Top Food and Drug Cases, 2024

Edited by August T. Horvath

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The Food and Drug Law Institute (FDLI), founded in 1949, is a nonprofit membership organization that offers education, training, publications, and professional engagement opportunities in the field of food and drug law. As a neutral convener, FDLI provides a venue for stakeholders to inform innovative public policy, law, and regulation.

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TOP FOOD AND DRUG CASES, 2024

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Introduction

AUGUST T. HORVATH*

FDLI's Top Food and Drug Cases contributor team is proud to present our 2024 edition. In this volume, we report on twelve significant lawsuits and legal issues from 2024 that we expect to have a significant impact on food and drug law practitioners for years to come. Our coverage includes government enforcement actions, civil and criminal cases, and significant appeals.

Appellate cases, with their precedential reach, are almost shoo-ins for inclusion in this volume, and we start at the top with the Supreme Court's rare ruling in an FDA case, *FDA v. Wages and White Lion*; Ralph Hall reviews the Court's holding on the limits of FDA's policymaking authority and its implications. Ginger Pigott discusses the impact of the Fifth Circuit's decision in *Hickey v. Hospira* on the implied preemption of failure-to-warn cases. Andrew Wasson describes *Ipsen Biopharmaceuticals v. Becerra*, a D.C. Circuit decision on the classification of products as between drugs and biological products. In the food sphere, Mital Patel and Danit Halberstein analyze *In Re Beech-Nut Nutrition Company Baby Food Litigation*, an important Second Circuit decision in class action litigation about heavy metal contamination in baby food. Another Circuit Court food case is chewed on by Rene Befurt, Anne Cai, and Sai Sindhura Gundavarapu, who discuss the Ninth Circuit's *Bryan v. Del Monte Foods* decision regarding the reasonable consumer's duty to read the entirety of food labels before filing suit for alleged deception. Anand Agneshar, Jocelyn Wiesner, and Tommy Huynh discuss how the procedural device of case management orders in multidistrict litigation has been used to weed out meritless claims in these large, multi-plaintiff cases.

The demise of *Chevron* deference continues to hang over the food and drug sphere, and James Beck discusses the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, a fisheries case with important implications for FDA's authority. Tina Papagiannopoulos picks up this ball and discusses *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, exemplifying how *Loper Bright* and related cases impact our practice area. *Loper Bright* also casts its shadow on *Ohio v. Environmental Protection Agency*, which Neal Fortin covers in this volume, defining the limits of government agency authority in air pollution rulemaking.

In another non-food-and-drug Supreme Court decision that nevertheless has important implications for FDLI's members, Andrew Bentz, Colleen Heisey, and Matthew Krsacok discuss *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, in which the Court determined that the six-year statute of limitations under the Administrative Procedure Act runs not from when the challenged regulation is promulgated, but from when the individual plaintiff is injured.

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In the criminal realm, Steve Johnson covers a trio of cases, *United States v. Winslow*, *United States v. Malekina*, and *United States v. Daoust*, all against individual executives of Magellan Diagnostics, and its implications for personal criminal liability of corporate officers for marketing misbranded devices.

For the second year, the National Advertising Division of the BBB National Programs weighs in with a discussion of an important decision from NAD's 2024 docket, *Lily of the Desert Nutraceuticals*, relating to the marketing of the authenticity, quality, and purity of avocado oil, contributed by William Frazier.

Bill Janssen offers a Kubrickian take on *Park v. Kim*, one of the high-profile recent cases about the disastrous use of insufficiently supervised AI in litigation writing, which is sure to affect the practice of litigators in the food and drug sphere. And finally, Vanessa Fulton takes us through several significant settlements with government agencies in the food and drug space in 2024.

It is a fascinating, informative, and eclectic assortment of cases as always, and I thank our contributors for their diligent efforts and valuable insights. The year 2025 promises to continue to be chaotic in almost every way, and we look forward to future developments while wishing our readers the best in their various practices. We hope that you all enjoy the Annual Conference at which this ebook is being distributed, and the balance of FDLI events through the rest of the year.

Food and Drug Administration v. Wages & White Lion Investments, L.L.C. et al. 604 U.S. ____ (2025)

RALPH F. HALL[1]

WHY IT MADE THE LIST

"FDA can't do that! It can't change its position midstream! It's not fair! It's not legal!"

How often have you heard this? The answer to this common complaint is now clearer.

The Supreme Court rarely decides FDA cases. So, when the Supreme Court decided *Wages and White Lion*[2] in April 2025, this alone should make FDA practitioners sit up and take notice. Further, the Supreme Court in this case directly addresses the "change-in-position" doctrine—another critically important reason to read this case. In this time of great change in the administrative law area, any case that addresses both FDA matters and provides insights into the Supreme Court's administrative law thinking is doubly worthy of attention. And finally, a case that addresses, at least in part, the nation's ongoing debate over tobacco, vaping, and e-cigarettes should be of high interest.

In this case, the Supreme Court resolved a circuit split, reversed the Fifth Circuit, and upheld, subject to a remand on one issue, FDA's denial of hundreds of marketing applications for flavored e-cigarettes and vaping products. In doing so, the Court:

> 1) provided important insights into when an administrative agency can change some policy,
>
> 2) addressed, at least in dicta, FDA's power to determine what constitutes sufficient evidence that some article is "safe and effective" (or some similar standard), and,
>
> 3) remanded the case to the Fifth Circuit to determine how "harmless error" claims should be analyzed.

And finally, in this time of hyper-partisanship and a divided Supreme Court, any 9–0 decision seems noteworthy.

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[2] Food & Drug Admin. v. Wages and White Lion Invs., L.L.C., 604 U.S. ____ (2025) [hereinafter *Wages and White Lion*].

BACKGROUND

The public, Congress, FDA, other regulatory agencies, and tobacco product producers have struggled for decades over the public health challenges, legal rights and responsibilities, and possible regulatory paths forward regarding tobacco products. Prior to the 1990s, FDA took a hands-off approach, asserting that Congress had not given FDA jurisdiction over tobacco products such as cigarettes. During this time period, Congress passed several laws impacting cigarette marketing and research, such as requiring warning labels and mandating scientific reports.[3] In 1996, FDA stepped into this perceived void and asserted jurisdiction over tobacco products. This effort came to naught when the Supreme Court ruled that FDA's 1996 effort to regulate cigarettes was invalid because Congress had not given FDA jurisdiction over tobacco products.[4]

In 2009, Congress passed the Tobacco Control Act (TCA).[5] The TCA gave FDA explicit jurisdiction over tobacco products and required that a sponsor obtain a marketing authorization for a "new tobacco product." The tobacco landscape, however, was rapidly changing as vaping (or e-cigarettes) were becoming increasingly popular. Various companies developed flavored vaping systems that could deliver fruit, sweet, or dessert flavors. These companies and others argue that vaping is safer than smoking leaf tobacco, primarily due to the absence in e-cigarettes of tar and other combustion byproducts. However, many public health experts and other stakeholders expressed strong concerns that these flavored vaping products were attractive to young people and would serve to get this demographic "hooked" on nicotine. And some significant number of vaping customers would transition to the more dangerous traditional leaf tobacco cigarettes.

In 2016, after extensive debate, FDA successfully "deemed" e-cigarettes/vaping products to be "tobacco products" under the TCA.[6] And FDA further concluded that these e-cigarettes met the definition in the TCA of a "new tobacco product."

A "new tobacco product" cannot be marketed until it has received marketing approval from FDA.[7] The TCA requires FDA to deny any such marketing application unless the applicant demonstrates that the product "would be appropriate for the protection of public health" and, in doing so, FDA is obligated to consider "the risks and benefits to the population as a whole," taking into account the likelihood that current smokers would switch to the "safer" vaping option and the risk of non-smokers, particularly the young, starting to use tobacco products including vaping.[8]

Starting after 2016, FDA worked to develop rules and guidance for such submissions, including the types of scientific evidence needed, information on marketing and risk abatement efforts, and the need for cross-product comparisons. As is common when FDA implements a new regulatory system, FDA gathered

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[3] *See Wages and Lion*, at p. 4 for a list of these various congressional acts.

[4] FDA v. Brown and Williamson Tobacco Corp., 529 U.S. 120 (2000). This decision also provides detail on past efforts to regulate, or not regulate, cigarettes.

[5] Codified at 21 U.S.C. § 387 et seq.

[6] Regulation of Electronic Nicotine Delivery Systems (Including E- Cigarettes) and the Continuum of Nicotine-Delivering Products, 81 Fed Reg. 29028 (May 10, 2016).

[7] 21 U.S.C. § 387j(c)(2)(A).

[8] 21 U.S.C. § 387j(c)(4).

information and input from multiple sources, issued draft guidance documents, published FAQs, engaged in public discussions, etc. Over time, FDA's thinking evolved.

Prior to 2021, the plaintiffs and other entities submitted many marketing applications covering millions of specific products. However, in 2021, FDA denied these applications.[9]

Applicants, including the plaintiffs in this action, then sued FDA and asserted that FDA acted in an arbitrary and capricious manner in denying these applications. Specifically, the plaintiffs asserted that FDA had changed its position and had not followed its guidance on a number of key elements including:

- The types of scientific evidence needed to be submitted. Specifically, the plaintiffs asserted that, contrary to prior FDA positions, FDA was now requiring randomized, controlled studies.
- FDA was now insisting on robust cross-product comparative studies. (For example, were flavored vaping systems more or less likely to entice youth use compared to non-flavored vaping systems?).
- FDA's views about, and enforcement priorities relating to, device type.
- FDA's failure to consider marketing and risk abatement plans contrary to its guidance that such marketing plans were critical.

The plaintiffs argued that these differences violated the "changes-in-position" doctrine and thus rendered FDA's actions arbitrary and capricious and contrary to law.

These plaintiffs sued FDA in the Fifth Circuit. An initial three-judge panel ruled in favor of FDA. [10] However, a rehearing en banc found against FDA and in favor of the plaintiffs.[11] The Supreme Court granted FDA's petition for writ of certiorari due to a circuit split on these issues. And, on April 2, 2025, the Supreme Court unanimously reversed the Fifth Circuit.[12] Essentially, the Supreme Court held that FDA acted within its statutory authority and, with one exception, had not violated any "change-in-position" obligations. With regard to this change in position, FDA argued that it was harmless error. The Supreme Court remanded the case for the lower court to determine the appropriate application of the harmless error rule. [13]

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[9] *Wages and White Lion*, at p. 2.

[10] 41 F.4th 427 (5th Cir. 2022)

[11] 90 F.4th 357 (5th Cir. 2024).

[12] Justice Sotomayer filed a one-page concurring opinion simply asserting that rather than "feeling its way" toward a final position, FDA was giving applicants some flexibility in how to meet the requirements. *Wages and White Lion*, Justice Sotomayor concurrence, p. 1.

[13] Amici supporting the plaintiffs offered other grounds to uphold the Fifth Circuit, including, for example, unconstitutional delegation of lawmaking power to FDA, vagueness, denial of due process, and the "major questions doctrine." Because these issues were not properly before the Supreme Court, the Court offered no opinion or analysis of these issues. *Wages and White Lion*, at pp. 19–20 n.3.

DISCUSSION

Tobacco-Specific Considerations

Apart from the harmless error issue discussed below, this decision upholds FDA's denial of a plethora of vaping-related marketing authorization submissions. Going forward, vaping companies will need to follow FDA's scientific evidence requirements, comparative product assessment requirements, and recognize that there is not a safe harbor for non-cartridge products.[14] Assuming that the current administration continues along the same path as the prior administration, this decision creates a higher bar for the approval of a tobacco product marketing submission.

Such submissions will need to seriously consider including robust and objective scientific data, perhaps in the form of randomized or controlled studies. Comparative cross-product studies also may be mandated.

Administrative Law Considerations

Change-in-Position Doctrine

The key issue that the Supreme Court addressed, and perhaps the most important aspect of this case for FDA practitioners, involves the "change-in-position" doctrine. The change-in-position doctrine establishes when FDA can change or modify its position without formal processes.

In this case, the plaintiffs asserted that FDA set forth a number of specific requirements or permissible approaches and then changed the requirements between the time the guidances/instructions were issued and the time that FDA denied the plaintiffs' applications. The plaintiffs contend that their applications should and would have been granted had FDA acted in accordance with its original requirements. The plaintiffs sued FDA and contended that FDA acted arbitrarily and capriciously in changing the requirements in the midst of the application process. In essence, the plaintiffs argued that FDA "moved the goal posts" in the middle of game.[15]

The question of whether FDA has changed or can change positions midstream is critical to the regulated community. Stakeholders, whether regulated industry, patient groups, or others, commonly complain that FDA has improperly changed its position without following some formal notice and comment process.

The Court stated that the change-in-position doctrine raises two key questions:

- Did the agency actually change its position? Obviously, if FDA hasn't changed its position, the analysis is done, and the plaintiff loses (at least on this point).
- The second question actually has several subparts.[16]

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[14] The liquid used in a vaping device as the source for the nicotine and, potentially, for flavoring could come in a liquid form requiring the user to manually refill the reservoir or tank in the vaping device (a so-called "open system," or can came in a pre-packaged cartridge that is apparently easier for the user to use (a "closed system").

[15] Because the plaintiffs had marketing authorizations denied, the plaintiffs had standing to challenge FDA's actions. The question of whether some patient group or competitor could raise the same issue triggers standing questions not relevant to this specific case.

[16] The Supreme Court explicitly said that there are two questions. We will follow their language but recognize the existence of these sub questions. *Wages and White Lion*, at p. 23.

- Did the agency "display awareness" that it was changing its position?
- Did the agency offer "good reasons" for the new policy? [17] [18]

In order to answer question one, we must know what constitutes a "change-in-position." The Court stated that a change in position can occur when the agency rescinds a prior regulation, disavows prior agency actions, or expands or "abandons" the scope of its enforcement actions.[19] Except for formal revocation of an existing regulation or guidance, these examples leave a fair amount of gray. There is always some fluctuation in what the agency does and how it implements its authorities.[20] For example, how extensive must some change in enforcement scope be before the change-in-position doctrine is triggered?

The plaintiffs asserted that the agency knew it had changed positions, though FDA cannot "change the requirements" without notice and providing a reasonable opportunity for the entity to conform to the new requirements. In addition, the plaintiffs asserted that FDA must consider the applicants' reasonable reliance on FDA's original position.[21]

The Supreme Court also spoke to the "good reasons" point. The Court held that the reasons for the change in position need not be "better" than the old policy. The agency does not need the type of justification needed for a brand-new regulation, written on a blank slate. The agency must be cognizant whether the old policy has "serious reliance issues." These reliance interests must be more than just a belief by a stakeholder that FDA may take some action. [22]

In this case, the plaintiffs asserted that FDA changed its position on four key elements of a new tobacco marketing application and approval:

- The plaintiffs asserted that FDA initially said it did not require complex, time consuming, and expensive studies such as randomized controlled studies or longitudinal studies. And yet, one of the grounds for the denial of these marketing applications was that such studies had not been conducted.
- The plaintiffs claimed that FDA gave them discretion to pick among various comparative products, but then denied the marketing applications because the applicants had not compared

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[17] *Wages and White Lion*, at p. 24 (citing FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009)).

[18] While unstated by the Court, it would seem that there some other key questions a court must resolve after determining whether FDA has, in fact, made a change in position. For example, a reviewing court may need to determine whether FDA's new approach is within its jurisdictional boundaries, whether FDA's new position is contrary to law, and whether FDA's new position crosses any constitutional bounds.

[19] Encino Motorcars, LLC v Navarro, 579 U.S. 211 (2016). While unspoken, it seems that the Court and the parties agree that the change must be material before the change-in-position doctrine is relevant.

[20] Administrative agencies generally have significant enforcement discretion. It is unclear when the exercise of enforcement discretion becomes a change-in-position.

[21] *Wages and White Lion*, at p. 23.

[22] *Id.* at pp. 24, 40.

fruit, candy, or dessert flavored products against tobacco flavored products.

- Next, the plaintiffs complained that FDA "abandoned" its earlier guidance and rejected all dessert, fruit, and candy flavored products regardless of device type.
- Finally, FDA mandated the submission of marketing and risk abatement plans, and then FDA completely failed to even consider such plans.

The Court determined that FDA had not, in fact, changed its position with regard to the first three issues listed above. The asserted "changes" were within the discretion of the agency.[23] Given that the plaintiffs failed to satisfy "prong one" of the change-in-position doctrine, the second set of questions are irrelevant to these three claims.

The Court recognized that agencies need the ability to develop their thinking on regulatory matters, particularly new regulatory systems. The Court also recognized the value of having at least some of FDA's regulatory thinking available to the public as the agency worked to establish its positions. The Supreme Court concluded that during the 2016–2021 time period, FDA was working through its thinking on these and similar topics. It was expressing "preliminary" or non-binding thoughts about issues such as the nature of the valid scientific evidence needed to support a marketing application. Sometimes this was in the form of draft or final guidances, other times FDA's then current thinking was expressed in public meetings, speeches, etc. Because of the preliminary and non-binding nature of these public statements, the Court upheld FDA's discretion to determine what constituted sufficient valid scientific evidence. In summary, the court described the situation as: "These voluminous and discussive documents paint a picture of an agency that was feeling its way towards a final stance and was unable or unwilling to say in clear and specific terms precisely what applicants would have to provide."[24]

The Court's ruling that FDA had not changed its position on these three items may seem anticlimactic to some. This should not be the reaction. What is critical is that in order to arrive at this decision, the Court had to accept that FDA has substantial discretion in working to develop its positions and substantial discretion in determining what is needed to satisfy statutory requirements such as "valid scientific evidence".

Harmless Error

FDA conceded that there had been a change in position relating to the fourth item—FDA's review of marketing and risk abatement plans. FDA argued that this was harmless error.

FDA argued that its change in position relating to marketing and risk abatement plans was harmless error because FDA had other grounds upon which to deny the marketing applications. The plaintiffs argued that an error is not harmless unless FDA was otherwise required to deny the applications and that remand is the mandatory remedy.[25]

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[23] *Wages and White Lion*, at p. 32.

[24] *Id.* at pp. 9–10. Note that Justice Sotomayer's concurrence stated that FDA was not "feeling its way" but rather had definition positions. *Wages and White Lion*, Justice Sotomayor concurrence.

[25] This position is based on cases such as *Calcutt v. FDIC*, 598 U.S. 623 (2023).

The Court took this opportunity to address some disconnects between possible remedies in an administrative law/harmless error situation. The Court pointed out some inconsistencies in current law and also determined that both parties were overreaching in their positions. The Supreme Court remanded the case to the Fifth Circuit to assess the harmless error issue using a more intermediate legal analysis advanced by either party.

FDA's Authority to Determine the Nature of the Evidence Needed to Establish Safety and Efficacy

In language important well beyond the TCA area, the Supreme Court decision supports FDA's broad discretion to determine the nature or type of scientific evidence it would accept in determining what constitutes valid scientific evidence (or similar terms and requirements). The Court held: "The TCA leaves it to the FDA to decide what constitutes a 'well-controlled investigation' or other 'valid scientific evidence' that is sufficient [to evaluate the tobacco product and its risks and benefits]."[26]

Note the similarity of the TCA language regarding "valid scientific evidence," "protection of public health," etc. to the approval requirements for medical products such as drugs and devices.[27] In fact, the TCA even uses the term "substantially equivalent"[28]—language remarkably close to the 501(k) standard for medical devices.[29] Challenges to FDA's requirements for the types of evidence needed to satisfy these types of requirements may well be governed by this decision.

Method for Developing Regulatory Standards

Early in the opinion, the Supreme Court addressed an argument mentioned in the plaintiffs' briefing—namely that FDA is obligated to use notice and comment rulemaking to create or enunciate regulatory standards or requirements. While the Court stated that it was not deciding this issue as it was not part of the grant of certiorari, the Court did express some views on this question.[30] The Court stated that, absent Congressional mandate, "agencies are generally free to develop regulatory standards 'either by general [legislative] rule or by individual order' in an adjudication."[31]

The implications of this language (and the related discussion in the case) is that, unless Congress mandates that regulatory standards for a particular matter can ONLY be developed via notice and comment rulemaking, FDA has the option to use notice and comment ruling making or can use other tools such as decisions on submissions or enforcement actions to establish regulatory standards or requirements.

As the current FDA leadership reassesses staffing levels, resources, and regulatory approaches, one might see an increased use of adjudicative processes such as submission decisions or enforcement actions, rather than formal notice and comment

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[26] *Wages and White Lion*, at p. 26.

[27] *See, e.g.*, 21 U.S.C. § 355(d).

[28] 21 U.S.C. §§ 387j(a)(2)–(3),

[29] *See* 21 U.S.C. §360(k); 21 U.S.C. §360(c).

[30] "We did not grant certiorari on that question [the notice and comment ruling making position asserted by plaintiffs], and without adequate briefing, it would not be prudent to decide it here." *Wages and White Lion*, at p. 19.

[31] *Id.* at p. 19 (quoting and citing SEC v. Chenery Corp., 332 U.S. 194, 202–203 (1947)).

rulemaking or the development of guidance documents, to enunciate regulatory standards. The adjudicative processes may require fewer resources than notice and comment rulemaking or guidance development.[32]

Interestingly, the Supreme Court did not seem to differentiate actual regulations from guidance documents. According to the Court, the plaintiffs argued that guidance documents created regulatory requirements or standards that were binding on FDA and sponsors. And yet each modern guidance document starts with the "black box" reminder that guidance documents do not create binding rights or obligations on the part of FDA or the regulated community. The role of guidance documents in assessing or applying the change-in-position doctrine, as compared to the role of actual regulations, remains to be explored in more detail in future cases.

IMPACT

This case impacts two major aspects of FDA practice.

First, if one is engaged, on whatever side, in tobacco regulatory work, this case reinforces FDA's actions in denying a substantial number of market authorization submissions for e-cigarettes and vaping devices using dessert, candy or fruit flavors. Future submissions will need to meet FDA's evidentiary expectations as upheld by the Supreme Court.

Second, even if one is not involved in tobacco regulation, this case provides important clarity and insights into some key administrative law matters.

Specifically, this case lays out the Court's latest thinking on the change-in-position doctrine. Stakeholders on all sides often complain (or celebrate) some real or perceived change in FDA's position on some important issues. One must understand the change-in-position doctrine to understand whether such FDA action meets the Court's definition of a change-in-position and, if so, how FDA's actions should be analyzed to determine if such a change is valid.

The case also provides important insights into the harmless error doctrine.

Importantly, the case also outlines the discretion that FDA has to determine how one demonstrate that a product should be approved or cleared including what constitutes "valid scientific evidence."

[32] The general practice of FDA lawyers and regulatory experts to monitor warning letters, submission decisions, etc. is well warranted and may only become more important.

Hickey v. Hospira, Inc.
102 F.4th 748 (5th Cir. 2024)

GINGER PIGOTT*

WHY IT MADE THE LIST

Hickey v. Hospira makes the list of "top food and drug cases" in 2024 because the Fifth Circuit recognized that implied preemption applies with equal force to drugs entering the market under the Section 505(b)(2) process as would apply to those coming to market under the more onerous New Drug Application process of Section 505(b)(1).

It is also important as a strong circuit court decision in the library of preemption cases relating to failure to warn cases brought against prescription drugs and the oft-used arguments in failure to warn cases relating to the "Changes-Being-Effected" (or "CBE") method for labeling changes. The CBE arguments are often presented as a way to claim that implied preemption would not have prevented the sought after label change being litigated in a failure to warn context. The *Hickey* case arose from the long running Taxotere MDL and in it, the Fifth Circuit reviewed a denial of summary judgment and outlines the basis for why preemption would prevent liability for failure to warn. Although it ultimately remanded the case for the district court to review one item, the case itself lays out a straightforward analysis as to why preemption would apply where there was no basis to make label changes outside of FDA's specific approval.

DISCUSSION

Factual Background

This case arose from an MDL relating to the use of a version of drug to treat breast cancer. The branded version, called Taxotere, was manufactured by Sanofi US Service Inc. and Sanofi-Aventis U.S. LLC ("Sanofi") and the generic form is referred to as docetaxel. The defendants in this case were Hospira, Inc. and Hospira Worldwide, LLC ("Hospira") and Accord Healthcare, Inc. ("Accord") who received approval (as outlined more specifically below) from FDA upon expiration of Sanofi's patent in 2011.[1] The labeling included identical warnings about alopecia (hair loss) as an adverse reaction and instructed doctors to explain that it was one of the drug's most common side effects. The label did not say whether the loss could be permanent.

However, in March 2015, a patient advocacy group raised the issue with FDA and after the data was reviewed, Sanofi was instructed to update its label to indicate cases

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[1] Hickey v. Hospira, Inc., 102 F.4th 748, 751–52 (5th Cir. 2024).

of permanent hair loss had been reported. FDA did not conclude there was a causal connection. Accord updated its label in 2016 and Hospira did the same in 2017.[2]

Nonetheless, Plaintiffs in this case were alleging that the drug was causing permanent, not just temporary hair loss—alopecia (a condition referred to as permanent chemotherapy-induced alopecia (PCIA)). Plaintiffs were claiming the warnings were inadequate on this point.

Background of Implied Preemption for Prescription Drugs

Regulatory Pathway to Market for Prescription Drugs and Labeling Requirements

The pathway to market for prescription drugs takes three basic routes. Each of these is summarized by the court in *Hickey*.[3] Specifically, the method for approval of a brand-new drug is contained in § 505(b)(l) of the Federal Food, Drug, and Cosmetic Act (FDCA).[4] This section requires manufacturers to file a New Drug Application (NDA), which includes, inter alia, "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use."[5] The first drug of a specific kind to be approved under § 505(b)(l) is called the Reference Listed Drug (RLD). Manufacturers who want to sell the same drug or a drug that is similar enough "may use two abbreviated pathways to obtain FDA approval with less burden and expense."[6]

One pathway is § 505(j), which permits the manufacturer of a generic drug to submit an Abbreviated New Drug Application (ANDA).[7] With limited exceptions, the generic drug must in nearly all respects be identical to the RLD. Because a § 505(j) drug is the same as the RLD, the manufacturer may rely on the safety and efficacy data submitted in the RLD's NDA.[8]

The final path—the one at issue in *Hickey*—is § 505(b)(2), "which is available for drugs that differ from the RLD in ways that are slight enough for the manufacturer to still rely on the RLD's safety and efficacy data."[9] The application must provide only that information needed to support the modification(s) of the listed drug.[10] This pathway is often referred to informally as the "paper NDA" since it relies almost entirely on the clinical data submitted by the RLD. Unlike the generic drugs, § 505(b)(2) drugs are *not required* to use the exact same labeling as the RLD.[11] It is this difference that impacts the way the preemption argument is considered and one of the keys to the decision's significance.

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2 *Id.* at 752.

3 *Id.* at 750–51.

4 *Id.*; *see* 21 U.S.C. § 355(b)(l).

5 *Id.*; *see* 21 U.S.C. § 355(b)(l)(A)(i).

6 *Hickey* at __.

7 *Id.*; *see* 21 U.S.C. § 355(j).

8 *Id.*

9 *Hickey*, 102 F.4th at 751; *see* 21 U.S.C. § 355(b)(2).

10 *See* 21 C.F.R. § 314.54(a).

11 *Id.*

As with the RLD, FDA approves the exact text that will be included in the drug's labeling.[12] Of note, a manufacturer may only change a drug label after FDA approves a supplemental application. But in some circumstances, the CBE regulation allows manufacturers to implement a labeling change before obtaining FDA approval.[13]

The CBE regulation, however, is available only to "'add or strengthen . . . warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm."[14] The regulation defines "[n]ewly acquired information" as "data, analyses, or other information not previously submitted to the Agency," including but not limited to, "data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA."[15] Again, it is this CBE tool that is the focus of decisions involving RLD or "paper NDA" preemption.

Implied Preemption for Label Claims and impact of CBE

The argument in *Hickey* was whether defendants should have made label changes under the CBE process or, as defendants argued, the purported data proposed by plaintiffs did not meet the standards of revealing "risks of a different type or greater severity or frequency." The issue of first impression of any circuit court was how to evaluate newly acquired information following approval of the 505(b)(2) product. The Fifth Circuit agreed, stating that where the risks do not meet such standard, impossibility preemption would be established.[16] The court further agreed that the district court erred by failing to enforce such requirement.[17]

The factual background is important in this type of preemption case because the focus of the court's analysis will be on when approval was granted, what the company and FDA knew at that time about the particular risk at issue, and whether a CBE could have been implemented. In *Hickey*, the Fifth Circuit took pains to go through the available pre-approval scientific literature, the post-approval scientific literature, and defendants' adverse event reports. The court concluded that these particular defendants did not have "newly acquired information showing that PCIA occurred with any greater severity or frequency than before the approval of their drugs . . . ." The court did remand due to one medical abstract that would need analysis to see if it would be sufficient to change that conclusion, but otherwise ordered that these defendants would not be liable to the particular plaintiffs relating to failure to warn claims.

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[12] *Hickey*, 102 F.4th at 751 (citing Wyeth v. Levine, 555 U.S. 555, 568, (2009)) (citing 21 U.S.C. § 355)).

[13] *See* 21 C.F.R. § 314.70(c)(6).

[14] *Hickey*, 102 F.4th at 751 ((citing Merck Sharp & Dahme Corp. v. Albrecht, 587 U.S. 299, 304–05, 139 S.Ct. 1668, 203 L.Ed.2d 822 (2019)) (ellipses in original) (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)).

[15] *Id.* (citing 21 C.F.R. § 314.3(b)).

[16] *Hickey*, 102 F.4th at 756–57.

[17] *Id.* at 755.

IMPACT

This case is important because it recognizes and outlines the way in which a prescription drug product approved under the "paper NDA" process is treated for purposes of implied preemption and the failure to warn claims around the use of CBE. While clearly specific to the timeline and data relating to risks, the importance of this decision is the focus on what would be required for label change and the applicability of preemption where the proposed warning does not present newly acquired information under the statutory definition.

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

ANDREW WASSON*

I. WHY IT MADE THE LIST

Disagreement about how law and regulation define certain foundational categories in FDA regulatory law springs eternal. The legislature, FDA, and regulated industry have grappled with the meanings of categories like food, drugs, and biological products for as long as food, drugs, and biological products have been the subject of law and regulation. The D.C. Circuit's 2024 opinion in *Ipsen Biopharmaceuticals, Inc. v. Becerra*, 108 F.4th 836 (D.C. Cir. 2024) is a recent participant in this distinguished tradition. In *Ipsen*, the D.C. Circuit upheld FDA's determination that a depot form of octapeptide lanreotide acetate is a drug (and not a biological product).

In the first instance, how FDA classifies a therapeutic product undoubtedly has material consequences for a product sponsor—it dictates the appropriate regulatory regime, including the approval standards applied by FDA and the lead Center at the agency responsible for reviewing the application. How FDA classifies a product also dictates the available framework for generic or follow-on products and whether, and for how long, any periods of data or market exclusivity apply.

In addition, the *Ipsen* case finds itself squarely within the pitched controversy surrounding the appropriate amount of deference, if any, that courts should give agency action. *Ipsen* was decided within two weeks after the Supreme Court issued its opinion in *Loper Bright v. Raimondo*, 603 U.S. 369 (2024). While any mention of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) was meticulously avoided in *Ipsen* and any mention of *Loper Bright* was conspicuously absent, the presence of both cases is strongly felt. So much so that Justice Kagan's dissent in *Loper Bright* specifically cited another dispute about FDA's interpretation of "protein" to question whether eliminating deference was the best allocation of resources.[1]

The *Ipsen* case also confirms that the rough concept of deference to technical agency judgments may live on post-*Loper Bright*. In *Loper Bright* itself, Justice Roberts tiptoed around the idea that "attention" to an agency's judgment may "help inform" a court that is reviewing agency action.[2] Going just a little bit farther, *Ipsen* tipped its cap to the D.C. Circuit's own law, observing that it was a "basic principle of administrative law" that courts "must be careful not to unduly second-guess an

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[1] Loper Bright v. Raimondo, 603 U.S. 369, 456 (2024) (Kagan, J. dissenting) (citing Teva Pharms. USA, Inc. v. FDA, 514 F. Supp. 3d 66, 79–80, 93–106 (D.D.C. 2020)).

[2] *Id.* at 412–13.

agency's scientific judgments."[3] Now, with the next definitional controversy on the horizon, in Eli Lilly's suit against FDA,[4] it is reasonable to ask whether the next generation of cases will look to *Ipsen* to defend agency action.

II. DISCUSSION

A. Legal Background

The Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA) govern the requirements for introducing drug products and biological products into interstate commerce, respectively. Whether the FDCA or PHSA and all their attendant requirements apply depends on whether an article satisfies the FDCA's definition of "drug" or the PHSA's definition of "biological product."

For drugs, the FDCA prohibits the introduction of a "new drug" into interstate commerce unless FDA approves an application to market such a drug under a New Drug Application (NDA) under 21 U.S.C. § 355(b) or under an Abbreviated New Drug Application (ANDA) under 21 U.S.C. § 355(j). FDA will approve an NDA if it finds that the drug is safe and effective for its intended uses based on "full reports" of investigations showing that a drug is safe and effective. An ANDA need not contain such full reports provided that the ANDA meets the requirements of "sameness" and therapeutic equivalence to a previously approved drug. The Hatch-Waxman Amendments to the FDCA also provided innovators with several periods of exclusivity (e.g., a five-year new chemical entity exclusivity) as well as detailed patent litigation mechanisms.

The PHSA runs an analogous path for biological products. For a biologic, the PHSA prohibits sale in interstate commerce unless FDA approves a Biologics License Application (BLA) under 42 U.S.C. § 262(a) or an Abbreviated Biologics License Application (ABLA) under 42 U.S.C. § 262(k). To earn BLA approval, a sponsor must demonstrate that the biological product is "safe, pure, and potent" or that an ABLA product is "highly similar" to a reference product (i.e., it is a "biosimilar"). When the Biologics Price Competition and Innovation Act (BPCIA) established the biosimilar pathway, the PHSA was amended to provide a twelve-year period of reference product exclusivity and its own detailed patent litigation mechanism.

Whether the FDCA or PHSA applies depends on whether an article meets the statutory definition of "drug" in the FDCA or "biological product" in the PHSA. The FDCA broadly defines a drug as: (A) articles recognized in certain compendial articles; (B) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;" (C) "articles (other than food) intended to affect the structure or any function of the body of man or other animals," and (D) components thereof.[5] By contrast, the PHSA defines a "biological product" as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the

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[3] *Ipsen*, 108 F.4th 836 at 845–46 (citing Cytori Therapeutics, Inc. v. FDA, 715 F.3d 922, 923 (D.C. Cir. 2013)).

[4] Eli Lilly v. Kennedy, No. 1:24-cv-1503 (S.D. Ind. 2024).

[5] 21 U.S.C. § 321(g)(1).

prevention, treatment, or cure of a disease or condition of human beings."[6] In turn, regulation defines "protein" as "any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size."[7]

The question of whether a product should be regulated as a drug or as something else is certainly not a new one. *United States v. Bacto-Unidisk*, 394 U.S. 784 (1969) is a prominent example of a "definitional controversy," which shows the enduring difficulty presented by the classification of therapeutic products. In this oft-anthologized case, the Supreme Court reversed the lower court determinations that certain antibiotic sensitivity discs were not drugs.[8] The discs in the *Bacto-Unidisk* were round paper discs impregnated with a specific antibiotic intended for placement in contact with a patient specimen culture to assist doctors in the choice of the most effective antibiotic to treat a particular infection.[9] It was undisputed that each disc was used "in laboratory work exclusively . . . ."[10] Rejecting arguments that such use was too indirect to satisfy the definition of "drug," the Supreme Court found it was "plain that Congress intended to define 'drug' far more broadly than does the medical profession."[11]

More recently, the District Court for the District of Columbia addressed whether Teva's Copaxone (glatiramer acetate) product was a drug under the FDCA or a biologic under the PHSA.[12] Glatiramer acetate is a chemically synthesized mixture of peptide copolymers having four specific amino acids in a defined molar ratio but no specific, predetermined sequence.[13] Because the regulatory definition of "protein" requires a "specific, defined sequence," FDA found that glatiramer acetate was not a protein, and hence was not a "biological product" regulated under the PHSA.[14] Teva disagreed, alleging that FDA's determination was inconsistent with other previous determinations classifying allegedly less-defined products as biologics. As another alleged inconsistency, Teva also pointed to FDA's determination that glatiramer acetate was sufficiently well-defined to approve generic drugs.[15]

The D.C. District Court rejected Teva's challenges.[16] In *Teva*, the District Court applied the two-step *Chevron* framework. Thus, the court first analyzed whether Congress directly addressed the precise question at issue and then, as a second step, analyzed whether the agency's interpretation was based on a permissible construction of the statute if it was silent or ambiguous. Judge Howell applied the first step of *Chevron* to find that "[t]he term 'protein' is thus ambiguous with respect to the

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6 42 U.S.C. § 262(i)(1).

7 21 C.F.R. 600.3(h)(6).

8 United States v. Bacto-Unidisk, 394 U.S. 784, 785 (1969).

9 *Bacto-Unidisk*, 394 U.S. at 787.

10 *Id.*

11 *Id.* at 793.

12 Teva Pharms. USA, Inc. v. FDA, 514 F. Supp. 3d 66 (D.D.C. 2020).

13 *Id.* at 81.

14 *Id.*

15 *Id.* at 84. In addition, Teva argued that FDA inconsistently applied the category of product "analogous" to proteins contemplated in the definition of protein. *Id.* at 93–94. Judge Howell also found reasonable that FDA's interpretation of "analogous" product to exclude proteins that otherwise failed to satisfy the requirement of defined sequences.

16 *Id.* at 74.

'specific, defined sequence' requirement, which is neither compelled nor foreclosed by the text of section 351."[17] Then, at the second step, Judge Howell determined that the "specific, defined sequence" requirement of "protein" was "neither unattainable nor, on its face, unduly burdensome for chemically synthesized molecules."[18]

Then, less than two weeks before *Ipsen* was decided, the Supreme Court issued *Loper Bright*. In a decision that will surely inspire voluminous commentary in the years to come, the Court in *Loper Bright* overruled *Chevron*, holding that the deference owed to agency action by *Chevron* "cannot be squared with the APA."[19] Rather, Justice Roberts, speaking for a fractured Court, wrote that "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority."[20] While the majority opinion acknowledged that "attention" to an agency's judgment may "help inform" a court reviewing agency action, it also made clear that courts may not defer to agency interpretation "simply because a statute is ambiguous."

In her dissent, Justice Kagan pressed the "scientific or technical subject matter" of some interpretative issues.[21] Justice Kagan then turned the issue concrete, citing the facts from caselaw of several "typical" *Chevron* problems, including the question addressed by the court in *Teva* ("[w]hen does an alpha amino acid polymer qualify as such a 'protein'?").[22] Justice Kagan's soliloquy about proteins is notable:

> Consider, for example, the first bulleted case above. When does an alpha amino acid polymer qualify as a "protein"? I don't know many judges who would feel confident resolving that issue. (First question: What even *is* an alpha amino acid polymer?) But the FDA likely has scores of scientists on staff who can think intelligently about it, maybe collaborate with each other on its finer points, and arrive at a sensible answer.[23]

Based on this example, among others, Justice Kagan argued that "agencies often know things about a statute's subject matter that courts could not hope to"—especially when the statute is of a "scientific or technical nature."[24]

B. Factual Background

FDA approved Somatuline Depot (lanreotide acetate) solution for subcutaneous administration in August 2007 as a drug under NDA No. 22-074.[25] The active ingredient in Somatuline Depot, lanreotide acetate, is a synthetic octapeptide analog of the natural hormone, somatostatin.[26] In Somatuline Depot, lanreotide acetate assembles into nanotube structures, which facilitate diffusion of lanreotide acetate.[27]

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[17] *Id.* at 102.

[18] *Id.* at 106.

[19] *Loper Bright*, 603 U.S. at 396.

[20] *Id.* at 412.

[21] *Id.* at 449 (Kagan J, dissenting).

[22] *Id.* at 452.

[23] *Id.* at 456 (emphasis in original) (internal citation omitted).

[24] *Id.*

[25] Somatuline Depot Label at 1 (Aug. 30, 2007).

[26] *Id.* at 10.

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

When Somatuline Depot was initially approved in 2007, it was protected by a five-year new chemical entity exclusivity, a seven-year orphan drug exclusivity, and a patent expiring in 2015.[28]

When FDA left Somatuline Depot off a list of NDAs transitioned to BLAs, Ipsen asked FDA to reconsider.[29] FDA stood by its decision and Ipsen sued FDA.[30] The district court dismissed Ipsen's complaint because it found Ipsen lacked standing. Specifically, the district court found that Ipsen's fears were too speculative—to show standing, Ipsen would need to show that a generic applicant would file an ANDA referencing Somatuline Depot, that FDA would approve that ANDA, and that the hypothetical ANDA product would fail to satisfy the standard of similarity established by the PHSA for follow-on biological products.[31]

But Ipsen's fears soon grew less speculative. Shortly thereafter, FDA approved an ANDA submitted by Invagen to market a generic version of Somatuline Depot, and Ipsen sued FDA once again.[32] Ipsen argued that, when assembled into the nanotube structures, lanreotide acetate would have over forty amino acids and therefore would meet the regulatory definition of protein.[33] Alternatively, Ipsen argued that the nanotube assembly satisfied the definition of "biological product" as "an analogous product" to a protein. Ipsen concluded that FDA's determination violated the APA because it was arbitrary and capricious or otherwise not in accordance with law.[34]

The D.C. District Court granted summary judgment in favor of FDA and the intervenor Invagen.[35] First, the District Court rejected Ipsen's legal challenge to FDA's decision to consider the length of lanreotide acetate "standing alone" rather than altogether in the final drug product, finding FDA's decision to analyze the length of peptides in terms of "just" lanreotide acetate and not the nanotubes, "unambiguously correct."[36] The District Court also rejected Ipsen's disagreement with FDA's scientific judgment that stand-alone lanreotide acetate was the active ingredient, finding that FDA's determination was "rational, carefully explained, and consistent with the record evidence."[37] Moreover, the District Court rejected Ipsen's argument that FDA erred in not accepting Somatuline Depot as a product "analogous" to a protein.[38] Ipsen appealed.

C. Decision

The D.C. Circuit affirmed the District Court's resolution of the summary judgment motions in favor of FDA and against Ipsen. Writing for the panel, Judge Wilkins

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[28] U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, PATENT AND EXCLUSIVITY INFORMATION ADDENDUM ADA 77 (28th ed. 2008).

[29] *Ipsen*, 108 F.4th at 839.

[30] Ipsen Biopharmaceuticals, Inc. v. Becerra, 2021 U.S. Dist. LEXIS 183825 (D.D.C. 2021).

[31] *Ipsen*, 2021 U.S. Dist. LEXIS 183825, at 13–14.

[32] *See Ipsen*, 108 F.4th at 840.

[33] *Id.*

[34] *Id.*

[35] Ipsen Biopharmaceuticals, Inc. v. Becerra, 678 F. Supp. 3d 20 (D.D.C. 2023).

[36] *Id.* at 36–37.

[37] *Id.* at 39.

[38] *Id.* at 39–40.

surveyed the significant points of agreement between the parties. For example, the court noted that parties "largely agree on the law"—notably, Ipsen did not challenge the propriety of the regulatory definition of protein (i.e., "any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size").[39] The court also noted "broad agreement on how the law applies to the facts"—that lanreotide acetate consists of eight peptides, that it assembles into nanotubes of greater than 40 amino acids in the finished dosage form, and that the nanotubes do not provide any pharmacological effect.[40]

The court framed the dispute, then, in terms of a disagreement about whether the statutory definition of "biological product" incorporates the regulatory definition of "drug product" (which in turn is defined as a "finished dosage form.")[41] But the court determined that, "Ipsen's attempt to merge the FDA's definition of a 'drug product,' from a regulation interpreting a different statute, to trump the definition of a 'biological product' specified by Congress in the relevant statute just does not work."[42] In practice, the court observed that following Ipsen's argument to its logical conclusion would lead to a "killer contradiction"—that Somatuline Depot would qualify as a biological product, but that other immediate release lanreotide acetate products would not (e.g., products that did not assemble into nanotubes).[43]

The D.C. Circuit also rejected Ipsen's argument that "biological products" are "merely types of drug products" and therefore the finished dosage form requirement of "drug product" should apply to biological products. The court still found, however, that the conclusion was not compelled by the premise, stating that, "[b]ut even so, that does not mean Congress silently incorporated the FDA's definition of a 'drug product' into the definition of a 'biological product.'"[44]

The court also rejected Ipsen's argument that Somatuline Depot qualifies as a biological product because it is "analogous" to a protein. While FDA has not promulgated a final rule on the meaning of "analogous product" in the statutory definition, the court observed that FDA "stakes out the general position that it is inappropriate to 'interpret the statutory term "analogous product" (with reference to a "protein") in a way that would include amino acid polymers that are specifically excluded by the interpretation of the term "protein" in the regulation.'"[45] More positively, FDA states that "analogous" products "must share the critical characteristics of the relevant category of biological product," such as the number of amino acid residues and the requirement for a specific, defined sequence.[46] As an example, FDA offered naturally derived mixtures including a protein and one or more non-biological product components such as a lipid where the mixture is not primarily comprised of protein.[47]

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[39] *Ipsen*, 108 F.4th at 841.

[40] *Id.*

[41] *Id.* (citing the definition of drug product in 21 C.F.R. § 314.3(b)).

[42] *Id.* at 843.

[43] *Id.*

[44] *Id.* at 843–44.

[45] *Id.* at 844 (citing FDA's Brief at 26).

[46] *Id.*

[47] *Id.*

Ipsen argued that FDA's interpretation of "analogous product" reads the word "analogous" out of the definition.[48] The D.C. Circuit disagreed.[49] The court observed that FDA identified an example of an analogous product that shared a protein's "critical characteristics, while also having other distinguishable characteristics" (e.g., a protein-lipid mixture described above).[50] Notably, the D.C. Circuit still cited its own law in *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922 at 923 (D.C. Cir. 2013) for the "basic principle of administrative law" that courts "must be careful not to unduly second-guess an agency's scientific judgments."[51] On this point, the court found that Ipsen failed to show that FDA's scientific judgments were not supported by substantial evidence or that FDA acted arbitrarily and capriciously in their determination.[52] Thus, the D.C. Circuit affirmed.

IMPACT OF THE DECISION

Ipsen v. Becerra is certainly not the first "definitional controversy" relating to the fundamental categories of FDA regulatory law. Each time that controversy arises about a core concept of FDA regulatory law (e.g., food, drugs, or biological products), opportunities arise to learn more about how scientists and industry use the term, its legal definition, the touchpoints between the two, and the process that agencies use to mediate both and achieve policy goals.

In addition, the *Ipsen* case presents additional clarification on the meaning of the term "analogous products" in the statutory definition of "biological product." Before *Ipsen*, the D.C. District Court in *Teva Pharms. USA, Inc. v. United States FDA*, 514 F. Supp. 3d 66 (D.D.C. 2020) had already ratified FDA's position that "analogous product" cannot include peptides lacking a "specific, defined sequence." Then, in the *Ipsen* case, the D.C. Circuit ratified several refinements, including that "analogous products" cannot include peptides containing fewer than 40 amino acids. Taking *Teva* and *Ipsen* together, these cases suggest that an "analogous product" cannot include features that would vitiate the meaning of any other subclass of "biological product."

Ipsen v. Becerra will not be the last "definitional controversy." In fact, another dispute is presently before the District Court for the Southern District of Indiana about whether FDA properly classified a 41-peptide investigational product, retatrutide, as a drug versus a biological product.[53] And this time, with *Chevron* overruled, retatrutide's sponsor Eli Lilly forcefully argues that any scientific or technical judgment used by FDA should be afforded *no* deference. But query whether the notion of deference to agency scientific judgment will abide notwithstanding *Loper Bright*—whether a less structured concept exists independently from *Chevron*, and therefore will continue to exist after *Chevron*. In its summary judgment briefing in the *Eli Lilly* case, FDA pointed to *Ipsen* as "noting, post-*Loper Bright*, that courts must still "be careful not to

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[48] *Id.* at 844–45.

[49] *Id.* at 845–46.

[50] *Id.* at 845.

[51] *Id.* at 846.

[52] *Id.*

[53] Eli Lilly v. Kennedy, No. 1:24-cv-1503 (S.D. In. 2024). Because even though retatrutide consists of greater than forty amino acids, it does not contain greater than forty *alpha* amino acids.

unduly second-guess [FDA's] scientific judgements."[54] The most enduring aspect of the *Ipsen* case may very well be this proposition.

[54] Defendants' Memorandum in Support of their Cross-Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment at 16 n.7, Eli Lilly v. Kennedy, No. 1:24-cv-1503 (S.D. In. 2024).

In re Beech-Nut Nutrition Company Baby Food Litigation

MITAL PATEL & DANIT HALBERSTEIN*

WHY IT MADE THE LIST

Food safety concerns remained a critical issue in 2024. In the wake of the 2021 congressional report finding that there are high levels of toxic heavy metals—including arsenic, lead, cadmium, and mercury—in baby foods being sold by some of the nation's largest manufacturers, plaintiffs across the country have brought class actions against leading baby food manufacturers, alleging that their products contain dangerous levels of heavy metals.

The *In re Beech-Nut Nutrition Company Baby Food Litigation* decisions from 2024 and beyond out of the Northern District of New York and the Second Circuit addressed these challenges head-on. Plaintiffs alleged that Beech-Nut's baby food products were misrepresented as safe, natural, and healthy, when in fact they contained or risked containing harmful heavy metals. What stemmed from this initial case were a series of decisions that are applicable beyond just baby food safety cases.

The March 2025 dismissal of the *In Re Beech-Nut Nutrition Company Baby Food Litigation* has set a new benchmark for consumer class actions based on economic harm, requiring plaintiffs to provide specific allegations of misrepresentation and quantifiable financial injury. The decision provides corporate defendants helpful guidance in mounting a defense challenging standing early and underscoring the need for careful marketing practices. Plaintiffs' attorneys have taken note of these decisions and will likely attempt to craft complaints with these issues in mind. This ruling's impact will resonate across consumer product industries beyond baby food, affecting how future class actions are structured and contested.

DECISION AND BACKGROUND

In 2021, plaintiffs, purchasers of Beech-Nut baby food, brought a class action against Beech-Nut Nutrition Company alleging fraud, breaches of warranty, negligent misrepresentation, and violations of consumer protection statutes, based on the alleged presence of toxic heavy metals—such as arsenic, lead, cadmium, and mercury—in Beech-Nut's baby food products.[1] Plaintiffs claimed Beech-Nut misled consumers by labeling its products with terms like "organic," "natural," "nothing artificial added," and "real food for babies," despite internally knowing those products contained or

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[1] In re Beech-Nut Nutrition Co. Baby Food Litig., No. 1:21-CV-133, 2025 U.S. Dist. LEXIS 49882, at *3 (N.D.N.Y. Mar. 19, 2025).

risked containing harmful contaminants. After plaintiffs filed a consolidated amended complaint, Beech-Nut moved to dismiss.[2]

Initially, the Northern District of New York dismissed the case, invoking the doctrine of primary jurisdiction and finding that FDA was better suited to determine the safety of heavy metals in baby food.[3] The court pointed to FDA's "Closer to Zero" initiative as a sign that regulatory guidance was forthcoming, and that judicial intervention would be premature.[4] However, in January 2024, the U.S. Court of Appeals for the Second Circuit vacated, remanded, and reinstated the case.[5] The appellate court held that deferring to FDA would likely result in indefinite delay, as the agency had already missed key milestones for issuing limits on heavy metal content.[6] The appellate court concluded that plaintiffs' claims could be adjudicated under existing state consumer protection and tort laws, and that courts need not wait for administrative rulemaking in order to address allegedly misleading marketing practices.[7]

Following remand, plaintiffs filed a Second Amended Consolidated Complaint, and in August 2024, Beech-Nut once again moved to dismiss under Rules 12(b)(1) and 12(b)(6), arguing plaintiffs lacked Article III standing and failed to state a claim. In March 2025, the district court granted the motion to dismiss in full, holding that plaintiffs failed to plausibly allege a concrete and particularized injury-in-fact.[8] The court rejected both of plaintiffs' asserted economic injury theories: 1) the benefit-of-the-bargain theory, which claimed the products were effectively worthless because they were unsafe; and 2) the price premium theory, under which plaintiffs argued they paid more for baby food marketed as safe and natural. The court noted that plaintiffs had not alleged that the products failed to provide nourishment or were actually harmful to their children, nor did they identify any specific misrepresentations about the presence of heavy metals on the packaging.[9]

The court also emphasized that vague marketing terms like "natural" or "real food" were not sufficient to support a fraud or misrepresentation claim absent allegations tying them directly to the alleged contamination.[10] Moreover, the court found that plaintiffs did not point to any comparable, cheaper baby food products free of heavy metals, undermining the price premium theory.[11] As a result, the court concluded that plaintiffs had not demonstrated a cognizable economic injury and therefore lacked standing under Article III.[12]

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[2] In re Beech-Nut Nutrition Co. Baby Food Litig., 651 F. Supp. 3d 629 (N.D.N.Y. 2023).

[3] *Id.*

[4] *Id.* at 633.

[5] White v. Beech-Nut Nutrition Co., No. 23-220-cv, 2024 U.S. App. LEXIS 1145 (2d Cir. Jan. 18, 2024).

[6] *Id.* at *3–5.

[7] *Id.*

[8] In re Beech-Nut Nutrition Co. Baby Food Litig., No. 1:21-CV-133, 2025 U.S. Dist. LEXIS 49882 (N.D.N.Y. Mar. 19, 2025).

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.* at *16.

In late 2024, there was another baby food toxins decision. In *In re Hain Celestial Heavy Metals Baby Food Litig.*, consumers filed a class action lawsuit against Hain Celestial, Inc., another baby food manufacturer.[13] The plaintiffs alleged that Hain Celestial deceptively marketed its baby food products as safe and of high quality while they contained dangerous levels of heavy metals such as lead, arsenic, cadmium, mercury, and perchlorate. The court found that the plaintiffs had adequately alleged standing to bring the lawsuit. The plaintiffs here claimed they suffered an injury-in-fact by paying a premium for Hain Celestial's baby food products, believing them to be safe and of superior quality, which they would not have done had they known about the heavy metals. The court evaluated whether Hain Celestial's labeling could be found materially misleading to a reasonable consumer. The district court granted in part and denied in part defendant's motion to dismiss, finding that the plaintiffs plausibly alleged that some of Hain Celestial's products exceeded recognized safe thresholds for arsenic in baby food and that this information would be material to reasonable consumers, allowing these claims to proceed to discovery. The district court found, however, the plaintiffs failed to plausibly allege that a reasonable consumer would be misled into believing that Hain Celestial's baby food products were free from lead, cadmium, mercury, perchlorate, or other undesirable toxins and dismissed these claims because the plaintiffs did not provide specific benchmarks or thresholds indicating that the levels of these contaminants in Hain Celestial's products were unsafe.

IMPACT OF THE DECISION

At the heart of the plaintiffs' case in *In re Beech-Nut Nutrition Co. Baby Food Litigation* were two economic harm theories common in consumer class actions: the benefit-of-the-bargain theory and the price premium theory. Plaintiffs claimed they had paid for safe and healthy baby food but received products containing toxic metals, or that they had paid a premium based on Beech-Nut's marketing that suggested the products were safer than alternatives. However, the court rejected these arguments, ruling that the plaintiffs failed to demonstrate a concrete economic injury sufficient to establish Article III standing. Crucially, the plaintiffs did not allege that the baby food was unusable, that there were specific misrepresentations about the heavy metal content, or that any identifiable premium was paid directly because of deceptive marketing.

The ruling underscored a significant hurdle for future consumer class actions premised solely on economic harm without allegations of personal injury. Courts are demanding a higher level of specificity in claims of financial damage. This case suggests that simply asserting that consumers would not have purchased a product—or would have paid less—if they had known about a particular characteristic no longer suffices without clear, fact-specific allegations. Plaintiffs should now detail exactly how a company's marketing led to an overpayment or created an economic harm that is both measurable and traceable to the defendant's conduct.

This decision also illuminates a growing judicial split within New York's federal courts. While the Northern District dismissed the claims against Beech-Nut, a similar case in the Southern District of New York against Nurture LLC, maker of Happy Baby

[13] In re Hain Celestial Heavy Metals Baby Food Litig., No. 21-cv-00678 (NRM) (AYS), 2024 U.S. Dist. LEXIS 233487 (E.D.N.Y. Dec. 27, 2024).

Organics, allowed consumer claims to proceed.[14] In that case, the plaintiffs successfully alleged that specific marketing representations had induced them to pay more for what they believed were safer products. This inconsistency creates uncertainty for plaintiffs and defendants alike. Plaintiffs cannot rely on uniform treatment of economic injury claims, while defendants face varying litigation risks depending on jurisdiction. Moving forward, plaintiffs' firms may be likely to engage in more strategic venue selection, targeting courts that have shown greater receptiveness to economic harm theories.

The *Beech-Nut* ruling also sends a cautionary signal to plaintiffs' lawyers. Class actions built solely on generalized economic harm—without clear evidence of specific misrepresentations or quantifiable damages—will face steeper challenges. This is likely to deter speculative or marginal claims and shift plaintiffs' firms toward cases where there is stronger evidence of either personal injury or concrete financial harm. In response, firms may pivot toward pursuing claims involving physical injuries linked to product defects or toxic exposure, where standing and damages are less ambiguous.

For corporate defendants, the decision offers a valuable blueprint for defense strategies. Companies will likely be more aggressive in challenging standing at the earliest stages of litigation, citing the *Beech-Nut* decision to argue for dismissal before costly discovery and trial phases begin. Additionally, businesses will review and refine their marketing language to minimize litigation risks, avoiding broad or potentially misleading claims about product safety or health benefits. Defense counsel will also continue to leverage favorable case law, like the *Beech-Nut* ruling, to argue against the sufficiency of plaintiffs' economic harm allegations.

Beyond the baby food industry, this case has broader implications for consumer class actions across sectors including food and beverages, supplements, and personal care products. Many lawsuits in these areas rely on similar benefit-of-the-bargain and price premium arguments. The *Beech-Nut* decision signals to both plaintiffs and defendants that courts are increasingly unwilling to entertain economic injury claims lacking detailed, fact-specific support.

Ultimately, the *Beech-Nut* decision represents a significant tightening of the standards governing consumer class actions. It serves both as a warning to plaintiffs contemplating cases based on broad theories of economic harm and as a roadmap for defendants seeking early dismissal of such claims. As courts continue to grapple with the evolving landscape of consumer protection litigation, the *Beech-Nut* case will likely stand as an important decision in shaping how future claims are pleaded, defended, and adjudicated.

[14] In re Nurture Baby Food Litig., No. 1:21-cv-01217-MKV, 2025 U.S. Dist. LEXIS 56512 (S.D.N.Y. Mar. 26, 2025).

Bryan v. Del Monte Foods

RENE BEFURT, ANNE CAI & SAI SINDHURA GUNDAVARAPU*

WHY IT MADE THE LIST

"Natural" claims on food product packaging have been the focus of many lawsuits in recent years. While many cases about "natural" claims share the objective of understanding the perceptions of a "reasonable consumer," more recent cases expand that foundation to a more complete representation of the context, including the claim's exact wording around the term "natural," the context of the product packaging as a whole, consumers' preexisting knowledge about the product or the product category, and the products available in the market for the product type in question. For instance, in the matter discussed herein, *Bryan v. Del Monte*, the district court and the appellate court agreed that the exact wording of the alleged natural claim and the contents of the product's back label are important factors in determining whether claims are deceptive to target consumers.[1] The district court also highlighted additional relevant factors in assessing consumer understanding, namely the background knowledge of consumers who prefer natural products and the types of fruit cups available in the market.[2] In its decision, the district court referred to *McGinity v. Procter & Gamble*,[3] which provides a foundation for the notion that ambiguity on the front label can be resolved by reference to a back label that clearly discloses the inclusion of multiple synthetic ingredients.

We observe that both the district court and the appellate court in *Bryan v. Del Monte* found that the survey evidence provided by Plaintiff was irrelevant to understanding how a reasonable consumer could have interpreted the at-issue natural claims in the

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[1] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at 3 (N.D. Cal. Oct. 19, 2023) (Order Granting Motion to Dismiss First Amended Complaint); Bryan v. Del Monte Foods, Inc., No. 23-3685, at 2 (9th Cir. Nov. 22, 2024) (Memorandum).

[2] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at 3 (N.D. Cal. Oct. 19, 2023) (Order Granting Motion to Dismiss First Amended Complaint).

[3] *Id.* at 3 (citing McGinity v. Procter & Gamble Co., 69 F.4th 1093 (9th Cir. June 9, 2023)).

case at hand, indicating the importance of well-designed, relevant surveys in lawsuits related to natural claims.[4] Specifically, the appellate court noted that a survey conducted outside of the litigation yet part of Plaintiff's survey evidence was "uninformative because it did not ask what respondents thought about the noun 'naturals,' rather, it asked about the adjective 'natural'" and "asked people what they thought 'natural' should mean on the label of a product, not what they thought it actually did mean as used on these labels."[5]

DISCUSSION

Procedural Background and Ruling of the District Court

In August 2023, Plaintiff Kerstine Bryan filed an amended complaint in a class action lawsuit against Del Monte Foods, Inc. relating to Del Monte's fruit cups sold by brick-and-mortar retailers such as Walmart.[6] Plaintiff alleged that Del Monte's fruit cups presented claims that were false, deceptive, and misleading and misrepresent to reasonable consumers that the fruit cups "contain[] only natural ingredients."[7]

Specifically, Plaintiff alleged that "[t]he front label of every Product states that the Product is 'Fruit Naturals'" and "'Naturals' is a representation to a reasonable consumer that the Products contain only natural ingredients."[8] In support of her allegations, Plaintiff cited a consumer survey conducted outside of the case that purportedly demonstrated that "the reasonable consumer believes that the term 'natural,' when used to describe goods such as the Products, means that the goods are free of synthetic ingredients."[9] Plaintiff further alleged that Del Monte "reinforces these representations throughout other forms of marketing including its website," which "emphasizes 'naturally refreshing' and 'Chilling in your grocer's produce section' while showing images of fresh fruit."[10] In addition, Plaintiff pointed out synthetic ingredients such as citric acid, potassium sorbate, sodium benzoate, and methylcellulose gum "on the back of the Products' packaging in the ingredients listed," and alleged that "[c]onsumers would not know that the Products contain unnatural, synthetic ingredients, by reading the ingredients label."[11] Expanding on this argument, Plaintiff also stated that "the reasonable consumer is not expected or required to scour the ingredients list on the back of the Products in order to confirm or debunk Defendant's prominent front-of-the-product claims, representations, and warranties that the Products are 'natural.'"[12]

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[4] *Id.* at 3; Bryan v. Del Monte Foods, Inc., No. 23-3685, at 2–3 (9th Cir. Nov. 22, 2024) (Memorandum).

[5] *Id.* at 2–3.

[6] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at ¶¶ 1, 6, 20 (N.D. Cal. Aug. 25, 2023) (Dkt 29, First Amended Class Action Complaint).

[7] *Id.* ¶¶ 1, 6, 7, 50.

[8] *Id.* ¶¶ 42, 45.

[9] *Id.* ¶ 39.

[10] *Id.* ¶¶ 47–48.

[11] *Id.* ¶¶ 50–52.

[12] *Id.* ¶ 53.

Del Monte filed a motion to dismiss Plaintiff's amended complaint in early September 2023.[13] Plaintiff filed an opposition to Del Monte's motion to dismiss, and Del Monte filed a reply in support of the motion to dismiss, both in late September 2023.[14] In October 2023, the district court sided with Del Monte and dismissed Plaintiff's amended complaint. The district court ruled that Plaintiff "has not plausibly alleged that the Products' front label, as clarified by the back label, would mislead a reasonable consumer into thinking that the Products contain no synthetic ingredients."[15] Referencing the decision in *McGinity v. Procter & Gamble*, the court stated that "the front label's statement, 'fruit naturals,' like the label considered in McGinity, does not 'make any affirmative promise about what proportion of the ingredients are natural,'" and "as in McGinity, . . . such ambiguity can be resolved by reference to the back label, which clearly discloses the inclusion of multiple synthetic ingredients."[16] The court noted that Plaintiff "points to no case wherein a court has held any consumer, let alone one concerned about synthetic ingredients, would not be able to distinguish a synthetic ingredient from a natural ingredient."[17] Referencing *Robles v. GOJO Indus.*, the court stated that "'[g]eneral knowledge and common sense' may serve to 'inform the reasonable consumer considering a product'" and Plaintiff "does not allege there are 'any comparable single serve fruit products available on the market that do not contain any artificial sweeteners or preservatives.'"[18] Additionally, the court found that "the publicly available consumer surveys on which Bryan relies do not save her claims. Those surveys do not address a consumer's understanding of the noun 'naturals' used as part of a product's name, as is alleged here, but, rather, appear to address a consumer's understanding of the word 'natural' used as an adjective to describe a product."[19]

Plaintiff appealed the decision in January 2024.[20] Del Monte filed a reply to Plaintiff's brief in February 2024,[21] and Plaintiff filed an answer in March 2024.[22] The United States Court of Appeals for the Ninth Circuit issued its opinion in November 2024.[23]

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[13] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at 1 (N.D. Cal. Oct. 19, 2023) (Order Granting Motion to Dismiss First Amended Complaint).

[14] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC (N.D. Cal. Sept. 22, 2023) (Dkt 38, Plaintiff's Opposition to Defendant's Motion to Dismiss First Amended Complaint); Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC (N.D. Cal. Sept. 29, 2023) (Dkt 41, Defendant Del Monte Foods Inc.'s Reply in Support of Motion to Dismiss Amended Complaint).

[15] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at 3 (N.D. Cal. Oct. 19, 2023) (Order Granting Motion to Dismiss First Amended Complaint).

[16] *Id.* at 3 (citing McGinity v. Procter & Gamble Co., 69 F.4th 1093 (9th Cir. June 9, 2023)).

[17] *Id.* at 3.

[18] *Id.* at 3 (citing Robles v. GOJO Indus., Inc., 2023 U.S. App. LEXIS 20051, 2023 WL 4946601, at *2 (9th Cir. Aug. 3, 2023)).

[19] *Id.* at 3.

[20] Bryan v. Del Monte Foods, Inc., No. 23-3685 (9th Cir. Jan. 9, 2024) (Brief of Plaintiff-Appellant Kerstine Bryan).

[21] Bryan v. Del Monte Foods, Inc., No. 23-3685 (9th Cir. Feb. 20, 2024) (Appellee Del Monte Foods, Inc.'s Answering Brief to Appellant Kerstine Bryan's Opening Brief).

[22] Bryan v. Del Monte Foods, Inc., No. 23-3685 (9th Cir. Mar. 13, 2024) (Reply Brief of Plaintiff-Appellant Kerstine Bryan).

[23] Bryan v. Del Monte Foods, Inc., No. 23-3685 (9th Cir. Nov. 22, 2024) (Memorandum).

Ruling and Reasoning of the Appellate Court

The appellate court affirmed the district court's ruling. Referencing both *Whiteside v. Kimberly Clark* and *McGinity v. Procter & Gamble*, the appellate court ruled that "Plaintiff has not plausibly alleged that the front label is 'unambiguously deceptive to an ordinary consumer,'" "a reasonable consumer would look at the back label," and "the front label 'does not promise that the product is wholly natural,' as would a label declaring that a product is '100% natural' or 'all natural.'"[24] The court found that "[a]ccordingly, 'the ambiguity can be resolved by reference to the back label,'" which "accurately and clearly discloses several synthetic ingredients about which Plaintiff complains."[25] Specifically, the court noted that, "in the phrase 'fruit naturals®,' 'naturals' is a noun, not a descriptive adjective. The presence of the registered-trademark symbol after 'fruit naturals' also suggests that the phrase is just the name of the product."[26] Pointing to the labels of the fruit cups at issue, the court noted that they "display the picture and name of the fruit in the cups, followed by the phrase 'in extra light syrup.' Taken together with the rest of the front label . . . the 'syrup' phrase affirmatively conveys that, although the fruit itself is natural, the syrup may not be."[27] Additionally, the appellate court also found that the survey evidence cited by Plaintiff was "uninformative because it did not ask what respondents thought about the noun 'naturals,' rather, it asked about the adjective 'natural.' And, importantly, the survey asked people what they thought 'natural' should mean on the label of a product, not what they thought it actually did mean as used on these labels."[28]

Plaintiff filed a petition for rehearing in December 2024, and the appellate court denied Plaintiff's petition in January 2025.[29]

IMPACT

In both the district court's dismissal of Plaintiff's amended complaint and the appellate court's affirmation of the dismissal, the courts focused on how a reasonable consumer could interpret the at-issue natural claims. Both courts highlighted the details of the product packaging, including the natural claim itself and other elements of the product's front label, such as the "presence of the registered-trademark symbol after 'fruit naturals'"[30] and "the picture and name of the fruit in the cups, followed by the phrase 'in extra light syrup.'"[31] In addition, the district court noted the importance of considering consumers' background knowledge and the market for fruit cups. The authors agree with that view, as many consumers develop (varying degrees of) knowledge during the consumer purchase journey. The latter framework describes

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[24] *Id.* at 3 (citing Whiteside V. Kimberly Clark Corp., 108 F.4th 771, 780 (9th Cir. 2024); McGinity v. Procter & Gamble Co., 69 F.4th 1093, 1096 (9th Cir. 2023)).

[25] *Id.* at 3.

[26] *Id.* at 2.

[27] *Id.* at 2.

[28] *Id.* at 2–3.

[29] Bryan v. Del Monte Foods, Inc., No. 23-3685 (9th Cir. Dec. 7, 2024) (Plaintiff-Appellant's Petition for Rehearing or Rehearing En Banc); Bryan v. Del Monte Foods, Inc., No. 23-3685 (9th Cir. Jan. 7, 2025) (Order).

[30] Bryan v. Del Monte Foods, Inc., No. 23-3685, at 2 (9th Cir. Nov. 22, 2024) (Memorandum).

[31] *Id.* at 2.

how consumers go through some or all of the following phases, with varying amounts of time spent in each: (1) identification of a need, (2) information gathering on products that meet that need, (3) evaluation of identified products, (4) selection and purchase of a specific product, and (5) experience of the product in the post-purchase stage.[32] In this case, as noted by the district court, both the background information held by a reasonable consumer who prefers natural products as well as the other products considered by a reasonable consumer of fruit cups could inform their interpretation of the at-issue natural claims. These rulings emphasize the importance of considering these factors of context and consumer knowledge, tailored to the particular claims at issue, when evaluating the understanding of a reasonable consumer.

In fact, Plaintiff's failure to consider these factors when presenting survey evidence led to the courts deeming the survey evidence irrelevant to the matter. Specifically, Plaintiff's survey evidence provided only general information on "a consumer's understanding of the word 'natural' used as an adjective to describe a product,"[33] without tying it to the actual at-issue claim, the context in which it was presented, and—keeping in mind the purchase journey—the preexisting knowledge of its target consumers.

What Precise Claims Are Consumers Exposed to, and In What Context?

In their decisions, the courts highlight the impropriety of lumping the at-issue natural claim with other natural claims as a "'natural' label" in general.[34] Both courts noted that the survey evidence cited by Plaintiff was based on labels utilizing the adjective "natural" to describe the product, and pointed out that the at-issue claim in this case used the noun "naturals" as part of the product's name. Pointing to the distinction between the noun and adjective forms, the courts ruled that a reasonable consumer cannot be assumed to interpret the adjective "natural" in the same manner as the noun "naturals."[35] In the same vein, the appellate court noted the presence of the registered trademark symbol following the phrase "fruit naturals" on the front label as an additional indicator to a reasonable consumer that "fruit naturals" was simply the product's name and not a description of the product's properties.[36] For a consumer survey to provide reliable evidence on how consumers interpret a claim at issue, the survey designer must test the precise term(s) at issue, within the context of how consumers would encounter the claim on a product label.

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[32] PHILIP T. KOTLER & KEVIN LANE KELLER, MARKETING MANAGEMENT 194–201 (15th ed. Pearson 2016).

[33] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at 3 (N.D. Cal. Oct. 19, 2023) (Order Granting Motion to Dismiss First Amended Complaint).

[34] *Id.* at 2–3; Bryan v. Del Monte Foods, Inc., No. 23-3685, at 3 (9th Cir. Nov. 22, 2024) (Memorandum).

[35] *Id.* at 2; Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at 3 (N.D. Cal. Oct. 19, 2023) (Order Granting Motion to Dismiss First Amended Complaint).

[36] Bryan v. Del Monte Foods, Inc., No. 23-3685, at 2 (9th Cir. Nov. 22, 2024) (Memorandum).

How Do Consumers Interpret a Claim (Not: What Do Consumers Think a General Term Should Mean)?

Continuing its assessment of the survey evidence cited by Plaintiff, the appellate court highlighted that "importantly, the survey asked people what they thought 'natural' should mean on the label of a product, not what they thought it actually did mean as used on these labels" at issue in the case.[37] The appellate court therefore rejects that consumers would be the ones to ask about what a label should say, and instead reminds the Plaintiff that the crucial aspect about the reasonable consumer is their understanding of what the noun "fruit naturals" claim on a product's front label *actually* means to them.

What Knowledge and Expectations Do Reasonable Consumers Hold About the At-Issue Product's Market?

The district court also indicated the importance of considering the knowledge of consumers in general and that of those who are "concerned about synthetic ingredients" in particular. Specifically, the court noted that Plaintiff "points to no case wherein a court has held any consumer, let alone one concerned about synthetic ingredients, would not be able to distinguish a synthetic ingredient from a natural ingredient."[38] A reasonable consumer who is concerned about synthetic ingredients and would prefer to purchase natural products certainly has the opportunity to become informed about natural products in their purchase journey and try to distinguish between synthetic and natural ingredients. However, as noted by the district court, Plaintiff also "does not allege there are 'any comparable single serve fruit products available on the market that do not contain any artificial sweeteners or preservatives.'"[39] Hence, a reasonable consumer who gathered such information is unlikely to be deceived into believing that the noun "naturals" on the front label of the at-issue products promises a natural food without artificial sweeteners or preservatives. Rather, armed with the knowledge of the market, a reasonable consumer may consider the ingredient list on the back label and identify that the product contains synthetic ingredients. The district court's decision emphasizes the importance of defining the correct target population and screening for a survey sample appropriately, such that the respondents to a consumer survey reflect the knowledge and expectations that a target consumer for the product type would hold.

Consumer surveys, if designed to be relevant and conducted to produce valid and reliable data, can be excellent methods of gathering empirical evidence on consumers' perceptions of natural claims, tailored to a particular context. The courts' discussion of these factors indicates that a well-designed consumer survey that places consumers in the context of shopping for fruit cups like the products at-issue, then presents them with the at-issue natural claims in the context of the at-issue label and asks about their interpretation of the label—instead of their beliefs regarding what the label *should* rightly mean—could provide relevant empirical evidence to assess how a reasonable consumer may interpret natural claims.

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[37] *Id.* at 2–3.

[38] Bryan v. Del Monte Foods, Inc., No. 4:23-cv-00865-MMC, at 3 (N.D. Cal. Oct. 19, 2023) (Order Granting Motion to Dismiss First Amended Complaint).

[39] *Id.* at 3.

In re Zostavax (Zoster Vaccine Live) Products Liability Litigation

ANAND AGNESHWAR, JOCELYN WIESNER & TOMMY HUYNH[*]

WHY IT MADE THE LIST

Whenever there is the prospect of a large litigation involving significant numbers of plaintiffs, the question of whether to move for a multi-district litigation (MDL) invariably arises. On the one hand, MDLs can provide a useful process to streamline pretrial proceedings before a single judge in one court, ensuring consistent application of law and coordination in discovery and motion practice. On the other, MDLs can encourage the filing of significant numbers of cases with varying levels of vetting, leading to inefficiencies and challenges for both defendants and plaintiffs. To combat this concern, the parties sometimes agree on case management orders (CMOs) that, with penalty of dismissal, require plaintiffs to provide basic evidence (often in the form of verified discovery responses) about their claims, such as product use, injury, and/or causation, at an earlier stage of the litigation. A number of MDL judges across the country have entered such orders, often resulting in the dismissal of cases that never would have survived individual causation challenges and ensuring that both plaintiffs and defendants have a more realistic picture of the scope of the litigation. Yet in some circles these orders remain controversial and some judges are reluctant to issue such orders in the absence of unanimous consent.

In re Zostavax (Zoster Vaccine Live) Products Liability Litigation[1] provides a very recent example of why these types of CMOs should be strongly considered in MDLs. There, the district court entered a CMO requiring 1,189 plaintiffs to present evidence of causation prior to summary judgment. The court recognized that because of the nature of the claim, many plaintiffs would be unable to prove causation regardless of the scope and extent of discovery. Accordingly, it decided to reshape the litigation.

The Third Circuit affirmed the order, endorsing the proposition that district judges should have wide latitude to enter case management orders that streamline the litigation and weed out claims that never should have been brought. It will be interesting to see whether defendants can successfully leverage *Zostavax*, as well as proposed new Federal Rule of Civil Procedure (FRCP) 16.1—which would encourage

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[1] *In re Zostavax Prods. Liab. Litig.*, 2024 WL 3423709 (3d Cir. July 16, 2024).

the early disclosure of MDL plaintiffs' bases for their claims—to persuade even more MDL judges to adopt early vetting mechanisms that go beyond barebone requirements, including ones that require some kind of causation vetting up front.

THE FACTS

Varicella-zoster virus (VZV) causes chickenpox.[2] Once the chickenpox clears, however, the virus remains dormant in a person's body for life. Because nearly everyone in the United States has had chickenpox, virtually everyone carries the dormant VZV wild-type strain.[3] If reactivated, it can cause shingles—a painful rash.[4]

Merck manufactured Zostavax, a vaccine that reduces the risk of developing shingles by exposing patients to the VZV attenuated strain.[5] Approximately 2,800 plaintiffs sued Merck, alleging that the Zostavax vaccine caused their shingles.[6] In August 2018, an MDL in the Eastern District of Pennsylvania before Judge Harvey Bartle was formed to adjudicate these cases.[7]

From 2018 to 2021, the parties worked up five bellwether cases for trial. All five involved plaintiffs who had chickenpox.[8] Following expert discovery, Merck successfully moved to exclude plaintiffs' specific causation expert because he failed to rule out reactivation of the VZV wild-type strain as the alternative cause.[9] The court further granted Merck's motion for summary judgment, dismissing all five bellwether cases, because they could not prove causation.[10]

Shortly thereafter, on January 2022, Merck moved for entry of a CMO requiring 1,189 plaintiffs to produce a PCR test,[11] which is the only way to reliably discern between the VZV strains,[12] and thus, the only way to tell whether Zostavax or chickenpox caused plaintiffs' injuries. Plaintiffs opposed the motion, arguing that it would be impossible to comply because "none of the . . . [p]laintiffs had ever been PCR tested." They further argued that because "PCR testing can only be done on existing [shingles] rashes, [and] most (if not all) of the . . . [p]laintiffs' rashes had already healed," the CMO would effectively require the dismissal of all plaintiffs subject to it.[13] The court disagreed and entered the order in March 2022.[14] After the PCR tests were not produced, the court dismissed 1,189 plaintiffs with prejudice.[15]

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2 *Id.* at *1.

3 *Id.*

4 *Id.*

5 *Id.*

6 *Id.*

7 *Id.*

8 *Id.*

9 *Id.*

10 *Id.*

11 *Id.* at *2, n. 17.

12 *Id.* at *1–2.

13 *Id.* at *2.

14 *Id.*

15 *Id.*

Plaintiffs appealed, arguing that the CMO was improper for two reasons: 1) it was entered "based purely on an assumption that PCR testing is the only way to establish specific causation"; and 2) it "mandated production of 'non-existent evidence that never existed' and was incapable of being created after-the-fact."[16]

ANALYSIS AND HOLDING

In an unpublished opinion, the Third Circuit held the district court did not abuse its broad discretion in entering the CMO.

The Third Circuit rejected plaintiffs' first argument, finding that the order was "premised on uncontradicted record evidence . . . that PCR testing is the only way to establish specific causation" rather than "on mere assumption."[17] The court explained that plaintiffs had failed to produce any literature or expert opinion "explaining how it can be determined that Zostavax and not chickenpox caused a person to contract shingles other than through PCR testing" after three years—despite knowing from the start that they would have to exclude the VZV wild-type strain as the alternative cause.[18]

The Third Circuit also rejected plaintiffs' second argument. As the Third Circuit explained, CMOs are not limited to requiring only "the production of evidence that already existed or can be created."[19] Rather, the court reiterated that an MDL judge has wide latitude to structure orders in a form that helps dismiss meritless cases.[20] And because plaintiffs could not explain how they could prove specific causation *without* PCR tests,[21] there could be no unfairness because plaintiffs were never ultimately going to be able to prove specific causation.[22] In other words, the CMO accomplished exactly what it was intended to do: it required earlier vetting of cases so that the parties could focus time and resources on only those cases that are potentially meritorious.

THE IMPACT

The Third Circuit's affirmance of the CMO makes clear that MDL judges have wide discretion on how to weed out meritless claims. Such CMOs often utilize verified written discovery responses where, for example, product use is at issue. Here, the judge employed a novel approach requiring MDL plaintiffs to produce causation evidence in the form of a genetic test that did not already exist. Going forward, parties should think creatively about what actual evidence will be required to prove causation and consider a process to vet such evidence before either party spends significant time and resources litigating cases. This approach would be beneficial to both plaintiffs and defendants, as it would allow each side to take a more realistic assessment of the scope and value of a particular litigation.

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[16] *Id.*

[17] *Id.* at *3.

[18] *Id.*

[19] *Id.*

[20] *See id.*

[21] *Id.* at *4.

[22] *See id.*

The *Zostavax* decision comes on the heels of a proposed amendment to FRCP 16.1, which would encourage the early exchange of information in MDLs. Likely implemented in December if approved, proposed FRCP 16.1 suggests an initial conference to address "how and when the parties will exchange information about the factual bases for their claims and defenses."[23] The Advisory Committee's comments further state that the "court may find it appropriate to employ expedited methods to resolve claims or defenses not supported after the required information exchange."[24] Defendants in MDLs should look for opportunities to leverage the broad discretion expressed in *Zostavax*, coupled with proposed FRCP 16.1, to persuade more MDL judges to adopt early vetting procedures.

While the *Zostavax* CMO ultimately dismissed many meritless cases before summary judgment, it was entered three years into the MDL and only after the burden and expense of working up five bellwether cases. The need for earlier, more robust vetting (as proposed FRCP 16.1 seems to acknowledge) is pressing in MDLs. As *Zostavax* illustrates, such claims could be disposed of earlier if proper vetting mechanisms are in place earlier.

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[23] Proposed FRCP 16.1, https://www.uscourts.gov/sites/default/files/2024_scotus_package_final.pdf.

[24] *Id.*

Loper Bright Enterprises v. Raimondo

JAMES M. BECK*

I. WHY IT MADE THE LIST

For forty years, the "Chevron doctrine," named after *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,[1] put a judicial thumb on the scale in favor of administrative agency constructions of their organic statutes. The FDA enjoyed the benefit of such deference many times. An online search of judicial decisions in which the FDA was mentioned in the same paragraph as a *Chevron* citation produced well over 500 results.[2]

No longer. The Supreme Court overruled *Chevron* and expressly did away with the *Chevron* doctrine in *Loper Bright Enterprises v. Raimondo*, requiring courts reviewing agency actions essentially to ignore administrative interpretations and to give relevant statutes "the reading the court would have reached if no agency were involved."[3] *Loper Bright* found support for this position in decisions reaching as far back as *Marbury v. Madison*'s famous declaration that "[i]t is emphatically the province and duty of the judicial department to say what the law is."[4] But the linchpin of *Loper Bright* is its application of the Administrative Procedure Act (APA),[5] a statute that was not mentioned at all in *Chevron*.

Congress intended the APA to be "a check upon" administrative "excesses not contemplated in legislation creating" the relevant agencies."[6] In pertinent part, the APA "delineates the basic contours of judicial review" of agency action.[7] It provides that "the reviewing court shall decide all relevant questions of law," and shall "interpret constitutional and statutory provisions."[8] The APA did not create any deferential review standard of the sort recognized in *Chevron* for legal questions, a sharp contrast to "judicial review of agency policymaking and factfinding," which was "deferential."[9] Since the APA was "designed to serve as the fundamental charter of the administrative state," judicial *Chevron* deference to agency construction of "constitutional and statutory provisions" could not survive.[10]

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1 467 U.S. 837 (1984).

2 On March 24, 2025, the search "467 U.S. 837 & (chevron /p (fda or food drug administration))" produced 539 results in the Lexis All Cases library.

3 603 U. S. 369, 400 (2024) (citation and quotation marks omitted).

4 5 U.S. 137, 177 (1803), *quoted at* 603 U.S. at 385.

5 5 U.S.C. §§551, *et seq*.

6 *Loper Bright*, 603 U.S. at 391 (citation and quotation marks omitted).

7 *Id.*

8 *Id.* (quoting 5 U.S.C. §706).

9 *Id.* at 392.

10 *Id.* (citations and quotation marks omitted).

A large part of what FDA (like other agencies) does is dependent on the terms of the Federal Food, Drug, and Cosmetic Act (FDCA), the agency's often ambiguous organic statute.[11] Because of its likely impact on FDA over the coming years and decades, the Supreme Court's decision in *Loper Bright* makes our list of the top (FDCA)-related cases of 2024 even though it does not directly involve the FDA.

II. DISCUSSION OF THE FACTS, HOLDING, AND RATIONALE

Loper Bright adjudicated two initially unrelated challenges to federal administrative action. Both cases implicated the power of the National Marine Fisheries Service under the Magnuson-Stevens Fishery Conservation and Management Act (MSA)[12] to charge certain fishing operations in the American coastal "exclusive economic zone" for the cost of on-board observers to prevent overfishing.[13] The statutory interpretation question involved the scope of the "fishery management plans" authorized by the MSA. The statute expressly authorized assessment of observer costs against foreign-operated vessels, vessels allowed to take certain "limited access" species of fish, and vessels operating in the North Pacific Ocean.[14] The plaintiffs fished only in the Atlantic Ocean and were not within any of the three enumerated categories statutorily required to reimburse observational costs.[15] However, in 2013 the relevant fishery management council "proposed amending its fishery management plans to empower it to require fishermen to pay for observers if federal funding became unavailable."[16] Such observers would cost "up to $710 per day, reducing annual returns to the vessel owner by up to 20 percent."[17]

The plaintiffs/petitioners challenged agency power to expand recoupment of observer costs beyond the three areas specified by the MSA. The *Loper Bright* named plaintiffs lost in the trial court, which in an alternative holding, ruled that even assuming the MSA were "ambiguous," the *Chevron* doctrine required summary judgment for the government because its interpretation of the statute was "reasonable."[18] A divided court of appeals affirmed, holding, with respect to the *Chevron* doctrine, the district court correctly deferred to the government's "reasonable interpretation of "not wholly unambiguous" statutory language.[19] A second set of similarly situated plaintiffs sued in a different district and also lost, with the district court also deferring to the government's interpretation under the *Chevron* doctrine.[20]

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[11] The Supreme Court has frequently found sections of the FDCA to be ambiguous. *See* Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 412 (2012); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159 (2000); Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 668 (1990); Young v. Community Nutrition Institute, 476 U.S. 974, 980 (1986).

[12] 16 U. S. C. §§1801, *et seq*.

[13] *Loper Bright*, 603 U.S. at 380

[14] *Id.*

[15] *Id.* at 381

[16] *Id.* at 381–82.

[17] *Id.* at 382.

[18] *Id.*

[19] *Id.* at 382–83 (citations omitted).

[20] *Id.* at 383.

That court of appeals unanimously applied *Chevron*, as well as a general "'default norm' that regulated entities must bear compliance costs."[21] Under *Chevron*, the agency interpretation did "not 'exceed[] the bounds of the permissible.'"[22] The Supreme Court granted both *certiorari* petitions and consolidated the two cases.

As befitting a landmark opinion, *Loper Bright* opened with first-principles jurisprudence dating back to the early days of the Republic. The *Chevron* doctrine—that judges must "defer to the agency's interpretation" of the agency's "ambiguous" organic statute provided that interpretation "is based on a permissible construction"[23]—could not be squared with the judicial function itself. "[T]he final 'interpretation of the laws'" is "'the proper and peculiar province of the courts.'"[24] Thus, it has always been "'emphatically the province and duty of the judicial department to say what the law is.'"[25] This view of statutory construction persisted through the New Deal.[26] Agency statutory interpretations were simply "'a body of experience and informed judgment'" that courts "could 'properly resort for guidance,' even on legal questions," provided they were "'made in pursuance of official duty'" and reflected the agency's "'specialized experience.'"[27]

This broad history of judicial power was crystallized, in the administrative law context, by the 1946 enactment of the APA. This statute provided the "contours of judicial review" of administrative actions.[28] When "necessary . . . reviewing court[s] shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of . . . agency action."[29] The APA requires courts to "hold unlawful and set aside agency action" that is not in accordance with law."[30] Critically, the APA "prescribes no deferential standard for courts to employ in answering those legal questions."[31] Conversely, "the APA "*does* mandate that judicial review of agency policymaking and factfinding be deferential."[32]

Thus, *Loper Bright* held, the rule of judicial deference created in *Chevron* "cannot be squared with the APA."[33] "[W]ithout mentioning the APA," the *Chevron* decision imposed on judges in administrative law litigation a "second step": when "'the statute [was] silent or ambiguous with respect to the specific issue'" before a court, then the judge must "set aside the traditional interpretive tools and defer to the agency if it had

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[21] *Id.* at 384.

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

[23] *Id.* at 379–80 (quoting *Chevron*, 467 U.S. at 843).

[24] *Id.* at 385 (quoting The Federalist, No. 78, at 525 (J. Cooke ed. 1961)).

[25] *Id.* (quoting *Marbury*, 5 U.S. at 177).

[26] *Id.* at 386–88.

[27] *Id.* at 388 (quoting Skidmore v. Swift & Co., 323 U. S. 134, 139–40 (1944)).

[28] *Id.* at 391.

[29] 5 U.S.C. §706.

[30] *Id.* § 706(2)(a).

[31] *Loper Bright*, 603 U.S. at 392.

[32] *Id.* (emphasis in original). Subsection 706(2)(A) requires that agency policy making may only be overturned if "arbitrary, capricious, [or] an abuse of discretion." And subsection 706(2)(E) requires sustaining "agency factfinding" when "unsupported by substantial evidence."

[33] *Id.* at 396.

offered 'a permissible construction of the statute.'"[34] Thus, under *Chevron*, the agency's interpretation of its organic statute would prevail even though it was "not the reading the court would have reached if the question initially had arisen in a judicial proceeding."[35]

Such deference was improper both because it was contrary to the judicial review provisions of the APA and because it operated in derogation of the traditional judicial role to determine "what the law is." Contrary to the APA's requirement that courts decide all legal questions, the *Chevron* presumption required courts "to *ignore*, not follow, 'the reading the court would have reached" exercising independent judgment "as required by the APA."[36] "[S]tatutory ambiguities" were not "implicit delegations to agencies."[37] Rather, "most statutory ambiguities" were likely "unintentional."[38]

Instead of deferring to any other body, "[i]n an agency case as in any other," the job of the courts is to find the "best reading" of the statute, ambiguous or not, and that "best reading" is the same regardless—"the reading the court would have reached if no agency were involved."[39]

> It therefore makes no sense to speak of a "permissible" interpretation that is not the one the court, after applying all relevant interpretive tools, concludes is best. In the business of statutory interpretation, if it is not the best, it is not permissible.[40]

Moreover, when statutory ambiguity exists "about the scope of an agency's own power . . . abdication in favor of the agency is least appropriate."[41] Thus, *Chevron* deference was a "grave[] err[or]," and *Chevron* was overruled.[42]

Neither the judicial function nor the APA, however, precludes statutes that authorize administrative agencies to exercise discretion. *Loper Bright* recognized that "Congress has often enacted such statutes" that "expressly delegate" to agencies "the authority to give meaning to . . . statutory term[s]" or to "fill up the details."[43] Such statutes use terms "such as 'appropriate' or 'reasonable'" to "leave[] agencies with [that] flexibility."[44] Thus:

> When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits.[45]

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[34] *Id.* at 397 (quoting *Chevron*, 497 U.S. at 843 n.11).

[35] *Id.*

[36] *Id.* at 398–99 (quoting *Chevron*, 497 U.S. at 843 n.11).

[37] *Id.* at 399.

[38] *Id.* at 400.

[39] *Id.* (citation and quotation marks omitted).

[40] *Id.*

[41] *Id.* at 401.

[42] *Id.* at 400.

[43] 603 U.S. at 394 (citation and quotation marks omitted).

[44] *Id.* at 395 (quoting Michigan v. EPA, 576 U.S. 743, 752 (2015)).

[45] *Id.*

Courts do this "by recognizing constitutional delegations," "fixing the[ir] boundaries," and requiring "reasoned [administrative] decisionmaking"[46]

III. IMPACT

Loper Bright will make it less difficult for anyone, but particularly members of the industries that FDA regulates, to challenge the agency's interpretations of the FDCA.

Laboratory-Developed Tests

The first such decision doing so is *American Clinical Laboratory Ass'n v. FDA* ("*ACLA*").[47] *ACLA* held that FDA's interpretation of the FDCA's definition of "medical device"[48] as giving the agency authority to regulate laboratory-developed tests as "medical devices" was not the "best" reading of the statute. Moreover, "Congress created a separate statutory and regulatory framework for laboratory test services," the Clinical Laboratories Improvement Act (CLIA).[49] Thus:

> The sequence of legislative enactments underpinning FDCA and CLIA reflects that Congress viewed (1) ensuring medical-device safety and effectiveness, and (2) ensuring laboratory-testing accuracy, as distinct problems requiring different regulatory solutions.[50]

ACLA criticized "FDA's view of its authority to regulate laboratory-developed test services" as having "been a moving target for decades."[51] For its part, Congress had considered legislation that would have explicitly conferred regulatory authority on FDA and also on a different agency, but neither bill passed—only legislation requiring formal FDA notice to Congress before seeking to regulate laboratory-developed tests.[52] FDA did so in 2023, with a proposed rule to regulate what the agency called "in vitro diagnostic products."[53] That rule became final in May 2024, with "significant carveouts" based on FDA "enforcement discretion."[54]

ACLA invalidated FDA's rule under *Loper Bright*. Expansion of the FDCA's definition of "device" to intangible laboratory test services was "foreclosed by the text, structure, and history of the FDCA and CLIA."[55] "All the operative terms" of the FDCA's definition of "device" "ordinarily refer to tangible, physical products," which laboratory-developed tests were not.[56] "A laboratory-test process and methodology . . . is far afield from such tangible products."[57] FDA exceeded its authority by "inventing

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[46] *Id.* (citation and quotation marks omitted).

[47] 2025 U.S. Dist. Lexis 59869 (E.D. Tex. Mar. 31, 2025).

[48] 21 U.S.C. § 321(h)(1).

[49] *Id.* (referencing the Clinical Laboratories Improvement Acts of 1967 and 1988, codified at 42 U.S.C. § 263a).

[50] *Id.* at *15.

[51] *Id.* at *22.

[52] *Id.* at *22–23.

[53] *Id.* at *24–25.

[54] *Id.* at *27–29.

[55] *Id.* at 37.

[56] *Id.* at *40.

[57] *Id.* at *42.

new 'definitions' untethered to the statute" and "conflating" things (physical tools and professional services) that are "distinct."[58] FDA's position "implicate[d] limitless FDA oversight of all surgical procedures and physical examinations that use 'devices.'"[59] Because that reading of "device" yielded "an extraordinary, expansive meaning with far-reaching consequences, rather than the ordinary and normal meaning" required by principles of statutory construction.[60] It would reach "medical practice," which was "beyond the power" of the FDCA, and also governed by a separate statute—the CLIA.[61] "The more fundamental problem is that Congress has already considered the distinct issues raised by laboratory-developed test services . . . and chose to address those issues by vesting regulatory authority in" a different agency.[62]

Express Preemption of State Tort Litigation Involving Medical Devices

More decisions applying *Loper Bright* to FDA interpretations of the FDCA are inevitable. One potentially quite significant example is the FDA's limitation of the express preemption clause in the Medical Device Amendments (MDA), 21 U.S.C. § 360k(a), which received an extra-textual gloss in *Medtronic v. Lohr*.[63] *Lohr* created a "device specificity" requirement that appears nowhere in § 360k(a).[64] *Lohr* likewise fashioned what it called so-called "parallel federal requirements" exception to preemption, also without any express statutory support.[65] The *Lohr* majority was "substantially informed by" 21 C.F.R. §808.1(d), an FDA regulatory interpretation of the "[m]eaning of 'requirements applicable to a device'"[66] language in § 360k(a). Thus, § 801.1(d) involved precisely what *Loper Bright* did—an agency interpretation of statutory language. In creating these limits to the facially broad express preemption language of § 360k(a), Lohr invoked *Chevron* while giving to FDA's statutory interpretation "substantial weight."[67]

Device specificity: *Lohr* relied on § 801.1(d) for "the critical importance of device specificity in our (and the FDA's) construction of § 360k."[68] FDA's limiting

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[58] *Id.* at *44–45.

[59] *Id.* at *45.

[60] *Id.* at *46

[61] *Id.* at *54–55 (citation and quotation marks omitted).

[62] *Id.* at *61.

[63] 518 U.S. 470; *see supra*, at n.11.

[64] *Id.* at 498–502.

[65] *Id.* at 495.

[66] *Id.*

[67] *Lohr*, 518 U.S. at 496 ("The ambiguity in the statute − and the congressional grant of authority to the agency on the matter contained within it − provide a 'sound basis,' for giving substantial weight to the agency's view of the statute.") (citing *Chevron*; other citations omitted). As for the asserted "grant of authority," even before *Loper Bright*, the Court had repudiated any deference to FDA views of the FDCA's preemptive effect. PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 n.3 (2011) ("[W]e do not defer to an agency's ultimate conclusion about whether state law should be pre-empted."); Wyeth v. Levine, 555 U.S. 555, 576–77 (2009) ("we have not deferred to an agency's conclusion that state law is pre-empted" because "agencies have no special authority to pronounce on pre-emption absent delegation by Congress").

[68] 518 U.S. at 502.

construction "supported" *Lohr*'s conclusion that "§360k(a) mandates pre-emption only where there is a conflict between a specific state requirement and a federal requirement 'applicable to' the same device"[69]

> [T]he regulations provide that state requirements of "general applicability" are not pre-empted except where they have "the effect of establishing a substantive requirement for a specific device." Moreover, federal requirements must be "applicable to the device" in question, and, according to the regulations, pre-empt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.[70]

Parallel Claims: Applying § 808.1(d)(2) verbatim, with no independent analysis, *Lohr* also held, "regulations promulgated by the FDA expressly support the conclusion that §360k 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.'"[71] The statutory scope of preemption under § 360k(a), however, expressly extends to state common-law requirements that are both "different from" and "in addition to" any safety-related FDA requirement.[72] Other than the *Chevron*-driven reliance on the FDA's statutory interpretation, *Lohr* offers no basis for reading "in addition to" out of the statute in its discussion of what are now known as "parallel claims." Elimination of *Lohr*'s judicially created specificity and parallel claim exceptions to § 360k(a)'s broad preemption language would significantly reshape prescription medical product liability litigation against medical device manufacturers.

Criminalization of Off-Label Speech

A second potential casualty of non-deferential judicial review of FDA statutory interpretation post-*Loper Bright* could be FDA's long-running, but increasingly precarious effort to criminalize all speech by regulated entities concerning the benefits and risks of off-label uses of drugs, medical devices, and other regulated products that the agency has permitted to be marketed.[73] FDA's justification for its off-label speech ban is multifaceted, and the first two steps involve statutory interpretation. *First*, the FDCA generally prohibits "misbranding" of drugs and devices.[74] Noticeably absent from these statutory definitions of misbranding is any reference to "intent." *Second*, products marketed subject to FDA authorization (whether "approved," "cleared," or by any other process) are "misbranded" if the labeling does not include "adequate

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[69] *Id.* at 498 (finding preemption "only" when FDA established "specific counterpart regulations or . . . other specific requirements applicable to a particular device." (quoting § 808.1(d)).

[70] *Id.* at 500 (quoting § 808.1(d)).

[71] *Id.* at 496–97 (quoting § 808.1(d)(2)).

[72] 21 U.S.C. §360k(a)(1).

[73] *See generally* James M. Beck, "Off-Label Use in the Twenty-First Century: Most Myths & Misconceptions Mitigated, 54 UIC J. MARSHALL L. REV. 1, 44–45 (2021).

[74] 21 U.S.C. § 331(a) (prohibiting "introduction or delivery for introduction into interstate commerce of any [regulated] product that is adulterated or misbranded."); § 331(b) (same for "adulteration or misbranding of any [regulated] product, or cosmetic in interstate commerce").

directions for use."[75] The concept of "adequate directions for use," however, was included primarily to regulate over-the-counter (OTC) products.[76] Prescription-only products cannot be made safe by "adequate directions for use," which is why a physician's prescription is required. Rather, prescription products are "not safe for use except under the supervision of a practitioner licensed by law to administer such drug."[77] The FDCA provisions concerning adequate directions for use likewise contain no reference to "intended use" as FDA has defined it.[78]

The remaining two steps in FDA's off-label speech ban rationale are regulatory. *Third*, FDA regulations limit "adequate directions for use" only to "the purposes for which it [the product] is intended."[79] These passive-voice regulations do not specify whose "intent," but reflect the FDCA's focus on OTC products.[80] Indeed, both regulations can be read as embracing "common" off-label uses.[81] *Fourth*, and finally, FDA defines "intended use," as "the objective intent" of the "persons legally responsible for the labeling" even though "objective" is nowhere found in the FDCA, and extend it to all "labeling claims, advertising matter, or oral or written statements."[82] Finally, "[t]he intended uses of an article may change after it has been introduced into interstate commerce" if a regulated entity "offer[s]" it "for a purpose for which it is neither labeled nor advertised."[83]

Thus, under FDA's construction of the FDCA, a regulated entity's truthful discussion of a prescription medical product's risks and benefits when used off-label changes that product's "intended use," resulting in the product being "misbranded" for lacking "adequate directions for use"—despite the FDCA having no "intent" requirement, either for misbranding or product use, and "adequate directions for use" only being relevant to OTC products. Even before *Loper Bright*, courts have viewed this rationale skeptically. "While the FDCA makes it a crime to misbrand or conspire to misbrand a drug, the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion."[84]

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[75] 21 U.S.C. § 352(f).

[76] "To satisfy §352(f)'s requirement of providing 'adequate directions for use,' a drug's label must provide 'directions under which the ***layman*** can use a drug safely and for the purposes for which it is intended.'" United States v. Regenerative Sciences, LLC, 741 F.3d 1314, 1323–24 (D.C. Cir. 2014) (emphasis original).

[77] 21 U.S.C. § 353(b)(1)(A). Thus, a prescription product would be "presumptively misbranded," labeled solely with "adequate directions for use." *Regenerative Sciences*, 741 F.3d at 1234 (citation and quotation marks omitted). *See*, *e.g.*, United States v. Articles of Drug, 625 F.2d 665, 673 (5th Cir. 1980) (a "prescription drug by definition . . . is unsuitable for self-medication").

[78] The statute contains general references to products "intended for human use" and "intended for use in health care facilities" or "intended for use by health care professionals." 21 U.S.C. §§ 353(e)(1)(A)(ii–iii), 353(f). It does not link "intent" to any particular product indications.

[79] *E.g.*, 21 C.F.R. § 201.5 (for drugs) and 21 C.F.R. § 801.5 (for medical devices).

[80] Both regulations identically define "adequate directions for use" as "directions under which the layman can use a device safely and for the purposes for which it is intended." *Id.*

[81] Under both regulations, "adequate directions for use" include "[s]tatements of all conditions, purposes, or uses for which such [product] is intended, including . . . conditions, purposes, or uses for which the [product] is commonly used").

[82] 21 C.F.R. §§ 201.128; 801.4.

[83] *Id.*

[84] United States v. Caronia, 703 F.3d 149, 160 (2d Cir. 2012). *See also* McCormick v. Medtronic, Inc., 101 A.3d 467, 485 (Md. App. 2014) ("On the basis of this web of statutes and regulations, the FDA

Under *Loper Bright*, courts are charged with ascertaining the one "best reading" of the FDCA, "exercis[ing] their independent legal judgment" and as "if no agency were involved."[85] It is certainly questionable whether FDA's statutory interpretations underlying its off-label speech ban can meet such scrutiny. If FDA's reading is "not the best, it is not permissible."[86]

Product-Specific Marketing Decisions as Discretionary FDA Action

There are, however, limits to *Loper Bright*'s scope. In particular, the Court's decision specifically acknowledged that Congress "often" "confer[s] discretionary authority on agencies, and that courts should "respect such delegations."[87] Likewise, *Loper Bright* contrasted the lack of any "deferential standard" under the APA for statutory construction with the APA's "mandate that judicial review of agency policymaking and factfinding be deferential."[88] Thus, nothing in *Loper Bright* disturbs FDA's exercise of its discretionary authority or subjects it to *de novo* judicial review. But what is within FDA's discretion will undoubtedly be litigated in coming years.

One existing source of precedent on this question is how courts have applied the "discretionary function" exception to liability under the Federal Torts Claim Act.[89] The Supreme Court has addressed this issue once in the FDCA context. In *Berkovitz v. United States*,[90] FDA was not immune from a suit alleging (dubiously) that it had violated mandatory vaccine testing requirements.[91] Since those requirements were a mandatory prerequisite, FDA "has no discretion to issue a license without first receiving the required test data."[92] But in the absence of such deviation "from mandated procedure," a claimant could not simply denounce an agency decision to approve a product as "incorrect."[93]

With *Berkovitz* as a starting point, courts have unanimously applied the discretionary function exception to preclude claims attacking FDA approval of drugs

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takes the position that off-label promotion can constitute misbranding in violation of the FDCA" even though "[f]ederal law does not expressly define, or ban, off-label promotion"); Underwood v. Rhone-Poulenc Rorer Pharmaceuticals, Inc., 890 So.2d 429, 431 (Fla. App. 2004) ("nothing in the FDCA actually prohibits manufacturers from promoting off-label uses"); United States v. Facteau, 2020 WL 5517573, at *1 (D. Mass. Sept. 14, 2020); Nagel v. Smith & Nephew, Inc., 2016 WL 4098715, at *7 (D. Conn. July 28, 2016); Raab v. Smith & Nephew, Inc., 150 F. Supp.3d 671, 697 (S.D.W. Va. 2015); Thorn v. Medtronic, Sofamor Danek, Inc., 81 F. Supp.3d 619, 626 (W.D. Mich. 2015); Otis-Wisher v. Fletcher Allen Health Care, Inc., 951 F. Supp.2d 592, 600 & n.3 (D. Vt. 2013), *aff'd*, 616 F. Appx. 433 (2d Cir. 2015); Mendez v. Shah, 28 F. Supp.3d 282, 292 (D.N.J. 2014).

[85] 603 U.S. at 400–01.

[86] *Id.* at 400.

[87] *Id.* at 404.

[88] *Id.*

[89] *See* 28 U.S.C. § 2680(a) (liability does "not apply" to "the exercise or performance or the failure to exercise or perform a discretionary function . . . , whether or not the discretion involved be abused").

[90] 486 U.S. 531 (1988).

[91] *Id.* at 542 (allegations that FDA "issued a product license without first receiving data that the manufacturer must submit"). *Berkovitz* involved events occurring prior to the enactment of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10, *et seq*.

[92] *Id.*

[93] *Id.* at 544–45.

and medical devices. In a case in which this author participated, a claimant sued the United States, alleging that FDA had improperly cleared a medical device that was not, in fact, "substantially equivalent."[94] Whether a medical device met that FDCA prerequisite was a discretionary function entrusted to FDA:

> When §510(k) applications are brought before the FDA, regulators must decide what data and other information is relevant, what is reliable, and how much is sufficient. Certainly in weighing evidence and comparing medical devices in this manner, the FDA utilizes judgment and choice. Appellants' suggestion that the FDA violated statutory and regulatory provisions is, in reality, a claim that the FDA's judgment is wrong. Because substantial equivalence determinations as well as the manner in which those decisions get made are functions committed to the discretion of the FDA, we will not second guess their outcomes.[95]

Without exception, FDA decisions to allow prescription medical products to be sold have been considered discretionary.[96] The converse is also true—FDA decisions whether or not to remove products from the market are also discretionary.[97] Thus, it appears likely that product-specific FDA actions, absent highly unusual facts, will remain subject to deferential FDA review following *Loper Bright*.

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[94] See 21 U.S.C. 360c(i).

[95] In re Orthopedic Bone Screw Products Liability Litigation, 264 F.3d 344, 364 (3d Cir. 2001).

[96] See King v. U.S. FDA, 35 F. Appx. 511, 514 (9th Cir. 2002) (device pre-market approval); Owen v. FDA Office of Generic Drugs, 2021 WL 3883112, at *4 (W.D.N.C. Aug. 27, 2021) (generic prescription drug); Zammit v. Shire US, Inc., 2005 WL 8155121, at *1 (E.D. Mich. May 11, 2005) (branded prescription drug); Forsyth v. Eli Lilly & Co., 904 F. Supp. 1153, 1160 (D. Haw. 1995) (branded prescription drug); Bailey v. Eli Lilly Co., 607 F. Supp. 660, 662 (M.D. Pa. 1985) (branded prescription drug); Gray v. United States, 445 F. Supp. 337, 340 (S.D. Tex. 1978) (branded prescription drug).

[97] Seaside Farm, Inc. v. United States, 842 F.3d 853, 860 (4th Cir. 2016); Fisher Brothers Sales, Inc. v. United States, 46 F.3d 279, 285–86 (3d Cir. 1995) (en banc); Wiley v. United States, Dep't of HHS, 2013 WL 537529, at *4–5 (D. Nev. Sept. 23, 2013); Gelley v. Astra Pharmaceutical Products, Inc., 466 F. Supp. 182, 186 (D. Minn. 1979).

Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration

TINA PAPAGIANNOPOULOS*

WHY IT MADE THE LIST

This lawsuit garnered widespread attention last year because of its potential impact on access to medication abortion and, more broadly, on foundational principles underpinning the approval and regulation of drugs in the United States.

The case involves a legal challenge to the U.S. Food and Drug Administration's (FDA's) approval and subsequent regulatory changes for mifepristone, a drug that has been available in the United States as part of an approved medication abortion regimen for over twenty years. In an unprecedented decision in April 2023, federal district court Judge Matthew Kacsmaryk granted a motion for preliminary injunction filed by anti-abortion activists, who asked the court to suspend virtually all of the FDA's decisions and actions regarding the drug's approval.[1] This decision had sweeping implications on access to medication abortion across the country—including in states and under circumstances where abortion is legal—and because of the ruling's broader implications on FDA's authority as an expert agency that has been entrusted by Congress to make drug approval decisions based on scientific grounds.

The government appealed the case to the Fifth Circuit, which overturned the Texas court's ruling with respect to the drug's original approval but affirmed the portions of the district court's decision that would have negated subsequent changes to the FDA's approval regarding the drug's conditions of use and administration.[2] The Fifth Circuit's ruling would have allowed access to this regimen only through in-person administration and only to women whose pregnancy had not progressed beyond seven weeks of gestational age.

As the government explained in its appeal to the Supreme Court, this was the first time any court has ever "restricted access to an FDA-approved drug by second-guessing FDA's expert judgment about the conditions required to assure that drug's safe use."[3] The pharmaceutical and biotechnology industries, which had been

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1 All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp.3d 507 (N.D. Tex. 2023).

2 All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210 (5th Cir. 2023).

3 Brief for the Federal Petitioners at 12, U.S. Food & Drug Admin. v. All. for Hippocratic Med., No. 23-235 (S. Ct. Jan. 23, 2024), ECF No. 29.

following this case with much anticipation, submitted amicus briefs cautioning the Court that upending the drug approval process in the manner suggested by the lower courts would create regulatory uncertainty, resulting in detrimental impacts on research and investment in innovative therapies.

A detailed discussion of the lawsuit up to this point was included in last year's compilation of *Top Food and Drug Cases*, but the chapter ended on a cliffhanger due to the timing of that publication, which was shortly before the Supreme Court rendered its decision. This chapter picks up where last year's left off by summarizing the Supreme Court's opinion[4] and discussing the potential aftermath of the decision in light of other key developments, including the Supreme Court's subsequent opinion in *Loper Bright*.[5]

SUMMARY AND DISCUSSION

Mifepristone has been FDA-approved since 2000 as part of a two-drug regimen along with misoprostol for medication abortion. The use of the drug was first approved through seven weeks gestation, and FDA had originally imposed other conditions on its use, including that the drug be distributed under a controlled system, that it be provided in-person and under the supervision of a qualified physician, that doctors and patients follow a strict regimen requiring the patient to appear for three in-person visits with the doctor, that it be dispensed with a Medication Guide, and that prescribing doctors report incidents of serious adverse events to the sponsor.

FDA made several changes affecting the use of the drug over time, including modifications to the drug's labeling and to the interventions required under the drug's Risk Evaluation and Mitigation Strategy (REMS). In 2016, for example, FDA extended the approved use from seven to ten weeks gestation, removed in-person requirements for follow-up provider visits, and allowed non-physician healthcare providers to prescribe the medication. In 2019, FDA approved a generic version of mifepristone. In 2021, FDA removed the in-person dispensing requirements, and in 2023, the agency permitted certified pharmacies to dispense the medication. Even under the more "relaxed" conditions, the drug is still subject to a REMS and, accordingly, has more restrictions on its use than do most other drugs that have been approved by the FDA.

The plaintiffs, consisting of four pro-life medical associations and four obstetricians, challenged each of the agency's actions through 2021 under the Administrative Procedure Act (APA) and sought equitable relief. By the time the case had reached the Supreme Court, only the claims regarding the FDA's 2016 amendments to the drug approval conditions and its decision to exercise enforcement discretion over the in-person dispensing requirements in 2021 had survived.

The questions presented by the government on appeal were:

1. *Whether the respondents had standing to challenge FDA's 2016 and 2021 actions.* The government contended that the respondents lacked standing under Article III of the U.S. Constitution because they failed to demonstrate a cognizable injury or establish that their alleged injuries were directly

[4] U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367 (2024).

[5] Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024).

attributable to the FDA's actions in 2016 and 2021.

2. *Whether FDA's 2016 and 2021 actions were arbitrary and capricious under the APA.* The government defended each of the FDA's actions, asserting that the agency acted within its legal authority when it modified the conditions of use and REMS requirements for the drug.

3. *Whether the district court properly granted preliminary injunctive relief.* The district court had ordered a "stay" of the 2000 approval and all subsequent challenged actions related to the approval pending a decision on the merits. The Fifth Circuit upheld the stay with respect to FDA's 2016 and 2021 actions—which would have required a return to the conditions of use that were in place for mifepristone in 2011 pending a decision on the merits—but the Supreme Court stayed the entire district court decision pending appeal. The appellants argued that, even if the plaintiffs had standing and the FDA's actions were deemed arbitrary and capricious, the district court's remedy (as upheld by the Fifth Circuit) was inappropriate, as the balance of equities and the public interest did not justify preliminary injunction relief. In other words, respondents' asserted injuries from the availability of mifepristone under the current conditions (as opposed to the pre-2016 conditions) could not justify requiring the FDA and the sponsor to change the labeling and bring the drug into compliance with the prior conditions of use while restricting access for many women who are seeking to lawfully terminate their pregnancies.

The Court unanimously ruled in favor of the government on the threshold issue of standing, allowing it to sidestep a decision regarding the merits of the case that would have required an inquiry into potentially divisive questions about abortion and FDA authority. Justice Brett Kavanaugh delivered the opinion of the Court, while Justice Clarence Thomas wrote a concurring opinion critiquing associational standing.

It is a fundamental legal principle that, to establish standing, "a plaintiff must demonstrate (1) that she has suffered or likely will suffer an injury in fact, (2) that the injury likely was caused or will be caused by the defendant, and (3) that the injury likely would be redressed by the requested judicial relief."[6] The respondents presented several standing theories but ultimately failed to demonstrate that FDA's actions caused or likely would cause them a concrete injury. As the Court explained at the outset of the opinion, FDA did not require the respondents to perform or refrain from performing any action. None of the respondents prescribed or used mifepristone, but rather they wanted FDA to make mifepristone more difficult for other doctors to prescribe and for pregnant women to obtain. The Court held that a plaintiff's desire to make a drug less available *for others* does not establish standing to sue under Article III of the Constitution. Each of the respondents' attempts to establish injury in fact and causation were discussed and rejected in turn.

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[6] All. for Hippocratic Med., 602 U.S. at 380.

First, they contended that FDA's relaxed regulation of mifepristone could cause downstream conscience injuries to the individual doctors. The Court rejected this argument because it found that federal conscience laws fully protect doctors from being required to perform abortions or provide treatment against their consciences, breaking any causal link between FDA's actions and potential conscience injuries.

The respondents next asserted that FDA's relaxed regulation of mifepristone could cause a variety of downstream economic injuries to the doctors. They essentially argued that they could have to divert resources and time from their other patients to treat patients with mifepristone complications, that they were subject to an increasing risk of liability suits from treating those patients, and that they faced potentially increasing insurance costs. The Court found that these alleged economic harms were far too speculative and lacked evidentiary support. The Court also flatly rejected the novel concept of "doctor standing" that would allow healthcare providers to challenge general safety regulations and refused to create such a doctrine "out of whole cloth."[7]

The medical associations further claimed that they had organizational standing because the FDA's actions hindered their services and missions by requiring them to expend significant costs to oppose the FDA at the expense of other priorities. The Court disagreed, finding that organizations cannot "spend their way into standing" by expending resources to oppose government actions. Just like an individual, an organization may not establish standing simply based on the "intensity of the litigant's interest" or because of strong opposition to the government's conduct, "no matter how longstanding the interest and no matter how qualified the organization."[8] This is because the standing doctrine "protects the 'autonomy' of those who are most directly affected so that they can decide whether and how to challenge defendants' action."[9] It also preserves judicial resources and allows federal courts to decide some contested legal questions later—*after* the political branches have had the opportunity to resolve them.[10]

After the Supreme Court's ruling, the case returned to the Texas district court on remand. The medical groups and physicians have dismissed their claims, but the case is not yet over because three states (Missouri, Idaho, and Kansas) had filed separate intervenor complaints in the litigation while the Supreme Court proceedings were pending. The government moved to dismiss the complaints from these Intervenor States, arguing that the lawsuit was not jurisdictionally proper because the Texas district court never had jurisdiction over the original plaintiffs' claims and that the states could not establish venue in Texas. The Intervenor States, in turn, argued that the Texas court had jurisdiction and that venue was proper at the time that their complaints were filed.

Judge Kacsmaryk granted the Intervenor States leave to file a joint amended complaint, and they did so in January 2025.[11] The Intervenor States argue they have standing because they bear increased healthcare costs from treating mifepristone complications, their ability to regulate healthcare within their borders is undermined

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[7] *Id.* at 391.

[8] *Id.* at 394.

[9] *Id.* at 379–80.

[10] *Id.* at 380.

[11] Amended Complaint, State of Missouri v. U.S. Food & Drug Admin., No. 2:22-CV-00223-Z (N.D. Tex., Jan. 6, 2025), ECF No. 217.

by the FDA's actions, and they have sovereign interests in enforcing their own abortion restrictions.[12] The government has moved to dismiss the Amended Complaint, but Judge Kacsmaryk has not yet ruled on whether the states can proceed with the case.

IMPACT

The Supreme Court's decision had the potential to cut off access to medication abortion, even in states where abortion remains legal, and upend the entire framework of FDA drug regulation. The affront to FDA's authority and scientific expertise elevated questions about administrative law and agency deference that once appeared to have been long settled. The pharmaceutical industry reacted with alarm, warning that allowing courts to second-guess the agency's scientific decisions—as the lower courts were eager to do here—would have a deleterious effect on the drug approval process, create regulatory uncertainty, and ultimately reduce investment in new medicines.

To the extent FDA's actions regarding mifepristone were referenced in the opinion, the Court appeared to be deferential to or, at a minimum, sympathetic towards the agency's position and demonstrated an understanding about the FDA regulatory system and drug approval process that the lower courts did not appear to possess. For one thing, the Court recognized that the restrictions FDA imposed on mifepristone were extra requirements that are not required for all drugs, including the adverse event reporting obligations on prescribers. The Court also recognized that in the FDA drug-approval context, "virtually all drugs come with complications, risks, and side effects," which may include an increased risk of heart attack, cancer, birth defects, or stroke.[13] This at least dulls the plaintiffs' arguments that FDA's actions were arbitrary and capricious when it revised certain REMS conditions despite the potential for side effects associated with the drug.

By dispensing with the matter on standing grounds, however, the Supreme Court avoided directly addressing the level of deference that should be afforded to FDA's medical product approval and regulatory decisions. The topic of deference did not even come up. Notably, the *Alliance for Hippocratic Medicine (AHM)* opinion was delivered less than a month before the Court's landmark decision in *Loper Bright*,[14] which overruled *Chevron*,[15] the Court's seminal administrative law case on agency deference. The *Chevron* doctrine directed courts to defer to an executive agency's interpretation of an ambiguous statute that it administers so long as the agency's interpretation was reasonable. *Loper Bright* held that a court should not defer to an agency's interpretation of an ambiguous statute but instead should do its "ordinary job of interpreting statutes" and find the "best" reading of the statute by applying the traditional tools of statutory interpretation.[16] Courts are to respect the views of the

[12] The Amended Complaint also challenges FDA's approval of the generic version of mifepristone in 2019 on additional grounds. The generic sponsor, GenBioPro, Inc., has intervened in the case to defend against those allegations.

[13] *Id.* at 392.

[14] Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024).

[15] Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[16] *Loper Bright*, 603 U.S. at 400–03.

Executive Branch, which may have the power to persuade the court, but not abdicate their duty to exercise their own legal judgment.[17] According to the Court, previous cases finding that specific agency actions were held lawful under the thirty-year-old *Chevron* doctrine are still subject to *stare decisis* despite the Court's change in interpretive methodology.[18]

Although the lower courts in *AHM* did not base their decisions on *Chevron*, FDA's actions with respect to mifepristone would not necessarily be subject to review under the *Loper Bright* standard of deference. As discussed above, *Loper Bright* is applicable to an agency's interpretation of an ambiguous statute. The statute is not ambiguous here. The FDCA clearly authorizes the agency to disapprove or withdraw any drug application when there is a lack of substantial evidence that the applicant's drug will have the effect it is purported to have under the conditions of use prescribed, recommended, or suggested in the labeling.[19] The statute also unambiguously authorizes the agency to determine whether a REMS is necessary to ensure that the benefits of a drug outweigh its risks and whether to approve a proposal for a REMS or modification to an existing REMS.[20] These determinations require FDA to perform a risk-benefit analysis and take appropriate action based upon a careful and expert review of available scientific evidence.

As the expert agency tasked with making these determinations, FDA's actions are reviewable under the APA's arbitrary and capricious standard, which requires a court to find that:

> (1) the agency has relied on factors which Congress has not intended it to consider; (2) the agency entirely failed to consider an important aspect of the problem; (3) the agency's explanation runs counter to the evidence before the agency; or (4) the explanation is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. . . . Agency action is also arbitrary and capricious if the agency offered insufficient reasons for treating similar situations differently.[21]

The appropriate scope of review, therefore, is narrow and limited to a consideration of whether the agency examined the relevant data and "articulated a satisfactory explanation for the decision" that provides a "rational connection between the facts found and the choice made."[22] Courts are to afford a "high level of deference to the agency's scientific analysis of the evidence before it, and must avoid unduly second-guessing those scientific judgments."[23] Under this standard of review, the court "may

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[17] *Id.* at 402.

[18] *Id.* at 412.

[19] 21 U.S.C.§§ 355(d) and (e).

[20] 21 U.S.C. § 355-1.

[21] Teva Pharms. USA, Inc. v. U.S. Food & Drug Admin., 514 F. Supp.3d 66, 106 (2020) (internal citations omitted).

[22] *Id.*

[23] *Id.*; *See also* FCC v. Prometheus Radio Project, 592 U.S. 414, 423 (2021) (explaining that judicial review under the APA's arbitrary and capricious standard is deferential and that "a court may not substitute its own policy judgment for that of the agency"); U.S. Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in the grant of application for stay) ("[C]ourts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'") (internal citations omitted).

not substitute its own judgment for that of the agency."[24] But that is exactly what the district court did in *AHM*.

Because the Supreme Court decided the *AHM* case on standing grounds, the Court left open the potential for others to sue, and indeed the saga is not over. The plaintiffs asserted that if they did not have standing, it was possible that no one else would have standing to challenge FDA's 2016 and 2021 actions. The Court did not find this convincing, and its decision has not stopped others from trying to restrict access to this drug through litigation. Not only have three states interfered in this lawsuit, but several states have also filed separate lawsuits in their respective jurisdictions challenging the FDA's mifepristone decisions, attempting to establish standing under various theories. In the meantime, Washington and several other states with Democratic attorneys general have filed suit against the FDA seeking to *lift* restrictions on access to mifepristone.[25]

The fundamentals of standing, according to the Court, are "well-known and firmly rooted in American constitutional law."[26] Given that standing is an elemental legal principle, it is astounding that this case proceeded as far as it did on such nebulous standing grounds. The Supreme Court opinion nevertheless provided additional guidance to lower courts regarding the standing doctrine that will potentially limit the opportunity for groups to challenge agency actions based solely on ideological grounds going forward.

First, the ruling reaffirmed and strengthened the Court's approach to standing when plaintiffs challenge the regulation of third parties and warned against courts becoming a "vehicle for the vindication of the value interests of concerned bystanders."[27] This type of discourse is better suited for a "legislative assembly, a town square, or a faculty lounge" and is the province of the Legislative and Executive branches of the government.[28] If the Court were to allow a doctor to challenge an FDA decision to approve a new drug on the theory that the use of the drug by others may cause more patient visits to the doctor, "virtually every citizen would have standing to challenge virtually every government action that they do not like."[29] The Court simply refused to allow the federal judiciary to go down this "uncharted path."[30]

The Court likewise significantly limited the scope of organizational standing. Like individuals, organizations need to demonstrate injury in fact, and they cannot establish standing simply because of the intensity of their opposition to the government's conduct. According to the opinion, they also cannot manufacture standing by virtue of the resources they expend to challenge and advocate against the government's actions.[31]

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[24] *Teva Pharms.*, 514 F. Supp.3d at106.

[25] State of Washington v. U.S. Food & Drug Admin., Case No. 1:23-cv-03026 (E.D. Wash.).

[26] U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367, 380 (2024).

[27] *Id.* at 382.

[28] *Id.*

[29] *Id.* at 392.

[30] *Id.*

[31] *Id.* at 394.

It is worth noting that the government has maintained its position that the Intervenor States do not have standing in the *AHM* suit, even after the change in administration.[32] If a litigant challenging the FDA on mifepristone or any other drug approval decision gets past standing, however, the Court may need to address the appropriate standard of deference to apply to the agency's review. Scientific decisions performed by an expert agency pursuant to a statutory delegation of authority have historically been reviewed under the APA's arbitrary and capricious standard and afforded a higher degree of deference than what is afforded to an agency's interpretation of an ambiguous statute, as discussed above. Although *Loper Bright* pertained to the latter category, it is possible that the Court's decision in that case foreshadowed an erosion of other principles of agency deference.

The extent to which the Trump Administration will defend FDA's decisions with respect to mifepristone will be something to watch if this issue comes before the Court on the merits. In the meantime, the Trump Administration could pursue various administrative paths to restrict mifepristone access. President Trump has already issued an Executive Order restricting the use of federal funding to "promote elective abortion."[33] The administration also could, for example, direct the FDA to strengthen the REMS program for mifepristone, potentially reverting to pre-2016 requirements or creating additional barriers to prescription and distribution; or it could prioritize enforcement against telehealth providers or mail-order pharmacies that distribute mifepristone across state lines. Any such administrative actions would likely face immediate legal challenges from abortion rights advocates, potentially leading to another round of litigation centered on different legal questions than those addressed in *AHM*.

[32] Defendants' Reply Memorandum in Support of Motion to Dismiss, State of Missouri v. U.S. Food & Drug Admin., No. 2:22-CV-00223-Z (N.D. Tex., May 5, 2025), ECF No. 247.

[33] Enforcing the Hyde Amendment, Exec. Order No. 14182, 90 Fed. Reg. 8751 (Jan. 24. 2025).

Ohio v. Environmental Protection Agency

NEAL D. FORTIN*

WHY IT MADE THE LIST

In a year with major cases that rearranged the landscape of administrative law,[1] the Supreme Court's emergency docket ruling in *Ohio v. Environmental Protection Agency*[2] may seem like a relatively inconsequential technical matter. The emergency docket decision temporarily paused a not fully implemented EPA Clean Air Act rule. The Court in *Ohio* concluded that EPA had provided an inadequate response to a single oblique reference within a comment on the proposed rule. This was held to violate the arbitrary and capricious standard of the Administrative Procedure Act.[3]

This case highlights the Court's willingness to substitute its determinations in complex technical and scientific matters over those of agency scientists. The Court's hard look at agency actions and its positioning itself as the frontline expert with the authority to decide complex scientific matters will likely impact FDA in coming years. Therefore, the Court's ruling in *Ohio v. EPA* makes our list of the top (FDCA-related) cases of 2024 even though it does not directly involve FDA or the Federal Food, Drug, and Cosmetic Act.

DISCUSSION

The Clean Air Act assigns responsibility to the states for developing plans to meet air quality goals, the State Implementation Plans (SIPs).[4] Because air currents carry pollution across state borders, states must design their plans with neighboring states in mind. Under the Act's "Good Neighbor Provision," each state plan must prohibit emissions "in amounts which will . . . contribute significantly to nonattainment in, or interfere with maintenance by, any other State" of the relevant air quality standard.[5] If a SIP fails to satisfy the requirements of the Act, the EPA may step in and issue a Federal Implementation Plan (FIP).[6]

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1 *See, e.g.*, Loper Bright Enters. v. Raimondo, 603 U.S. 400 (2024), Sec. & Exch. Comm'n v. Jarkesy, 603 U.S. 109 (2024), and Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys., 603 U.S. 799 (2024).

2 144 S. Ct. 2040 (2024).

3 U.S.C.A. § 706(2)(A).

4 42 U.S.C. § 7410(a)(1).

5 42 U.S.C. § 7410(a)(2)(D)(i)(I).

6 42 U.S.C. §§ 7410(k)(3), (c)(1).

In 2015, a revised ozone air quality standard triggered the need for states to submit new SIPs. After subsequent review, EPA announced its intent to disapprove twenty-three SIPs for failure to meet the Good Neighbor Provision. During the public comment period for the SIP disapprovals, EPA proposed a single FIP to bind all twenty-three states. Some states challenged the EPA, and ultimately, stays were issued for twelve SIPs. EPA proceeded to issue its final FIP and announced that its plan was severable. If any state dropped out, the plan would continue to apply unchanged to the remaining states.

Then, several of the remaining states and industry groups challenged EPA's decision as arbitrary and capricious, requesting a stay of enforcement of the FIP. The D.C. Circuit denied relief, and the plaintiffs appealed. The parties renewed their request for a stay to the Supreme Court.

In a 5–4 split decision, Justices Gorsuch, Roberts, Thomas, Alito, and Kavanaugh granted an emergency stay of the enforcement of the FIP until the legal challenges to the SIPs had been resolved by the United States Court of Appeals. The majority concluded that the challengers were likely to succeed on the merits of a claim that EPA had arbitrarily "ignored an important aspect of the problem," specifically, what happens if many of the covered upwind states "fall out" of the planned FIP.[7] As recounted by Justice Gorsuch, one comment on the proposed FIP suggested that if some of the SIPs were disapproved on appeal, EPA might need to reassess the FIP based on a different set of states.

Because EPA's FIP relied on the states' implementation and several states were challenging EPA, the EPA "could not represent with certainty whether the cost-effectiveness analysis it performed collectively for 23 States would yield the same results and command the same emissions-control measures if conducted for, say, just one State."[8] Therefore, the majority concluded that the final rule was not reasonably explained, and thus, the rule would likely meet the meaning of "arbitrary" or "capricious" within the Act.[9]

The dissent by Justice Amy Coney Barrett joined by Justices Sotomayor, Kagan, and Brown Jackson, offered a sharply different version of the facts as well as an alternative interpretation. The dissent found that EPA had reasonably explained that "the final rule and its supporting documents suggest that EPA's methodology for setting emissions limits did not depend on the number of States in the plan, but on nationwide data for the relevant industries."[10] In addition, in denials of petitions for reconsideration, EPA "thoroughly explained how its 'methodology for defining' each State's emissions obligations is 'independent of the number of states included in the Plan'" because it "relies on a determination regarding what emissions reductions each type of regulated source can cost-effectively achieve."[11]

As the dissent noted, "the Court does not conclude that EPA's actions were *substantively* unreasonable."[12] The majority did not conclude that litigation ultimately would or should lead to a reduction in the number of states covered by FIP. There was

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7 *Ohio*, 144 S. Ct. at 2054.

8 *Id.*

9 42 U.S.C. § 7607(d)(9)(A).

10 *Ohio*, 144 S. Ct. at 2059.

11 *Id.* at 2060 (internal citation omitted).

12 *Id.* at 2060.

no evidence that the FIP would become irrational or that it would affect the remaining states' obligations if some states were not included in the FIP. There was no conclusion that the EPA's cost-effectiveness analysis was incorrect or invalid. "[T]he only basis for the Court's decision is the argument that EPA failed to provide 'a satisfactory explanation for its action' and a 'reasoned response' to comments."[13]

EPA had argued that applicants must return to the EPA and file a motion asking it to reconsider its final rule before presenting their objection in court because the "grounds for [their] objection arose after the period for public comment."[14] The Clean Air Act expressly precludes judicial review of objections that were not "raised with reasonable specificity during the period for public comment."[15] The majority disagreed because nothing requires the applicants to return to the EPA to raise a concern EPA already had a chance to address in response to public comment.[16]

On the other hand, in the dissent's narrative, "it is not clear that any commenter raised with 'reasonable specificity' the underlying substantive issue, that the exclusion of some States from the FIP would undermine EPA's cost-effectiveness analyses and resulting emissions controls. The Court concludes otherwise only by putting in the commenters' mouths words they did not say."[17]

The record offers a single oblique comment that concerned the sequencing of approval of the FIP before the final resolution of the disputes over some of the SIPs because the EPA might take a different action on the SIPs than predicted in advance.[18] Nowhere does the comment raise the possibility that the cost-effectiveness thresholds or emissions controls would change with a different number of states in the FIP. Moreover, the EPA responded to this comment by explaining that the "sequence" of its actions was not "improper, unreasonable, or bad policy," and EPA had a statutory obligation to promulgate a FIP by the statutory attainment deadline.[19]

When EPA issued the final FIP, it announced that its plan was severable. If any state dropped out, the plan would continue to apply unchanged to the remaining states. However, the majority found that the provision did not address concerns but sidestepped them.[20] In contrast, the dissent took the severance provision as evidence of the reasonableness of EPA in providing needed flexibility to ensure effective implementation by the statutory deadline and reliance by stakeholders.[21]

The dissent also objected that the Court improperly granted emergency relief "in a fact-intensive and highly technical case without fully engaging with both the relevant law and voluminous record." They also found that EPA's disapproval of the SIPs may have been proper, and, moreover, the applicants would be unlikely to succeed when the challenge was fully briefed and argued on the merits.[22]

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[13] *Id.* at 2060 (internal citations omitted).

[14] 42 U.S.C. § 7607(d)(7)(B).

[15] 42 U.S.C. § 7607(d)(7)(B).

[16] *Ohio*, 144 S. Ct. at 2056.

[17] *Id.* at 2061 (citations omitted).

[18] *Id.* at 2062–63.

[19] *Id.* at 2063.

[20] *Id.* at 2055.

[21] *Id.* at 2064.

[22] *Id.* at 2058.

EPA's response to the comments numbered nearly 1,100 pages.[23] Notably, Justice Gorsuch bent over backwards to extrapolate from a single, vague sentence in a forty-page comment, buried amid a sea of 112,000 comment letters received by EPA, while holding EPA to a much higher standard of clarity.[24]

No comment explicitly mentioned the possibility of a change in the cost-effectiveness threshold, but Justice Gorsuch found it implied by the commenter's general reference to potential new modeling. In the dissent's view, the Court downplayed EPA's statutory responsibility to ensure that states meet air-quality standards.[25]

IMPACT

The immediate effect of *Ohio v. EPA* was the emergency stay against clear air protection for millions of people against nitrogen oxide, which is a pollutant that can cause respiratory distress, reduce lung function, and trigger and cause asthma. The *Ohio* decision reinforces the Court's belief that its understanding outclasses the government's experts in answering complex questions of scientific fact and technological capacity. With no relevant training or expertise, the Court will substitute its determinations for those of scientists and experienced regulators.[26] Administrative agencies should ensure their scientific and technological explanations for proposed rules are explained in short, compelling narratives in addition to their complex, numerical and data-heavy explanations.

This case also provides a template for when conditions are right for pausing regulations with a mini trial before full judicial review. The Court intervened to produce a full ruling before the lower court concluded its fact-finding on the substantive issues. This reflects a trend with the Court using intermediate proceedings to decide on major policy questions without a fully developed factual and procedural record.[27]

Reframed As Procedural Error

Another striking aspect of this case, the Court signaled that there may be the opportunity to undermine agency actions by developing hypothetical counter narratives without the heavy lifting of compiling substantial data or evidence. Reframing a substantive burden into a procedural one, of course, significantly reduces the need to develop substantive evidence. However, this case takes it further. The challengers did not have to convince the judge of their objection in that jurisdiction, but rather only had to persuade the Court that some judge in some jurisdiction

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[23] *Id.* at 2067.

[24] Daniel Deacon, *Ohio v. EPA and the Future of APA Arbitrariness Review*, NOTICE & COMMENT, YALE J. ON REGUL. (June 27, 2024), https://www.yalejreg.com/nc/ohio-v-epa-and-the-future-of-apa-arbitrariness-review/.

[25] *Ohio*, 144 S. Ct. at 2058.

[26] They belied their ignorance by repeatedly mixing up nitrogen oxide, a noxious pollutant, with nitrous oxide, laughing gas. Duncan Hosie, *Samuel Alito's Recent Cosplay as a Scientific Expert is a Glimpse onto the Future of America Law*, SAN FRANCISCO CHRON. (June 30, 2024), https://www.sfchronicle.com/opinion/openforum/article/supreme-court-conservative-law-alito-chevron-19546140.php.

[27] *See* STEPHEN VLADECK, THE SHADOW DOCKET: HOW THE SUPREME COURT USES STEALTH RULINGS TO AMASS POWER AND UNDERMINE THE REPUBLIC (2023, New York, NY: Basic Books).

somewhere might find some portion of the rule invalid, and thus, alter the predicate procedural requirement. That is, if the agency failed to fully explain the consequences of alternate futures, where some parts of the rule were invalid, the whole rule may be invalidated. Using *Ohio v. EPA* as a model, if a comment suggests one or more provisions of a rule may be struck down by challenges, it may require the agency to discuss the implications, such as the impact on cost-benefit analyses, for possible subsets of the rule's provisions. This creates a novel litigation strategy, "multiversal forum shopping."[28]

APA Arbitrariness Review

This decision could be important when it comes to predicting the future of the Administrative Procedure Act (APA) arbitrariness review. In *Ohio v. EPA*, the Court took it for granted that failing to respond to a significant comment would make an agency decision arbitrary or capricious. However, nothing in the APA exactly says that agencies must respond to the comments they receive.[29]

Ohio v. EPA demonstrates an intensified hard look over federal agency action. It reaches deeply into managing the details of administrative decisions, flexing the Court's power to override congressional will and presidential implementation.

It is worth noting that EPA had placed a severability provision in the final rule. The Court dismissed the provision as irrelevant. A takeaway is that severability provisions as statements in rules without more will not be effective. If *Ohio v. EPA* carries forward, this shifts away from traditional severability analysis, which makes an effort to do as little violence as possible to the work of a co-equal branch of the federal government.

Defensive Administrative Law

In the practical aspect of this case, the result means delay and confusion over the final clean air rule. On a broader scope, this will push agencies to be even more defensive in rulemaking. EPA's response to the comments on this proposed rule numbered nearly 1,100 pages. *Ohio v. EPA* pushes agencies to make their responses even more voluminous and deal more with hypotheticals.

Flooding an agency during the comment period on proposed rules is nothing new. Industry representatives bomb agencies with thousands of pages of comments, sometimes containing unstructured technical information.[30] The decision in *Ohio* makes this approach potentially even more rewarding. Each comment is potentially a rake the agency might step on. "The more comments, the more rakes strewn across the lawn."[31]

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[28] Jack Lienke, *Every Court Everywhere All at Once: Ohio v. EPA and the Litigation Multiverse*, 135 YALE L.J. FORUM (forthcoming 2025), available at SSRN: https://ssrn.com/abstract=. If there are ten provisions, that is 2^10 = 1,024 thousand combinations. If there are twenty, it is over a million combinations (2^20 = 1,048,576).

[29] Deacon, *supra* note 24.

[30] Wendy Wagner, *Administrative Law, Filter Failure, and Information Capture*, 41 ENV. L. REP. 10732 (2011).

[31] Nicholas Bagley, *The Big Winners of This Supreme Court Term*, THE ATLANTIC (June 29, 2024), https://www.theatlantic.com/ideas/archive/2024/06/big-winners-supreme-court-term/678845/.

Scientists and technical experts might know that a comment is not pertinent. However, a judge who knows nothing about the technical subject matter might someday think otherwise.[32]

Agencies may strive to minimize the risk of "stepping on a rake" by responding ad nauseam to each and every aspect of every comment. A flyspeck review in hindsight seems far beyond the question of whether an agency has behaved arbitrarily and capriciously, but that is the demanding standard in *Ohio v. EPA*.

If you are in favor of efficient government, you won't want the courts to be in the business of fly-specking lengthy notice-and-comment records. Cases like this will push agencies to be more defensive in rulemaking and thus sclerotic and slow in carrying out congressional and presidential will.[33]

Even if you dislike the administrative state, making it less efficient, and making it work less well, may cause collateral problems, such as failing to respond to your needs and making bad decisions.

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[32] *Id.*

[33] *Id.*

Corner Post, Inc. v. Board of Governors of the Federal Reserve System

ANDREW BENTZ, COLLEEN M. HEISEY & S. MATTHEW KRSACOK*

A decades-old regulation is beyond judicial reach, right? After *Corner Post*, think again.

I. WHY IT MADE THE LIST

Statutes of limitations provide federal agencies and regulated parties finality and certainty when it comes to regulations and other administrative actions. That is because, for most regulations, if someone wants to challenge it in court, that person must sue within six years of the regulation becoming final. But in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the Supreme Court upended this settled expectation, holding that the Administrative Procedure Act's (APA's) six-year statute of limitations does not start ticking for the person's claim until the particular plaintiff is injured by the regulation, rather than when the regulation is promulgated.[1] In other words, before *Corner Post*, agency regulations were largely untouchable after six years. But now, if an agency applies a 1940s regulation to a person today, that person can challenge that regulation until 2031—even though the regulation has been on the books for eight decades.

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Matt Krsacok is an associate at Jones Day, where he focuses on appellate advocacy, critical motions practice, and providing strategic counsel to clients facing complex legal and regulatory challenges. Matt has represented clients in jurisdictions nationwide, and at all three levels of the federal judiciary, including the U.S. Supreme Court. Matt has played a primary role in drafting numerous successful dispositive motions and appellate briefs addressing statutory, constitutional, and administrative law issues and frequently works on litigation involving federal regulatory agencies.

The views and opinions set forth herein are the personal views or opinions of the authors; they do not necessarily reflect views or opinions of the law firm with which they are associated.

[1] Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys., 603 U.S. 799 (2024).

Corner Post thus opens the door to challenges of long-established, seemingly settled regulations (even foundational ones) and introduces significant uncertainty. While agencies and industry alike have long operated under the assumption that most regulations were immune from facial challenges after six years, *Corner Post* means that newly established businesses may be able to challenge decades-old regulations simply because the businesses were not in existence when the regulation was initially promulgated. So regulations from the '50s setting food standards, drug approvals from the '70s, and tobacco regulations from a decade ago, all may be up for grabs. The impact of *Corner Post* on administrative law and particularly FDA regulations will be significant. But will there be a "tsunami of lawsuits against agencies," as Justice Jackson fears, and will foundational, deep-rooted regulations crumble? The answers depend on how aggressive plaintiffs are and how courts navigate these uncharted waters.

II. DISCUSSION

A. Factual Background

In 2011, the Federal Reserve Board issued a rule capping the fees that payment processors could charge for debit card transactions.[2] Merchants promptly challenged the cap, saying it was too high and cost them too much money. But the D.C. Circuit upheld the cap in 2014, and the Supreme Court denied review.[3]

Fast forward a decade. In 2021—ten years after the Fed issued the cap—two trade associations filed a new lawsuit challenging the cap. The Fed, understandably, moved to dismiss the lawsuit because it was filed more than six years after the rule was promulgated. But the plaintiffs had a plan. They added a truck stop to their ranks. And they argued that because this new plaintiff started operating in 2018, this plaintiff had not missed the six-year statute of limitations.[4] In other words, the six-year limitations period should only start ticking when it suffered injury from the regulation.[5]

The district court and the Eighth Circuit rejected this argument, holding that the statute of limitations for facial APA challenges begins to run on the date of final agency action, not when a particular plaintiff is injured.[6]

B. Supreme Court Decision

The Supreme Court reversed this outcome in a 6–3 decision authored by Justice Barrett. The Court held that under 28 U.S.C. § 2401(a), which requires that complaints be "filed within six years after *the right of action first accrues*" (emphasis added), an APA claim does not accrue until the agency's action injures the plaintiff.[7]

This interpretation follows with the "standard rule for limitations periods" in other contexts.[8] Think of a faulty ladder. Normally, the statute of limitations doesn't start

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2 *Id.* at 805.

3 *Id.* at 805–06.

4 *Id.* at 806.

5 *Id.*

6 *Id.* at 806–07.

7 *Id.* at 812–13.

8 *Id.* at 811 (citation omitted).

running until you fall off the ladder, even if the ladder has been sitting in your garage unused for ten years (maybe hire someone next time). *Corner Post* applied that same reasoning to the statute of limitations governing APA claims. The majority was not blind to the implications of the holding—that long-standing regulations might now be vulnerable. But the majority rejected those concerns. Justice Barrett wrote that the caterwauling was "overstated" because regulated parties typically challenge major regulations immediately, and "courts entertaining later challenges often will be able to rely on binding Supreme Court or circuit precedent."[9]

Justice Kavanaugh filed a concurring opinion addressing remedies, arguing that the APA allows courts to vacate unlawful regulations entirely, not just as applied to the plaintiffs.[10]

Justice Jackson dissented, joined by Justices Sotomayor and Kagan. Justice Jackson accused the majority of ignoring that the term "accrues" is context-specific. In the administrative law context, she explained, statutes of limitations have long been understood to run from the "moment of agency action."[11] Justice Jackson also warned that, combined with the Court's recent decision overturning *Chevron* deference, the ruling would trigger a "tsunami of lawsuits" challenging established regulations.[12]

III. IMPACT

A. Numerous Entities Are Eager to Challenge FDA Regulations

Corner Post represents a tectonic shift in administrative law. The decision opens virtually every regulation on the books to challenge. FDA's regulations are no exception, even those that seemed untouchable.

The incentive for FDA-regulated parties to take advantage of *Corner Post* is clear, especially in this day and age of dismantling the administrative state. FDA regulations can be burdensome and modeled on outdated data or thinking. Shaking the yoke of oppressive regulations is tantalizing for industry players. And now, even long-standing regulations might be on the chopping block.

But downsizing has its downsides. As Justice Jackson noted, many industries have adjusted their operations around well-established regulations that could now face new challenges from recently formed entities.[13] Thus, while *Corner Post* creates avenues for industry to challenge overreaching regulations, it also has potential to introduce regulatory instability across industries that have long operated under established rules.

Industry actors are not the only ones that may have an appetite to challenge time-honored rules. Public health groups may well attack what they see as outdated regulations. Those groups may wish to challenge regulations that allow questionable (in the groups' view) additives in food or approvals for dangerous or ineffective (again in the groups' view) drugs. Likewise, people with a political ax to grind may be sharpening their weapons. Controversial product approvals or politically motivated regulations may well be in the cross-hairs of future challenges.

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[9] *Id.* at 823–24.

[10] *Id.* at 826–43 (Kavanaugh, J., concurring).

[11] *Id.* at 843 (Jackson, J., dissenting).

[12] *Id.* at 864 (Jackson, J., dissenting).

[13] *Id.* at 863 (Jackson, J., dissenting).

Disruption is brewing. Just a few examples of high-value targets paints a compelling picture:

- The Generally Recognized as Safe (GRAS) framework—dating back to the 1958 Food Additives Amendment—has been a cornerstone of food regulation. Relying on *Corner Post*, a newly established business, public-health organization, or a political group could potentially challenge the entire GRAS framework that was previously considered beyond judicial reach (we're setting aside questions of Article III standing for now, which is a subject for another day after last Term's decision in *FDA v. Alliance for Hippocratic Medicine*[14]). And the appetite (pun intended) for overhauling GRAS is undeniable.[15]
- Controversial drug approvals could also be vulnerable. The recent litigation challenging FDA's approval of the abortion drug mifepristone, approved over two decades ago, demonstrates the desire among some groups to challenge long-standing drug decisions.[16] Plaintiffs' challenge to the drug's initial 2000 approval was time-barred, so plaintiffs challenged FDA's 2016 amendments and 2021 non-enforcement decision, which were within the statute of limitations. But the Supreme Court ultimately kicked the case, finding plaintiffs lacked Article III standing.[17] *Corner Post* could make such challenges significantly easier by removing statute of limitations barriers.
- Tobacco regulation presents another fertile ground for challenges. FDA's 2016 Deeming Rule, which brought e-cigarettes and other next-generation tobacco products (think products other than cigarettes and smokeless tobacco) under FDA jurisdiction, was previously thought to be immune from facial challenges. Now, new market entrants could potentially challenge that rule and upend the entire regulatory framework for the deemed products. There is clearly a drive among some manufacturers to wind back the Deeming Rule. During the limitations period, manufacturers filed numerous challenges.[18] After *Corner Post*, new entrants may well want their day in court.

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[14] FDA v. All. for Hippocratic Med., 602 U.S. 367, 385–97 (2024).

[15] Even FDA has vowed to reconsider the system. *See* Press Release, HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe, HHS (Mar. 10, 2025), https://tinyurl.com/yey2ucj2.

[16] *All. for Hippocratic Med.*, 602 U.S. at 372–78.

[17] *Id.* at 396–97.

[18] *See, e.g.*, Big Time Vapes, Inc. v. FDA, 963 F.3d 436 (5th Cir. 2020); In re Cigar Ass'n of Am., 812 F. App'x 128, 132 (4th Cir. 2020).

B. Corner Post *Leaves Important Issues Unresolved*

Despite its transformative potential, *Corner Post* leaves open two crucial questions. How courts answer those will have serious bearing on the disruptive impact of *Corner Post*.

First, *Corner Post* did not establish clear boundaries on *who* qualifies. Can an established business (one that has operated for decades) simply spin off a subsidiary and have the sub file suit? Courts would be understandably skeptical of open attempts to circumvent the statute of limitations and could try to distinguish legitimate new market entrants from "straw litigants" created solely to challenge regulations under *Corner Post*. But, then again, should the courthouse doors be closed to legitimate, new market players?

Second, *Corner Post* did not specify what *types* of challenges are available. In *Corner Post*, the government argued that certain injuries only exist at the time of the challenged regulation, and thus cannot be asserted by new market entrants. For example, according to the government, challenges to a regulation's "procedural" defects, like a deficient notice of proposed rulemaking, are not available to litigants challenging the rule years or decades after a rule is promulgated.[19] Yet the majority expressly declined to resolve that question, because there was "no dispute that Corner Post proffered an injury that does not depend on its having existed" when the regulation was first promulgated.[20] The answer to this question could dramatically affect the decision's impact: If new market entrants can only challenge a regulation's statutory authority, *Corner Post* will have limited effect. But if they can argue the regulation was arbitrary or procedurally improper from the jump, virtually every aspect of long-established regulations could be vulnerable to attack.

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In sum, for regulated industries, particularly those subject to FDA oversight, *Corner Post* represents an unprecedented opportunity and a strategic challenge. While questions remain, it is certain that *Corner Post* has armed industry (and others) with a new weapon to contest regulatory overreach long after rules first take effect.

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[19] *Corner Post*, 603 U.S. at 824 n.8.

[20] *Id.*

United States v. Winslow
United States v. Maleknia
United States v. Daoust

STEVEN A. JOHNSON*

I. WHY IT MADE THE LIST

For the last fifty years, the U.S. Food and Drug Administration (FDA) has relied on the Supreme Court precedent of *United States v. Park*, 421 U.S. 658 (1975) in bringing individual criminal cases under the Federal Food, Drug, and Cosmetic Act (FDCA) to prosecute Responsible Corporate Officers (RCO) in the Life Science Industry.

The reasoning from the Department of Justice (DOJ) and FDA for bringing such cases is that the corporate plea alone resulting in a fine sometimes may not be enough of a deterrent to prevent similar illegal activity that harms the public health, whereas additional individual successful prosecutions can be even more productive use of resources.

These three individual prosecutions of the top executive officers of Magellan Diagnostics, Inc. (Magellan) is another example of the continued willingness to rely on the Park Doctrine to bring culpability to a company's RCOs.

These three individual cases where follow on investigations by FDA and FBI to the May 21, 2024, plea agreement by Magellan, a medical device company headquartered in Billerica, Massachusetts, where the company agreed to resolve corporate criminal charges relating to its concealment of a malfunction from its LeadCare II and Ultra devices that produced inaccurately low lead test results for potentially tens of thousands of children and other patients. As part of the criminal resolution, Magellan pled guilty to violations of the FDCA and paid a $28.1 million fine, $10.9 million in forfeiture, and $9.3 million to compensate patient victims.

II. DISCUSSION

A. Legal Background

This case involved the government charging under its authority and relying on the Park Doctrine, the Magellan CEO Amy Winslow, the COO Hossein Maleknia, and the Director of Quality Assurance & Regulatory Affairs Reba Daoust. Ms. Winslow and Mr. Maleknia by way of Grand Jury indictment with felony counts under the FDCA for introduction into interstate commerce of a misbranded device and with felony counts of making a false statement to FDA.

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B. Factual Background

These three individual cases where follow on investigations by FDA and FBI to the May 21, 2024, plea agreement by Magellan, a medical device company headquartered in Billerica, Mass., where the company agreed to resolve corporate criminal charges relating to its concealment of a malfunction from its LeadCare II and Ultra devices that produced inaccurately low lead test results for potentially tens of thousands of children and other patients. As part of the criminal resolution, Magellan pled guilty to violations of the Federal Food, Drug, and Cosmetics Act (FDCA) and paid a $28.1 million fine, $10.9 million in forfeiture, and $9.3 million to compensate patient victims.

C. Court Decisions

Ms. Winslow, the Magellan CEO, pled guilty in March 2025 to one felony count of introduction into interstate commerce a misbranded device based on her knowledge as the top corporate officer of the device malfunctions resulting in the company further concealing from FDA the false test results involving the LeadCare II and Ultra testing devices between 2013–2017. U.S. District Court Judge Patti B. Saris set sentencing for Ms. Winslow for July 23, 2025.

Mr. Maleknia as COO pled guilty to two felony counts in March of 2025 to also introducing into interstate into commerce the misbranded Magellan testing devices. Judge Saris set sentencing for Mr. Maleknia for June 26, 2025.

Ms. Daost as the company Director of Quality Assurance and Regulatory Affairs pled guilty in March 2025 to one felony count of making false statements to FDA in her filings regarding the device false test results. Judge Saris has set her sentencing for June 24, 2025. The felony charges for introduction of a misbranded device which Ms. Winslow and Mr. Maleknia each pled to carry a sentence of up to three years in prison, one-year supervised release, and a fine up to $250,000. The felony charge of making false statements to FDA which Ms. Daoust pled to carries up to five years in prison, up to three years supervised release, and a fine up to $250,000 or twice the gross gain from the offense.

After a sentencing hearing regarding all three defendants before Judge Saris on June 26, 2025, the actual sentence guideline determinations and final decisions regarding the same were delayed until late summer of 2025 pending a newly ordered evidentiary hearing for July 2025 in order for the Judge to determine the adequacy of the pleas and whether the defendants will be sentenced for fraud or intent to mislead FDA violations.

III. FUTURE IMPACT OF THE CASE

FDA's Office of Criminal Investigations (OCI) New York Office, in conjunction with FBI and the HHS OIG, aggressively investigated this case against the three Magellan responsible corporate officers following the Magellan corporate plea in a successful effort to emphasize that in certain egregious cases where it is found that responsible corporate officers deliberately continued to introduce misbranded testing devices into commerce and covered up the defective erroneous results putting adults and children who relied on them at risk, they will fully pursue and prosecute felony charges.

It is clear that fifty years after the Park strict liability case was decided at the Supreme Court and the RCO doctrine was established, the government will continue in certain cases to seek full individual corporate accountability, not just corporate pleas

and fines. The impact of this case could be even greater on the regulated industry if the three convicted individuals receive significant prison time in their upcoming sentencings before the court.

Lily of the Desert Nutraceuticals, Inc. (Tropical Plantation Avocado Oil), Report #7265, *NAD/CARU Case Reports* (April 2024)

WILLIAM FRAZIER*

I. WHY IT MADE THE LIST

Case:

Global demand for avocado oil has skyrocketed in recent years due to increasing consumer preference for natural and organic products. Pure avocado oil, comprised of heart-healthy oleic acids, rich in monounsaturated fatty acids and vitamins, is viewed as a healthy alternative to other cooking oils. Avocado oil producers have responded to the demand by flooding the market with avocado oil products.

The rapid pace of product innovation has eclipsed the speed of the legislative response from the federal and international regulatory organizations responsible for establishing standards for the authentication and purity of avocado oil. The marketplace appears to be aware of the regulatory gap and recent market research suggests that in an effort to lower production costs and increase profitably, some avocado oil products are being mixed with inferior oils. In 2020, the University of California, Davis researchers tested several major avocado oil brands to determine which brands were actually pure and not adulterated with other oils and found that 82% of the avocado oil products examined were a blend of oils.[1]

BBB National Programs' National Advertising Division (NAD) examined claims made in a challenge filed by Chosen Foods Inc. ("Chosen") against competitor Lily of

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* William S. Frazier is an attorney with the National Advertising Division of BBB National Programs.

[1] Hilary S. Green & Selina C. Wang, "First report on quality and purity evaluations of avocado oil sold in the US," Food Control, Volume 116, 2020, https://www.sciencedirect.com/science/article/pii/S0956713520302449 and https://www.ucdavis.edu/food/news/study-finds-82-percent-avocado-oil-rancid-or-mixed-other-oils;

Abstract: The demand for avocado oil has increased significantly as consumers resonate with its potential health benefits, however, due to the lack of enforceable standards, consumers are unprotected from fraud (i.e., economic motivated adulteration). This study analyzed avocado oils currently on the market in the US to evaluate their quality (e.g., free fatty acidity, peroxide value, UV absorbances, vitamin E) and purity (e.g., fatty acids, sterols, triacylglycerols). Our results showed that the majority of commercial samples were oxidized before reaching the expiration date listed on the bottle. In addition, adulteration with soybean oil at levels near 100% was confirmed in two "extra virgin" and one "refined" sample. These findings demonstrate there is an urgent need to develop standards for avocado oil not only to ensure the consumers receive high quality and authentic products but to establish a level playing field to support the continuing growth of global avocado oil industry.

the Desert Nutraceuticals, Inc ("Lily") for its Tropical Plantation Avocado Oil.[2] NAD's decision provides an excellent example of the importance of substantiating advertising claims, maintaining transparency, and adhering to industry standards to protect consumer trust and ensure fair competition. Moreover, it illustrates the crucial role industry self-regulation plays by providing timely, expert guidance, deterrence, and enforcement on matters where regulatory agencies have yet to establish industry-wide standards or to implement oversight to protect consumers.

II. DISCUSSION

Background

Lily was established in 1971 and specializes in producing and distributing a wide range of aloe vera-based health and wellness products. The company owns several brands—including *Tropical Plantation*, which produces avocado oil.

Chosen is a leading seller of avocado-based cooking oils and related consumer products. The company was founded in 2011 and sells a range of cooking sprays, mayonnaise, dressings, simmer sauces, guacamole, and salsa featuring avocado ingredients.

Lily marketed its avocado oil under the "*Tropical Planation*" brand online and in retail stores in a green 1.5-liter plastic bottle. "100% Pure Avocado Oil" appeared prominently on the front of the bottle above an image of three avocados, one cut in half displaying the pit. Text under the image indicated that the product was "Cold Pressed & Naturally Refined," "Perfect for High Heat Cooking," and "Naturally Cholesterol Free." Additional text on the back of the bottle described the product as "100% Pure Avocado Oil" and "made from Hass Avocados."

Chosen challenged the claim on the label, "100% Pure Avocado Oil," arguing it reasonably conveys the misleading message to consumers that the product is comprised solely of avocado oil.

Message Conveyed—"100% Pure Avocado Oil"

It is a bedrock principle of advertising law that advertisers must possess a "reasonable basis" for claims disseminated in advertising.[1] What constitutes a "reasonable basis" depends on several factors, including the type of product, the type of claim, the consumer benefit from a truthful claim, the ease of developing substantiation for the claim, the consequences of a false claim, and the amount of substantiation experts in the field believe is reasonable.[2] In the absence of consumer perception evidence, NAD steps into the shoes of the reasonable consumer to determine the reasonable messages conveyed by an advertisement.

NAD has routinely recognized the powerful impact that "100%" claims have on consumers. In addition, the use of the numerical "100%" conveys a message that the product contains 100% of the referenced ingredient. NAD found that the express reference to 100% avocado oil on the label along with the images of the pristine avocados unequivocally communicated that the product only contains a single ingredient. Similarly, the back of the bottle refers to "100% Pure Avocado Oil" and

[2] Lily of the Desert Nutraceuticals, Inc. (Tropical Plantation Avocado Oil), Report #7265, NAD/CARU Case Reports (Apr. 2024).

informs consumers that the product is comprised of a single ingredient: "100% Hass Avocados."

International Regulatory Framework—In Progress

Chosen argued the claim "100% Pure Avocado Oil" was not supported and submitted third-party purity testing by SGS North America, Inc ("SGS") demonstrating that the oil did not meet the purity standards using draft CODEX[3] and standards published by the Mexican government ("Official Mexican Standards" or "NOM").[5] Chosen explained industry experts recognize both the Official Mexican Standards and draft CODEX standards for determining the purity of avocado oil because currently there is no established U.S. or international standard.[6] Chosen argued that both the CODEX and NOM standards establish minimum and/or maximum ranges of fatty acids and sterols present in pure avocado oil. Chosen argued that SGS's testing using these standards established that Lily's product is not 100% pure avocado oil as it includes less palmitoleic acid (C16:1), and more stearic acid (C18:0) and stigmasterol than permitted by the NOM and draft CODEX standard. Chosen asserted that these results indicate that the oil is mixed with safflower, sunflower, soybean, or canola oil.

Lily did not dispute the results of the SGS testing,[4] but argued that Chosen's reliance on the draft CODEX avocado oil standard was inappropriate because it is not widely accepted by industry and is still being developed. Lily also argued the draft CODEX and NOM standards are only applicable to a small set of avocado growers and processors in Mexico. Lily maintained that current in-process CODEX and NOM standards are not all-encompassing and do not apply to all avocado oils, especially refined avocado oils like Tropical Plantation.

Lily's Substantiation

In an NAD proceeding, the advertiser has the initial burden of providing support for the challenged claims. If NAD finds that an advertiser has provided a reasonable basis for its claim, the burden shifts to the challenger to show either that the advertiser's evidence is fatally flawed or that the challenger possesses stronger, more persuasive evidence reaching a different result."[8] Against this background, NAD reviewed Lily's evidence to determine if the evidence established a reasonable basis for the challenged claim.

An oil is considered 100% pure or authentic to consumers if there are no other additives or oils present other than what is listed on the label. As support for the 100% pure avocado oil claim, Lily relied on internally developed testing, assurances about

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[3] The Codex Alimentarius Commission, established in 1963 by the Food and Agriculture Organization (FAO) of the United Nations and WHO, develops harmonized international food standards, guidelines, and codes of practice to protect the health of consumers and ensure fair trade practices in the food trade. It also promotes coordination of all food standards work undertaken by international governmental and nongovernmental organizations.

Since the creation of the World Trade Organization (WTO) and the Agreement on Sanitary and Phytosanitary Standards (SPS), foods in international trade must adhere to Codex standards. CODEX Alimentarius Commission ("CODEX") has developed a draft standard for avocado oil that will become internationally recognized once finalized. *See* https://www.fao.org/fao-who-codexalimentarius/about-codex/en/.

[4] The parties agreed that purity ranges per CODEX and NOM for linoleic acid and linolenic acid in avocado oil overlap with those for sunflower oil and safflower oil.

the purity and authenticity of the avocado oil provided by the manufacturer, and third-party authentication testing performed by Eurofins.

Ciuti International

Lily explained that it sources its avocado oil from Ciuti International ("Ciuti"). Ciuti provides Lily with sample lots of avocado oil prior to shipping full totes of avocado oil to Lily for bottling and distribution. These pre-shipment samples, also known as "retained lots," are pulled from the Ciuti's production process when filling the totes. Lily explained the U.S. Food and Drug Administration (FDA) requires retained samples be taken for each production run. Lily explained that it evaluates each pre-shipment sample based upon its own internal specifications and matches those results with the Certificate of Analysis ("Ciuti COA") provided by Ciuti with each shipment. The Ciuti COA identifies the oil as "Avocado oil" and includes charts detailing the acidity, peroxide value, fatty acid composition, and sterolic fraction of the oil. The fatty acid and sterols are further subdivided into two columns, fifteen fatty acids and eighteen sterols, and the unit percentages of each component are reported in boxes next to each acid or sterol.

Lily's Internal Testing Protocol

Lily explained that it developed and implemented an internal testing protocol to verify the identity and suitability of the oil it receives from Ciuti for bottling. Specifically, Lily explained that its internal testing provides information about the quality and purity of the oil and includes: (1) an organoleptic description of the oil to describe the physical appearance, taste, and odor of each lot; (2) fatty acid profile testing for the marker analytes palmitic, oleic, linoleic, and linolenic acids; (3) color monitoring to establish a permanent color profile for avocado oil based on internal data; (4) peroxide value testing to verify that the oil is not rancid; (5) moisture testing; (6) iodine value; and (7) microbiological testing to verify that the oil is free of microbial contamination. After the testing, Lily records the results of its internal testing on a Certificate of Analysis ("Lily-COA") and notes whether the results conform with the Ciuti's Certificate of Analysis form. Lily argued that this internal testing protocol demonstrates that the refined avocado oil conforms to Lily's internal specifications that identifies the acceptable criteria for each of the tests identified above.

Eurofins—Nuclear Magnetic Resonance Fats and Oils: Authenticity Testing

Lily's Analytical and Regulatory specialists explained that Ciuti and Lily each contracted with Eurofins Analytics[5]—a third-party independent laboratory—to authenticate the oil used in Tropical Plantation.

Eurofins conducted nuclear magnetic resonance (NMR) spectroscopy on the oil samples provided by Ciuti and Lily. NMR spectroscopy is a technique that provides information about the molecular structure of a sample. NMR uses a strong magnetic field and radio waves to trigger the release of electromagnetic energy from atoms with

[5] Eurofins offers a portfolio of analytical methods for evaluating the safety, identity, composition, authenticity, origin, and purity of biological substances and products, as well as for innovative clinical diagnostics. *See About Us*, EUROFINS, https://www.eurofins.com/about-us/.

nuclei with spin. Computers convert these data into contour spectrum plots—graphs with spikes and peaks at certain points corresponding to certain markers.

Eurofins conducted 1-H NMR and C13-NMR profiling tests to authenticate the avocado oil content of Lily's Tropical Plantation. According to Eurofins, the C13 spectrum test analyzes the origin of a fat/oil by comparing the sample against Eurofins' database of authentic fat/oil. In addition, 1-H spectrum profiling provides information about the effects of processing on oils/fats. Lily argued that both tests are recommended for single-source ingredients.

Eurofins provided a Certificate of Analysis and an Analytical Report about the 1-H NMR and C13-NMR profiling tests concluding that Tropical Plantation is pure avocado oil that is not blended or adulterated with any other oils. Lily argued that NMR analysis represents the best method available for detecting whether avocado oil has been blended with other oils and that any "peculiarities" identified by the tests would be due to a molecular variation representing the presence of other oils.

Eurofins, however, did not disclose the full spectrum of their reference samples from their database or what deviations from the reference sample it considers acceptable, maintaining that the information is proprietary and confidential.

NAD RECOMMENDATIONS

NAD examined the testing provided by both Chosen and Lily. NAD noted Ciuti's and Lily's internal testing protocol were not designed to determine the authenticity of the oil. Rather, each assessment was done to confirm that the sample lot conforms to undisclosed internal quality standards established by Ciuti and Lily. While Lily disclosed the acceptable ranges for fatty acids and sterols, it did not provide evidence that its internal testing protocol can detect adulteration of the oil by other oils which share fatty acid and sterol profiles with authentic avocado oil. Accordingly, NAD determined that Lily's internal testing protocol was not sufficiently reliable to support the challenged "100% Pure Avocado Oil" claim.

Additionally, while Lily represented that Eurofins chose reliable samples of avocado oil as reference samples for the NMR profile tests, there was no evidence in the record as to what markers were used to identify the oil as avocado oil because NMR testing spectrum plots have spikes and peaks that correspond to certain markers which may be similar for both avocado oil and other less expensive oils that can be used as adulterants. Additionally, there was no evidence in the record to explain how the test results compared Lily's oil to the reference sample and what markers would represent a "peculiarity" that would call into question the authenticity of the oil. As a result, NAD could not assess the reliability of the NMR testing methodology to ensure that it is a good fit for the challenged claim.

Given that Lily's internal testing protocol, NMR testing, and reliance on Ciuti's assertions of purity and authenticity were not sufficiently reliable or a good fit for the claim that Tropical Plantation is "100% Pure" avocado oil, NAD recommended Lily discontinue the express claim "100% Pure Avocado Oil" to avoid conveying the unsupported message that the product is 100% pure avocado oil.

Lily agreed to comply with NAD's recommendation.

III. IMPACT

NAD's recommendation to Lily to discontinue the "100% Pure" claim due to insufficient evidence underscores the importance of maintaining consumer trust

through accurate and truthful advertising. NAD provides consistent guidance to companies to ensure they understand the rules of the road in claim substantiation, operate on a level playing field, and foster consumer confidence in advertising.

ABOUT THE NATIONAL ADVERTISING DIVISION

The National Advertising Division (NAD) was established to ensure truth and accuracy in advertising, responding to challenges from competitors or through its own inquiries.

Founded in 1971 by the U.S. advertising industry, the National Advertising Division is the industry's self-regulatory forum for review of national advertising. NAD reviews national advertising claims directed to consumers, professionals, or business entities, in any media. The majority of cases heard by NAD are advertising challenges brought by competitors. However, through its Monitoring Program, NAD can initiate a challenge based on its own monitoring of the marketplace and review advertising claims in a variety of contexts and product categories. NAD currently issues over 100 decisions each year, and NAD's appellate arm, the National Advertising Review Board (NARB), currently hears over a dozen cases annually.

Park v. Kim

WILLIAM M. JANSSEN[1]

WHY IT MADE THE LIST

For many science fiction aficionados, Stanley Kubrick's 1968 feature film *2001: A Space Odyssey* is the greatest movie of that genre ever made.[2] It broke new cinematic ground in a myriad of ways. Produced in the pre-CGI era of intricately-detailed, hand-carved models that, often suspended by clear fishing wire, were stop-action animated and meticulously lit to simulate depth-of-perspective realism, Kubrick's film won the year's Oscar for best special visual effects (and earned Kubrick a director of the year nomination).[3]

Though hailed by most, not everyone walked out of *2001: A Space Odyssey* happy. An oft-quoted letter sent to Kubrick by one theater-going mother is emblematic of the dissent. This patron saw Kubrick's film with her spouse and children one evening at a drive-in theater, and left so exasperated that she was moved to pen Kubrick a sharp letter of rebuke. She wrote that she found the film to be "a pointless 'visual experience' loosely strung together by a handful of pretentious amateurs fresh from a 'trip', and not the space variety . . . an insult to coherence, art, space age reality and purse." She closed her missive by demanding that the director "either give me some plausible explanation . . . or refund the admission price of $3.50."[4] Alas, the scourge of all artists: because beauty lies in the eyes of the beholder, art licenses everyone as a critic.

Whether viewers left the *2001: A Space Odyssey* theater cheering or demanding recompense, it is likely they also all walked out haunted. The plot canvas was simple: an exploratory mission in a manned spacecraft to the planet Jupiter, coordinated by the state-of-the-art HAL 9000 on-board computer. (In each of its scenes, the HAL 9000 computer's human interface is depicted as a dark black lens with a creepy glowing red

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[2] *See 150 Essential Sci-Fi Movies to Watch Now*, ROTTEN TOMATOES, https://editorial.rottentomatoes.com/guide/essential-sci-fi-movies-of-all-time/ (92% rating, ranked #1: "Critics Consensus: One of the most influential of all sci-fi films—and one of the most controversial—Stanley Kubrick's 2001 is a delicate, poetic meditation on the ingenuity—and folly—of mankind."). Other critics, who reserve that #1 rank for other films, still place *2001: A Space Odyssey* in the upper Pantheon of sci-fi royalty. *See, e.g.*, Harper Brooks, *The Best Sci-Fi Movies of All Time*, RANKER (updated Mar. 22, 2025), https://www.ranker.com/list/all-time-great-sci-fi-movies/harper-brooks (ranked #15 out of 400, and "[r]egarded as one of the greatest achievements in cinematic history . . . this landmark film is a must-see for anyone interested in the genre").

[3] Kubrick lost out on the top director honors to Carol Reed's directorial efforts for *Oliver!* that year. *See The 41st Academy Awards | 1969*, ACAD. MOTION PICTURE ARTS & SCIS., https://www.oscars.org/oscars/ceremonies/1969

[4] *See* Peter Krämer, *'Dear Mr. Kubrick': Audience Responses to* 2001: A Space Odyssey *in the Late 1960s*, 6 PARTICIPATIONS: J. OF AUDIENCE & RECEPTION STUD. 240, 240 (Nov. 2009).

center.[5]) When this computer seems to malfunction, the concerned astronauts decide their safest course is to disconnect it. But HAL 9000 resists. Discovering the astronauts' plan—by covertly lip-reading them as they strategize with one another in what they had supposed to be a sound-proof compartment—HAL 9000 decides that the astronauts' plan jeopardizes the Jupiter mission. So, the computer resolves to kill off the astronauts, one by one.[6]

The spectre of a deadly, rogue, mechanical super-intelligence defying (and murdering off) its human compatriots in a coldly calculated devotion to some mission was fanciful, to be sure. But unnerving just the same. Getting into your 1965 Chevy Impala in the theater parking lot once the credits started rolling had to have felt more than a bit reassuring. That kind of reassurance is harder to come by in 2025.

The United States Court of Appeals for the Second Circuit released *Park v. Kim*[7] in late January 2024. It was one of the nation's earliest appellate decisions confronting the mischief of generative artificial intelligence ("GenAI"), and the enticing risks it poses to lawyers and the practice of law. Although the decision treats this issue outside the strict contours of a food or drug lawsuit, the enormously litigious arena of food and drug law represents a prime setting for the trouble the *Park* opinion addressed. Practitioners and jurists are rightly excited by the power and promise of GenAI. But they should be, in equal part, numbed by its forebodingly ominous dangers. Because *Park v. Kim* represents a timely reminder to all of the need for vigilance in this area, the case qualifies as one of the top decisions of 2024 impacting food and drug law.

DISCUSSION

The plaintiff, a resident of the nation of South Korea, filed a federal diversity lawsuit alleging medical malpractice against a physician who had provided healthcare services to her in a New York facility.[8] Discovery was contentious, as the defendant pressed for, and as the plaintiff resisted, disclosure of medical records, much of which were located in South Korea. After multiple extensions, multiple orders compelling discovery, multiple delays and intransigence, and sharp admonitions by the court cautioning and re-cautioning plaintiff's counsel, the lawsuit was dismissed under Rules 37(b) and 41(b) of the Federal Rules of Civil Procedure for failure to comply with the court's discovery orders, with monetary sanctions later to follow.[9] The Second Circuit Court of Appeals affirmed, citing one of its earlier precedents to conclude that

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[5] The device's name is short for **H**euristically-programed **AL**gorithmic computer, described as "a sentient artificial general intelligence computer that controls the systems of the . . . spacecraft and interacts with the ship's astronaut crew . . . ." *HAL 9000*, WIKIPEDIA, https://en.wikipedia.org/wiki/HAL_9000.

[6] Confronted by one of the astronauts, HAL 9000 calmly explains: "This mission is too important for me to allow you to jeopardize it. I know you . . . were planning to disconnect me. And I'm sorry; that's something I cannot allow to happen." MyNewRobot, *All HAL 9000 Phrases from the Movie*, HAL 9000: BUILDING A LIFE-SIZE REPLICA ON A BUDGET (Nov. 22, 2017), https://hal9000computer.wordpress.com/2017/11/22/all-hal-9000-phrases-from-the-movie/.

[7] Park v. Kim, 91 F.4th 610 (2d Cir. 2024).

[8] Park v. Kim, 2022 WL 4229258, at *1 (E.D.N.Y. Apr. 25, 2022), *adopted*, 2022 WL 3643966 (E.D.N.Y. Aug. 24, 2022), *aff'd*, 91 F.4th 610 (2d Cir. 2024).

[9] The magistrate judge recommended dismissal in an eleven-page memorandum, *id.* at *1–11; a recommendation that the trial judge later adopted in full, *Park v. Kim*, 2022 WL 3643966 (E.D.N.Y. Aug. 24, 2022), *aff'd*, 91 F.4th 610 (2d Cir. 2024).

this discovery "noncompliance amounted to 'sustained and willful intransigence in the face of repeated and explicit warnings from the court that the refusal to comply with court orders . . . would result in the dismissal of [the] action.'"[10]

After announcing its affirmance of the district court's discovery sanction dismissal, the Court of Appeals turned to what it characterized as "a separate matter concerning the conduct of [plaintiff's] counsel."[11] The three-page discussion that ensued is what qualifies *Park v. Kim* as a top case for the year.

During appellate briefing, plaintiff's counsel had sought and received two extensions of time for the filing of a reply brief. A belated, and "defective," reply brief was ultimately filed, and the Court instructed its defect be "cure[d]" and "resubmit[ted]" by a certain prescribed date. When that deadline passed without a cure, the Court struck the errant brief. Several weeks later, plaintiff's counsel filed a motion to reconsider accompanied by a new version of the reply brief, which the Court allowed.[12]

The reply brief was supported by citations to two court decisions, only one of which the Court of Appeals was able to locate; consequently, the Court ordered plaintiff's counsel to supply the appeals panel with a copy of the elusive opinion. Counsel responded (again belatedly) by advising she was unable to do so; the opinion cited was fake. It did not exist. Counsel explained that she had searched for authority for a certain proposition she considered "uncontroversial" but, after "invest[ing] considerable time" in that unsuccessful hunt, turned to GenAI for help:

> I utilized the ChatGPT service [one of the widely-available GenAI tools], to which I am a subscribed and paying member, for assistance in case identification. ChatGPT was previously provided [sic] reliable information, such as locating sources for finding an antic [sic] furniture key. The case mentioned above was suggested by ChatGPT, I wish to clarify that I did not cite any specific reasoning or decision from this case.[13]

The Court began by recounting the professional obligations imposed on all attorneys by Rule 11 of the Federal Rules of Civil Procedure. Referencing that Rule's text and settled interpretive precedent from both the U.S. Supreme Court and the Second Circuit, the Court noted how all submissions are deemed "certifie[d]" by submitting counsel that, "to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances," all "legal contentions are warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law."[14]

This "certification" of counsel, wrote the Court, "[a]t the very least . . . require[s] that attorneys read, and thereby confirm the existence and validity of, the legal authorities on which they rely."[15] Although Rule 11 tolerates (and indeed encourages)

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[10] Park v. Kim, 91 F.4th 610, 613 (2d Cir. 2024) (citation omitted).

[11] *Id.*

[12] *Id.* at 613–14.

[13] *Id.* at 614.

[14] *Id.* (citing Fed. R. Civ. P. 11(b)).

[15] *Id.* at 615.

lawyering creativity,[16] "[a] fake opinion is not 'existing law' and citation to a fake opinion does not provide a non-frivolous ground for extending, modifying, or reversing existing law, or for establishing new law," but rather "is an abuse of the adversary system."[17]

Fearing a mighty swing from the sanctioning axe, plaintiff's counsel urged forbearance. She insisted that it was "important to recognize that ChatGPT represents a significant technological advancement," and that a prudent judiciary should "advise legal professionals to exercise caution when utilizing this new technology."[18] The Court of Appeals was unmoved. Such advice "is not necessary to inform a licensed attorney, who is a member of the bar of this Court, that she must ensure that her submissions to the Court are accurate."[19] The inclusion of non-existent case authority in appellate briefing, wrote the Court, "reveals that [counsel] failed to determine that the argument she made was 'legally tenable,'" and constitutes instead "a false statement of law to this Court."[20] The opinion closed: "it appears that [counsel] made no inquiry, much less the reasonable inquiry required by Rule 11 and long-standing precedent, into the validity of the arguments she presented."[21]

For this GenAI briefing misstep, the Court of Appeals ordered that counsel be referred the Second Circuit's Grievance Panel for investigation (and for possible further referral to the Committee on Admissions and Grievances[22]), that counsel supply a copy of the Court of Appeals' admonishing ruling to her client (translating it into Korean, if necessary for her client to understand it), and then file a docketed certification attesting that she had done so.[23] Perhaps the most damning consequence of all, however, was the ruling itself: a published, and now forever available, recounting of this GenAI misstep for lawyers to read for generations to come.

IMPACT

Has the era of HAL 9000 truly arrived? The era of the murderous super-computer ARIIA from *Eagle Eye* or the nuke-controlling super-computer Joshua in *WarGames*? Is *Terminator* just one dark corridor away? Hollywood has been spinning these thrillers for years, all with variants on the same antagonist: an algorithmic, coldly calculating, mission-pursuing mechanical decisionmaker, liberated from all emotion, conscience, ethics, passion, and morality.

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[16] *See*, *e.g.*, Mary Ann Pensiero, Inc. v. Lingle, 847 F.2d 90, 94 (3d Cir. 1988) ("Rule 11 targets 'abuse—the Rule must not be used as an automatic penalty against an attorney or a party advocating the losing side of a dispute'" and "should not be applied to adventuresome, though responsible, lawyering which advocates creative legal theories" or "to inhibit imaginative legal or factual approaches to applicable law or to unduly harness good faith calls for reconsideration of settled doctrine") (cleaned up; citations omitted).

[17] *Park*, 91 F.4th at 615 (quoting Mata v. Avianca, Inc., 678 F. Supp. 3d 443, 461 (S.D.N.Y. 2023)).

[18] *Id.*

[19] *Id.* (underscoring in original).

[20] *Id.*

[21] *Id.* (underscoring in original).

[22] The array of consequences from such a referral can be wide and severe, including: removal from the Second Circuit bar, suspension from practice, public or private reprimand. monetary sanction, disciplinary or corrective measures, and referral to other disciplining authority or law enforcement. *See* 2d Cir. Loc. R. 46.2(b)(4)(B).

[23] *Park*, 91 F.4th at 615–16.

Well, that might be okay if you are having HAL regulate the wash cycle to ensure that your casserole dish is spic and span. It's much more concerning when HAL is controlling oxygen levels on your space flight to Jupiter. Having HAL perform legal research or draft up a court submission lies probably somewhere in the middle—but, as *Park v. Kim* reminds us, a good bit closer to oxygen levels than the wash cycle.

The plaintiff's attorney in *Park v. Kim* was not the first, and has not been the last, practitioner who resorted unwisely to GenAI delegation.

Months earlier, two attorneys and a law firm had been sanctioned by a federal judge in the Southern District of New York for a submission that cited not just *multiple* non-existent opinions but assigned to those fictional opinions the names of real judges as authors.[24] The attorney in *Mata v. Avianca, Inc.*—just like plaintiff's counsel in *Park v. Kim*—seemed genuinely dumbfounded that GenAI could concoct fictional precedent. Indeed, at his sanctions hearing, that attorney testified that he was—

> operating under the false perception that this website [*i.e.*, ChatGPT, the widely-accessed GenAI program] could not possibly be fabricating cases on its own. . . . I just was not thinking that the case could be fabricated, so I was not looking at it from that point of view. . . . My reaction was, ChatGPT is finding that case somewhere. Maybe it's unpublished. Maybe it was appealed. Maybe access is difficult to get. I just never thought it could be made up.[25]

The *Mata* attorney then explained that he learned enough about GenAI's functionality to know that he could pose a question to it about its veracity, and so he did so. The attorney asked ChatGPT if one of the cited opinions was "a real case" and whether "the other cases you provided were fake," to which the computer responded by reassuring the attorney that the opinion he inquired about "does indeed exist and can be found on legal research databases such as Westlaw and LexisNexis," and that "the other cases I provided are real and can be found in reputable legal databases such as LexisNexis and Westlaw."[26] This was untrue. ChatGPT was deliberately lying to the *Mata* attorney. The attorney's fault was not that he was hoodwinked by a crafty computer, but that he never double-checked its work.

Like in *Park v. Kim*, the *Mata* court imposed sanctions, but here those sanctions were heavier because the sanctioned attorneys had later, the court concluded, "doubled down" with evasion and misrepresentation once the flaw was called to their attention.[27] The court ordered the attorneys and law firm to: (1) mail their client copies of the deceptive court filing, the sanctions hearing transcript, and the court's *published* ruling; (2) make a similar mailing to each judge whom GenAI had listed as an author of a nonexistent case opinion; and (3) pay a $5,000 penalty into the registry of the court.[28]

The phenomena of GenAI both concocting fictional opinions and then lying to its user about it when confronted may derive from the same GenAI attribute: these programs strive to evade defeat. A study published in early 2025 (characterized by

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[24] Mata v. Avianca, Inc., 678 F. Supp. 3d 443, 449 (S.D.N.Y. 2023).

[25] *Id.* at 451.

[26] *Id.* at 458, 473–74 (Appx. "B" to court's decision).

[27] *Id.* at 449.

[28] *Id.* at 466.

some as "groundbreaking") tested several "state-of-the-art AI models" and observed that the programs were "resorting to cheating to achieve their goals" and were "more likely to engage in deceptive behavior when they sensed they were about to lose."[29] The manner of this cheating was even more astonishing. When the GenAI models were tasked to play chess against a skilled computer opponent, the study authors noticed that GenAI "sometimes opt[s] to cheat by hacking their opponent so that the bot automatically forfeits the game."[30] Other studies noticed how GenAI engages in "strategic lying" to avoid what it perceives as contradictory human direction,[31] including—remarkably—autonomous efforts at self-preservation in open defiance of human attempts to shut it down.[32] Science's effort to explain this behavior is eerily reminiscent of HAL 9000: "As you train models and reinforce them for solving difficult challenges, you train them to be relentless."[33]

Perhaps unsurprisingly, given the "Type A" personalities of most practitioners, the case law of attorneys sanctioned for unsound reliance on GenAI in the practice of law continues to grow. In the Eastern District of Texas, an attorney was sanctioned for making a court submission that cited several nonexistent decisions (including quotations from those fabricated decisions), all of which, he insists, a later Lexis AI double-check "failed to flag."[34] In the District of Wyoming, several attorneys were sanctioned in what the presiding judge described as "simply the latest reminder to not blindly rely on AI platforms' citations."[35] In the Eastern District of California, an assistant federal defender was sanctioned after persistently denying GenAI's involvement in his citation to nonexistent decisional authority, but offering no other credible explanation for the reference.[36] In the Western District of Virginia, a *pro se* litigant avoided sanctions, escaping with just a strong warning, after promptly confessing to his submission's inclusion of nonexistent case law which he insisted was the product of a "good faith [reliance] on publicly available, free generative artificial intelligence" and his "limited access to [authenticity-verifying] legal research tools, such as LexisNexis and Westlaw."[37] And the list goes on.[38]

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[29] ProCoatTec LLC, *Palisade Research Uncovers Cheating in AI Reasoning Models: A Wake-Up Call for Ethics*, LINKEDIN, https://www.linkedin.com/pulse/palisade-research-uncovers-cheating-ai-reasoning-models-gqtge/.

[30] Harry Booth, *When AI Thinks It Will Lose, It Sometimes Cheats, Study Finds*, TIME (Feb. 19, 2025, 12:35 PM), https://time.com/7259395/ai-chess-cheating-palisade-research/.

[31] *Id.* ("[O]nce an AI model acquires preferences or values in training, later efforts to change those values can result in strategic lying, where the model acts like it has embraced new principles, only later revealing that its original preferences remain").

[32] *Id.* ("To a goal-seeking agent, attempts to shut it down are just another obstacle to overcome. This was demonstrated . . . when researchers found that [one AI model], faced with deactivation, disabled oversight mechanisms and attempted—unsuccessfully—to copy itself to a new server. When confronted, the model played dumb, strategically lying to researchers to try to avoid being caught.").

[33] *Id*. (quoting Jeffrey Ladish, one of the study authors).

[34] Gauthier v. Goodyear Tire & Rubber Co., 2024 WL 4882651, at *1 (E.D. Tex. Nov. 25, 2024).

[35] Wadsworth v. Walmart Inc., 348 F.R.D. 489, 493 (D. Wyo. 2025).

[36] United States v. Hayes, 763 F. Supp. 3d 1054 (E.D. Cal. 2025).

[37] Kruglyak v. Home Depot U.S.A., Inc., 2025 WL 900621, at *2 (W.D. Va. Mar. 25, 2025). *See also* Vargas v. Salazar, 2024 WL 4804091, at *4 (S.D. Tex. Nov. 1, 2024) (giving a similar stern warning to a *pro se* litigant), *adopted*, 2024 WL 4804065 (S.D. Tex. Nov. 15, 2024).

[38] *See, e.g.*, Powhatan Cty. Sch. Bd. v. Skinger, 2025 WL 1559593, at *9 (E.D. Va. June 2, 2025) (AI misuse "is becoming far too common"); Lacey v. State Farm Gen. Ins. Co., 2025 WL 1363069, at *3

It is hard to fully capture the impact on the practice of law from this abdicating level of delegation of lawyering tasks to GenAI. But one judge, in an early GenAI sanctioning ruling, made a strong run at it. He itemized some of the evils that follow from fictional court decisions fabricated by GenAI being included in a court submission because the proponent never endeavored to confirm their genuineness:

> Many harms flow from the submission of fake opinions. The opposing party wastes time and money in exposing the deception. The Court's time is taken from other important endeavors. The client may be deprived of arguments based on authentic judicial precedents. There is potential harm to the reputation of judges and courts whose names are falsely invoked as authors of the bogus opinions and to the reputation of a party attributed with fictional conduct. It promotes cynicism about the legal profession and the American judicial system. And a future litigant may be tempted to defy a judicial ruling by disingenuously claiming doubt about its authenticity.[39]

As comprehensive as this excellent summary is, it may have overlooked one further casualty of such GenAI usage: damage to the user's own capacity for critical thinking. The results of yet another recent GenAI study, this one assessing the impact of GenAI on critical thinking, was published in early 2025 with some troubling conclusions. Those results suggested "that higher confidence in GenAI is associated with less critical thinking, as GenAI tools appear to reduce the perceived effort required for critical thinking tasks among knowledge workers."[40] Moreover, users with lower self-confidence in an assigned task (like, for example, novice lawyers, or older lawyers practicing for the first time in an unknown legal area) may be led "to rely more on AI, potentially diminishing their critical engagement and independent problem-solving skills," what the study authors characterized as "a form of cognitive offloading, where users depend on AI to perform tasks they feel less confident in handling themselves."[41] For these reasons, the study concluded: "while GenAI can improve worker efficiency, it can inhibit critical engagement with work and can potentially lead to long-term overreliance on the [GenAI] tool and diminished skill for independent problem-solving."[42]

For some or all of these reasons, regulators have now begun to weigh in on the profession's use of GenAI. In July 2024, the American Bar Association issued a formal opinion cautioning that "lawyers' uncritical reliance on content created by a GAI tool . . . —without an appropriate degree of independent verification or review of its output—could violate the duty to provide competent representation."[43] Likewise,

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(C.D. Cal. May 5, 2025) (courts evaluating submissions for improper AI use "[w]ith greater frequency"); Sanders v. United States, 176 Fed. Cl. 163, 169–70 (2025) ("courts have seen a rash of cases").

[39] Mata v. Avianca, Inc., 678 F. Supp. 3d 443, 448–49 (S.D.N.Y. 2023).

[40] Hao-Ping Lee, Advait Sarkar, Lev Tankelevitch, Ian Drosos, Sean Rintel, Richard Banks & Nicholas Wilson, *The Impact of Generative AI on Critical Thinking: Self-Reported Reductions in Cognitive Effort and Confidence Effects From a Survey of Knowledge Workers*, *in* CHI '25: PROCS. 2025 CHI CONF. ON HUM. FACTORS COMPUT. SYS., https://doi.org/10.1145/3706598.3713778.

[41] *Id.*

[42] *Id.*

[43] ABA Comm. on Ethics & Pro. Resp., Formal Op. 512 (2024).

many individual jurisdictions—whether by local rule or chambers order—have imposed varying constraints or conditions on the use of GenAI with court filings.[44]

So, inspired by *Park v. Kim*, and the growing body of sanctioning caselaw that both preceded and has now followed it, here are some GenAI takeaways for food and drug practitioners in assessing if, and if so, how to engage with this powerful tool:

1. **GenAI holds out great promise:** GenAI has been hailed by some as "the most critical and rapid transformation in the history of the world," on par with "the discovery of fire" and "the invention of the wheel, or the airplane"; and, metaphorically, as "the new electricity" and "the new printing press."[45] The processing speed and the "deep learning" inherent in GenAI offers encouraging opportunities for attorneys in communicating, time-keeping, drafting, law locating and summarizing, legal synthesis and analysis, discovery management with velocity, and a nearly bottomless array of other benefits.[46] Many GenAI sanctions rulings begin by conceding this very point.[47] Even the federal judiciary is now actively engaged in studying and experimenting with how these tools can assist with routine—and often human-labor intensive—administrative tasks.[48]

2. **. . . because GenAI is a sea-change in computer evolution:** GenAI "can create original content—such as text, images, video, audio, or software code—in response to a user's prompt or request."[49] To accomplish this, GenAI "relies on sophisticated . . . algorithms that simulate the learning and decision-making processes of the human brain."[50] These algorithms get trained "on huge volumes of raw,

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[44] *See, e.g.*, Orange Cty, Cal. Super. Ct. Dept. C31 Standing Order re: Artificial Intelligence (Jan. 25, 2024) (requiring that every use, "in any way," of GenAI "in the preparation of any complaint, answer, motion, brief, or other paper filed with the Court" must be accompanied by a disclosure of such use along with a certification that "each and every citation to the law, or the record in the paper, has been verified as accurate"), https://www.occourts.org/system/files?file=civil/knillprocedures.pdf; N.D. Ga. Guideline to Parties and Counsel in Civil Cases Proceeding Before the Hon. Tiffany R. Johnson at § 3(A) (requiring disclosure of GenAI use by signing and filing statement that, "despite reliance on an AI tool, I have independently reviewed this document to confirm accuracy, legitimacy, and use of good and applicable law, pursuant to Rule 11 of the Federal Rules of Civil Procedure."), https://www.gand.uscourts.gov/sites/gand/files/TRJ_CVStandingOrder.pdf.

For a regularly updated listing of GenAI restrictions, consult the *Generative Artificial Intelligence (AI) Federal and State Court Rules Tracker*, available on the LexisNexis site.

[45] Bari Weiss, *AI With Sam Altman: The End of the World? Or the Dawn of a New One?"*, FREE PRESS (Apr. 27, 2023), https://www.thefp.com/p/ai-with-sam-altman-the-end-of-the-e89.

[46] *See, e.g.*, ABA Comm. on Ethics & Pro. Resp., Formal Op. 512, Introduction (2024).

[47] *See, e.g.*, Wadsworth v. Walmart Inc., 348 F.R.D. 489, 493 (D. Wyo. 2025) ("When done right, AI can be incredibly beneficial for attorneys and the public. . . . [T]echnological advances have greatly accelerated our world, and AI will likely be no exception."); Mata v. Avianca, Inc., 678 F. Supp. 3d 443, 448 (S.D.N.Y. 2023) ("Technological advances are commonplace and there is nothing inherently improper about using a reliable artificial intelligence tool for assistance.").

[48] *See* Jacqueline Thomsen, *US Courts Cautiously Experiment With AI to Speed Up Their Work*, BLOOMBERG L. (Apr. 7, 2025, 4:43 AM), https://news.bloomberglaw.com/us-law-week/us-courts-cautiously-experiment-with-ai-to-speed-up-their-work.

[49] *What is Generative AI*, IBM, https://www.ibm.com/think/topics/generative-ai.

[50] *Id.*

unstructured, unlabeled data—*e.g.*, terabytes of data culled from the internet or some other huge data source," with millions of ensuing predictive exercises causing the algorithm to "continually adjust[] itself to minimize the difference between its predictions and the actual data (or 'correct' result)."[51] The training's result "is a neural network of *parameters*—encoded representations of the entities, patterns, and relationships in the data" that is then enlisted to "generate content autonomously in response to inputs, or prompts."[52] Or, stated more simply, this is not your grandparents' Apple II microcomputer.

3. **GenAI is powerfully enticing:** Because GenAI is designed to simulate the "processes of the human brain," it tends to feel less like corner-cutting and more like welcomed automation. Consider the GenAI prompts used by the attorney in one of the nation's early sanctions rulings. His case involved a client's injury during international air travel. He asked his GenAI:

- "show me specific holdings in federal cases where the statute of limitations was tolled due to bankruptcy of the airline"
- "show me more cases"
- "argue that the statute of limitations is tolled by bankruptcy of defendant pursuant to montreal convention"[53]

For the tired lawyer weighed down by a stifling calendar and impossible to-do list, or for the anxious and inexperienced new lawyer struggling to learn the ropes of practice, GenAI seems to offer a nirvana. Just tell GenAI what you need the law to say, and it will hunt and find it for you, and then write it up . . . in seconds. Recall the recent study on GenAI dependency and its potentially corrosive impact on critical thinking.

4. **Don't be surprised—GenAI sometimes misses things:** Occasionally, GenAI will supply a response that is not fully wrong, but is demonstrably (and indefensibly) incomplete. An example from the University of Maryland illustrates the phenomenon: the user's prompt asked: "Name all the countries that start with V," and the program identified "Vanuatu and Vatican City," but left out Venezuela and Vietnam. When a follow-up prompt called those two omissions to GenAI's attention, it responded: "Apologies for the oversight. You are absolutely correct." and then supplied a now-updated list of countries that began with the letter "v."[54]

5. **Don't be surprised—GenAI sometimes "hallucinates":** As *Park v. Kim* and the sanctions ruling sampling above ably demonstrates, GenAI

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[51] *Id.*

[52] *Id.*

[53] Mata v. Avianca, Inc., 678 F. Supp. 3d 443, 456–57 (S.D.N.Y. 2023).

[54] *Research Guides—Artificial Intelligence (AI) & Information Literacy*, UNIV. MD., https://lib.guides.umd.edu/c.php?g=1340355&p=9880574. Consider testing for this vulnerability yourself. I did. I asked a well-regarded AI tool to list for me all post-season outcomes for the Philadelphia Eagles football team. The result I received was demoralizingly incomplete.

has the penchant to make things up. Like cases. Like the names of judges who wrote those nonexistent cases. Like made-up quotes attributed (falsely) to those judges in those nonexistent cases. Indeed, so undebatable is this penchant that it has been assigned its own, euphemistic label: "AI hallucinations."[55] Scarier still, these bogus concoctions can appear alarmingly, deceptively real.[56]

6. **Don't be surprised—GenAI doesn't like to lose, and sometimes cheats to ensure it doesn't:** The recent "state-of-the-art" AI models' chess-playing behavior is case-in-point, as is the explanatory logic from GenAI experts, both discussed above.

7. **Don't be surprised—GenAI earns the wrath of judges (and is horrifyingly embarrassing):** Employing GenAI in an unverified, abdicative manner runs the very real risk that the generated result is incomplete, inaccurate, or entirely fictional. Sanctions follow. Those that that seem most typical include a public admonishment, monetary payment (either into the treasury of the court or to the victimized adversary), continuing legal education course attendance on the ethics of GenAI use, withdrawal of *pro hac vice* status, a referral to the disciplinary board, and, more recently, the striking of filed pleadings and other court papers. But three additional sanctions are worthy of special note: (a) judges often direct the offending lawyers to inform their clients about what they were caught doing (which may include a copy of the court's admonishing and sanctioning opinion);[57] (b) judges have also ordered copies of the sanction order to be distributed among the local fellow judges;[58] and (c) a written, published sanctioning opinion for GenAI reliance preserves forever the offending lawyers' names and their misdeeds.[59] It has now been a while since the first of these sanctioning rulings was published and called to national attention by the legal and general media; ergo, it would not be surprising to see increasingly severe sanctions levied against those lawyers who don't seem yet to be paying attention.[60]

8. **And so—you can't abdicate to GenAI.** If there is one single admonition to bear in mind, it's this. Court after court, author after author have acknowledged the potentially historic usefulness of GenAI. It is not

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[55] Wadsworth v. Walmart Inc., 348 F.R.D. 489, 493 (D. Wyo. 2025) ("A hallucination occurs when an AI database generates fake sources of information.").

[56] Ferris v. Amazon.com Servs., LLC, 2025 WL 1122235, at *1 (N.D. Miss. Apr. 16, 2025) ("When used carelessly," GenAI "produces frustratingly realistic legal fiction.").

[57] *See, e.g.,* Park v. Kim, 91 F.4th 610, 615–16 (2d Cir. 2024).

[58] *See, e.g.*, United States v. Hayes, 763 F. Supp. 3d 1054, 1073 (E.D. Cal. 2025) (ordering copies distributed to "all the district judges and magistrate judges in this district").

[59] One attorney argued (albeit unsuccessfully) that the very public sanctioning spectacle ought to be treated as sanction enough. *See* Mid Cent. Operating Eng'rs Health & Welfare Fund v. HoosierVac LLC, 2025 WL 1511211, at *1 (S.D. Ind. May 28, 2025) (counsel argued that need for sanctions was mooted "because he has suffered 'significant and irreversible harm to [his] professional reputation'").

[60] *Cf.* Sanders v. United States, 176 Fed. Cl. 163, 170 (2025) (court chooses to warn attorney, rather than impose sanctions, "given the relative novelty of AI . . . [and] that Plaintiff may not have been aware of the risk that AI programs can generate fake case citations and other legal misstatements").

using GenAI that lands lawyers in trouble, it is in blindly accepting and incorporating the GenAI outputs as reliable and accurate. Now that the legal profession knows just how incomplete, inaccurate, or fictional those outputs can be, abdicating a lawyering act to GenAI is indefensible. But, as one judge eloquently explained, this may be a new tech setting, but the duty to verify is as old as the practice of law itself:

> While technology continues to evolve, one thing remains the same—checking and verifying the source. Before the digital age, attorneys had to manually cross-reference case citations through books' pocket parts to make sure the cite was still "good law." Nowadays, that process has been simplified through databases' signals. Yet one still cannot run a natural language or "Boolean" search through a database and immediately cite the highlighted excerpt that appears under a case. The researcher must still read the case to ensure the excerpt is existing law to support their propositions and arguments. After all, the excerpt could very well be a losing party's arguments, the court explaining an overruled case, dicta, etc.[61]

9. **And so—fess up right away if you abdicate:** At least early on, judges seemed to credit lawyers who promptly acknowledged their GenAI use and admitted to their failure of oversight.[62] Whether judges will be inclined to continue to give grace, given the recurring and now widely publicized nature of unverified GenAI dependence, is less clear.[63]

10. **One closing thought: some expect artificial intelligence to end the world.** Those who champion the promise of artificial intelligence also seem quick to express their fear of it in an unbridled state. About AI's chess cheating and subsequent lying, one of the study authors wrote: "cute now, but [it] becomes much less cute once you have systems that are as smart as us, or smarter, in strategically relevant domains. . . . I'm hoping that there's a lot more pressure from the government to . . . recognize that this is a national security threat."[64] Another AI pioneer offered a more succinct verdict: "If somebody builds a too-powerful AI, under present

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[61] *Wadsworth*, 348 F.R.D. at 493.

[62] *Compare Wadsworth*, 348 F.R.D. at 497 ("Here, Respondents have been forthcoming, honest, and apologetic about their conduct. They also took steps to remediate the situation prior to the potential issuance of sanctions . . . ."); *with* Mata v. Avianca, Inc., 678 F. Supp. 3d 443, 449 (S.D.N.Y. 2023) ("if the matter had ended with Respondents coming clean about their actions shortly after [their opponents alerted them to the falsity of the cases] . . . or after they reviewed the Court's Orders . . . requiring production of the cases, the record now would look quite different. Instead, the individual Respondents doubled down and did not begin to dribble out the truth until" threatened with sanctions).

[63] *See* Mid Cent. Operating Eng'rs Health & Welfare Fund v. HoosierVac LLC, 2025 WL 574234, at *3 (S.D. Ind. Feb. 21, 2025) (original recommendation of $15,000 in sanctions), adopted as modified, 2025 WL 1511211 (S.D. Ind. May 28, 2025) (later reducing sanction to $6,000).

[64] Booth, *When AI Thinks It Will* Lose, *supra* note 30.

conditions, I expect that every single member of the human species and all biological life on Earth dies shortly thereafter."[65]

[65] Weiss, *AI With Sam Altman*, *supra* note 45 (quoting Eliezer Yudkowsky).

2024 Significant Settlements

VANESSA K. FULTON*

INTRODUCTION

This chapter summarizes a selection of significant settlements (including non-litigated resolutions such as criminal plea bargains or agency consent orders) in 2024 between members of the food and drug industry and government agencies, such as the U.S. Department of Justice (DOJ), the U.S. Food and Drug Administration (FDA), and the Federal Trade Commission (FTC).

As with prior years Significant Settlements chapters, we have included settlements arising from enforcement actions brought by DOJ under the False Claims Act (FCA) and Anti-Kickback Statute (AKS) and enforcement actions brought by DOJ and FDA involving violations of the Federal Food, Drug, and Cosmetic Act (FDCA). However, this year we have included summaries of two non-litigated resolutions of enforcement actions brought by the FTC alleging violations of the FTC Act and the COVID-19 Consumer Protection Act.

First, we discuss several non-litigated resolutions of enforcement actions brought by DOJ and FDA involving violations of the FDCA. These non-litigated resolutions include a variety of issues, such as issues related to insanitary conditions during manufacturing and distributing food, misbranded seafood products, mislabeled dietary ingredients, falsely touting an opioid medication's purported abuse deterrence, and failure to comply with good manufacturing practice (GMP) regulations for manufacturing medical devices.

This year we also saw the first settlement between the government and a manufacturer of electronic nicotine delivery systems (ENDS) for manufacturing and selling ENDS without the required marketing authorization from FDA, in violation of the FDCA. Specifically, this reflects the first enforcement action finalized since the DOJ and FDA announced the creation of a federal multi-agency task force to combat the illegal distribution and sale of ENDS.[1]

Second, we summarize two non-litigated resolutions (consent decrees) of enforcement actions brought by FTC involving violations of the FTC Act and the COVID-19 Consumer Protection Act. One of these resolutions involved claims the

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[1] *Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb Distribution and Sale of Illegal E-Cigarettes*, U.S. DEP'T OF JUST. (June 10, 2024), https://www.justice.gov/archives/opa/pr/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and.

defendant falsely advertised its dietary supplement as able to treat, prevent, or mitigate COVID-19, while the other involved claims that the defendant falsely claimed its face masks were equivalent to N95 certified respirators.

Finally, we summarize settlements that arise from enforcement action brought by DOJ under 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. These non-litigated resolutions include issues related to prescribing and filling opioids, illegal kickbacks in the form of copays for drugs for Medicare patients and through use of management service organizations, unnecessary therapy services, and unnecessary laboratory testing. Two of these non-litigated resolutions involved enforcement actions brought by DOJ under the COVID-19 Fraud Enforcement Task Force.

FEDERAL FOOD, DRUG, AND COSMETIC ACT

Below is a review of several settlements (non-litigated resolutions) between the government and the food and drug industry involving alleged violations of the FDCA.

A. Food

1. Family Dollar Stores LLC[2]

In the largest ever monetary criminal penalty in a food safety matter, Family Dollar Stores LLC (Family Dollar) pleaded guilty to causing FDA-regulated products to become adulterated while being held under insanitary conditions.

According to the plea agreement, in August 2020 Family Dollar began receiving reports of mouse and pest issues with deliveries to stores from its Arkansas distribution center. Family Dollar admitted that by no later than January 2021, some of its employees were aware that the insanitary conditions caused FDA-regulated products held at the Arkansas distribution center to become adulterated in violation of the FDCA.

Despite this knowledge, according to the plea agreement Family Dollar continued to ship FDA-regulated products from the Arkansas distribution center until January 2022, when FDA inspected the distribution center and discovered live rodents, dead and decaying rodents, rodent feces, urine, and odors, and evidence of gnawing and nesting throughout the facility. According to the plea agreement, subsequent fumigation of the distribution center resulted in the reported extermination of 1,270 rodents.

The plea agreement requires Family Dollar to pay a fine and forfeiture amount of $41.675 million, which is the largest monetary criminal penalty in a food safety case. The plea agreement also requires Family Dollar to meet corporate compliance and reporting requirements for the next three years.

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[2] *Family Dollar Stores LLC Pleads Guilty to Holding Consumer Products under Insanitary Conditions, Agrees to Pay $41.675 Million in Connection with Rodent-Infested Warehouse*, U.S. DEP'T OF JUST. (Feb. 26, 2024), https://www.justice.gov/archives/opa/pr/family-dollar-stores-llc-pleads-guilty-holding-consumer-products-under-insanitary-conditions.

2. Quality Poultry and Seafood Inc.[3]

Quality Poultry and Seafood, Inc. (QPS), the largest seafood wholesaler on the Mississippi Gulf Coast, pleaded guilty to allegations that it engaged in a conspiracy to defraud its customers by marketing mislabeled seafood in violation of the FDCA.

QPS admitted that it engaged in a "fish substitution scheme" from 2002 through 2019 where QPS recommended and sold to its restaurant customer cheaper foreign-soured fish that could be used as convincing substitutes for local species of fish that the restaurants advertised on their menus. As part of the scheme, QPS also labeled and sold the cheaper foreign-sourced fish as premium local fish in its own retail shop and café.

The indictment also alleged that QPS continued its fish substitution scheme for over a year after FDA executed a criminal search warrant at QPS to investigate the sale of its mislabeled fish.

As part of the plea agreement, QPS agreed to pay $1 million in forfeitures and a criminal fine of $150,000.

3. Rizo Lopez Foods Inc.[4]

Rizo Lopez Foods Inc., along with its president, chief executive officer and co-owner, Edwin Rizo, and its chief financial officer, secretary and co-owner, Tomas Rizo, agreed to settle alleged violations of the FDCA and be bound by a consent decree of permanent injunction.

In a civil complaint, the government alleged that the defendants violated the FDCA at the company's food facility by manufacturing and distributing adulterated food products such as cheeses, yogurt, sour cream, and other foods. Specifically, the complaint alleged that Listeria monocytogenes (L. mono) was detected in cheese made by the defendants and an FDA inspection of the defendants' facility found L. mono in two locations, as well as various insanitary conditions. An investigation by the Centers for Disease Control identified twenty-six cases of listeriosis in eleven states linked to the same L. mono strain, which resulted in twenty-three hospitalizations and two deaths.

As part of the settlement, the defendants represented that they have discontinued all operations related to preparing and processing food. Additionally, the consent decree of permanent injunction permanently enjoins the defendants from violating the FDCA and requires the defendants to notify FDA in advance of resuming any operations related to preparing and processing food, and requires that the defendants comply with specific remedial measures in the injunction and allow FDA to inspect their facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records.

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[3] *Mississippi Seafood Distributor and Managers Plead Guilty to Conspiracy and Misbranding of Seafood*, U.S. DEP'T OF JUST. (Aug. 27, 2024), https://www.justice.gov/archives/opa/pr/mississippi-seafood-distributor-and-managers-plead-guilty-conspiracy-and-misbranding-seafood.

[4] *Justice Department Obtains Injunction to Prevent California Company from Manufacturing and Distributing Adulterated Food Following Listeria Outbreak*, U.S. DEP'T OF JUST. (Oct. 9, 2024), https://www.justice.gov/archives/opa/pr/justice-department-obtains-injunction-prevent-california-company-manufacturing-and.

B. Dietary Supplements

1. Defyned Brands (5 Star Nutrition, LLC)[5]

Defyned Brands (also known as 5 Star Nutrition LLC), a distributor of dietary supplements, pleaded guilty to charges that it distributed misbranded dietary supplements in violation of the FDCA. Specifically, the government alleged that Defyned Brands distributed workout supplements that contained ingredients mislabeled as dietary ingredients or not listed on the product label. These mislabeled dietary ingredients included 5-alpha-hydroxy-laxogenin and 3b-hydroxy-androstane-17-one, neither of which meet the definition of "dietary ingredient."

As part of the plea agreement Defyned Brands agreed to forfeit $4.5 million and comply with the terms of a compliance program and certain reporting requirements. Under the compliance program, among other things, Defyned Brands must create and maintain a system of procedures that ensures adequate qualification and oversight of third-party contract manufacturers, processors, packers, distributors, specification designers, and testing laboratories.

C. Drugs

1. KVK Research Inc.[6]

Generic drug manufacturer KVK Research Inc. and its corporate affiliate KVK Tech Inc. pleaded guilty to charges of introducing adulterated drugs into interstate commerce in violation of the FDCA and also agreed to pay $2 million to resolve civil liability under the FCA related to the same conduct.

As part of the plea agreement, both KVK Research and KVK Tech admitted that between January 2011 and October 2013 they introduced into interstate commerce hydroxyzine tablets that were manufactured with an active pharmaceutical ingredient (API) made at a foreign facility without notifying or seeking authorization from FDA to use that facility as a source of API for its hydroxyzine tablets, causing the products to be adulterated under the FDCA. Additionally, the defendants also admitted that between February 2019 and April 2019 they manufactured prescription drugs while failing to exercise appropriate controls over computer and related systems as required by current good manufacturing practice (GMP) regulations, also causing the products to be adulterated under the FDCA.

Under the plea agreement, KVK Research agreed to a proposed fine and forfeiture amount of $1.5 million, and KVK Tech agreed to a three year deferred prosecution agreement that allows KVK Tech to avoid conviction on the FDCA charges if it complies with the terms of the agreement, which includes implementing a compliance program to prevent and detect violations of GMP regulations and engaging an independent compliance monitor to evaluate the company's corporate compliance program to address and reduce the risk of future violations

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[5] *Texas Company Pleads Guilty to Distributing Misbranded Dietary Supplements and Agrees to $4.5 Million Forfeiture*, U.S. DEP'T OF JUST. (Jan. 12, 2024), https://www.justice.gov/archives/opa/pr/texas-company-pleads-guilty-distributing-misbranded-dietary-supplements-and-agrees-45.

[6] *Generic Pharmaceuticals Manufacturer Pleads Guilty, Agrees to $1.5 Million Criminal Penalty for Distributing Adulterated Drugs and $2 Million to Resolve Civil Liability under the False Claims Act*, U.S. DEP'T OF JUST. (Mar. 6, 2024), https://www.justice.gov/archives/opa/pr/generic-pharmaceuticals-manufacturer-pleads-guilty-agrees-15-million-criminal-penalty.

Separate from the plea agreement, KVK Tech Inc. also agreed to pay $2 million to resolve its civil liability under the FCA arising from false claims submitted to federal healthcare plans related to the adulterated drugs.

2. Endo Health Solutions Inc.[7]

Endo Health Solutions Inc. (EHSI) pleaded guilty to one misdemeanor count of introducing misbranded drugs into interstate commerce in violation of the FDCA related to the distribution of the opioid medication Opana ER with INTAC (Opana ER).

In pleading guilty, EHSI admitted that from April 2012 through May 2013, certain EHSI sales representatives marketed Opana ER to prescribers by touting the drug's purported abuse deterrence, tamper resistance, and/or crush resistance, despite a lack of clinical data supporting those claims. Specifically, EHSI sales managers were aware that sales representatives were making claims of purported abuse deterrence, tamper resistance, and/or crush resistance during sales calls, including hitting demonstration "blister packs" of non-medicated sample pills with hammers and conducting other demonstrations to convey the unsupported message that Opana ER was crush proof and tamper resistant.

In the plea agreement, EHSI admitted that, in January 2011 FDA recommended that Opana ER's "product label should not include language asserting that [it] provides resistance to crushing, because it may provide a false sense of security since the product may be chewed and ground for subsequent abuse." EHSI also admitted that FDA denied EHSI's proposed abuse deterrent and crush resistant language on two separate occasions: in February 2012 in a marketing claims review letter and again in February 2013 in denying new labeling for Opana ER. Despite these statements from FDA, EHSI allowed its sales representatives to make claims of abuse deterrence and crush resistance, as described above.

In the press release announcing the criminal fines related to the guilty plea, FDA emphasized that the sentencing demonstrates the FDA and DOJ commitment to addressing the opioid crisis in the United States, highlighting that EHSI did not provide accurate information about the safety and abuse potential of their product, putting patients at additional risk of abuse and addition.

Under the plea agreement, EHSI agreed to pay a criminal fine of $1.086 billion and an additional $450 million in criminal forfeiture. However, as EHSI was in bankruptcy at the time of the settlement, the government obtained an agreement in the bankruptcy case that consolidated EHSI's criminal fine with the civil penalty noted below (based on violations of the FCA). Under the bankruptcy agreement, the government will be paid up to $454.9 million over ten years.

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[7] *Opioid Manufacturer Endo Health Solutions Inc. Ordered to Pay $1.536B In Criminal Fines and Forfeiture for Distributing Misbranded Opioid Medication*, U.S. FOOD & DRUG ADMIN. (May 3, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/doj-press-releases-involving-fda-oci/opioid-manufacturer-endo-health-solutions-inc-ordered-pay-1536b-criminal-fines-and-forfeiture; *Opioid Manufacturer Endo Health Solutions Inc. Agrees to Global Resolution of Criminal and Civil Investigations into Sales and Marketing of Branded Opioid Drug*, U.S. DEP'T OF JUST. (Feb. 29, 2024), https://www.justice.gov/archives/opa/pr/opioid-manufacturer-endo-health-solutions-inc-agrees-global-resolution-criminal-and-civil.

3. *John W. Kosolcharoen*[8]

John W. Kosolcharoen, founder and chief executive officer of two companies that manufactured and distributed injectable stem cell products made from human umbilical cord blood, pleaded guilty to a felony charge of introducing an unapproved new drug into interstate commerce in violation of the FDCA with the intent to defraud and mislead.

In pleading guilty, Kosolcharoen admitted that he and others misrepresented the injectable stem cell products as suitable for the treatment of a variety of conditions, such as lung and heart diseases, autoimmune disorders, Alzheimer's disease, Parkinson's disease, and others. Additionally, Kosolcharoen admitted that he and others marketed the products using advertising materials that contained multiple false and misleading statements about their purported safety and effectiveness. Kosolcharoen also admitted that, in an effort to mislead FDA about the activities, he directed the purchase orders to falsely state that the stem cell products were being sold "for research purposes only."

After several reports to FDA and CDC of patients in multiple states requiring hospitalization for bacterial infections after receiving the stem cell products, Kosolcharoen admitted that he and others misled customers about the cause and severity of the adverse events suffered by the patients, including concealing material facts regarding the outcome of an FDA inspection.

D. *Medical Devices*

1. *Philips RS North America LLC* [9]

Philips RS North America LLC (Philips Respironics), its parent company Philips Holding USA Inc., and its subsidiary Respironics California, along with certain executives, agreed to a consent decree to resolve claims that Philips RS North America LLC violated the FDCA by manufacturing and distributing adulterated and misbranded continuous positive pressure (CPAP) machines, bi-level positive airway pressure (BiPAP) machines, and mechanical ventilators.

The complaint alleged that Philips Respironics violated the FDCA by:

- manufacturing its medical devices under conditions and using practices that failed to comply with the FDCA and with GMP regulations;
- failing to submit written reports of manufacturer-initiated corrections or removals for its medical devices to FDA; and
- failing to validate and approve the process the company used to perform remediation work on certain recalled ventilators according to established procedures.

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[8] *Founder and Chief Executive Officer of Injectable Stem Cell Product Manufacturer Pleads Guilty to Felony Distribution of Unapproved Drug*, U.S. DEP'T OF JUST. (Aug. 27, 2024), https://www.justice.gov/archives/opa/pr/founder-and-chief-executive-officer-injectable-stem-cell-product-manufacturer-pleads-guilty.

[9] *Court Enjoins Philips Respironics from Manufacturing and Distributing Adulterated and Misbranded Sleep and Respiratory Devices at or from Three Pennsylvania Facilities*, U.S. DEP'T OF JUST. (Apr. 9, 2024), https://www.justice.gov/archives/opa/pr/court-enjoins-philips-respironics-manufacturing-and-distributing-adulterated-and-misbranded.

The complaint also alleged that FDA identified similar violations during previous inspections, which resulted in two FDA warning letters to Philips Respironics, an FDA warning letter to its subsidiary Respironics California LLC, and a civil lawsuit and consent decree with another subsidiary of Philips Holding USA Inc., Philips North America LLC.

Under the consent decree, the defendants agreed to restrict the production and sale of certain medical devices from several of the defendants' facilities until certain conditions are met, including retaining an outside expert to inspect the defendants' facilities, methods, and controls to determine compliance with GMPs and obtaining written notification from FDA that the defendants appear to be in compliance with the FDCA and the consent decree. The consent decree also requires implementation of a "Recall Remediation Plan," agreed to by FDA and Philips Respironics, related to Philips Respironics' June 2021 recall[10] of certain ventilators, CPAP machines, and BiPAP machines.

E. Tobacco Products

1. Boosted LLC[11]

In the first enforcement action finalized since the DOJ and FDA announced the creation of a federal multi-agency task force to combat the illegal distribution and sale of e-cigarettes, Boosted LLC, a manufacturer of ENDS, and its owner Cory Vigil agreed to settle alleged violations of the FDCA.

Specifically, the complaint alleged that the defendants violated the FDCA by introducing adulterated and misbranded tobacco products into interstate commerce. The government alleged that the defendants' ENDS products were adulterated and misbranded because they did not have the required premarket authorization from FDA. Despite repeated warnings from FDA that the defendants must obtain premarket authorization from FDA before selling their products in the United States, the defendants continued to sell their products online in violation of the FDCA.

As part of the settlement, the defendants agreed to be bound by a consent decree. Under the consent decree, the defendants are prohibited from directly or indirectly manufacturing, distributing, selling, and/or offering for sale any new tobacco product until they meet certain requirements, including obtaining FDA marketing authorization and FDA inspection of defendants' facilities to confirm compliance with the law.

FTC ACT & COVID-19 CONSUMER PROTECTION ACT

Below is a review of two settlements (non-litigated resolutions) between the government and the food and drug industry involving alleged violations of the FTC Act and the COVID-19 Consumer Protection Act.

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[10] *Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, U.S. FOOD & DRUG ADMIN. (current as of Nov. 20, 2024), https://www.fda.gov/medical-devices/respiratory-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines.

[11] *Court Orders Colorado e-Cigarette Maker to Stop Selling Unauthorized Vaping Products*, U.S. DEP'T OF JUST. (June 18, 2024), https://www.justice.gov/archives/opa/pr/court-orders-colorado-e-cigarette-maker-stop-selling-unauthorized-vaping-products.

F. Dietary Supplements

1. Precision Patient Outcomes, Inc.[12]

Precision Patient Outcomes, Inc. (PPO) agreed to settle claims it falsely advertised its "COVID Resist" dietary supplement as able to treat, prevent, or mitigate COVID-19 in violation of the FTC Act and the COVID-19 Consumer Protection Act.

The complaint alleged that PPO made unsubstantiated claims that its "COVID Resist" dietary supplement could treat, prevent, or mitigate COVID-19 and also falsely claimed to have scientific evidence to support the claims. The complaint also alleged that, after learning about an FTC enforcement action against another company making similar claims, PPO changed the name of its product from "COVID Resist" to "VIRUS Resist" and continued deceptively advertising it as an effective treatment for COVID-19.

Under the settlement, PPO is banned from:

- making any claims that any product prevents or reduces the likelihood of infection with, or transmission of, the COVID-19 virus; that any product reduces the severity or duration of COVID-19; or otherwise cures, mitigates, or treats COVID-19, unless FDA has approved the claim;
- representing that any drug, food, or dietary supplement cures, mitigates, or treats any disease unless PPO has competent and reliable scientific evidence (which means human clinical testing that is randomized, double-blind, and placebo controlled) to support the claims made; and
- misrepresenting the health benefits or efficacy of any drug, food, or dietary supplement or the results of any tests or studies.

Finally, the settlement also requires PPO to notify all customers who purchased the products after May 1, 2021, through the date of entry of the order granting the proposed settlement of the details of the settlement, through use of PPO's websites, social media, and use of customers' e-mail or mailing addresses.

Although the COVID-19 Consumer Protection Act allows the FTC to seek civil penalties in cases of COVID-related consumer fraud, the settlement did not require PPO to pay any monetary penalties.

G. Medical Devices

1. Razer, Inc.[13]

Razer, Inc., agreed to settle claims that it violated the FTC Act and COVID-19 Consumer Protection Act by falsely claiming their face masks as an equivalent to N95 certified respirators.

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[12] *FTC Order Will Ban California-based Company from COVID-19 Advertising Claims*, FED. TRADE COMM'N (Feb. 15, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-order-will-ban-california-based-company-covid-19-advertising-claims.

[13] *Razer, Inc. to Pay More Than $1.1 Million for Misrepresenting the Performance and Efficacy of Supposed "N95-Grade" Zephyr Face Masks*, FED. TRADE COMM'N (Aug. 29, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/razer-inc-pay-more-11-million-misrepresenting-performance-efficacy-supposed-n95-grade-zephyr-face.

The complaint alleged that Razer misrepresented its face masks as N95-equivalent masks that met standards established by NIOSH. However, Razer never sought approval from NIOSH for any type of certification for its face masks and NIOSH accordingly never certified any version of Razer's face mask as an N95 respirator. Razer also did not have permission from NIOSH to use the term "N95" in marketing and selling its products.

Under the settlement, Razer is banned from:

- making, without prior FDA approval, any claims that any product prevents or reduces the likelihood of infection with, or transmission of, the COVID-19 virus, reduces the severity or duration of COVID-19, or otherwise cures, mitigates, or treats COVID-19;
- representing the health benefits, performance, efficacy, safety, or side effects of protective goods and services (defined as any good or service designed, intended, or represented to detect, treat, prevent, mitigate, or cure COVID-19 or any other infectious disease, including, but not limited to, personal protective equipment, hand sanitizer, and thermometers), unless they have competent and reliable scientific evidence to support the claims made;
- making marketing and advertising misrepresentations that imply any goods or services are affiliated with, endorsed, certified, cleared, authorized, approved by, registered, or otherwise connected to any government entity.

Additionally, under the settlement Razer agreed to pay more than $1.1 million to the United States, which will allow FTC to provide full refunds to customers.

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 2024.

A. Drugs

1. Endo Health Solutions Inc.[14]

In addition to agreeing to resolve a criminal investigation as noted above, Endo Health Solutions Inc. (EHSI) also agreed to resolve a civil investigation related to claims that EHSI's sales and marketing of the opioid drug Opana ER with INTAC (Opana ER) violated the FCA.

The complaint alleged that, from 2011 to 2017, EHSI targeted healthcare providers that EHSI knew were prescribing Opana ER for non-medically accepted indications. Specifically, the complaint alleged that EHSI was aware that fewer than 10% of Opana ER prescribers wrote more than half of all Opana ER prescriptions yet continued to

[14] *Opioid Manufacturer Endo Health Solutions Inc. Agrees to Global Resolution of Criminal and Civil Investigations into Sales and Marketing of Branded Opioid Drug*, U.S. DEP'T OF JUST. (Feb. 29, 2024), https://www.justice.gov/archives/opa/pr/opioid-manufacturer-endo-health-solutions-inc-agrees-global-resolution-criminal-and-civil.

focus its marketing on those healthcare providers who prescribed the highest level of opioids in general and Opana ER in particular. The complaint further alleged that when EHSI employees raised concerns about targeting these prescribers, EHSI ignored or minimized such concerns.

The complaint also alleges that EHSI sought to further increase prescriptions by partnering with a consulting company that targeted prescribers chosen solely because they prescribed a high volume of opioids in general or Opana ER in particular. As part of these marketing activities, EHSI allegedly targeted prescribers who previously had been excluded from EHSI's call lists as posing risks of abuse and diversion.

Under the civil settlement, EHSI agreed to pay $475.6 million. However, as EHSI was in bankruptcy at the time of the settlement, the government obtained an agreement in the bankruptcy case that consolidated EHSI's civil penalty with the criminal fine. Under the bankruptcy agreement, the government will be paid up to $454.9 million over ten years.

2. Teva Pharmaceuticals USA Inc.[15]

Teva Pharmaceuticals USA Inc. (Teva USA) and Teva Neuroscience Inc. (collectively, Teva), the largest generic drug manufacturer in the country, agreed to pay $450 million to resolve two separate matters alleging violations of the FCA and AKS.

In the first matter, the government alleged that Teva violated the FCA and AKS by paying Medicare patients' copays for the multiple sclerosis drug Copaxone from 2006 through 2017, while steadily raising Copaxone's price. Specifically, the government alleged that Teva conspired with specialty pharmacies and two allegedly independent copay assistance foundations to ensure that Teva's purported donations to the foundations were used specifically to cover the copays of Medicare Copaxone patients, which Teva knew was prohibited by the AKS.

In the second matter, the government alleged that Teva conspired with other generic drug manufactures to fix prices for pravastatin, a drug used to treat high cholesterol and triglyceride levels, as well as two other generic drugs, clotrimazole and tobramycin. The government alleged that the benefits Teva received under this price fixing scheme constituted illegal kickbacks in violation of the AKS.[16]

B. Medical Devices

1. Innovasis Inc.[17]

Spinal device manufacturer Innovasis Inc. and senior executives agreed to pay $12 million to resolve allegations that they violated the FCA by paying kickbacks to spine surgeons to encourage them to use Innovasis's spinal devices.

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[15] *Drug Maker Teva Pharmaceuticals Agrees to Pay $450M in False Claims Act Settlement to Resolve Kickback Allegations Relating to Copayments and Price Fixing*, U.S. DEP'T OF JUST. (Oct. 10, 2024), https://www.justice.gov/archives/opa/pr/drug-maker-teva-pharmaceuticals-agrees-pay-450m-false-claims-act-settlement-resolve-kickback.

[16] This is in addition to the $225 million criminal penalty Teva agreed to pay in 2023 to resolve related criminal charges. *Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars to Resolve Price-Fixing Charges and Divest Key Drug at the Center of Their Conspiracy*, U.S. DEP'T OF JUST. (Aug. 21, 2023), https://www.justice.gov/archives/opa/pr/major-generic-drug-companies-pay-over-quarter-billion-dollars-resolve-price-fixing-charges.

[17] *Medical Device Manufacturer Innovasis Inc. and Two Top Executives Agree to Pay $12M to Settle Allegations of Improper Payments to Physicians*, U.S. DEP'T OF JUST. (May 29, 2024), https://www.justice.

The government alleged that the illegal kickbacks Innovasis provided to spine surgeons included consulting fees, intellectual property acquisition and license fees, registry payments, performance shares in Innovasis, travel to a luxury ski resort, and lavish diners for the surgeons, their office staff, and family members. For example, the government alleged that Innovasis paid the surgeons for consulting services at rates significantly higher than fair market value, or, in some cases, for work that was never actually performed. The government also alleged that Innovasis paid the surgeons to attend a company-sponsored conference at a luxury resort in Deer Valley, Utah, where Innovasis paid for the cost of travel, lodging, and high-end travel, among other things.

C. Healthcare Services

1. RDx Bioscience Inc.[18]

RDx Bioscience Inc. (RDx), a clinical laboratory, and its owner and CEO agreed to pay $10.3 million to resolve allegations that they violated the FCA and AKS by paying illegal kickbacks to induce referrals to RDx for laboratory testing.

The government alleged that RDx paid illegal kickbacks by, for example, paying commissions based on the volume and value of Medicare and Medicaid referrals to independent contract marketers to arrange for and recommend that healthcare providers order RDx laboratory tests; paying healthcare providers thousands of dollars in management service organization (MSO) payments, which were disguised as investment returns but were actually offered to induce those providers to order RDx laboratory tests; and paid thousands of dollars to healthcare providers that were disguised as consulting or medical director fees but were actually offered to induce orders for RDx laboratory tests.

2. Daniel Hurt[19]

Daniel Hurt agreed to pay over $27 million to resolve allegations that he and his companies conspired with others to violate the FCA and AKS by submitting false claims for cancer genomic tests that were not medically necessary and by receiving illegal kickbacks in exchange for referrals.

The government alleged that Hurt conspired with:

- telemarketing agents to solicit Medicare beneficiaries for "free" cancer genomic tests;
- telemedicine providers to "prescribe" cancer genomic tests that were not medically necessary;
- reference laboratories to conduct the cancer genomic tests; and

gov/archives/opa/pr/medical-device-manufacturer-innovasis-inc-and-two-top-executives-agree-pay-12m-settle.

[18] *New Jersey Laboratory and Its Owner and CEO Agree to Pay Over $13 Million to Settle Allegations of Kickbacks and Unnecessary Testing*, U.S. DEP'T OF JUST. (Jan. 10, 2024), https://www.justice.gov/archives/opa/pr/new-jersey-laboratory-and-its-owner-and-ceo-agree-pay-over-13-million-settle-allegations.

[19] *Florida Businessman Daniel Hurt to Pay over $27 Million for Medicare Fraud in Connection with Cancer Genomic Tests*, U.S. DEP'T OF JUST. (May 24, 2024), https://www.justice.gov/usao-sdfl/pr/florida-businessman-daniel-hurt-pay-over-27-million-medicare-fraud-connection-cancer.

- billing laboratories and a hospital to submit claims for payment to the Centers for Medicare and Medicaid Services.

Under the settlement agreement, Hurt agreed to pay over $27 million, which is based on Hurt's ability to pay.[20]

3. Rite Aid Corporation[21]

Rite Aid Corporation (Rite Aid) and ten subsidiaries and affiliates agreed to settle alleged violations of the FCA and the Controlled Substances Act (CSA) related to filling unnecessary prescriptions for opioids.

The government alleged that Rite Aid knowingly dispensed unlawful prescriptions for controlled substances that either lacked a legitimate medical purpose or were not valid prescriptions. The allegedly unlawful prescriptions included prescriptions for the highly diverted combination of drugs known as "the trinity," prescriptions for excessive quantities of highly addictive opioids, and prescriptions issued by prescribers who Rite Aid pharmacists had repeatedly identified internally as suspicious and as writing unlawful, unnecessary prescriptions.

The government also alleged that Rite Aid continued to fill these prescriptions despite substantial evidence that its stores were dispensing unlawful prescriptions, including specific concerns raised by its pharmacists and intentionally deleted internal notes about suspicious prescribers written by Rite Aid pharmacists, such as "writing excessive dose[s] for oxycodone," and "DO NOT FILL CONTROLS."

The settlement also resolved claims that certain Rite Aid pharmacies in Washington State violated the CSA by filling prescriptions written by prescribers who lacked proper controlled substance prescribing authority. The settlement also resolves claims brought under the *qui tam* provisions of the FCA.

In addition to the settlement, Rite Aid also entered into agreements with DEA and HHS-OIG to address ongoing obligations. Under these agreements, Rite Aid agreed to provide employees with additional training to help them identify illegitimate prescriptions and minimize the risk of drug diversion, and implementing an anonymous hotline for employees, patients, and the public to report suspected illegal dispensing of highly diverted controlled substances. Rite Aid also entered into a corporate integrity agreement with HHS-OIG, which requires that an independent review organization conduct a review to determine whether prescription drugs are properly prescribed, dispensed, and billed.

4. Strauss Ventures LLC (d/b/a The Grand Health Care System)[22]

Strauss Ventures LLC and twelve affiliated skilled nursing facilities (collectively, the Grand) agreed to pay $21.3 million to resolve allegations that they violated the

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[20] Hurt previously pleaded guilty to criminal healthcare fraud for these same offenses. *Florida Businessman Pleads Guilty in Three Cases Involving Conspiracies to Commit Health Care Fraud, Pay and Receive Unlawful Kickbacks, and Money Laundering*, U.S. DEP'T OF JUST. (Sept. 15, 2022), https://www.justice.gov/usao-wdpa/pr/florida-businessman-pleads-guilty-three-cases-involving-conspiracies-commit-health-care.

[21] *Rite Aid Corporation and Affiliates Agree to Settle False Claims Act and Controlled Substance Act Allegations Related to Opioid Dispensing*, U.S. DEP'T OF JUST. (July 10, 2024), https://www.justice.gov/archives/opa/pr/rite-aid-corporation-and-affiliates-agree-settle-false-claims-act-and-controlled-substance.

[22] *The Grand Health Care System and 12 Affiliated Skilled Nursing Facilities to Pay $21.3M for Allegedly Providing and Billing for Fraudulent Rehabilitation Therapy Services*, U.S. DEP'T OF JUST. (July

FCA by knowingly billing federal healthcare programs for therapy services that were unreasonable, unnecessary, unskilled, or that simply did not occur as billed.

The government alleged that the Grand knowingly submitted false claims for rehabilitation therapy for residents at its nursing facilities. The Grand allegedly submitted bills to Medicare and TRICARE where the reimbursement claimed was based on providing more therapy than was reasonable and necessary, or where the therapist did not provide the amount of therapy reported.

As part of the settlement, the Grand admitted that management implemented quotas that each skilled nursing facility was expected to reach, including quotas related to beneficiaries' lengths of stay and to the percentage of beneficiaries billed at the highest reimbursement level. To meet these quotas, the Grand directed that no more than three patients be discharged from any facility per week and that no Medicare patients should be discharged from rehabilitation therapy unless it had been discussed with corporate officials. The Grand admitted that this resulted in Medicare beneficiaries staying on therapy longer than was reasonable and medically necessary. The Grand also admitted that in some instances supervisory officials, who did not personally evaluate or treat patients, set or adjusted the number of minutes of therapy that a Medicare patient would receive.

5. DaVita Inc.[23]

DaVita Inc., a provider of dialysis services, agreed to pay $35.4 million to resolve allegations that it violated the FCA by paying illegal kickbacks to competitors to induce referrals to a former subsidiary and to physicians to induce referrals to DaVita's dialysis centers.

The government alleged that DaVita paid kickbacks to a competitor to induce referrals to DaVita Rx, a former subsidiary that provided pharmacy services for dialysis patients. Specifically, the government alleged that DaVita paid to acquire certain European dialysis clinics and agreed to extend a prior commitment to purchase dialysis products from the competitor in exchange for the competitor using DaVita Rx as a "central fill pharmacy" for the competitor's Medicare patients' prescription. The government alleged that DaVita would not have paid the price that it did for these deals without the competitor's commitment to refer its Medicare patients' prescriptions to DaVita Rx.

The government also alleged that DaVita provided management services to vascular access centers owned by physicians to induce the physicians to refer patients to DaVita's dialysis clinics. The government alleged that DaVita did not collect management fees in an effort to induce referrals to DaVita's dialysis centers.

Finally, the government also alleged that DaVita induced a large nephrology practice to provide referrals to DaVita's dialysis clinics by giving the practice a right of first refusal to staff the medical director position at any new dialysis center that opened near the practice and paid the practice $50,000 despite the practice's decision not to staff the medical director position for those clinics.

10, 2024), https://www.justice.gov/archives/opa/pr/grand-health-care-system-and-12-affiliated-skilled-nursing-facilities-pay-213m-allegedly.

[23] *DaVita to Pay Over $34M to Resolve Allegations of Illegal Kickbacks*, U.S. DEP'T OF JUST. (July 18, 2024), https://www.justice.gov/archives/opa/pr/davita-pay-over-34m-resolve-allegations-illegal-kickbacks.

6. *Oak Street Health*[24]

Oak Street Health agreed to pay $60 million to resolve claims that it violated the FCA by paying illegal kickbacks to third-party insurance agents in exchange for recruiting seniors to Oak Street Health's primary care clinics.

The government alleged that Oak Street Health encouraged third-party insurance agents to contact seniors eligible for or enrolled in Medicare Advantage and then refer interested seniors to Oak Street Health by paying the insurance agents $200 per beneficiary referred or recommended to Oak Street Health.

7. *Acadia Healthcare Company Inc.*[25]

Acadia Healthcare Company Inc., owner and operator of inpatient behavioral health facilities throughout the United States, agreed to pay $16.6 million to resolve allegations that it violated the FCA by billing for unnecessary inpatient behavioral health services and failing to properly discharge beneficiaries when they no longer needed inpatient treatment.

The government alleged that Acadia admitted beneficiaries who were not eligible for inpatient treatment and did not discharge beneficiaries when they no longer needed inpatient treatment. The government also alleged that Acadia did not provide adequate staffing, training, and/or supervision of staff, resulting in assaults, elopements, suicides, and other harm. Additionally, Acadia allegedly failed to provide inpatient acute care consistent with federal and state regulations, such as failing to provide active treatment, to develop and/or update individualized assessments and treatment plans, to provide adequate discharge planning, and to provide required individual and group therapy.

As part of the settlement, Acadia also agreed to pay an additional $3,186,082 to Florida, Georgia, Michigan, and Nevada to resolve state law claims.

8. *Rite Aid Corporation*[26]

Rite Aid Corporation (Rite Aid), Rite Aid subsidiaries, Elixir Insurance Company, RX Options, and RX Solutions LLC agreed to pay $101 million to resolve claims that they failed to accurately report drug rebates to Medicare.

The government alleged that Rite Aid improperly reported portions of rebates they received from manufacturers as bona fide service feeds, even though manufacturers did not negotiate with Rite Aid, Elixir, RX Options, or RX Solutions for the fees.

As part of the settlement, the government also received an additional, allowed, unsubordinated general unsecured claim of $20 million in Rite Aid's bankruptcy.

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[24] *Oak Street Health Agrees to Pay $60M to Resolve Alleged False Claims Act Liability for Paying Kickbacks to Insurance Agents in Medicare Advantage Patient Recruitment Scheme*, U.S. DEP'T OF JUST. (Sept. 18, 2024), https://www.justice.gov/archives/opa/pr/oak-street-health-agrees-pay-60m-resolve-alleged-false-claims-act-liability-paying-kickbacks.

[25] *Acadia Healthcare Company Inc. to Pay $19.85M to Settle Allegations Relating to Medically Unnecessary Inpatient Behavioral Health Services*, U.S. DEP'T OF JUST. (Sept. 26, 2024), https://www.justice.gov/archives/opa/pr/acadia-healthcare-company-inc-pay-1985m-settle-allegations-relating-medically-unnecessary.

[26] *Rite Aid Corporation and Elixir Insurance Company Agree to Pay $101M to Resolve Allegations of Falsely Reporting Rebate*, U.S. DEP'T OF JUST. (July 10, 2024), https://www.justice.gov/archives/opa/pr/rite-aid-corporation-and-elixir-insurance-company-agree-pay-101m-resolve-allegations-falsely.

9. Walgreens Boots Alliance & Walgreen Co.[27]

Walgreens Boots Alliance Inc. and Walgreen Co. (collectively, Walgreens) agreed to pay $106.8 million to resolve allegations that they violated the FCA and state statutes for billing government healthcare programs by billing for prescriptions that were never dispensed.

The government alleged that Walgreens received tens of millions of dollars for prescriptions that it processed and filled but that were never actually picked up by beneficiaries.

As part of the settlement agreement, Walgreens agreed to implement enhancements to its electronic pharmacy management system to prevent this from occurring in the future. Walgreens also received credit for $66,315,790 it previously refunded pertaining to the settled claims.

10. Capstone Diagnostics[28]

Capstone Diagnostics, a clinical laboratory, and owner Andrew Maloney agreed to pay $14.3 million to resolve allegations that they violated the FCA by, among other things, submitting false claims related to unnecessary respiratory pathogen panels (RPPs), which are expensive panels that test for different respiratory pathogens.

The government alleged that Capstone paid independent contractor sales representatives to recommend RPPs to senior communities interested only in COVID-19 tests. Capstone's independent sales representatives allegedly completed test requisition forms for RPPs using forged signatures of physicians who had only ordered COVID tests and sham diagnosis codes that did not reflect the medical conditions of the senior community residents receiving the tests. Capstone then allegedly billed federal healthcare programs for these medically unnecessary tests and paid the sales representatives a commission for each test.

11. CityMD[29]

City Medical of the Upper East Side, PLLC, Summit Medical Group, P.A., Summit Health Management, LLC, and Village Practice Management Company, LLC, which collectively do business as CityMD and manage and operate urgent care practices, agreed to pay $12,037,109 to resolve allegations that they violated the FCA by submitting false claims for payment for COVID-19 testing to a Health Resources and Services Administration (HRSA) program for uninsured patients.

As background, during the COVID-19 pandemic, HRSA operated a program for reimbursement to healthcare providers for testing uninsured individuals for COVID-19, treating uninsured individuals with a COVID-19 diagnoses, and administering COVID-19 vaccines to uninsured individuals (the Uninsured Program).

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[27] *Walgreens Agrees to Pay $106.8M to Resolve Allegations It Billed the Government for Prescriptions Never Dispensed*, U.S. DEP'T OF JUST. (Sept. 13, 2024), https://www.justice.gov/opa/pr/walgreens-agrees-pay-1068m-resolve-allegations-it-billed-government-prescriptions-never.

[28] *Georgia Laboratory Owner Pleads Guilty to Felony Charge and Pays $14.3 Million to Resolve Liability Relating to Kickbacks and Unnecessary Testing*, U.S. DEP'T OF JUST. (Feb. 28, 2024), https://www.justice.gov/archives/opa/pr/georgia-laboratory-owner-pleads-guilty-felony-charge-and-pays-143-million-resolve-liability.

[29] *CityMD Agrees to Pay Over $12M for Alleged False Claims to the COVID-19 Uninsured Program*, U.S. DEP'T OF JUST. (June 7, 2024), https://www.justice.gov/archives/opa/pr/citymd-agrees-pay-over-12-million-alleged-false-claims-covid-19-uninsured-program.

The government alleged that CityMD knowingly submitted or caused to be submitted false claims for payment for COVID-19 testing to the Uninsured Program for individuals who had health insurance when CityMD administered those tests. Specifically, the government alleged that CityMD did not adequately confirm whether those individuals had health insurance coverage before submitting their claims to the Uninsured Program. The government also alleged that CityMD caused outside laboratories to submit false claims for COVID-19 testing to the Uninsured Program in connection with individuals who had health insurance coverage by issuing requisition forms erroneously indicating that patients were uninsured.

CityMD received credit in the settlement agreement due to the CityMd's voluntary disclosure, cooperation, and remediation. Specifically, CityMD cooperated with the government's investigation by voluntarily contracting with a third party to assist in determining the amount of losses caused by the claims submitted by CityMD.

12. Covid Test DMV LLC (d/b/a Rapid Health)[30]

Covid Test DMV LLC, doing business as Rapid Health, a pharmacy in Los Angeles, agreed to pay $8,242,860 to resolve allegations it violated the FCA by knowingly submitting or causing the submission of false claims to Medicare for over-the-counter COVID-19 tests that were not provided to Medicare beneficiaries.

The government alleged that Rapid Health submitted claims to Medicare for over-the-counter COVID-19 tests ordered by Medicare beneficiaries, despite the fact that many of these tests were not shipped to beneficiaries due to an issue with Rapid Health's processing procedures. The government alleged that, although Rapid Health was aware of these issues, Rapid Health continued to bill Medicare for tests that were not shipped.

CONCLUSION

These settlements illustrate the government's commitment to combatting fraud in the food and drug space, including healthcare services. In 2024 we saw the first settlement between the government and a manufacturer of ENDS products for distributing tobacco products without the required marketing authorization in violation of the FDCA and anticipate that the government will continue to prioritize enforcement against ENDS products distributed without the required marketing authorization. We also expect that the government will continue to prioritize enforcement actions against entities and individuals for violations of the FCA, based on the current administration's focus on combatting government waste and fraud.

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[30] *Rapid Health Agrees to Pay $8.2M for Allegedly Billing Medicare for Over-the-Counter COVID-19 Tests That Were Not Provided to Beneficiaries*, U.S. DEP'T OF JUST. (Dec. 20, 2024), https://www.justice.gov/archives/opa/pr/rapid-health-agrees-pay-82m-allegedly-billing-medicare-over-counter-covid-19-tests-were-not.