the manufacturer's product").

[39] *Id.* at 476.

[40] *Id.* at 463, 474.

[41] *Id.* at 469–70.

[42] *Id.* at 471–72.

[43] *Id.* at 473 (citations omitted).

[44] *Id.* at 472.

The imposing of this added duty of care, admonished the Court of Appeals, hinges in part on "whether the manufacturer's product can function without the other product."[45] This is the duty's trigger because "it would be unfair to allow a manufacturer to avoid the minimal cost of including a warning about the perils of the joint use of the products when the manufacturer knows that the combined use is both necessary and dangerous."[46] And that is not unfair to the manufacturer, the court concluded, because when "a manufacturer creates a product that cannot be used without another product," that manufacturer "has a substantial, albeit indirect, role in placing the third-party product in the stream of commerce" and thus "derives a benefit from the sale of the essential third-party product, as the manufacturer is able to sell its own product to customers precisely because the third party has sold to those customers another item that is essential to the product's function."[47]

A simple example helps illustrate the court's standard. If the manufacturer's vehicle requires diesel (not gasoline) or gasoline (not diesel), the *In re New York City Asbestos Litigation* standard would impose upon the manufacturer a legal duty to warn the vehicle's user against filling up with the wrong type of fuel—if doing so would create a foreseeable danger.

Applying its standard to the facts in *In re New York City Asbestos Litigation* was simple for the Court of Appeals in that case.[48] That defendant manufactured valves for use in high-pressure, high-temperature steam pipes, but those valves could not function practically without gaskets, insulation, and packing around the valve stems. The defendant manufacturer knew this. It specified the use of asbestos-containing components for that valve-stem-surrounding purpose, packaged new valves it sold with asbestos-containing gaskets, and marketed a sheet of asbestos-based material for users when the aging gaskets wore out and needed to be replaced. The Court of Appeals ruled, on those facts, that the valve manufacturer owed a duty to warn about the risks of using asbestos materials with its valves.[49]

Ms. Silverstein's case seemed equally easy to resolve for the Appellate Division of the New York Supreme Court; the ruling took only two brief paragraphs. Ice packs were not necessary or essential for the CoolSculpting device to operate; to the contrary, while the CoolSculpting treatment was underway, there apparently was no ice pack involvement of any sort. The CoolSculpting device's manufacturer did not supply ice packs with its product, nor does the user's manual suggest that ice packs were required "as a matter of design, mechanics, or economic necessity . . . to enable the manufacturer's product to function as intended."[50] Unlike the asbestos gaskets needed for the high-pressure stem valves to function, ice packs played no role—essential or otherwise—in the operation of the CoolSculpting device. Pivotally, the ice packs were

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[45] *Id.* at 474. In the different but analytically similar context of component parts, the law may hold component part suppliers liable "for harm to persons or property caused by a product *into which the component is integrated* if" the component is defective or the integration causes a defect. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5 (1998) (emphasis added). Again, incorporation *into the product* is the point of liability.

[46] *Id.*

[47] *Id.*

[48] The Court of Appeals ruling came in a consolidated case; the facts recounted in this paragraph concern just the first of the two consolidated factual settings.

[49] *Id.* at 463–78.

[50] *Id.* at 463, 474.

applied to Ms. Silverstein's torso by her medical professionals only after the CoolSculpting treatment had finished and she was discharged to go home. By any measure, the standard announced in *In re New York City Asbestos Litigation* was found to be plainly inapplicable.

The Appellate Division's task was made easier in several further respects. First, the ice packs used with Ms. Silverstein were not "a most sophisticated and even mysterious article" that defied common appreciation; to the contrary, Ms. Silverstein's treaters (and, one could surmise, laypersons in general) readily understood how ice packs worked and the risks they posed to bare skin. Second, the ice packs were not wrapped around Ms. Silverstein's body by the CoolSculpting manufacturer, but by her treating medical professionals who were making personalized treatment decisions about how best to care for her. Third, in the trial court's retelling of Ms. Silverstein's allegations, the ice packs were not the true culprit here. According to the lawsuit, the injury-causing error wasn't the decision to use ice packs, but to place them directly on Ms. Silverstein's bare skin ("the ice packs should have been wrapped in gauze or paper towels before application to her skin")—an alleged error in professional technique.[51] Fourth, ice packs were not a fungible, degradable commodity that could not support a warning or be accompanied by a written one supplied by the treaters. Fifth, there was no economic synergy of any sort between the CoolSculpting device manufacturer and the ice packs maker.

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Enterprising lawyers will never cease attempting to press the boundaries of duty theory in products cases. Nor should they. Legal creativity is the engine of change. A century ago, Dean Ames aspirationally characterized "the spirit of reform" as a quest to bring "our system of law more and more into harmony with moral principles."[52] Yet, the balance between autonomy and utilitarianism will never be perfectly fixed, and the law needs clear and certain benchmarks to set duty theory fairly. In *Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc.*, the New York appeals court added a valuable new chapter to that task.

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[51] *Silverstein I*, 2024 WL 3255440 at *1.

[52] James Barr Ames, *supra* note 2, at 113.

The Rise of Big Food Litigation: Is a Landmark Decision in Pennsylvania Only the Beginning?

ANAND AGNESHWAR & JOCELYN WIESNER*

For decades, the plaintiffs' bar rode the wave of "Big Tobacco" litigation, bringing lawsuits across the country that allege deliberate concealment of the addictive nature of nicotine and the health consequences of tobacco. That playbook is now being imported into novel litigation against the food and beverage industry. The ultra-processed food (UPF) litigation landscape is young, but it is moving fast. A landmark ruling from the Eastern District of Pennsylvania in August 2025 in a personal injury case provides the first meaningful judicial signpost for how these cases will be evaluated — and offers important lessons for defendants and their counsel. At the same time, new complaints by the City of San Francisco and additional personal injury plaintiffs, coupled with accelerating regulatory activity, make clear that the Pennsylvania dismissal is a pause, not an end.

I. WHAT ARE ULTRA-PROCESSED FOODS—AND WHY DOES THE DEFINITION MATTER?

There is a threshold question that requires attention: What constitutes ultra-processed foods? Currently, there is no universally accepted scientific or legal definition of "ultra-processed food." This definitional ambiguity is more than a technicality—it sits at the heart of both the litigation and the regulatory landscape, and will shape what legal theories and defenses are available to both plaintiffs and defendants.

Thus far, plaintiffs have relied on the NOVA classification system, a framework that categorizes foods based on degree of processing rather than nutritional content. Under NOVA, "ultra-processed foods" are described as "industrial formulations made entirely or mostly from substances extracted from foods . . . derived from food constituents . . . or synthesized in laboratories from food substrates." Common examples include soft drinks, packaged snacks, frozen meals, breakfast cereals, processed meats, and candy.

The NOVA definition is broad, however, and has the potential to sweep in foods with documented health benefits, such as certain whole grain products, yogurts, plant-based proteins, and even infant formula. FDA, for its part, is seeking to establish a uniform definition—which was expanded to come as early as April 2026. In July 2025, FDA, HHS, and USDA jointly published a Request for Information seeking public input to develop a uniform federal definition of UPFs—the first such effort in agency

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history.[1] As discussed further below, the outcome of that process could have significant implications for UPF litigation going forward.

II. *MARTINEZ V. KRAFT HEINZ*: THE TEST CASE AND ITS LESSONS

Background

Martinez v. Kraft Heinz Company[2] is widely regarded as the opening salvo in what may become large-scale UPF mass tort litigation. The case, originally filed in Philadelphia County on December 10, 2024, and subsequently removed to the Eastern District of Pennsylvania, names eleven of the largest food and beverage companies in the country: Kraft Heinz Company, Inc., Coca-Cola, PepsiCo Inc., General Mills, Inc., Nestlé USA Inc., WK Kellogg Co., Mars Incorporated, Inc., Mondelez International, Inc., Post Holdings, Inc., ConAgra Brands, Inc., and Kellanova.

Plaintiff Bryce Martinez, a Pennsylvania teenager, alleged that his regular consumption of unspecified UPFs throughout his adolescence caused him to develop type 2 diabetes and non-alcoholic fatty liver disease at age sixteen—conditions the complaint characterized as historically confined to older adults. The 147-page, 668-paragraph complaint explicitly invoked the tobacco litigation framework, alleging that "Big Tobacco took over the American food environment" in the 1980s.[3] The complaint further argued that tobacco companies deliberately transplanted their "addiction science" and marketing techniques directly into the food industry through a series of acquisitions and mergers with food companies. The complaint asserted a wide array of state law claims, including negligence, failure to warn, breach of implied warranty, fraudulent misrepresentation and concealment, and concerted action.

Notwithstanding the length, the complaint was relatively bereft of relevant details. Although it alleged that over 100 brands encompassing thousands of products contained UPFs, it failed to allege *which* specific products plaintiff consumed. Further, the complaint relied on general studies suggesting an association between UPFs and various health consequences without identifying a link between any specific UPF he consumed and his alleged injuries. This approach reflects a fundamental weakness in UPF personal injury claims: even strong population-level epidemiological studies do not establish specific causation for an individual plaintiff.

The Court's Decision

On August 25, 2025, Judge Mia Roberts Perez dismissed the complaint in its entirety, finding it "woefully deficient" on two independent grounds: failure to plausibly allege specific causation, and failure to provide sufficient notice to defendants under Federal Rule of Civil Procedure 8.

A plaintiff asserting a products liability claim must plausibly allege both general causation (that the substance is capable of causing the observed harm) and specific causation (that it actually caused the plaintiff's harm). Focusing on specific causation, the court heavily criticized the lengthy complaint for containing only nine specific allegations about the plaintiff: the "most substantive of which being that Plaintiff

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1 90 Fed. Reg. 35,305 (July 25, 2025).

2 No. 2:25-cv-00377 (E.D. Pa.).

3 Compl. at 7.

regularly ingested UPFs and was diagnosed with type 2 diabetes and non-alcoholic liver disease at the age of 16."[4] The complaint contained no allegations regarding how often he consumed defendants' products, in what quantities, over what time period, or how those consumption patterns related to the onset of his conditions. Because the plaintiff had failed to "plead more than a mere possibility of causation," it did not pass muster under Rule 8.[5]

Although the court did not rule on general causation, it clearly recognized the hurdles plaintiff would face given the "reality that these diseases have a multitude of causes."[6] As the court emphasized, type 2 diabetes and non-alcoholic fatty liver disease have numerous potential causes—including genetics, sedentary lifestyle, and diet generally—and attributing these conditions to specific defendants' products without particularized factual allegations was implausible under *Twombly*.

The court also found that the complaint independently failed Rule 8's notice requirement. The complaint named eleven defendants and pointed to more than 100 brands, placing thousands of products at issue, without attributing particular conduct or specific products to particular defendants. Such shotgun pleading makes it "impossible for each Defendant to determine what conduct, design, promotion, sale, or product Plaintiff is referring to."[7]

Notwithstanding the pleading deficiencies, Judge Perez expressed sympathy for the public health concerns underlying the litigation, noting that the court was "deeply concerned about the practices used to create and market UPFs, and the deleterious effect UPFs have on children and the American diet."[8]

Nor did she address the defendants' remaining legal arguments, including whether the complaint compelled unsupported scientific speech in violation of the First Amendment, or whether the claims were preempted by federal food labeling laws. Nonetheless, the court's heavy criticism of the complaint reflects a practical reality that personal injury plaintiffs will face significant challenges in pleading—and ultimately proving—causation.

The plaintiff subsequently filed a motion for leave to amend in late November 2025, which remains pending as of the date of this article. That proposed complaint, however, continues to suffer from significant deficiencies. For example, it relies on general literature linking UPFs generally to certain diseases without discussing any particular product, and fails to meaningfully contend with the allegation that plaintiff consumed UPFs from 180 *different* products (let alone the multitude of other environmental factors at play).

III. UPF LITIGATION ACROSS THE COUNTRY

Martinez was only the first salvo in the UPF litigation. In the first three months of 2026, the same firms in *Martinez* have filed copycat complaints across the country

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4 Op. at 1.

5 *Id.* at 4.

6 Op. at 4.

7 Op. at 6.

8 Op. at 2.

alleging harm from consumption of UPFs—signaling their intent to seek an MDL.[9] These personal injury cases target the same group of defendants and utilize the same tobacco-framework set forth in *Martinez*. And importantly, plaintiffs are learning: While they draw directly on the original *Martinez* narrative framework, they have mirrored the more detailed (albeit likely still deficient) product-specific, defendant-specific consumption allegations found in the proposed amended *Martinez* complaint in a clear attempt to overcome a motion to dismiss.

Take *Lawton v. Kraft Heinz Co.*[10] for example. Much like in *Martinez*, the plaintiff alleges that he regularly consumed UPFs, which led to his diagnosis of type 2 diabetes at age nine. And as with the proposed amended *Martinez* complaint, the plaintiff alleges which specific products he consumed and at what regularity. For example, the complaint alleges that the plaintiff regularly consumed Capri Sun approximately three times per week, Cool Whip approximately three times per month, Jell-O Pudding approximately three times per week, Velveeta approximately three times per year, and Stove Top approximately four times per year.

The complaint further alleges that plaintiff's long-term, chronic, and regular exposure to these specific products—beginning as early as 2011 and continuing until his 2019 diagnosis—caused chronic metabolic dysfunction, a chronic inflammatory state, and increased insulin resistance that substantially contributed to his type 2 diabetes. The complaint alleges there are "no plausible alternative explanations" for J.L.'s injuries, and expressly argues that, had he not regularly consumed UPFs manufactured by the defendants over many years, he would not have been diagnosed at age nine.

This level of product-level specificity now appearing in UPF complaints is likely a direct and deliberate response to the fatal defect Judge Perez identified in *Martinez*. Whether it is sufficient is yet to be seen as these cases are still in their infancy: In both Lawton v. Kraft Heinz and Muthusami v. Kraft Heinz, courts adopted coordinated briefing schedules permitting defendants to file omnibus motions to dismiss, but to date no motions have been ruled on.[11]

IV. *PEOPLE V. KRAFT HEINZ*: THE GOVERNMENT ACTION IN CALIFORNIA

On December 2, 2025, San Francisco City Attorney David Chiu filed suit in San Francisco Superior Court against the same eleven food manufacturers. The case—*People v. Kraft Heinz Co.*—was filed on behalf of the People of the State of California and subsequently removed to the Northern District of California in January 2026.[12] On

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[9] *See, e.g.*, Lawton v. Kraft Heinz Co., No. 1:26-cv-44 (S.D. Miss.); Ford v. Kraft Heinz Co., No. 3:26-cv-00077 (E.D. Ark. Mar. 5, 2026); Jenkins v. Kraft Heinz Co., No. 2:26-cv-00115 (E.D. La.) (voluntarily dismissed without prejudice on March 30, 2026); Muthusami v. Kraft Heinz Co., No. 6:26-cv-00113 (M.D. Fla.); Sanford v. Kraft Heinz Co., No. 7:26-cv-01430 (S.D.N.Y.).

[10] No. 1:26-cv-44 (S.D. Miss.).

[11] Defendants filed a motion to dismiss in Lawton on May 1. The court set the deadline to file a motion in Muthusami for June 17, 2026. Those motions may provide the next meaningful judicial guidance regarding whether plaintiffs' more product-specific allegations are sufficient to overcome the causation and notice deficiencies identified in Martinez.

[12] People v. Kraft Heinz Co., No. 4:26-v-00183 (N.D. Cal.).

April 23, 2026, Judge Jon Tigar granted the City's motion to remand, returning the case to San Francisco Superior Court.

The same law firm that filed the *Martinez* case—Morgan & Morgan—are co-counsel, signaling a coordinated litigation campaign across multiple fronts.

The California complaint, which seeks both injunctive relief and civil penalties, asserts violations of California's Unfair Competition Law, Business & Professions Code § 17,200, and the state's public nuisance statute. As with the personal injury cases, the complaint draws analogies to tobacco litigation, alleging that defendants followed the "Big Tobacco Playbook," engaging in deliberate actions to make UPFs addictive and target vulnerable populations.

Government actions like this are perhaps more dangerous than personal injury cases—though not immune from significant challenges. Unlike in personal injury cases, government plaintiffs acting under consumer protection or public nuisance theories generally need to demonstrate only general causation—that defendants' conduct was capable of contributing to public harm. They generally do not have to prove that any particular consumer was deceived or suffered actual harm; only whether the deception is material and would deceive a reasonable consumer. This eliminates the central vulnerability that doomed the original *Martinez* complaint.

Moreover, government actors asserting consumer protection civil penalties do so in the hopes of obtaining huge awards: Such plaintiffs often allege that each individual purchase is its own penalty, each subject to a statutory penalty of thousands of dollars.

That said, government cases like this are not without burden. As with personal injury cases, government actors will have to contend with the amorphous nature of UPFs and the relative scientific uncertainty. Such claims will likewise face federal preemption headwinds as well as strong First Amendment arguments against any theory that would compel disclosure of nutritional characterizations.

V. THE REGULATORY LANDSCAPE: WHY DEFINITION WILL DEFINE THE LITIGATION

The UPF litigation is unfolding against a backdrop of evolving regulatory action. Both FDA Commissioner Marty Makary and HHS Secretary Robert F. Kennedy Jr. have raised concerns about the potential link between UPFs and chronic diseases. FDA, for example, stated that the United States "faces a growing epidemic of preventable diet-related chronic diseases" and that researchers "have found links between the consumption of [UPFs] and a range of negative health outcomes."[13]

On July 25, 2025, FDA, HHS, and USDA jointly published a Request for Information (RFI) seeking public input on a uniform definition of ultra-processed foods.[14] The RFI explicitly acknowledged that "there is no single, universally accepted definition of UPFs" and that classification systems vary significantly. Although no definition has come out of that process yet, the comment period closed in October 2025 and Kennedy had previously indicated that a definition would be issued in April 2026 with "front-of package food labeling" to follow.[15]

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[13] *See Ultra-Processed Foods*, U.S. FOOD & DRUG ADMIN. (Sept. 18, 2025), https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/ultra-processed-foods.

[14] Docket No. FDA-2025-N-1793; 90 Fed. Reg. 35,305.

[15] Notably, some states have begun moving ahead of federal regulators. California enacted legislation in October 2025 establishing a statutory definition of certain "ultra-processed foods of concern" in the

The RFI process bears close monitoring. The definitional question that was central to defendants' motion to dismiss in *Martinez* will eventually have a federal answer, and that answer could reshape the litigation landscape in critical ways. For example, a formal definition could act as a bright line standard for litigation defining which specific products are (and are not) subject to potential liability. Conversely, to the extent FDA steps in to regulate UPFs and the corresponding product labels, doing so could serve as a preemption shield against state tort claims requiring additional or different disclosures or designs.

THE IMPACT

Despite the speed and coordination with which the UPF litigation wave is building, defendants have substantial grounds to defeat it—both in individual personal injury actions and in the more formidable government cases.

On the personal injury side, causation is not merely a pleading problem. The prevailing scientific literature on UPFs, while generating epidemiological associations at a population-level, do not establish causation at the individual level. As the court in *Martinez* recognized in granting dismissal of the original complaint, the alleged "diseases have a multitude of causes" and confounding factors,[16] including genetics, socioeconomic status, overall dietary patterns, physical activity, and other lifestyle factors. Even if a plaintiff could surpass that hurdle, given the prevalence of UPF as currently defined, it will be difficult if not impossible for plaintiffs to link an injury to any particular defendant. Plaintiffs who consume a dozen different defendants' products daily cannot reliably attribute a complex, multifactorial metabolic condition to any one product, any one defendant, or even UPF consumption as a whole. Individually tried, these cases are unlikely to withstand summary judgment on causation in any jurisdiction that applies a rigorous *Daubert* standard to expert testimony on specific causation.

The prospects for aggregation through multidistrict litigation (MDL) or class action do not materially improve plaintiffs' position, and may in fact sharpen the defense. Although there is no MDL yet, it would appear that the plaintiffs' bar is positioning itself for one by filing cases across the country. If the plaintiffs' bar is successful in consolidating these cases, defendants should vigorously push for a schedule that requires early resolution of the key causation questions.

On the class action front, a putative class of UPF consumers—alleging personal injury or consumer fraud—would face nearly insuperable obstacles under Rule 23(b)(3). The causation inquiry in any individual UPF injury case is inherently plaintiff-specific: which advertisements was plaintiff exposed to, which products did this person consume, in what quantities, over what period, against what genetic and lifestyle background, to name just a few. Such questions cannot be resolved on a class-wide basis.

Government cases present a more serious challenge—but not an insurmountable one. Although these consumer protection plaintiffs need not prove individual reliance

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school-food context, creating one of the first state-law frameworks directed specifically at UPFs. While the statute is limited in scope, plaintiffs and regulators may seek to invoke such state-level definitions in future litigation as evidence of emerging regulatory consensus.

[16] Op. at 4.

or specific causation for each affected consumer, they will face significant scientific hurdles as with personal injury cases.

Taken together, these defenses—causation science, class certification obstacles, federal preemption, and First Amendment protection—provide a robust architecture for contesting UPF litigation at every stage, and defendants and their counsel should be developing each of them in parallel.

CONCLUSION

The UPF litigation wave is not a hypothetical. The *Martinez* dismissal provides a real-time demonstration of the pleading standards plaintiffs must meet and the arguments defendants have available. But additional complaints, filed just months later and directly designed to correct the deficiencies of the original complaint in *Martinez*, show that plaintiffs' counsel are reacting quickly—and in a coordinated fashion. The City of San Francisco action, meanwhile, presents a fundamentally different legal threat that the *Martinez* dismissal does not address.

The dismissal is no doubt correct, but is not the end of the story. Companies should closely track developments across the cases and whether they survive early motions to dismiss or jurisdictional challenges.

Note: As of the date of publication, the plaintiff in Martinez v. Kraft Heinz *has filed a motion for leave to amend his complaint, which remains pending before Judge Perez in the Eastern District of Pennsylvania. The San Francisco action,* People v. Kraft Heinz*, was remanded on April 23, 2026, but is still at its earliest procedural stages. A case management conference is currently set for July 1, 2026.* Lawton v. Kraft Heinz *was filed on February 12, 2026 in the Southern District of Mississippi. Defendants filed a motion to dismiss as well as a motion to stay proceedings pending resolution of the MTD on May 1; both motions remain pending.*

2025 Significant Settlements

HELEN K. RYAN & LAURA K. SCHWENDEMAN*

INTRODUCTION

This chapter summarizes a selection of significant settlements[1] in 2025 between members of the food and drug industry and government agencies, such as the U.S. Department of Justice (DOJ) and the U.S. Food and Drug Administration (FDA). As with prior years' "Significant Settlements" chapters, we have included settlements arising from enforcement actions brought by the DOJ under the False Claims Act (FCA) and Anti-Kickback Statute (AKS) and enforcement actions involving violations of the Federal Food, Drug, and Cosmetic Act (FDCA).

The FDCA-specific resolutions pertain to a variety of issues, such as unapproved medical devices due to reintroduction of a significantly changed or modified device, misbranded medical devices due to concealment of known defects, and failure to provide FDA with prior import notice. Consistent with prior years, the settlements arising from enforcement of the FCA, which imposes liability on persons and companies who defraud governmental programs and contracts, and the AKS, which prohibits the knowing and willful payment of remuneration to induce or reward referrals of items or services that are reimbursable by federal healthcare programs, far outnumber those for violations of the FDCA. These FCA and AKS resolutions include the first time a management consulting firm has been held criminally liable for advice resulting in the commission of a crime by a client; two settlements involving falsified, misrepresented, manipulated, and duplicated data and images related to federally funded research; and kickback allegations relating to high-profile migraine and HIV medications.

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[1] In this chapter, the term "settlements" is used as an umbrella term and includes both true settlements and other non-litigated resolutions such as criminal plea bargains.

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Below is a review of several settlements between the government and the food and drug industry involving alleged violations of the FDCA brought by DOJ in 2025.

This past year marked a significant reorganization of the DOJ's enforcement structure related to FDCA enforcement.[2] On September 25, 2025, DOJ created the Enforcement & Affirmative Litigation Branch in the Civil Division, assigning civil cases arising under the FDCA, Consumer Product Safety Act, Federal Trade Commission Act, and other statutes to the new Enforcement Section, one half of the new branch. In its announcement, DOJ stated that some of the new section's priorities will include "unfair and deceptive trade practices from China, or false and misleading claims about drugs and dietary supplements manufactured by pharmaceutical companies."[3] This reorganization is a part of the broader dissolution of the DOJ's Consumer Protection Branch (CPB) on September 30, 2025.

CPB was previously primarily responsible for both criminal and civil enforcement action under statutes relating to consumer protection, including the FDCA. Following dissolution of CPB, DOJ's FDCA enforcement functions are split, with civil functions in the Civil Division's Enforcement & Affirmative Litigation Branch and criminal functions in the Criminal Division's Health & Safety Unit (HSU) of the Fraud Section, the latter of which was established on December 2, 2025.[4] In updating its website after the reorganization late last year, DOJ characterized HSU's priorities as "criminal actions against companies and individuals who fail to maintain sanitary facilities, distribute adulterated or misbranded food or drug products, conceal safety-related information from the FDA, or make significant misrepresentations to the public."[5] It remains to be seen whether this overhaul will result in any substantive changes to the manner, methods, or strategy for FDCA enforcement actions.

A. Food

1. Able Groupe Inc.[6]

Able Groupe Inc. (Able Groupe) agreed to pay $304,640 as part of the DOJ's $2.3 million total recovery proposal under its plea agreement for failing to provide prior notice to FDA before importing food, in violation of the FDCA. This case marks the first time a defendant has pled guilty to a felony violation for failing to provide prior import notices to FDA. Able Groupe admitted to selling infant formula to U.S.

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[2] *The Department of Justice Creates New Civil Division Enforcement & Affirmative Litigation Branch*, U.S. DEP'T OF JUST. (Sept. 25, 2025), https://www.justice.gov/opa/pr/department-justice-creates-new-civil-division-enforcement-affirmative-litigation-branch.

[3] *Id.*

[4] *Health & Safety Unit*, U.S. DEP'T OF JUST., https://www.justice.gov/criminal/criminal-fraud/health-safety-unit (Dec. 2, 2025); *see Branching Off: The Restructing of the DOJ's Consumer Protection Branch and What it Means for Companies*, Mayer Brown (Jan. 16, 2026), https://www.hoganlovells.com/en/publications/branching-off-the-restructuring-of-the-dojs-consumer-protection-branch-and-what-it-means.

[5] *Health & Safety Unit*, U.S. DEP'T OF JUST., https://www.justice.gov/criminal/criminal-fraud/health-safety-unit (Dec. 2, 2025)..

[6] *Online Seller of Infant Formula Pleads Guilty to Smuggling and Violating FDA Prior Notice Requirements*, U.S. DEP'T OF JUST. (Nov. 21, 2025), https://www.justice.gov/opa/pr/online-seller-infant-formula-pleads-guilty-smuggling-and-violating-fda-prior-notice.

consumers in 2019 after importing the formula products from Europe without prior notice to FDA. Some of Able Groupe's infant formula products were listed on FDA Import Alerts due to their failure to meet nutrient or labelling requirements, and the company admitted it used false commodity descriptions as a means to avoid detection and detention of the products upon their entry into the United States. In 2021, an FDA inspection revealed over 76,000 units of formula were smuggled into the U.S., after which the company recalled the units and ceased operations.

B. Drugs

2. AniCell Biotech LLC[7]

AniCell Biotech LLC (AniCell) agreed to a consent decree of permanent injunction to settle allegations of distributing unapproved and adulterated animal drugs in violation of the FDCA. AniCell operated out of two facilities in Arizona, where DOJ alleged that it made and distributed animal cell- and tissue-based products (ACTPs) derived from the amniotic tissue of horses for use in animals without the approval of FDA.

The government's complaint also alleged that the company and its CEO made claims on its website and in promotional materials that the ACTPs were intended for use in animals to treat various diseases and to promote tissue regeneration and healing. In response, FDA issued multiple warnings to the company, including a written warning letter regarding its need to submit its new animal drugs to FDA for approval, and conducted several inspections. Under the consent decree, AniCell is enjoined from violating the FDCA and is required, among other things, to destroy its unapproved products, allow future audits and inspections, and to cease operations of its facilities until it is in compliance with the consent decree, with a few exceptions.

C. Medical Devices

1. Aesculap Implant Systems[8]

Aesculap Implant Systems LLC (AIS) agreed to pay $38.5 million as part of a civil settlement and non-prosecution agreement to resolve allegations of violations of the FDCA, including its introduction of two adulterated medical devices into interstate commerce without proper FDA clearance due to a former AIS employee's alleged fraud. The non-prosecution agreement stated that the employee was in charge of the AIS's FDA clearance submissions for two surgical medical devices and had fraudulently represented to his employer—verbally and through forged documents—

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[7] *Court Enjoins Arizona Animal Drug Manufacturer from Distributing Unapproved Drugs*, U.S. DEP'T OF JUST. (Apr. 29, 2025), https://www.justice.gov/opa/pr/court-enjoins-arizona-animal-drug-manufacturer-distributing-unapproved-drugs; United States v. AniCell Biotech LLC, et al., No. CV-23-01803-PHX-SPL, Order, ECF No. 41 (D. Ariz. Apr. 17, 2025), https://anicellbiotech.com/wp-content/uploads/2025/04/AniCell-Order-granting-Motion-to-Approve-Concent-Decree-041725.pdf?x49210.

[8] *Aesculap Implant Systems Agrees to Pay $38.5M to Resolve False Claims Act Allegations Related to Knee Implant Failures and Enters into a Non-Prosecution Agreement Related to the Introduction of Two Adulterated Medical Devices into Interstate Commerce*, U.S. DEP'T OF JUST. (Nov. 17, 2025), https://www.justice.gov/opa/pr/aesculap-implant-systems-agrees-pay-385m-resolve-false-claims-act-allegations-related-knee; *B. Braun Unit Inks $38.5M Deal To End FCA Knee Implant Case*, LAW360 (Nov. 17, 2025), https://www.law360.com/articles/2412096/b-braun-unit-inks-38-5m-deal-to-end-fca-knee-implant-case; *Med Device Employee Gets 1 Year For Forging FDA Clearance*, LAW360 (Jan. 24, 2024), https://www.law360.com/articles/1789498/med-device-employee-gets-1-year-for-forging-fda-clearance.

that the devices had been cleared by FDA despite him having never submitted any documentation. The former AIS employee has since pled guilty to one felony count of violating the FDCA and was sentenced to one year in prison and one year of supervised release in 2024. AIS has since recalled the two surgical devices, obtained FDA clearance for both, and fully reimbursed all purchasers who bought the devices before true clearance was obtained.

The settlement also resolves allegations of violations of the FCA. AIS sold a knee replacement implant medical device system to physicians and hospitals despite allegedly knowing and without disclosing that it would fail prematurely after surgery. DOJ alleged that this ultimately resulted in false claims being made to Medicare and Medicaid. The device's issues resulted from the implant's failure to properly adhere to the bone cement in patients' knees, causing the device to loosen from the bone.

Finally, this settlement resolves AKS allegations that the company knowingly and willfully made unlawful payments to a Georgia orthopedic surgeon after he experienced issues with the knee replacement implant device system. The company allegedly offered and paid remuneration to induce the surgeon to recommend and continue to use their medical devices in the form of consulting payments, free international travel, entertainment, and more.

After the alleged false claims and alleged offers of remuneration, a number of events ensued: two third-party distributors filed a *qui tam* whistleblower suit, physicians complained about the knee replacement device system, AIS allegedly failed to track, record, and report adverse incident reports to the FDA, and the company chose to stop selling all of its knee replacement medical devices.

2. *Kimberly-Clark Corporation*[9]

Kimberly-Clark Corporation (Kimberly-Clark) agreed to pay $40.4 million to resolve federal criminal charges brought by DOJ for alleged violations of the FDCA. DOJ alleged that Kimberly-Clark introduced adulterated medical devices (disposable surgical gowns) into commerce by selling them to hospitals and healthcare providers in the United States and abroad.

In 2010, Kimberly-Clark obtained FDA pre-market clearance for its AAMI Level 4 "Microcool" surgical gowns, complying with FDA's requirement that surgical gowns demonstrate blood-borne pathogen resistance in critical zones, including the sleeve, by preventing fluids from penetrating the gown. DOJ alleged that, after Kimberly-Clark changed or modified the surgical gowns' fabric, it obtained fraudulent test results as to whether the new version of the product constituted a significant change or modification such that a new premarket notification or 510(k) was required to be submitted to FDA. The results of the fraudulent testing showed that the new version of the gown was still compliant with the AAMI Level 4 requirements and applicable FDA standards. Thus, Kimberly-Clark declined to submit a new 510(k) for the new version of the product before bringing it to market and marketing the gowns as AAMI Level 4 compliant, or providing the highest level of protection against fluid and

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[9] *Kimberly-Clark Corporation to Pay Up to $40M to Resolve Criminal Charge Related to the Sale of Adulterated MicroCool Surgical Gowns*, U.S. DEP'T OF JUST. (Aug. 28, 2025), https://www.justice.gov/opa/pr/kimberly-clark-corporation-pay-40m-resolve-criminal-charge-related-sale-adulterated; United States v. Kimberly-Clark Corp., No. 3:25-cr-00399-N, Order, ECF No. 3 (N.D. Tex. Aug. 28, 2025), https://assets.law360news.com/2382000/2382100/https-ecf-txnd-uscourts-gov-doc1-177117954446.pdf.

viruses. As the results of this testing were fabricated, Kimberly-Clark was alleged to have introduced $49 million worth of adulterated medical devices into commerce with an intent to defraud and mislead.

Although there was no evidence of patients experiencing physical harm as a result of the misbranding and adulteration of the gowns, DOJ stated that Kimberly-Clark's actions defrauded FDA and endangered patients and medical professionals. The company has since ceased manufacturing the surgical gowns at issue. The deferred prosecution agreement (DPA) states the company's $40.5 million payments will be disbursed as follows: $24.5 million to the U.S. Treasury for criminal monetary penalties; $3.9 million in profit forfeiture; and up to $12 million in victim compensation.

3. Former Executives of Magellan Diagnostics, Inc.[10]

Three former corporate executives of Magellan Diagnostics, Inc. pled guilty and were sentenced in federal court on felony charge(s) of introduction of misbranded medical devices into interstate commerce under the FDCA as a part of their individual plea agreements to avoid jail time. The three executives, Amy Winslow (former CEO), Hossein Maleknia (former COO), and Reba Daoust (former Director of Quality Assurance and Regulatory Affairs) all received home detention in lieu of prison time and criminal fines of varying amounts.

Their individual criminal cases brought by DOJ are a continuation and result of the criminal investigation of their employer, whose alleged failure to notify FDA about serious malfunctions in its lead-testing medical devices resulted in inaccurately low level blood tests in children and adults. Magellan's medical device products—LeadCare Ultra, LeadCare II, and LeadCare Plus—detected lead levels and lead poisoning in the blood of children and adults using either venous (i.e., blood draws through the arm) or fingerstick samples. Before launching its LeadCare II product, DOJ alleged that Magellan performed internal temperature and humidity tests that revealed differing blood lead levels from the same test sample based upon how long the blood-treatment reagent was left to incubate.

LeadCare II was predominately used to test fingerstick samples and accounted for more than half of all blood lead tests conducted in the United States from 2013 to 2017. The other two products, LeadCare Plus and LeadCare Ultra, predominantly were used to test venous samples.

According to the executives' criminal indictments, Magellan applied for FDA pre-market clearance of its LeadCare Ultra device, which involved performance testing on lead present in blood samples. DOJ alleged that one of Magellan's executives was informed about the failed results of the testing which showed a malfunction in the device likely to result in inaccurate test results before its submission to the FDA for clearance. Magellan did not notify FDA of the malfunction and the device was

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[10] *Three Former Executives for Magellan Diagnostics Sentenced for False Statements and FDCA Violations*, U.S. DEP'T OF JUST. (Nov. 24, 2025), (https://www.justice.gov/usao-ma/pr/three-former-executives-magellan-diagnostics-sentenced-false-statements-and-fdca; *United States v. Amy Winslow, Hossein Maleknia, and Reba Daoust*, U.S. DEP'T OF JUST. (Mar. 11, 2025), https://www.justice.gov/usao-ma/victim-and-witness-assistance-program/united-states-v-amy-winslow-hossein-maleknia-and-reba-daoust; *2nd Ex-Magellan Exec Avoids Jail Over Faulty Lead Tests*, LAW360 (Oct. 30, 2025), https://www.law360.com/articles/2405893/2nd-ex-magellan-exec-avoids-jail-over-faulty-lead-tests; United States v. Winslow, et. al., No. 1:23-cr-10094-PBS, Order No. 1 (D. Mass. Apr. 4, 2023), https://www.justice.gov/usao-ma/file/1580646/dl?inline.

subsequently cleared. DOJ also alleged that after the product's clearance, the other two executives were informed of the test results and the company conducted more tests which showed the same malfunction. The product was brought to market without notice to consumers or FDA of the existence of a malfunction. When the malfunction was discovered by consumers, the defendant executives approved a customer letter downplaying the nature, extent, risk, and frequency of the malfunction, and several months later, notified FDA of the malfunction in a materially false and misleading manner, according to DOJ. DOJ argued that the executives' actions deliberately misled FDA and caused an estimated thousands of children and other patients to receive inaccurately low lead test results. DOJ stated that it will continue to hold individuals accountable for concealing known defects in products sold by their employer company which endanger public health and safety in order to maintain profit.

FALSE CLAIMS ACT & ANTI-KICKBACK STATUTE

Below is a review of some of the key FCA and AKS settlements between the food and drug industry and the government in 2025, including the first time a management consulting firm (McKinsey & Company Inc.) has been held criminally responsible for advice resulting in the commission of a crime by a client (Purdue Pharma LP).

In addition to negotiating the settlements detailed below, in July 2025 DOJ's Civil Division and the Department for Health and Human Services (HHS) re-established the DOJ-HHS False Claims Act Working Group, jointly led by the HHS General Counsel, Chief Counsel to HHS Office of Inspector General (HHS-OIG), and the Deputy Assistant Attorney General of the Commercial Litigation Branch. The Working Group itself is comprised of leadership from the HHS Office of General Counsel, the Centers for Medicare & Medicaid Services Center for Program Integrity, the Office of Counsel to the HHS-OIG, and the DOJ's Civil Division, as well as designees representing U.S. Attorneys' Offices.[11]

The Working Group's priority enforcement areas are: Medicare Advantage; drug, device or biologics pricing, including arrangements for discounts, rebates, service fees, and formulary placement and price reporting; barriers to patient access to care, including violations of network adequacy requirements; kickbacks related to drugs, medical devices, durable medical equipment, and other products paid for by federal healthcare programs; materially defective medical devices that impact patient safety; and manipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare covered products and services. The Working Group will also focus on DOJ's other previously-announced areas of FCA enforcement focus: combatting Diversity, Equity, and Inclusion programs, and gender transition-related healthcare.[12]

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[11] *DOJ-HHS False Claims Act Working Group*, U.S. DEP'T OF JUST. (July 2, 2025), https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group.

[12] Memorandum from Assistant Attorney General Brett A. Shumate, Civil Division, U.S. Dep't of Just. to All Civil Division Employees, *Civil Division Enforcement Priorities* (June 11, 2025), https://www.justice.gov/civil/media/1404046/dl?inline.

A. Management Consulting

1. McKinsey & Company Inc.[13]

In the first time a management consulting firm has been held criminally responsible for advice resulting in the commission of a crime by a client, McKinsey & Company Inc. (McKinsey), a global management consulting firm, agreed to pay $650 million to resolve a criminal and civil investigation into the firm's advice to opioids manufacturer Purdue Pharma L.P. (Purdue) concerning the sales and marketing of Purdue's extended-release opioid drug, OxyContin, including a 2013 engagement in which McKinsey advised on steps to "turbocharge" sales of OxyContin by, among other strategies, intensifying marketing to High Value Prescribers.

McKinsey agreed to pay a penalty of over $231 million, a forfeiture amount of over $93 million (reflecting all money it was paid by Purdue from 2004 to 2019) and a payment of $2 million to the Virginia Medicaid Fraud Control Unit to resolve the criminal allegations. McKinsey also entered into a civil settlement agreement to pay over $323 million to resolve its liability under the FCA for allegedly providing advice to Purdue Pharma L.P. that caused the submission of false and fraudulent claims to federal healthcare programs for medically unnecessary prescriptions of OxyContin, as well as allegedly failing to disclose to FDA conflicts of interest arising from McKinsey US's concurrent work for Purdue and FDA. Additionally, Martin E. Elling, a former McKinsey senior partner who worked on Purdue matters, was sentenced to six months of incarceration, two years of supervised release, and a $4,000 fine after he pled guilty to knowingly destroying records, documents and tangible objects with the intent to impede, obstruct and influence the investigation.

Along with the civil settlement, McKinsey US entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG, HHS-OIG's first CIA with a management consulting firm, which contains novel obligations regarding risk assessment and quality control. First, the CIA requires McKinsey's Compliance Committee to establish a robust risk evaluation process, evaluating engagement risks and providing quality oversight for certain client deliverables. Second, it requires McKinsey to establish a Quality Review Program to assess the quality of McKinsey's advice to certain life sciences and health care clients with the dual goals of ensuring that McKinsey complies with applicable laws and does not provide or assist clients with plans, advice, or strategies that violate the law. HHS-OIG will select an independent Compliance Expert to review McKinsey's systems and processes under the Quality Review Program and to review a sample of McKinsey client engagements, including the advice provided to those clients.

As part of the government's resolution with McKinsey, the company entered into a five-year DPA in connection with a criminal information filed in the U.S. District Court for the Western District of Virginia against McKinsey's U.S. subsidiary, McKinsey & Company Inc. United States (McKinsey U.S.). The information charges McKinsey U.S. with one felony count of knowingly destroying records, documents,

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[13] *Justice Department Announces Resolution of Criminal and Civil Investigations into McKinsey & Company's Work with Purdue Pharma L.P.; Former McKinsey Senior Partner Charged with Obstruction of Justice*, U.S. DEP'T OF JUST. (Dec. 13, 2024), https://www.justice.gov/archives/opa/pr/justice-department-announces-resolution-criminal-and-civil-investigations-mckinsey-companys; *Former Senior Partner at McKinsey & Company Sentenced*, U.S. DEP'T OF JUST. (May 23, 2025), https://www.justice.gov/usao-wdva/pr/former-senior-partner-mckinsey-company-sentenced.

and tangible objects with the intent to impede, obstruct, and influence the investigation and one misdemeanor count of knowingly and intentionally conspiring with Purdue and others to aid and abet the misbranding of prescription drugs, held for sale after shipment in interstate commerce, without valid prescriptions.

As part of the resolution, McKinsey agreed to implement a significant compliance program, including a system of policies and procedures designed to identify and assess high-risk client engagements. As part of this compliance program, McKinsey will implement new document retention procedures and training for all partners, officers, and employees who provide or implement advice to clients. This compliance program is in addition to the provisions negotiated between McKinsey and the Department in a concurrent resolution with McKinsey & Company Africa. McKinsey also agreed to not do any work related to the marketing, sale, promotion or distribution of controlled substances during the five-year term of the DPA.

B. Scientific Research

1. Dana-Farber Cancer Institute[14]

Dana-Farber Cancer Institute (Dana-Farber) agreed to pay $15 million to resolve allegations of violations of the FCA. Allegedly, Dana-Farber caused the submission of false claims to the National Institutes of Health (NIH) by falsely certifying compliance with grant terms and conditions, spending grant funds on unallowable expenses, and obtaining grants through false and misleading statements.

As part of the settlement, Dana-Farber admitted that its researchers used funds from six NIH grants to conduct research that resulted in 14 publications in scientific journals containing misrepresented and/or duplicated images and data. The publications reused images to represent different experimental conditions; duplicated images to represent different testing conditions, mice, and/or timepoints; or rotated, magnified, or stretched images. Further, Dana-Farber admitted that a supervising researcher failed to exercise sufficient oversight over these researchers, resulting in unallowable spending from those six NIH grants. Dana-Farber also admitted that another researcher received four NIH grants after submitting grant applications that discussed a journal article authored by the researcher but did not disclose that certain images and data in that article were misrepresented and/or duplicated.

2. Athira Pharma Inc.[15]

Athira Pharma Inc. (Athira), a late clinical stage pharmaceutical development company, agreed to pay $4,068,698 to resolve allegations of violations of the FCA. Allegedly, between January 1, 2016, and June 20, 2021, Athira failed to report allegations that its former CEO, Leen Kawas, falsified and manipulated scientific images in her doctoral dissertation and in published research papers that were referenced in several grant applications submitted to NIH, including in a grant that NIH funded in 2019. Specifically, Athira violated its regulatory obligations to disclose the allegations to NIH in grant applications and Research Progress Performance

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[14] *Dana-Farber Cancer Institute Agrees to Pay $15M to Settle Fraud Allegations Related to Scientific Research Grants*, U.S. DEP'T OF JUST. (Dec. 16, 2025), https://www.justice.gov/opa/pr/dana-farber-cancer-institute-agrees-pay-15m-settle-fraud-allegations-related-scientific.

[15] *Athira Pharma Inc. Agrees to Pay $4M to Settle False Claims Act Allegations Related to Scientific Research Misconduct*, U.S. DEP'T OF JUST. (Jan. 6, 2025), https://www.justice.gov/archives/opa/pr/athira-pharma-inc-agrees-pay-4m-settle-false-claims-act-allegations-related-scientific.

Reports, and to disclose them to the Department of Health and Human Services Office of Research Integrity in Small Business Organization Statements, Institutional Assurances, or Annual Reports on Possible Research Misconduct.

C. Drugs

1. Biohaven Pharmaceutical Holding Company Ltd.[16]

On behalf of its wholly-owned subsidiary Biohaven Pharmaceutical Holding Company Ltd. (Biohaven), pharmaceutical company Pfizer Inc. (Pfizer) agreed to pay $59,746,277 to resolve allegations of violations of the AKS and FCA. Allegedly, prior to Pfizer's acquisition of the company, Biohaven knowingly caused the submission of false claims to Medicare and other federal health care programs by paying kickbacks to health care providers to induce prescriptions of Biohaven's migraine drug Nurtec ODT.

Allegedly, from March 1, 2020, through Sept. 30, 2022 (after which Pfizer acquired Biohaven and terminated the programs), Biohaven paid improper remuneration such as speaker honoraria and meals at high end restaurants to health care professionals to induce them to prescribe Nurtec ODT in violation of the AKS. Biohaven selected certain health care providers to be part of the Nurtec speaker bureau and provided them paid speaking opportunities with the intent that the speaker honoraria and meals would induce them to prescribe Nurtec ODT. Certain prescribers who attended multiple programs on the same topic received no educational benefit from attending repeat programs and certain Biohaven speaker programs were attended by individuals with no educational need to attend, such as the speakers' spouses, family members, or friends, or colleagues from the speakers' own medical practice.

2. Walgreens Boots Alliance, Walgreen Co., and various subsidiaries[17]

Walgreens Boots Alliance, Walgreen Co., and various subsidiaries (collectively, Walgreens) agreed to pay $300 million to resolve allegations of violations of the FCA. Walgreens will owe an additional $50 million if the company is sold, merged, or transferred prior to fiscal year 2032.

Allegedly, from around August 2012 through March 1, 2023, Walgreens illegally filled millions of invalid prescription for opioids and other controlled substances—prescriptions for excessive quantities of opioids, opioid prescriptions filled significantly early, and prescriptions for the especially dangerous and abused combination of three drugs known as a "trinity." Walgreens pharmacists filled these prescriptions despite clear red flags indicating a high likelihood that the prescriptions were invalid because they lacked a legitimate medical purpose or were not issued in the usual course of professional practice. Walgreens pressured its pharmacists to fill prescriptions quickly and without taking the time needed to confirm that each

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[16] *Pfizer Agrees to Pay Nearly 60M to Resolve False Claims Allegations Relating to Improper Physician Payments by Subsidiary*, U.S. DEP'T OF JUST. (Jan. 24, 2025), https://www.justice.gov/opa/pr/pfizer-agrees-pay-nearly-60m-resolve-false-claims-allegations-relating-improper-physician.

[17] *Walgreens Agrees to Pay Up to $350M for Illegally Filling Unlawful Opioid Prescriptions and for Submitting False Claims to the Federal Government*, U.S. DEP'T OF JUST. (Apr. 21, 2025), https://www.justice.gov/opa/pr/walgreens-agrees-pay-350m-illegally-filling-unlawful-opioid-prescriptions-and-submitting.

prescription was lawful. Walgreens's compliance officials also allegedly ignored substantial evidence that its stores were dispensing unlawful prescriptions and even intentionally deprived its own pharmacists of crucial information, including by refusing to share internal data regarding prescribers with pharmacists and preventing pharmacists from warning one another about certain problematic prescribers.

In addition to the monetary payments, Walgreens entered into agreements with DEA and HHS-OIG to address its future obligations in dispensing controlled substances. Walgreens and DEA entered into a memorandum of agreement that requires the company to implement and maintain certain compliance measures for the next seven years. Walgreens also entered into a five-year CIA with HHS-OIG, which further requires Walgreens to establish and maintain a compliance program that includes written policies and procedures, training, board oversight, and periodic reporting to HHS-OIG related to Walgreens's dispensing of controlled substances.

3. Gilead Sciences Inc.[18]

Gilead Sciences, Inc. (Gilead) agreed to pay $202 million to resolve allegations of violations of the AKS and FCA and made extensive factual admissions regarding the company's conduct. Gilead allegedly offered and paid kickbacks in the form of honoraria payments, meals, and travel expenses to healthcare practitioners who spoke at or attended Gilead speaker events to induce them to prescribe its antiretroviral HIV medications.

As part of its marketing efforts and to increase sales, Gilead conducted events known as "HIV Speaker Programs" at which a healthcare provider involved in the treatment of HIV was engaged to present a slide deck (prepared by Gilead) and facilitate discussion about one of the drugs or a topic concerning HIV to other healthcare providers involved in the treatment of HIV, with the HIV Speaker Programs often being held in the evening at restaurants.

From January 2011 to November 2017, Gilead conducted HIV Speaker Programs in order to promote and increase the sales of its HIV drugs. While the HIV Speaker Programs were supposed to be educational in nature with the cost of any meals provided to be modest, Gilead's HIV Speaker Programs provided kickbacks to healthcare providers by:

- holding HIV Speaker Programs at high-end restaurants that were inappropriate for educational events;
- allowing attendees to attend HIV Speaker Programs on the exact same topic again and again (over 250 prescribers of Gilead's HIV drugs attended HIV Speaker Programs on the same topic three times or more within a six-month period, and over 80 attended five or more on the same topic within a six-month period) and, thereby, obtain free lavish meals for events that held minimal educational value for them; and

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[18] *U.S. Attorney Announces $202 Million Settlement With Gilead Sciences For Using Speaker Programs To Pay Kickbacks To Doctors To Induce Them To Prescribe Gilead's Drugs*, U.S. DEP'T OF JUST. (Apr. 29, 2025), https://www.justice.gov/usao-sdny/pr/us-attorney-announces-202-million-settlement-gilead-sciences-using-speaker-programs.

- paying for HIV Speakers to travel to speak at desirable destinations—at times at the HIV Speaker's request.

Further, Gilead's compliance program failed to prevent these improper practices, even though Gilead knew that it had to comply with the AKS and the company's own data should have put Gilead on notice of many of these abuses.

D. Wound Care

1. Alexandra Gehrke, Jeffrey King, Apex Medical LLC[19]

The owners of several Arizona wound graft companies, Alexandra Gehrke and her husband, Jeffrey King, pled guilty to conspiracy to commit health care fraud and wire fraud and were sentenced to 15.5 and 14 years in prison, respectively, for causing over $1.2 billion of false and fraudulent claims to be submitted to Medicare and other health insurance programs. Gehrke and King were additionally ordered to pay restitution and to forfeit fraudulent proceeds obtained personally and through companies they owned and controlled: Gehrke was ordered to pay $614,945,420 in restitution and to forfeit $279,912,916 in fraudulent proceeds, King was ordered to pay $605,690,110 in restitution and to forfeit $130,813,658 in fraudulent proceeds.

In addition to the criminal case, Gehrke and the wound graft marketing company she owned, Apex Medical LLC, agreed to pay $279,912,916, and King agreed to pay $30 million, related to their respective civil liability under the FCA, resolving allegations that they knowingly submitted false claims to Medicare and other federal health care programs for medically unnecessary wound allografts, received illegal kickbacks from a wholesale wound allograft distributor in exchange for orders, purchases, and referrals and paid illegal kickbacks to other parties.

According to court documents, Gehrke and King orchestrated a large-scale wound-care scheme from 2022 through 2024. Gehrke solely owned and operated two companies that contracted with medically untrained "sales representatives" to find elderly Medicare beneficiaries throughout Arizona with wounds of any kind. Once the sales representatives identified these patients, many of whom were in hospice care, Gehrke directed the sales representatives to order expensive bioengineered skin substitutes—amniotic membrane allografts made from human placental tissue—to be placed on the wounds. To maximize profits, Gehrke required the sales representatives to order only the largest sizes of grafts available, even if the sizes of grafts or the use of grafts as treatment were not medically appropriate or reasonable.

Gehrke referred the patients identified by the sales representatives first to a company she owned, and later in the scheme to a company co-owned by King. Both of these companies were enrolled as Medicare providers and could submit claims to Medicare. Through these companies, Gehrke and King purchased the grafts from a wholesale graft distributor. They also contracted with nurse practitioners to apply the grafts and billed Medicare and other health insurers for the grafts applied. Gehrke and King instructed the nurse practitioners to suspend their medical judgment and apply whatever quantities and sizes of grafts were ordered by the medically untrained sales representatives, regardless of medical necessity.

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[19] *Wound Graft Company Owners Sentenced for $1.2B Health Care Fraud and Agree to Pay $309M to Resolve Civil Liability Under the False Claims Act*, U.S. DEP'T OF JUST. (Dec. 12, 2025), https://www.justice.gov/opa/pr/wound-graft-company-owners-sentenced-12b-health-care-fraud-and-agree-pay-309m-resolve-civil.

The financial incentive for the sales representatives to order large numbers and sizes of allografts, combined with Gehrke and King's requirement that nurse practitioners apply all grafts ordered, resulted in large grafts applied to small wounds, several grafts applied to single wounds, grafts applied to non-existent wounds and grafts applied to terminally ill patients receiving palliative care, some of whom died within days or the same day of the allograft application.

2. *Dr. Ameet Vohra and his companies, including Vohra Wound Physicians*[20]

Dr. Ameet Vohra and his companies, including Vohra Wound Physicians Management LLC (Vohra), agreed to pay $45 million to resolve allegations of FCA violations. Dr. Vohra and his companies allegedly knowingly caused the submission of claims to Medicare for medically unnecessary surgical procedures, for more lucrative surgical procedures when only routine non-surgical wound management had been done, and for evaluation and management services that were not billable under Medicare coverage and coding rules.

Dr. Vohra allegedly orchestrated and implemented a scheme, via his senior management team, in which Vohra pressured, trained, and provided financial incentives for Vohra physicians to perform wound debridement procedures during as many patient visits as possible regardless of the patients' needs, while having programmed its electronic health record and billing software to ensure that Medicare was always billed for the higher-reimbursed surgical excisional procedure and to create false medical record documentation to support the scheme.

In connection with the settlement, Vohra will enter into a five-year CIA with HHS-OIG, under which Vohra must develop and maintain a compliance program, implement a risk assessment process, and hire an independent review organization to review its claims and health information technology systems. The CIA also requires monitoring of Vohra's operations and obligates company executives and owners to certify compliance annually with the terms of the CIA.

E. Medical Devices

1. *Semler Scientific Inc. and Bard Peripheral Vascular Inc.*[21]

Semler Scientific Inc. (Semler) and its former distributor, Bard Peripheral Vascular Inc., and related companies (Bard) agreed to pay nearly $37 million to resolve allegations of FCA violations: $29.75 million from Semler and $7.2 million from Bard. The parties allegedly knowingly caused, and conspired to cause, the submission of false claims to Medicare for photoplethysmography tests performed using the FloChec and QuantaFlo devices in connection with the diagnosis of peripheral arterial disease (PAD).

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[20] *Vohra Wound Physicians and its Owner Agree to Pay $45M to Settle Fraud Allegations of Overbilling for Wound Care Services*, U.S. DEP'T OF JUST. (Nov. 21, 2025), https://www.justice.gov/opa/pr/vohra-wound-physicians-and-its-owner-agree-pay-45m-settle-fraud-allegations-overbilling.

[21] *Semler Scientific Inc. and Bard Peripheral Vascular Inc. to Pay Nearly $37M to Resolve False Claims Act Allegations Relating to FloChec and QuantaFlo Devices*, U.S. DEP'T OF JUST. (Sept. 26, 2025), https://www.justice.gov/opa/pr/semler-scientific-inc-and-bard-peripheral-vascular-inc-pay-nearly-37m-resolve-false-claims.

Providers traditionally diagnose PAD by conducting a test called an ankle brachial index (ABI) to estimate the severity of the blood vessel blockage in a patient's limbs. To qualify for Medicare reimbursement, PAD testing must include an ABI test plus certain additional testing; Medicare does not cover noninvasive vascular tests that use photoelectric plethysmography, which uses a light sensor to detect changes in blood volume. From approximately 2010 through 2024, Semler manufactured, marketed, and distributed the FloChec and QuantaFlo devices to customers throughout the United States for use in connection with the diagnosis of PAD. Both devices use a light sensor to detect changes in blood volume. Additionally, when FDA cleared FloChec and QuantaFlo, the agency told Semler that the devices did not perform an ABI and could not be called a "digital ABI."

Semler and Bard allegedly falsely claimed that tests conducted using the FloChec and QuantaFlo devices were reimbursable by Medicare and caused healthcare providers to submit false claims to Medicare, while knowing the tests were not reimbursable because the devices do not perform an ABI and because the devices use photoelectric plethysmography. Even after Semler received concerns from third parties about reimbursement, Semler allegedly continued to market the devices as reimbursable by Medicare.

Bard served as Semler's distributor from 2012 through 2022. As part of the settlement, Bard admitted certain allegations and received cooperation credit under Justice Department guidelines. In addition to the civil settlement, Semler entered into a five-year CIA with HHS-OIG, which obligates Semler to undertake substantial internal compliance reforms.

2. Diopsys Inc.[22]

Diopsys Inc. (Diopsys) agreed to pay up to $14.25 million to resolve allegations of FCA and various state law violations with guaranteed payments of $1,225,000 and contingent payments of up to $13,025,000. Diopsys allegedly knowingly submitted or caused others to submit false claims for payment to Medicare and Medicaid in connection with certain vision testing services.

Diopsys' NOVA device is an electrophysiological device that FDA cleared for visual evoked potential testing. Allegedly, from January 1, 2015, through December 31, 2021, Diopsys caused healthcare providers to submit false claims to Medicare and Medicaid for services in which the NOVA device was utilized for medically unnecessary uses, specifically electroretinography vision testing, a substantially different vision test for which the NOVA device lacked FDA clearance. Diopsys additionally allegedly made substantial changes to the NOVA device that it never submitted to FDA for clearance or approval despite knowing that such a submission was required.

CONCLUSION

These settlements and criminal enforcement cases illustrate the government's commitment to combatting adulteration, misbranding, and fraud in the food and drug

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[22] *Diopsys Inc. Agrees to Pay up to $14.25 Million to Resolve Alleged Federal False Claims Act and State Law Violations Relating to Vision Testing*, U.S. DEP'T OF JUST. (Mar. 28, 2025), https://www.justice.gov/opa/pr/diopsys-inc-agrees-pay-1425-million-resolve-alleged-federal-false-claims-act-and-state-law.

space, including healthcare services. Especially given the current administration's focus on combatting government waste and fraud, and the re-establishment of the DOJ-HHS False Claims Working Group, we expect coming years to hold many more high-profile cases and resulting big-ticket settlements.