Top Food and Drug Cases, 2023, & Cases to Watch, 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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Introduction

AUGUST T. HORVATH*

Welcome to the 2023 edition of FDLI's annual roundup of Top Food and Drug Cases. This year, we have a bumper crop of thirteen chapters on individual cases or topics that got our attention during the past year, and we welcome several new contributors to the volume. As always, we span government enforcement, civil and criminal lawsuits, and significant appeals. This year we also introduce a chapter on a significant case in the industry self-regulatory sphere. We conclude with a summary of key 2023 FDA regulatory initiatives and sketch a few cases to watch in the coming months.

When the Supreme Court rules on cases in the food and drug space, it naturally gets our attention and makes this year's list. Andrew Wasson describes the Supreme Court's ruling in *Amgen v. Sanofi*, an important patent case with implications well beyond the biologics products that are the subject of the ruling. Bryant Godfrey and Tina Papagiannopoulos discuss the high-profile mifepristone approval case argued before the Court in March, *Alliance for Hippocratic Medicine v. FDA*.

The stakes are always high in criminal matters. This year, Lynn Tyler describes *United States v. Facteau*, an important First Circuit ruling on the First Amendment as a defense to criminal charges relating to off-label drug promotion. Steve Johnson reports on the criminal case *United States v. Stoll*, with its important ruling on individual criminal liability even at the non-executive level.

If you thought you might escape social media by opening this ebook, we have bad news for you. Three of our cases this year concern this topic. Brigid Bondoc and Atiq Chowdhury discuss *Murthy v. Missouri*, a high-profile case in which FDA and federal officials were alleged to have violated the First Amendment by "coercing" social media platforms to limit the spread of misinformation about COVID treatments and other issues. Somewhat relatedly, Jonathan Berman and Colleen Heisey look at *Apter v. Dep't of Health & Human Servs.*, in which plaintiffs successfully challenged FDA's authority to combat the spread of misinformation regarding ivermectin as a COVID remedy by tweeting its own positions on appropriate treatment. Bill Janssen covers a key decision about the discoverability of social media activity in a New Jersey appellate court, and explains why the ruling is important to food and drug practitioners.

Other cases span the realm of pharmaceutical-related disputes. Justine Lenehan and Dan Logan cover one of the hottest legal issues of the past few years, the potential demise of *Chevron* deference via the case *Relentless v. Dep't of Commerce*, and its implications for food and drug law. Ginger Pigott and Richard Tabura discuss *Shikada v. Bristol-Myers Squibb*, a state enforcement action alleging a deceptive practice in failure to disclose the differential efficacy of a drug across ethnic populations. Anand Agneshwar, Jocelyn Wiesner, and Tommy Huynh report on the *Gilead Tenofovir Cases*, in which the California Court of Appeal addressed the theory that a drug

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manufacturer can be negligent by not advising consumers that it knows of a different, not-yet-approved, medication that might be better for the same indication.

Food labeling class actions continue to litter the national litigation docket, and two chapters deal with aspects of these cases. Rene Befurt, Anne Cai, Sean Flanagan, and Tom Rahr discuss *Horti v. Nestle Nutrition*, concerning whether the placement of a protein drink on the shelf adjacent to other products for the treatment of diabetes contributed to a false impression that the protein drink is a diabetes treatment. Mital Patel covers the Ninth Circuit's ruling in *McGinity v. Procter & Gamble*, clarifying the circumstances under which a reasonable consumer is expected to have reviewed a food's ingredient statement before lodging a claim of deceptive advertising based on the package's front panel.

This year we welcome Melissa Brown from the National Advertising Division of the Better Business Bureau National Programs, who describes a self-regulatory challenge to Novartis' promotion of its Kisqali cancer drug.

I again express my heartfelt gratitude to our contributors for their diligent efforts and valuable insights as reflected in their contributions. Some of our authors have been contributing to this volume for longer than the seven years that I have been editing it, while others have joined at various times and some are brand new. To all regardless, I am equally indebted for making my job painless and for providing the heart and soul of this important and always eagerly anticipated FDLI publication.

On behalf of the entire team, we wish all of our gentle readers a happy and productive balance of 2024 and hope to see you at FDLI's events.

Amgen Inc. v. Sanofi

ANDREW WASSON*

WHY IT MADE THE LIST

The Supreme Court does not often hear patent cases, leaving most of the heavy lifting on patent matters to the United States Court of Appeals for the Federal Circuit. So when the Court takes up a patent case, it becomes canon. Such is the case for *Amgen v. Sanofi*.[1] And while it is undeniably and thoroughly a patent case, its adjacency to the regulation of biologics, especially to the patent-specific provisions of the Biologics Price Competition and Innovation Act (BPCIA), makes it worth a close look by FDA regulatory attorneys.

In *Amgen v. Sanofi*, the Supreme Court examined the statutory "enablement" requirement for patents with claims that essentially recite an antibody by its function. Broadly, the "enablement" requirement necessitates that a patent specification describe a claimed invention in terms that "enable" persons ordinarily skilled in the art "to make and use" the invention.[2] Here, the Court upheld the determinations of the lower courts that Amgen's patent description failed to enable a skilled artisan to make and use the claimed invention over the full scope of the claims. The Supreme Court's holding in *Amgen* is a clear caution signal regarding functionally drafted claims relating to antibodies.

DISCUSSION

Legal Background

It is a foundational concept in patent law that a patent specification must describe the claimed invention in a way that would permit a skilled artisan to make or use it. While a patent provides a monopoly to the inventors for a limited period, the specification's description of an invention will eventually place the innovation into the hands of the public as soon as the patent expires (the so-called *quid-pro-quo* justification of patent law). This bargain dates back to the Constitution itself, which famously provides Congress the authority to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[3] Today, the requirement for an enabling specification is codified by Section 112(a) of the current Patent Act.[4] In

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1 Amgen Inc. v. Sanofi, 598 U.S. 594, 143 S. Ct. 1243 (2023).

2 35 U.S.C. 112(a).

3 U.S. CONST., art. I, § 8, cl. 8.

4 35 U.S.C. § 112(a).

particular, Section 112(a) requires "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same."[5]

Given the longstanding foundational nature of the enablement requirement, it should be no surprise that it has been the subject of significant judicial attention over the years—originally by the Supreme Court and more recently by the Federal Circuit. The Supreme Court's early treatment of the enablement requirement naturally arose outside of the life sciences, often in the context of pioneering nineteenth century technological advances like Morse's electromagnetic telegraph and Edison's incandescent light bulbs.[6] But the rapid expansion of the pharmaceutical and biotechnology industries in the 1980s and 1990s began to generate opportunities for courts to apply the enablement standard to the life sciences. The work of clarifying the enablement standard, especially as applied to the life sciences, was largely taken up by the Federal Circuit beginning with its founding in 1982. This difficult task continues today.

Almost immediately after its inception, the Federal Circuit decided *In re Wands*, which has served as a well-worn touchstone for enablement caselaw.[7] In *Wands*, the Federal Circuit observed that it was "well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation."[8] To guide this inquiry, *Wands* articulated the following factors:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[9]

These factors are known colloquially as the "*Wands* factors."

Over the years, the Federal Circuit was repeatedly faced with evaluating whether a specification was sufficient to enable broad claims reciting a genus of compounds defined largely by function. In making these evaluations, the Federal Circuit often emphasized the breadth of the challenged claims, the limited teachings of the specification, and the unpredictability of the art. For example, in *Wyeth & Cordis Corp. v. Abbott Laboratories*, the Federal Circuit contrasted claims covering tens of thousands of rapamycin compounds with a specification that disclosed the immunosuppressive and antirestenotic activity of a single compound (sirolimus).[10] In *Wyeth*, the Federal Circuit observed that the specification "discloses only a starting point for further iterative research in an unpredictable and poorly understood field."[11]

Other cases followed. In *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc*., the Federal Circuit cited the breadth of the claims, the "sparse" guidance given

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[5] *Id.*

[6] *See, e.g.*, O'Reilly v. Morse, 15 How. 62 (1854); The Incandescent Lamp Patent, 159 U.S. 465 (1895); Holland Furniture Co. v. Perkins Glue Co., 277 U. S. 245 (1928).

[7] *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988).

[8] *In re Wands*, 858 F.2d at 737.

[9] *Id.*

[10] Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F.3d 1380 (Fed. Cir. 2013).

[11] *Wyeth*, 720 F.3d at 1386.

by the specification, and the unpredictability of the art to uphold the district court's decision invalidating a genus of compounds largely defined by function and limited structural requirements.[12] Likewise, in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, the Federal Circuit yet again affirmed a district court determination invalidating claims where it found that identifying functional compounds would be like "finding a needle in a haystack."[13]

Factual Background

This case arises from a long and winding procedural posture. Amgen initially sued Sanofi and Regeneron in 2014, alleging that the biological product Praluent (alirocumab) infringed, *inter alia*, U.S. Patent Nos. 8,829,165 ("the '165 patent") and 8,859,741 ("the '741 patent").[14] The parties stipulated to infringement of claims 19 and 29 of the '165 patent and claim 7 of the '741 patent.[15] After a jury trial in 2016, the jury found that the patents were not invalid for lack of enablement and written description and the district court entered a permanent injunction.[16]

On appeal, the Federal Circuit vacated the permanent injunction and remanded for a new trial.[17] Critically, the Federal Circuit found that the district court improperly excluded post-priority-date evidence relating to enablement and written description.[18] On remand, the jury again determined that Sanofi failed to show the patents were invalid for failing to satisfy the enablement and written description requirements.[19] This time, however, the district court granted Sanofi's motion for judgment as a matter of law (JMOL) for lack of enablement.[20] Now, Amgen appealed and the Federal Circuit affirmed the district court's decision.[21]

Harnessing tailored antibodies for therapeutic purposes has been one of the major revolutions of modern biotechnology.[22] Antibodies are comprised of amino acid chains and are part of the immune system's natural mechanism of targeting and eliminating antigens from the body.[23] Antibody targeting is accomplished by portions of the antibody known as complementarity-determining regions, or "CDRs," which can uniquely bind to a specific location on an antigen (known as an "epitope").[24] Whether an antibody binds to an epitope depends on whether both have

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[12] Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019).

[13] Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1162 (Fed. Cir. 2019).

[14] *See, e.g.*, Amgen Inc. v. Sanofi, 987 F.3d 1080, 1083–84 (Fed. Cir. 2021) ("*Amgen II*") (describing procedural posture).

[15] *Id.*

[16] *Id.*

[17] Amgen v. Sanofi, 872 F.3d 1367, 1371 (Fed. Cir. 2017) ("*Amgen I*").

[18] *Id.*

[19] *Amgen II*, 987 F.3d at 1084.

[20] *Id.* (the district court denied Sanofi's motion for JMOL on written description).

[21] *Id.*

[22] *See* Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in support of Respondents at 8.

[23] *Id.*

[24] *Id.* at 9.

compatible interlocking surfaces.[25] This fit depends on the three-dimensional shape of the antibody, which in turn depends on how the amino acid chains of an antibody fold based on their sequences.[26] In *Amgen*, the Supreme Court recognized that "[a]ntibodies are incredibly diverse"[27] and "aspects of antibody science remain unpredictable."[28]

The antibodies claimed by the patents-in-suit bind a protein called PCSK9 and block the binding of PCSK9 to low density lipoprotein receptor (LDLR) protein.[29] Researchers had come to realize that blocking PCSK9 and LDLR interactions could be a way to treat patients with high LDL cholesterol.[30] Normally, LDL receptors extract LDL cholesterol from the bloodstream. Because PCSK9 degrades LDL receptors (leading to less extraction of LDL cholesterol), blocking the interaction of PCSK9 and LDLR by an antibody would facilitate LDL extraction.[31]

The patents-in-suit here claim antibodies by their function.[32] Critically, the claims do not recite the primary amino acid sequence of the claimed antibodies.[33] Rather, the claims are defined by the antibody's ability to bind one or more specified residues in the PCSK9 epitope and its functional ability to block the binding of PCSK9 to LDLR.[34] By contrast, the specification identifies the amino acid sequence of twenty-six antibodies that bind to the required residues in PCSK9 and block the binding of PCSK9 and LDLR.[35]

DECISION

The Supreme Court affirmed the lower court's invalidation of the asserted claims for failure to meet the enablement standard.[36] In an eloquently written opinion, speaking for a unanimous Court, Justice Gorsuch walked through the Court's early enablement cases and then analogized them to antibody technology.[37] The common thread running through the Court's early precedent could be boiled down simply: "[t]he more one claims, the more one must enable."[38] Because Amgen sought to claim "an entire universe of antibodies" and the specification inspired at most "research assignments," the Supreme Court upheld the lower court determinations.[39]

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[25] *Id.* at 10–12.

[26] *Id.*

[27] *Amgen*, 143 S. Ct. 1248.

[28] *Id.* at 1249.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.* at 1250.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.* at 1258.

[37] *Id.* at 1251–55.

[38] *Id.* at 1254.

[39] *Id.* at 1256.

The Court looked to its early cases for instruction. For example, the Court recounted Morse's attempt to patent not only the specific telegraphs he designed, but also the "essence" of his invention, which generally covered the use of electrical current for printing at any distance.[40] The *Morse* Court balked at this breadth, thinking it impossible for any specification to support this general idea.[41] Likewise in *Incandescent Lamp*, the Court described the failed attempt at covering Thomas Edison's bamboo filament light bulbs with a patent seeking "sovereignty over [the] entire kingdom" of all carbonized fibrous or textile material filaments.[42] And finally, the Court pointed to *Holland Furniture*, where the court rejected an attempt to cover not only the starch glue described in the specification, but other starch derivative glues that exhibited qualities "as good as animal glue."[43]

But the Court took pains to emphasize that an enabled specification need not disclose how to make and use every embodiment falling within a recited genus.[44] For instance, citing *Incandescent Lamp*, the Court observed that the disclosure of a "general quality" running through a class could be sufficient to reliably enable the entire class.[45] Along those lines, the Court explained that the specification permitted reasonable experimentation to reach the full scope of the claims.[46] Of course, the line between "reasonable" and "undue" may be a difficult one to draw.

Amgen argued that it would not have been undue experimentation to reach the full scope of the claims based on the specification. Amgen argued that the specification taught skilled artisans to make the entire universe of antibodies in two ways. In the so-called "roadmap approach," Amgen contended that the specification provided a stepwise "roadmap" that would guide skilled artisans to generate and test antibodies in a stepwise fashion.[47] In the so-called "conservative substitution" approach, Amgen argued that a skilled artisan would start with the twenty-six disclosed antibodies and would substitute amino acids known to have similar properties.[48] The Court found neither approach sufficient.[49] Calling the approaches merely a "research assignment" and a "hunting license," the Court found that the specification still left the skilled artisan faced with "painstaking experimentation" and uncertainty given the art.[50]

The Court also dismissed Amgen's criticisms of the Federal Circuit.[51] For example, Amgen argued that the Federal Circuit "conflated" the enablement standard with the length of time necessary to create every embodiment within the claims.[52] While the Court agreed that "enablement is not measured against the cumulative

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[40] *Id.* at 1252–53 (describing O'Reilly v. Morse, 15 How. 62 (1854)).

[41] *Id.*

[42] *Id.* at 1253–54 (describing The Incandescent Lamp Patent, 159 U.S. 465 (1895)).

[43] *Id.* at 1254 (describing Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245 (1928)).

[44] *Id.* at 1254–55.

[45] *Id.* at 1254.

[46] *See id.* at 1255.

[47] *Id.* at 1250.

[48] *Id.*

[49] *Id.* at 1256.

[50] *Id.* at 1256–57.

[51] *Id.* at 1257.

[52] *Id.*

time and effort it takes to make every embodiment within a claim," the Court did not read the Federal Circuit's opinion as implying anything to the contrary.[53] The Court also disagreed with Amgen's argument that the Federal Circuit's holding established a special standard for genus claims.[54] The Court agreed with Amgen in principle that there is a single unitary enablement standard, but again disagreed that the Federal Circuit applied anything but the correct standard.[55]

IMPACT OF THE DECISION

In some ways, the Court's decision in *Amgen* does not present a departure from Federal Circuit precedent for the enablement of genus claims in the life sciences. The Supreme Court confirmed that broad genus claims defined by function demand a level of disclosure that matches the breadth of the claims. As described above, the Federal Circuit had repeatedly upheld decisions invalidating functionally defined genus claims covering vast numbers of species in uncertain arts. Here, the Supreme Court avoided tangling with Federal Circuit precedent and opted to walk through its own historical precedents, brought to life by Justice Gorsuch's rich and compelling storytelling. But both threads ultimately reach the same conclusion. As summed up by the Court in *Amgen*: the more one claims, the more one has to enable.

It was not a long wait to see the impact of *Amgen*. In *Baxalta Inc. v. Genentech, Inc.*, the Federal Circuit upheld the district court's summary judgment finding claims directed to an antibody that binds Factor IX or Factor IXa and that increases procoagulant activity.[56] The Federal Circuit found the facts in *Baxalta* "materially indistinguishable" from *Amgen*.[57] The Federal Circuit stated that the trial and error testing necessitated by the specification "leaves the public no better equipped to make and use the claimed antibodies than the inventors were" when they set out to discover them.[58] The Federal Circuit also confirmed that *Amgen* did not disrupt the longstanding *Wands* factors.[59]

The issues raised in *Amgen v. Sanofi* are closely adjacent to issues faced by FDA regulatory attorneys in the biologics space. For example, FDA attorneys counseling on Biologics License Applications (BLA) approval requirements should be sensitive to the patent issues faced by their patent attorney colleagues. Moreover, arguments regarding the validity of patents covering antibody biologics are often directly applicable to the patent resolution mechanisms of the BPCIA. In both instances, coordination and communication between FDA regulatory attorneys and patent attorneys are helpful to ensure consistent decision-making.

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[53] *Id.*

[54] *Id.*

[55] *Id.*

[56] Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362 (Fed. Cir. 2023).

[57] *Baxalta*, 81 F.4th at 1366.

[58] *Id.* at 1367.

[59] *Id.*

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

BRYANT GODFREY & TINA PAPAGIANNOPOULOS*

I. WHY THIS CASE MADE THE LIST

Mifepristone has been available in the United States as part of an approved medication abortion regimen for over twenty years. In an unprecedent decision, a Texas district court granted a motion for summary judgment filed by anti-abortion activists, who asked the court to suspend virtually all of the U.S. Food and Drug Administration's (FDA's) decisions and actions with respect to the drug's approval. The Texas court's order caught nationwide attention because of its sweeping implications on access to 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 case was appealed 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 negate subsequent changes to the FDA's approval regarding the drug's conditions of use and administration. If these changes take effect, access to this regimen will be available only through in-person administration, and only to women whose pregnancy has not progressed beyond seven weeks of gestational age.

The Fifth Circuit's decision is now pending before the Supreme Court. According to the government, "[T]his case marks the first time any court has restricted access to an FDA-approved drug by second-guessing FDA's expert judgment about the conditions required to assure that drug's use."[1] The pharmaceutical and biotechnology industries have been following this case with anticipation and have cautioned the Court that upending the drug approval process in the manner suggested by the lower courts would have devastating ripple effects on research and investment in innovative therapies.

Oral arguments were held on March 26, 2024, and a decision is expected by the end of June.

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[1] 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.

II. SUMMARY OF THE CASE

The regulatory status of mifepristone hangs in the balance pending a Supreme Court appeal of decisions made by a federal court in Texas and the Fifth Circuit Court of Appeals in *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*.[2] Mifepristone is the first part of a two-drug regimen, which has been legally prescribed by physicians for use with misoprostol since 2000 for the medical termination of early pregnancy.

The case was brought in November 2022 by four anti-abortion medical organizations, the Alliance for Hippocratic Medicine (AHM), American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), American College of Pediatricians (ACOP), and Christian Medical & Dental Associations (CMDA) on behalf of themselves, their members, and their patients, and four individual doctors on behalf of themselves and their patients. Plaintiffs filed a motion for a preliminary injunction in the U.S. District Court for the Northern District of Texas, naming the U.S. Food and Drug Administration (FDA), the FDA Commissioner and other top officials, the U.S. Department of Health and Human Services (HHS), and the HHS Secretary as defendants. The motion asked the court to overturn virtually all of FDA's reviews and actions with respect to mifepristone since 2000—which would render the product an unapproved drug—and essentially disregard the federal drug approval regime that has long relied on FDA's scientific expertise in making approval decisions. Allegations in the complaint challenge the procedural integrity of FDA's review process as well as the underlying safety and effectiveness data relied upon by FDA to approve mifepristone in 2000 and subsequent changes to the labeling and conditions of use.

The defendants' opposition to the motion for preliminary injunction refuted the allegations of procedural inadequacies, explained FDA's authority to review and approve drugs as mandated by Congress, and detailed the extensive twenty-three-year history of safety and effectiveness data supporting all of FDA's actions regarding the use of mifepristone.

Numerous *amicus curiae* briefs have been filed in support of both sides. For example, amicus briefs were filed in the district court by twenty-two states and several organizations in support of the plaintiffs' motion.[3] Amicus briefs in support of FDA, filed by twenty-one states and the District of Columbia, American College of Obstetricians and Gynecologists, the American Medical Association, and other medical professionals, and nineteen FDA law scholars, highlighted the extensive safety profile of mifepristone and the thoroughness of FDA's review, and warned of the potential unraveling of a rigorous regulatory framework for the approval of all drugs.[4] Amicus briefs were also filed in the appellate courts by a variety of interested

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[2] All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 22-cv-223 (Apr. 7, 2023), 2023 WL 2825871; All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210 (5th Cir. 2023).

[3] Amicus Curiae Brief of Miss. et al. in Supp. of Pls.' Mot. For Prelim. Inj., All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z (N.D. Tex. Feb. 10, 2023), ECF 55-1.

[4] Brief for the States of N.Y. et al. as Amici Curiae in Supp. of Defs. & in Opp'n to Pls.' Mot. For Prelim. Inj., All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z (N.D. Tex. Feb. 10, 2023), ECF 59-1; Brief of Amici Curiae Medical & Pub. Health Soc'ys in Opp'n to Pls.' Mot. for Prelim. Inj., All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z (N.D. Tex. Feb. 10, 2023), ECF 99-1; Unopposed Mot. of Food & Drug Law Scholars for Leave to File Amicus

persons and organizations, including pharmaceutical industry groups, patient advocacy groups, reproductive rights groups, religious coalitions, and members of Congress.

A. Factual Background/Regulatory History of Mifepristone

A review of the regulatory history of mifepristone and some of the associated political tug-of-war is necessary to fully understand this case.

FDA first approved a new drug application (NDA) for mifepristone, branded as Mifeprex, for use with misoprostol (a previously approved drug) in September 2000 for medical termination of intrauterine pregnancy through seven weeks gestation. This approval followed a tumultuous and politically fraught journey to the U.S. market and involved a lengthy four years of FDA deliberations from the time of submission to approval, notwithstanding strong support from the American Medical Association (AMA), a battery of completed clinical studies, and a decade of postmarketing experience in France, Sweden, and the United Kingdom.[5]

Mifeprex was approved pursuant to FDA's regulations in 21 C.F.R. 314 Subpart H.[6] As part of its approval, FDA required confirmatory post-market studies as well as certain conditions of use: that the drug be provided in-person and under the supervision of a qualified physician, distributed under a controlled system, and dispensed with a patient Medication Guide (MedGuide). The supervising physician was required to attest to being able to accurately assess the duration of a pregnancy, diagnose an ectopic pregnancy, and provide surgical intervention in cases of incomplete abortion or severe bleeding or assure that patients have access to appropriate follow up care if needed to manage complications. The supervising physician was also required to notify the sponsor in the event of an ongoing pregnancy that was not terminated subsequent to the conclusion of the treatment procedure and to report any hospitalization, transfusion, or other serious events to the sponsor.

In August 2002, plaintiff AAPLOG, along with the Christian Medical Association and Concerned Women for America, submitted a citizen petition requesting that FDA revoke the approval of Mifeprex and impose an immediate stay on the drug's approval pending final action on the petition.[7] The petitioners raised safety arguments about the abortion regimen, argued that the approval violated the legal requirements of FDA's accelerated approval regulations in Subpart H, and questioned the scientific quality of the trials used to support the product's NDA.

Curiae Brief in Supp. of Defs., All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z (N.D. Tex. Feb. 10, 2023), ECF 70.

[5] Associated Press, *AMA Endorses Testing, Use of French Abortion Pill*, WASH. POST, June 28, 1990; Derek Hawkins, *For Abortion Pill Mifepristone, Political Battle is Nothing New*, WASH. POST, Mar. 22, 2024; U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, REP. TO CONG. REQUESTERS, FOOD & DRUG ADMIN.—APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX (Aug. 2008), https://www.gao.gov/assets/gao-08-751.pdf.

[6] U.S. FOOD & DRUG ADMIN., Approval Letter (Mifeprex), NDA 20-687, (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.

[7] Citizen Pet. from Am. Ass'n of Pro-Life Obstetricians & Gynecologists, Docket No. FDA-2002-P-0364 (Aug. 20, 2002).

Congress subsequently enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA).[8] In response to safety concerns surrounding Vioxx and other prescription drugs, FDAAA added Risk Evaluation and Mitigation Strategies (REMS) authorities to the Federal Food, Drug, and Cosmetic Act (FDCA), which expanded upon and integrated FDA's existing tools (such as labeling and communication plans, restricted dispensing, and patient registries) to manage safety issues with select drugs and ensure that the benefits of such drugs outweighed the risks of serious complications. Drugs that were approved prior to 2007 were automatically deemed by FDAAA to be subject to an approved REMS if they were subject to "elements to assure safe use" (ETASU) under Subpart H regulations.[9]

FDAAA required sponsors of such "deemed" drugs to submit a proposed REMS to FDA. Danco Laboratories, LLC, the sponsor of the Mifeprex NDA, submitted a supplemental new drug application (sNDA) with a proposed REMS, and FDA approved the sNDA in June of 2011.[10] The 2011 REMS required a MedGuide, ETASU, a controlled distribution system, and a timetable for submission of assessments of the REMS.[11] The ETASU required that prescribers of Mifeprex be specially certified and that they sign a Prescriber's Agreement Form agreeing that they meet the specified qualifications (which were the same as those required in the initial approval); that they will follow the guidelines in the agreement; and that they will report any ongoing pregnancy not terminated subsequent to the conclusion of the treatment procedure as well as any hospitalization, transfusion, or other serious event to Danco. In addition, the drug could only be dispensed in certain health care settings by or under the supervision of a certified physician and only to patients who signed a Patient Agreement Form. These agreements required that the patient return to the provider's office or clinic two days later to receive misoprostol and return for a follow-up visit fourteen days later.

On March 29, 2016, FDA approved a subsequent sNDA filed by Danco to modify Mifeprex's indication, labeling, and REMS.[12] Specifically, FDA approved a labeling change that extended the indication from seven weeks to ten weeks gestation based on safety and effectiveness data from multiple studies that were submitted to FDA in the supplement. FDA also assessed the mifepristone REMS program to "determine whether each element remains necessary to ensure that the drug's benefits outweigh the risks."[13] The revised REMS reduced the number of required in-person clinic visits required to one. Mifepristone was still required to be dispensed in person by or under the supervision of a certified prescriber in certain healthcare settings. However, the patient was permitted to take the misoprostol tablets at home and the Patient Agreement recommended, but did not require, that the patient follow up with

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[8] U.S. Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 100-85, 121 Stat. 823 (2007).

[9] Pub. L. No. 110-85, § 909(b)(1); *see also* 73 Fed. Reg. 16,313 (Mar. 27, 2008).

[10] U.S. FOOD & DRUG ADMIN., SUPP. APPROVAL (MIFEPREX), NDA 020687/S-014 (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf.

[11] U.S. FOOD & DRUG ADMIN., RISK EVALUATION & MITIGATION STRATEGY (REMS) (MIFEPREX), NDA 20-687 (2011), https://www.fda.gov/media/164648/download.

[12] U.S. FOOD & DRUG ADMIN., SUPP. APPROVAL (MIFEPREX), NDA 020687/S-020 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf [hereinafter 2016 Approval Letter].

[13] *Id.*

the healthcare provider a week or two after taking mifepristone.[14] FDA determined, after reviewing several published studies, that at-home administration of misoprostol was safe because of "exceedingly low rates of serious adverse events" and that there was no significant difference in outcomes based on whether patients underwent self-assessment of health or had follow-up appointments via phone call or in-person.[15] FDA allowed other healthcare providers, not only physicians, who meet the REMS certification requirements to prescribe mifepristone, finding no serious health concerns associated with such prescribing. Although prescribing providers were required to report deaths to Danco, the revised REMS no longer required that prescribers report other serious adverse events to Danco. FDA also dispensed with the requirement that the MedGuide specifically be part of the REMS "to minimize the burden on the healthcare delivery system of complying with the REMS."[16]

On the same day, FDA denied the 2002 citizen petition requesting to revoke the original Mifeprex NDA.[17] The agency defended its original approval of the drug under Subpart H, pointed out that the application was deemed to have in effect a REMS in 2007 and has had an approved REMS since 2011, and responded to the petitioners' arguments with respect to the safety of the drug and the quality of the clinical trials the agency relied upon when it approved the application. FDA also advised the petitioners that its concurrent decision to approve an sNDA with updated dosing and labeling does not reflect a decision that there were any safety or effectiveness concerns with the previous regimen.

In March 2019, plaintiffs AAPLOG and ACOP filed a citizen petition with FDA requesting that the agency "restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000," retain the Mifeprex REMS, and continue limiting the dispensing of Mifeprex so that it could only be dispensed to patients in clinics, medical offices, and hospitals by or under the supervision of a physically present certified physician who has ruled out ectopic pregnancy. The citizen petition argued that the drug should be limited to seven weeks of gestation and that certified prescribers should be required to report "deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications directly to FDA."[18]

FDA approved an abbreviated new drug application (ANDA) submitted by GenBioPro, Inc. for a generic version of mifepristone on April 11, 2019 and approved a "shared system" REMS that was required for all mifepristone products

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[14] *Id.*

[15] U.S. FOOD & DRUG ADMIN., SUMMARY REVIEW FOR REGULATORY ACTION (MIFEPREX), NDA 020687/S-020 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf.

[16] 2016 Approval Letter, *supra* note 12.

[17] Citizen Pet. Denial Resp. from U.S. Food & Drug Admin. to the Am. Ass'n of Pro-Life Obstetricians & Gynecologists et al., Docket FDA-2002-P-0364 (Mar. 29, 2016), https://www.regulations.gov/document/FDA-2002-P-0364-0002.

[18] Citizen Pet. From Am. Ass'n of Pro-Life Obstetricians & Gynecologists & Am. Coll. of Pediatricians, Docket FDA-2019-P-1534 (Mar. 29, 2019), https://www.regulations.gov/document/FDA-2019-P-1534-0001.

approved for medical abortion.[19] The ETASU under the shared system REMS were substantially the same as those under the 2016 REMS for Mifeprex.[20]

The agency announced in March 2020 that FDA would exercise enforcement discretion during the COVID-19 public health emergency by refraining from enforcing laboratory testing (e.g., liver enzyme testing) or imaging study requirements (e.g., magnetic resonance imaging) in applicable REMS programs.[21] On April 20, 2020, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal Fetal Medicine (SMFM) sent a letter to FDA requesting that the agency expand this policy to REMS requirements for mifepristone and certain other prescription drugs requiring in-person administration because these requirements serve as a barrier to accessing the treatment and "cause unnecessary delays in obtaining time-sensitive healthcare, without supporting improvements to patient safety or outcomes."[22] Numerous other organizations similarly urged FDA to suspend the in-person administration requirement of the mifepristone REMS on the same public health grounds.[23]

In May 2020, ACOG and other parties, supported by *amici curiae* briefs from national health organizations and twenty-three state attorneys general, successfully filed suit in U.S. district court to enjoin the Trump Administration from enforcing the in-person requirements.[24] The district court concluded that these requirements placed a "substantial obstacle" to women securing abortions during the pandemic, allowing for mail delivery of mifepristone nationwide.[25] The Trump Administration appealed and fought the injunction throughout 2020, and in January 2021, the Supreme Court granted an emergency stay of the injunction.[26]

The change in Administration, the ACOG lawsuit, and a pending 2017 lawsuit filed by the American Civil Liberties Union (ACLU), persuaded FDA Acting Commissioner Janet Woodcock and Center for Drug Evaluation and Research (CDER) Director Patrizia Cavazzoni to undertake a comprehensive review of the mifepristone REMS.[27] FDA wrote to the ACOG and SMFM in April 2021 in response to their April 2020 letter explaining that the agency had conducted a

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[19] U.S. FOOD & DRUG ADMIN., ANDA APPROVAL (MIFEPRISTONE), ANDA 091178 (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.

[20] U.S. FOOD & DRUG ADMIN., INITIAL SHARED SYSTEMS REMS APPROVAL (Apr. 2019), https://www.fda.gov/media/164650/download.

[21] U.S. FOOD & DRUG ADMIN, POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY GUIDANCE FOR INDUSTRY AND HEALTH CARE PROFESSIONALS, DOCKET NO. FDA-2020-D-1106 (Mar. 2020), https://www.regulations.gov/document/FDA-2020-D-1106-0018.

[22] Letter from the Am. Coll. of Obstetricians & Gynecologists & Soc'y for Maternal-Fetal Med. to the U.S. Food & Drug Admin. (Apr. 20, 2020), https://www.aclu.org/documents/letter-fda-acog-and-smfm.

[23] Letter from Organizations and Health Care Providers to Food & Drug Admin. (Apr. 28, 2020), https://downloads.regulations.gov/FDA-2020-D-1106-0100/attachment_1.pdf.

[24] Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 472 F. Supp. 3d 183 (D. Md. 2020).

[25] *Id.* at 216.

[26] U.S. Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578 (Jan. 2021).

[27] J. Mot. to Stay Pending Agency Review, Chelius v. Becerra, 2023 U.S. Dist. LEXIS 137629 (2023), No. 1:17-00493 JAO-RT (D. Haw. May 7, 2021), ECF 148.

literature and adverse event review and decided to exercise enforcement discretion during the public health emergency towards the mifepristone in-person dispensing and patient requirements, as well as the dispensing of mifepristone by mail under a certified provider's supervision following a telehealth consultation by a certified provider.[28]

In December 2021, FDA completed its comprehensive review of the mifepristone REMS program and decided to make its COVID-related changes permanent.[29] The agency directed the drug's sponsors to submit proposals to revise the shared system REMS to permit the drug to be dispensed by certified licensed health care providers and pharmacies (including retail pharmacies) and require that pharmacies that dispense the drug be certified accordingly. The sponsors subsequently prepared a proposed REMS modification and submitted it to their respective applications.

FDA also responded to the plaintiffs' 2019 citizen petition in December 2021 by denying their request to restore and strengthen the regimen and prescriber requirements and granting in part and denying in part the request to retain the mifepristone REMS.[30] Specifically, FDA found that certain elements of the REMS program (such as the healthcare provider certification) continued to be necessary to ensure safe use but that the REMS must be modified to remove the requirement that mifepristone be dispensed in person only in certain healthcare settings.

FDA approved the drug sponsors' application supplements on January 3, 2023, permanently removing the in-person dispensing requirements from the shared system REMS.[31] The REMS requires pharmacies that intend to become certified to dispense mifepristone to complete a Pharmacy Agreement Form. By signing this form, the pharmacy agrees to establish processes and procedures to ensure compliance with various requirements, including verifying that the prescriber is certified, ensuring that the patient receives the drug within an appropriate time period, tracking and verifying the receipt of each shipment of the drug, and fulfilling various reporting and recordkeeping requirements.[32]

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[28] Letter from U.S. Food & Drug Admin. to Am. Coll. of Obstetricians & Gynecologists & Soc'y For Maternal-Fetal Med. (Apr. 12, 2021), https://www.aclu.org/documents/fda-response-acog-april-2021.

[29] Letter from U.S. Food & Drug Admin. to The Society of Family Planning (Dec. 16, 2021), https://www.aclu.org/sites/default/files/field_document/fda_letter_to_chelius.pdf.

[30] Response Letter from U.S. Food & Drug Admin. to Citizen Pet. Submitted by Am. Coll. of Obstetricians & Gynecologists & Soc'y for Maternal-Fetal Med., Docket No. FDA-2019-P-1534-0016 (Dec. 16, 2021), https://www.regulations.gov/document/FDA-2019-P-1534-0016.

[31] U.S. FOOD & DRUG ADMIN., SUPP. APPROVAL (MIFEPREX), NDA 02000687/S-025 (Jan. 03, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/020687Orig1s025ltr.pdf [hereinafter MIFEPREX NDA SUPP. APPROVAL]; U.S. FOOD & DRUG ADMIN., PRIOR APPROVAL SUPP. APPROVAL (MIFEPRISTONE), ANDA 091178/S-004 (Jan. 03, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/091178Orig1s004ltr.pdf; U.S. FOOD & DRUG ADMIN., SUMMARY REVIEW (MIFEPREX), NDA 020687/S-025 (Jan. 3, 2023), https://www.accessdata.fda.gov/DRUGSATFDA_DOCS/NDA/2023/020687ORIG1S025.PDF; U.S. FOOD & DRUG ADMIN., APPROVED RISK EVALUATION AND MITIGATION STRATEGIES (REMS) (Mar. 23, 2023), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.

[32] MIFEPREX NDA SUPP. APPROVAL, *supra* note 31; U.S. FOOD & DRUG ADMIN., ANDA 091178, GENBIOPRO PHARMACY AGREEMENT FORM (MIFEPRISTONE TABLETS, 200MG) https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Pharmacy_Agreement_Form_for_GenBioPro_Inc..pdf.

B. Lower Court Decisions

In the pending lawsuit, the plaintiffs asked the district court in their complaint and motion for preliminary injunction, among other things, to overturn:

> (1) FDA's 2000 approval of Mifeprex;
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> (2) FDA's 2016 changes to the Mifeprex REMS and drug labeling;
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> (3) FDA's 2016 denial of the first citizen petition;
>
> (3) FDA's 2019 approval of the generic version of mifepristone;
>
> (4) FDA's subsequent changes to the Mifepristone REMS Program, including the 2021 enforcement discretion decision; and
>
> (5) FDA's 2021 response to the plaintiffs' second citizen petition concerning the in-person dispensing requirement for mifepristone.[33]

The plaintiffs also asked the court to enter declarative relief including a declaration that the FDCA prohibits FDA from approving any marketing application "that fails to limit distribution of chemical abortion drugs" under a federal law enacted in 1873 referred to as the Comstock Act, which prohibits sending any articles designed, adapted, or intended for producing abortion through the U.S. mail.[34] As explained below, such declarative relief is not consistent with an opinion taken by the U.S. Justice Department's Office of Legal Counsel in December 2022, which concluded that the Comstock Act does not prohibit the mailing of mifepristone or misoprostol where the sender lacks the intent that the recipient will use them unlawfully.[35]

Shortly after the Supreme Court overturned *Roe v. Wade* in June of 2022, the United States Postal Service (USPS) asked the Department of Justice (DOJ) for guidance on how to approach the mailing of medication abortion. Specifically, USPS asked DOJ to opine on whether the mailing of mifepristone and misoprostol violates the Comstock Act, which provides that "[e]very article or thing designed, adapted, or intended for producing abortion," as well as "[e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion," is a "nonmailable matter" that USPS may not lawfully deliver.[36]

The DOJ opinion notes that the "consensus interpretation" over the last century, among courts, Congress, and USPS has been that the Comstock Act does not prohibit a sender from conveying such items where the sender does not intend for the items to be used unlawfully. In practice, this means the Comstock Act would not encompass the mailing of such items where the individual does not have knowledge that the items will be used unlawfully. Notwithstanding the significant variation in abortion laws across states, the relevant drugs can be used lawfully to some degree in all fifty

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[33] Pls.' Brief in Supp. of their Mot. for Prelim. Inj., U.S. Food & Drug Admin. v. All. for Hippocratic Med., No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022), ECF 7, U.S. LEXIS 1504 (2023).

[34] Compl. at 111, All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022), ECF 1.

[35] U.S. Dep't of Justice, Mem. Op. for the Gen. Counsel U.S. Postal Service, Slip Op., Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions (Dec. 23, 2022), https://www.justice.gov/olc/opinion/file/1560596/dl?inline.

[36] Comstock Act, 18 U.S.C. 1461.

states. According to the memo, "the fact that the drugs are being mailed to a jurisdiction that significantly restricts abortion is not a sufficient basis for concluding that mailing" violates the statute.

The defendants' opposition to the plaintiffs' motion for preliminary injunction argues, among other things, that 1) plaintiffs have no legal standing or interest allowing them to challenge FDA's approvals and related actions; 2) most, if not all, of plaintiffs' claims are barred by the statute of limitations; 3) the only possibly actionable challenge is to FDA's 2019 denial of plaintiffs' citizen petition, in which they only asked FDA to revert the 2016 REMS restrictions for mifepristone to the original restrictions established in 2000; and 4) plaintiffs have suffered no harm, much less any imminent or irreparable harm, to justify a preliminary injunction.[37] As the holder of the approved NDA for Mifeprex, Danco was permitted to intervene in the case and filed its own opposition to the plaintiffs' demands, citing two-plus decades of safety and effectiveness data and information and multiple FDA evaluations.[38]

The government also argues that FDA's approval decisions are made pursuant to the FDCA and the Public Health Service Act (PHSA). Although the Comstock Act and other laws (such as state wholesale distribution laws and state licensing laws concerning the practice of medicine) may affect how a medical product is used or distributed, FDA is not required to account for these laws and does not have the authority to deny a drug application based on the implication of these laws. Even if FDA were required to consider the Comstock Act, the government argues, FDA's decisions related to in-person dispensing were not inconsistent with the Comstock Act because the Comstock Act does not prohibit the mailing or other conveyance of abortion-inducing drugs under all circumstances.[39]

A hearing on the motion for preliminary injunction was held on Wednesday, March 15, 2023, in the District Court for the Northern District of Texas, Amarillo Division, before Judge Matthew J. Kacsmaryk. Judge Kacsmaryk issued a preliminary injunction order on April 7, 2023 that purported to stay every decision FDA has made regarding mifepristone since its approval in 2000, including modifications to the drug's conditions for use in 2016, the approval of the generic version in 2019, and the 2021 suspension of the requirement for in-person dispensing under the drug's REMS. The Texas court rejected several substantial procedural arguments that were raised by the government (including standing, statute of limitations, and ripeness) to find that plaintiffs had a substantial likelihood of success on the merits that FDA's approval of the drug was arbitrary and capricious.

On April 12, 2023, a panel of the United States Court of Appeals for the Fifth Circuit granted in part an emergency request by the government and Danco to stay the Texas Order pending a decision on the merits.[40] The Fifth Circuit's emergency stay order preserved FDA's 2000 approval of the drug based on the statute of

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[37] Defs.' Opp'n to Pls.' Mot. for Prelim. Inj., All. for Hippocratic Med. v. U.S. Food & Drug Admin., 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023), ECF 28.

[38] Intervenor Danco Lab'ys, LLC's Mem. of Points & Auths. in Opp'n to Pls.' Mot. for a Prelim. Inj., All. for Hippocratic Med. v. U.S. Food & Drug Admin., 2:22-cv-00223-Z (N.D. Tex. Jan. 10, 2023), ECF 50.

[39] Defs.' Opp'n to Pls.' Mot. for Prelim. Inj., *supra* note 37, at 28–30.

[40] All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 23-10362 (5th Cir. Apr. 12, 2023) https://www.ca5.uscourts.gov/opinions/unpub/23/23-10362.0.pdf.

limitations, but it declined to reject the Texas Order's rulings with respect to changes FDA made to the drug's approval beginning in 2016. The Fifth Circuit's ruling would therefore have preserved some levels of access to Mifeprex (the brand drug) but with the same restrictions and conditions of use that were in place in 2011 and would have restricted access to the generic mifepristone.

In response to a motion for an emergency stay of relief filed by the government and Danco, the Supreme Court ruled on April 21, 2023 that the entire Texas Order be stayed pending the appeal in the Fifth Circuit and a potential petition for the Appellate Decision to be reviewed by the Supreme Court.[41] This order ensured that brand and generic mifepristone would remain available under the current conditions of use at least through the Fifth Circuit's decision.

The government's appeal to the Fifth Circuit contended that the Texas court inappropriately substituted its own judgment for the expert opinion of FDA, mischaracterized the level of clinical trial evidence necessary to support a drug's conditions of use, and erred in its evaluation of the science. According to the appellants, the court ignored the vast record of safety and efficacy that the agency considered during its comprehensive administrative reviews of the data as well as the decades-long history of safe use, and instead relied upon studies that were not part of the administrative record and that were scientifically unsound.

The Fifth Circuit affirmed in part and vacated in part, vacating the district court's holdings that FDA's original approval of mifepristone in 2000 and approval of a generic in 2019 were unlawful. The court found that the claim with respect to the 2000 approval was likely barred by the statute of limitations and that the plaintiffs did not establish organizational injury based on the approval of the generic version of the drug. However, the court found that FDA's 2016 amendments to the drug approval conditions and decision to exercise enforcement discretion in 2021 were arbitrary and capricious under the Administrative Procedure Act (APA).[42]

The government appealed the Fifth Circuit's decision to the Supreme Court.

C. Issues Before the Supreme Court

Below are the issues that were presented to the Supreme Court.

> (1) Whether the Alliance (and other respondents) have standing to challenge FDA's 2016 and 2021 actions.
>
> (2) Whether FDA's 2016 and 2021 actions were arbitrary and capricious under the APA.
>
> (3) Whether the district court properly granted preliminary injunctive relief.

The appellants argued that the respondents lacked standing under Article III of the U.S. Constitution because they were unable to establish a cognizable injury or that their asserted injuries were fairly traceable to FDA's 2016 and 2021 actions.[43] The government also defended each of FDA's actions, arguing that the agency acted lawfully when it changed the conditions of use and REMS requirements for the drug.

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[41] Order on Application for Stay, Danco Lab'ys., L.L.C. v. All. for Hippocratic Med., No. 22A901, 598 U.S. __ (Apr. 21, 2023).

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

[43] Brief for the Federal Petitioners, *supra* note 1.

According to appellants, even if the plaintiffs had standing and FDA's actions were arbitrary and capricious, the district court's remedy was improper because the balance of equities and the public interest did not support preliminary injunction relief.

Article III Standing

Whether the respondents have Article III standing is a paramount issue. Respondents alleged that they and their members are harmed by FDA's actions regarding mifepristone because women experiencing complications from taking mifepristone can "overwhelm the medical system" and place "enormous pressure and stress" on doctors to treat these emergencies; these doctors may be forced into situations in which they feel complicit in facilitating an abortion against their moral beliefs; and doctors who are forced to treat these women are unable to practice "evidence-based medicine" due to their inability to obtain informed consent given the "inaccurate and false safety profile" of this regimen that FDA allegedly created.[44] Respondents also alleged that their efforts to treat women who experience complications from mifepristone due to FDA's actions have diverted them away from other priorities.[45]

The government vehemently contests that the respondents have standing because these assertions of harm rely upon a series of speculative contingencies that include the actions of independent actors. At the heart of the argument is whether the respondents have a cognizable injury. The Fifth Circuit held that the respondents made a sufficient showing of associational standing because a certain percentage of women who take mifepristone will experience adverse events or require surgical abortions, that some percentage of these women will seek emergency care, and that some of the organizations' members are likely to treat patients who experience such adverse effects.[46] The circuit court found that there was a substantial risk of injury to the respondents' members and that the injury was cognizable because providing this treatment may violate the conscience of these physicians, divert time and resources away from their other patients, and expose them to greater liability and insurance costs.[47]

According to the appellants, the respondents failed to establish whether any of their members have conscientiously objected to performing such procedures and, if so, why they chose to proceed rather than invoking applicable conscience protections. The government further points out that "stress and pressure" are part of the job for doctors who have chosen to provide emergency care in hospital settings, and the respondents "have not cited any authority suggesting that simply being presented with a person in need of emergency care qualifies as an Article III injury to a doctor whose chosen profession is treating patients in an emergent setting."[48] The appellants further contend that the respondents' standing argument is based on a "statistical probability that some of their unidentified members might be called upon to treat women" who were prescribed the drug and experienced "exceedingly rare"

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[44] Pls.' Brief in Supp. Of their Mot. for Prelim. Inj., *supra* note 33, at 8–9.

[45] *Id.* at 7.

[46] *All. for Hippocratic Med.*, 78 F.4th at 232–33.

[47] *Id.* at 235–36.

[48] Brief for the Federal Petitioners, *supra* note 1, at 26.

adverse events.[49] Moreover, the government argues that the Fifth Circuit erred in holding that the respondents' alleged injuries are fairly traceable to FDA's actions in 2016 and 2021, which made incremental changes addressing the drug's conditions of use.[50] Such an attenuated statistical approach to standing, the government argues, has been emphatically rejected by the Supreme Court.[51]

Administrative Procedure Act

The appeal also challenged the Fifth Circuit's holdings that FDA acted arbitrarily and capriciously in violation of the APA when it approved the changes to the conditions of use and the revised REMS in 2016 and when it removed the in-person dispensing requirement in 2021. The Fifth Circuit found that FDA's failure to consider the cumulative effect of increasing the maximum gestational age in the conditions of use from seven weeks to ten weeks, expanding the types of healthcare providers who could prescribe mifepristone, removing the in-person requirements for the misoprostol administration and subsequent follow-up appointment, removing the prescribers' obligation to report non-fatal adverse events, and other changes to the approval and REMS conditions in 2016 were likely arbitrary and capricious.[52]

The Fifth Circuit also found shortcomings in FDA's explanations for its decision in 2021 to remove the in-person dispensing requirement and therefore determined that the respondents were likely to succeed in showing that this action also violated the APA.[53] The court found FDA's rationale deficient in part because FDA examined adverse event data collected during a period of time when prescribers were no longer required to report non-fatal adverse events, eliminating "perhaps the best source of data" on the drug's safety profile.[54] FDA's rationale was also deficient, according to the court, in part because FDA also relied on studies that were "merely not inconsistent" with its conclusion rather than studies that affirmatively supported its position.[55]

The appellants defended FDA's decisions by pointing to the agency's "exhaustive review" of "experience and data gained in the last 20 years from millions of women in the U.S. and abroad" and discussing various studies that supported the agency's decisions.[56] With respect to FDA's actions in 2016, the government argues that the APA only requires an agency to review the record and reasonably consider the relevant issues and provide a reasonable explanation for its decisions. The agency was not required under this standard to commission or conduct scientific studies that examined the cumulative effect of its changes but rather would be justified in relying on the data that it had used to determine that the changes that it had concluded were safe individually to predict that the changes would be safe collectively.[57] Despite this

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[49] *Id.* at 12.

[50] *Id.* at 28–29.

[51] *Id.* at 18.

[52] *All. for Hippocratic Med.*, 78 F.4th at 246.

[53] *Id.* at 250–51.

[54] *Id.* at 249–51.

[55] *Id.* at 250–52.

[56] Brief for the Federal Petitioners, *supra* note 1, at 35.

[57] *Id.* at 36–37.

point, the appellants contend that FDA had in fact considered "at least three studies that closely mirrored challenged aspects of the 2016 conditions" and that the agency had adequately explained its reasoning.[58]

The appellants likewise defended FDA's decision in 2021 when it removed the in-person dispensing requirement by discussing FDA's analysis of reported clinical studies and review of adverse event data. The government pointed out that manufacturers of all drugs are required to report adverse events, which FDA routinely monitors, and that FDA's changes in 2016 did not remove the reporting requirements governing mifepristone's sponsors. According to the government, the arbitrary and capricious standard under the APA is deferential and "does not give litigants or the courts a license to unduly second-guess the agency's scientific judgements," and the APA did not "compel FDA to maintain heightened reporting requirements it had determined were unnecessary to account for changes in risk that FDA had determined would not occur."[59]

Balance of Harms and Public Interest

Lastly, the appellants contend that even if the plaintiffs have standing and were likely to succeed on the merits of their claim that FDA's actions were arbitrary and capricious, the lower courts erred in their deliberation of the balance of equities and public interest factors necessary to support preliminary injunction relief. According to the government, the portions of the district court order that were affirmed by the Fifth Circuit "would impose grave harms on the government, mifepristone's sponsors, women seeking legal medication abortions, and the public" and that "respondents' asserted injuries cannot remotely justify the disruptive alteration of the status quo that the district court's preliminary relief would entail."[60]

III. IMPLICATIONS FOR ACCESS TO MIFEPRISTONE

The plaintiffs almost succeeded in blocking FDA's approval of mifepristone entirely and depriving women across the country of a treatment that FDA has determined to be safe and effective for terminating early pregnancy when used in accordance with the drug's approved conditions of use. For many patients, medication abortion is a safer method than surgical abortion, which can carry heightened risks for some patients, such as those who are allergic to anesthesia. Access to surgical abortion is also limited for many patients, even in states where abortion is legal, due to practicalities and costs associated with undergoing surgery.

Although the Fifth Circuit did not affirm the district court's decision in its entirety, reverting to the conditions of approval and REMS that were applicable to mifepristone in 2016 would deny access to this treatment for women whose pregnancy has progressed beyond seven weeks of gestational age while simultaneously forcing women to overcome additional hurdles to obtain the regimen in a timely manner.

Republican states favor the in-person dispensing requirements because allowing patients to access a prescriber through telehealth services and receive the regimen

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[58] *Id.* at 38–39.

[59] *Id.* at 42–44.

[60] *Id.* at 42–46.

through the mail threatens their ability to enforce their respective state's abortion bans. Democratic states, on the other hand, argue that continued access to mifepristone is especially important in meeting the increased demand for clinics caused by an influx of out-of-state patients seeking abortion care. They contend that imposing restrictions on access to mifepristone would reduce the availability of care to both in-state and out-of-state patients and will potentially drive more patients toward procedural abortion. These states also stress the importance of telehealth services in expanding care to rural and underserved areas.[61]

Attorneys general from Missouri, Idaho, and Kansas filed a motion to intervene as plaintiffs in the case in hopes of scoring an end run around the respondents' potential standing issues and obtain a ruling on the merits because the states could "assert many harms the private plaintiffs cannot."[62] In particular, the states can allege that state-run insurance programs and hospitals have incurred direct monetary harm resulting from the adverse effects of mifepristone and that the states have incurred harm to their sovereign interests in creating and enforcing their laws. The motion cautions that "a holding that the private plaintiffs lack standing would nearly guarantee this case comes before this Court again on an emergency application or certiorari petition within months."[63] These states succeeded in their efforts to intervene in the district court case, but the Supreme Court denied their motion.

IV. IMPLICATIONS ON FDA'S AUTHORITY

This lawsuit has garnered widespread attention because the Supreme Court's pending decision will have ramifications that extend well beyond access to medication abortion. The government has stressed the uniqueness of this case, noting that FDA has identified no other example "where a court has second-guessed FDA's safety and efficacy determination and ordered a widely available FDA-approved drug to be removed from the market—much less an example that includes a two-decade delay."[64]

Congress has delegated the responsibility to evaluate the safety and efficacy of drugs and other medical products to FDA, an agency with the requisite scientific expertise to determine whether a sponsor's NDA contains substantial evidence demonstrating that the drug is safe and effective for its intended use, based on adequate and well-controlled investigations.[65] FDA's NDA approval process is rigorous and involves a careful analysis by scientists across many disciplines to determine whether the drug's benefits outweigh its risks.

Instead of affording deference to FDA's decisions with respect to mifepristone, the district court substituted its own judgment for that of the FDA. The court relied upon select studies that would hardly meet FDA's standards for valid scientific evidence while disregarding the extensive amount of evidence from studies and data

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[61] Brief for States of N.Y. et al. as Amici Curiae in Support of Petitioners, U.S. Food & Drug Admin. v. All. for Hippocratic Med., No. 23-235 (S. Ct. Oct. 12, 2023).

[62] Notice of Intervention Below, and Mot. of Mo., Idaho & Kan. to Intervene at 2, U.S. Food & Drug Admin. v. All. for Hippocratic Med., No. 23-235 (S. Ct. Jan. 22, 2024).

[63] *Id.* at 11.

[64] Defs. Opp'n to Pls.' Mot. for Prelim. Inj., *supra* note 37, at 31.

[65] 21 U.S.C. § 355(d); 21 C.F.R. §§ 314.50, 314.105(c).

that FDA considered as part of the administrative record. Moreover, the court excoriated FDA for not imposing the same conditions in the product labeling and in the REMS program that were present in the clinical trials that supported the agency's decisions. This criticism is entirely misguided. Most clinical trials are conducted under more restrictive conditions than those that are ultimately imposed in a product's approved labeling, and the statute does not require FDA to limit a drug's approved conditions of use to the exact conditions outlined in the supporting clinical trial protocols.

The lower courts' decisions have alarmed the pharmaceutical and biotechnology industries, which depend upon FDA's regulatory process for the scientific evaluation and approval of their products. Shortly after the district court's opinion was issued, dozens of biotech and pharmaceutical company leaders signed an open letter criticizing Judge Kacsmaryk's ruling as a brazen act of judicial interference, expressing their concerns that the decision undermines FDA's authority over drug approvals and sets a dangerous precedent. The letter states:

> As an industry we count on the FDA's autonomy and authority to bring new medicines to patients under a reliable regulatory process for drug evaluation and approval. Adding regulatory uncertainty to the already inherently risky work of discovering and developing new medicines will likely have the effect of reducing incentives for investment, endangering the innovation that characterizes our industry.
>
> Judicial activism will not stop here. If courts can overturn drug approvals without regard for science or evidence, or for the complexity required to fully vet the safety and efficacy of new drugs, any medicine is at risk for the same outcome as mifepristone.[66]

Several organizations have filed amicus briefs stressing this point. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed an amicus brief with the Supreme Court warning that the Fifth Circuit's ruling upends the settled FDA regulatory regime and paved a new path to contest initial and supplemental drug approvals, which "threatens to stifle pharmaceutical innovation by disrupting industry's reasonable investment-backed opportunities."[67] A group of pharmaceutical companies, executives, and investors filed a separate amicus brief explaining the importance of respecting FDA's scientific judgment and regulatory flexibility in fostering the development of innovative therapies and pointing out the flaws in the lower courts' criticisms of FDA's decisions with respect to mifepristone.[68] In particular, the brief lambasts the lower courts for expecting FDA to limit a drug's approved labeling to the precise conditions of use that were studied in clinical trials and to only approve labeling and REMS changes upon review of studies that evaluated the consequences of proposed changes as a whole. The group argues that the decisions create an impossible and impractical drug approval standard that, if allowed to take effect, "will result in a seismic shift in the clinical

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[66] Open Letter from Various Pharm. Execs. in Supp. of FDA's Auth. to Regulate Meds. https://docsend.com/view/2ahvmwy8djzxax3g (last viewed Apr. 20, 2024).

[67] Brief for the Pharm. Rsch. & Manufacturers of Am. as *Amicus Curiae* in Supp. of Pet'rs at 3–4, U.S. Food & Drug Admin. v. All. for Hippocratic Med., No. 23-235 (S. Ct. Oct. 12, 2023).

[68] Brief of Pharm. Cos., Execs. & Investors as *Amici Curiae* in Supp. of Applicants, U.S. Food & Drug Admin. v. All. for Hippocratic Med., No. 23-235 (S. Ct. Oct. 12, 2023).

development and drug approval process" that would chill drug development and investment.[69]

The implications of this case on administrative law extend beyond agency deference. It is astonishing, for example, that the lower courts accepted the standing arguments that were made by the plaintiffs. If standing is permitted on such speculative and attenuated grounds, FDA could be exposed to lawsuits from a host of litigants who disagree with FDA's choices on moral or other bases. This poses a threat not just to FDA but also to regulated industry, healthcare providers, and patients who rely on FDA to make scientifically sound decisions that are in the interest of the public health. This would also set a dangerous precedent that could be used to award standing to a broad range of parties that seek to challenge an action by other administrative agencies. The Supreme Court's decision also could set an unfeasible precedent with respect to an agency's obligation to consider the implications of its actions on laws that are not within the four corners of its governing statutes.

[69] *Id.* at 17–18.

U.S. v. Facteau: First Circuit Upholds Misdemeanor Convictions for Off-Label Promotion

LYNN C. TYLER*

Late last year, in *United States v. Facteau*, the First Circuit upheld the misdemeanor convictions of two defendants on ten counts of distributing adulterated and misbranded medical devices based on off-label promotion.[1] This article will focus on the court's analysis of the defendants' First Amendment defense, which it rejected primarily based on *Wisconsin v. Mitchell*.[2] The First Circuit relied on *Mitchell* for the proposition that "the first amendment does not apply to the 'evidentiary use of speech to establish the elements of a crime or to prove motive or intent.'"[3]

WHY IT MADE THE LIST

After a string of losses dating back over fifteen years, the verdict in *Facteau* was the first time the government had overcome a First Amendment defense to score a (partial) victory in an off-label promotion case. Although the defendants were acquitted on related felony charges, the district court had sentenced them to time served and to fines of $1,000,000 and $500,000, respectively, on the misdemeanor convictions. The First Circuit has now upheld those convictions and sentences in the face of the defendants' First Amendment and due process defenses, among others. The importance of the case is confirmed by the large number of sophisticated *amici curiae* who submitted briefs.

DISCUSSION

William Facteau was the CEO, and Patrick Fabian was the VP of Sales, of a medical device company named Acclarent. In its opinion, the First Circuit stated the evidence most favorable to the verdict supported the following facts. Beginning in or about 2005, Facteau, Fabian, and others at Acclarent caused Acclarent to develop and design a device known as the Relieva Stratus Microflow Spacer (Stratus) to release the steroid Kenalog-40 in the nasal passages over ten to fourteen days. The Stratus did not elute saline for any significant period of time.

Facteau, Fabian, and others understood that FDA would likely require significantly more testing and clinical data to permit the interstate distribution of the

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1 United States v. Facteau, 89 F.4th 1 (1st Cir. 2023).

2 508 U.S. 476, 489 (1993).

3 *Facteau*, 89 F.4th at *23.

Stratus as a steroid delivery device than it would require for a device that did nothing more than maintain a space in the sinuses and release saline. Facteau, Fabian, and others therefore pursued a strategy to obtain marketing authorization more quickly by concealing from FDA that they intended the Stratus to be used as a steroid delivery device. Instead, they falsely claimed that the Stratus was a sinus spacer for use with saline that was substantially equivalent to an existing legally marketed spacer.

Six months after securing clearance for the Stratus as a sinus spacer, Acclarent requested additional clearance to market the Stratus for drug delivery. In May 2007, FDA denied Acclarent's request to expand the Stratus's indication to include drug delivery, finding that combining drug delivery with a device would make the Stratus a combination product and require a more extensive approval process. As late as 2010, FDA declined to approve a clinical study involving the use of the Stratus with Kenalog-40. Acclarent never obtained FDA approval of the Stratus as a drug delivery device.

Nonetheless, beginning in September, 2008, Facteau, Fabian, and others marketed the Stratus almost exclusively as a steroid delivery device. Sales representatives were not trained about any benefits of using the Stratus solely as a spacer without saline or Kenalog-40. Instead, the sales representatives were told that the Stratus was designed for use with Kenalog-40. In several internal trainings, the Stratus was presented as a drug delivery device, not a saline device.

A "physician discussion guide" for the Stratus included a potential physician question and a recommended answer that "the only agent that works optimally with the current [Stratus] is [Kenalog-40]." There was testimony that no physicians used the Stratus to deliver saline and those who used it did so with Kenalog-40. Some physicians testified that they were never told to use the Stratus as a spacer or to deliver saline, and saw no benefit to those uses. Instead, they were told to use it to deliver Kenalog-40. At physician conferences, Acclarent demonstrated the use of the Stratus with Kenalog-40, not saline. A physician training video and a slide presentation showed how to use the Stratus with Kenalog-40.

Because Acclarent never received premarket approval or clearance to market the Stratus as a steroid delivery device, the government alleged that it was adulterated and misbranded. The government's theory was that a medical device is "misbranded" if a 510(k) notification had not been submitted to FDA at least ninety days before the device was introduced into interstate commerce or if it was intended for a new use for which a 510(k) notification was required but not submitted to FDA.

Among several defenses, Facteau and Fabian argued that the promotion of the Stratus as a steroid delivery device was truthful and non-misleading, and therefore protected by the First Amendment.

The government's case against Facteau and Fabian had to overcome the adverse results in several prior cases where FDA's (or other) restrictions on promotion collided with the First Amendment. Some of the older cases on this issue include *Washington Legal Foundation v. Henney*, *Thompson v. W. States Med.Ctr.*, *Sorrell v. IMS Health, Inc.*, *U.S. v. Caronia*, and *Amarin Pharma., Inc. v. U.S. FDA*.

The tide began to turn in the government's favor in *United States v. Vascular Solutions, Inc.* ("VSI").[4] The government pursued charges against VSI for

[4] 181 F. Supp. 3d 342 (W.D. Tex. 2016).

misbranding based on off-label promotion. In a motion *in limine*, VSI argued that the court should apply heightened scrutiny because the government was applying a content- and speech-based ban on speech. The district court denied VSI's motion *in limine*, rejecting VSI's First Amendment argument because the government stated it intended to prove the misbranding violation by relying only on conduct. The court also followed *Mitchell*'s holding that speech may serve as an overt act in a conspiracy case, stating that "[t]he Court . . . sees no First Amendment threat from this proposed use of speech."[5] Despite these legal wins for the government, it lost the case when the jury acquitted VSI and its CEO of all charges.

In the *Facteau* case, the district court's jury instructions reflect that it followed *Caronia* by ruling that the Federal Food, Drug, and Cosmetics Act (FDCA) does not make off-label promotion a crime, but also followed *Mitchell*, *VSI*, and other cases by ruling that the defendants' speech could be used as evidence of a crime:

> *The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime.* Rather, the FDCA crimes charged are conspiring to introduce, and causing the introduction of, devices into interstate commerce that were adulterated or misbranded. Although you may not convict a Defendant of a crime based solely on truthful, non-misleading statements regarding off-label use, even truthful statements about an off-label use can be considered as evidence. To put it another way, to convict, there must be a criminal act. *Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.*[6]

The jury found the defendants guilty of causing the introduction of an adulterated device into interstate commerce and causing the introduction of a misbranded device into interstate commerce. The jury also found the defendants lacked the intent to defraud or mislead, so the convictions were misdemeanors, not felonies. Further, the convictions were based on the lack of a required premarket notification for the Stratus's intended use, and not on false or misleading labeling or lack of adequate instructions for use.

On appeal, the defendants challenged the instruction quoted above based on the First Amendment. The First Circuit began its opinion with a fairly extensive review of FDCA provisions and related FDA regulations on adulteration and misbranding, premarket approval and 510(k) clearance, and intended use. The court concluded the review by stating:

> In sum, it is unlawful for a manufacturer to commercially distribute a device for an intended use that represents a "major change or modification" from the specific use for which the device received

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[5] *Id.* at 345.

[6] Dkt. No. 436 at 27 (emphasis added). *See also id.* at 26 ("It is not illegal in and of itself for a device manufacturer to provide truthful, not misleading information about an off-label use. The FDCA does not prohibit or criminalize truthful, not misleading off-label promotion.").

> § 510(k) clearance. Such off-label marketing would amount to the commercial distribution of an "adulterated" and "misbranded" device.[7]

The court then turned to the defendants' First Amendment defense. As noted in the introduction, it rejected this defense primarily based on the Supreme Court's decision in *Mitchell*. In *Mitchell*, the Court held that the government's use of the defendant's speech as proof of his intent in an aggravated battery case did not implicate the First Amendment. Based on *U.S. v. Caronia*,[8] Facteau argued:

> that permitting the jury to consider his off-label promotional speech in assessing his guilt under the FDCA amounts to the de facto criminalization of his protected speech, creating a "backdoor" through which the government may sneak past the First Amendment's reach and punish appellants simply for the things they said about Stratus.[9]

The First Circuit distinguished *Caronia*, however, because:

> Unlike in *Caronia*, the government's case here relied on a wide array of evidence, which included not only promotional speech about off-label uses but also internal communications regarding regulatory and marketing strategy and the product's physical design. It is not the case, as it was in *Caronia*, that the government set out to punish appellants for what they said about the product; rather, what appellants said about Stratus simply shed light on how they intended it to be used.[10]

The court further distinguished *Caronia* on the grounds that *Facteau*'s jury "found appellants guilty of misbranding because Stratus lacked the proper regulatory clearance -- a theory of misbranding less intertwined with appellants' speech" and that unlike the salesman-defendant in *Caronia*, Facteau and Fabian were high-level executives responsible for the product design and regulatory and sales strategy behind the Stratus.[11]

Facteau made another First Amendment argument based on FDA guidance explaining when truthful, non-misleading speech regarding off-label uses will not be considered evidence of a product's intended use. According to this argument, although *Mitchell* may generally permit a jury to consider promotional speech as evidence of intent, "any evidence so presented because it is not protected by the safe harbor would be the product of a government policy that unequally foists the burden of potential evidentiary use upon certain speech based on its content."[12] The court rejected this argument as well, however, because Facteau failed to demonstrate that the FDA safe harbor burdened speech. "Far from burdening what device manufacturers may say, the safe harbor guidance expands, rather than contracts, the domain of speech that the government shields from being used as evidence."[13]

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7 89 F.4th at *15.

8 703 F.3d 149 (2d Cir. 2012).

9 89 F.4th at *24.

10 *Id.*

11 *Id.* at *25.

12 *Id.* at *26.

13 *Id.* at *28.

IMPACT

Despite the acquittals on the felony charges, *Facteau* represents a significant victory for the government. It has another precedent authorizing the use of speech as evidence of a crime in this context. Further, the defendants likely spent millions in legal fees and have been convicted and sentenced to pay substantial fines, in addition to the time served in prison. These results should have a deterrent effect on others contemplating off-label promotion of FDA-regulated products.

United States v. Stoll

STEVEN A. JOHNSON*

I. WHY IT MADE THE LIST

In what is becoming more common, the U.S. Food and Drug Administration (FDA) successfully brought a criminal prosecution through the Department of Justice (DOJ) against a lower-level company individual instead of a responsible company executive in a life science company for violations of the Federal Food, Drug and Cosmetic Act (FDCA). This is significant case in that it was a successful prosecution not of a regulated company corporately, but individually of a lower-level non-executive of a medical device company, and it involved the unique criminal acts of an employee fraudulently creating an agency clearance letter with a forged FDA official's digital signature on the document.

II. DISCUSSION

A. Legal Background

This case involved the government charging under its authority, a regulatory affairs specialist, Peter Stoll, with misbranding and adulterating a medical device under 21 U.S.C. 331(a) and 331(a)(2) of the Federal Food, Drug and Cosmetic Act (FDCA). Specifically, the FDCA makes it a criminal violation for any individual to do any act which results in the misbranding or adulteration of a medical device that is introduced into interstate commerce.

B. Factual Background

This case initiated when the government charged a regulatory affairs specialist, Peter Stoll, with misbranding and adulterating a medical device. The devices were the ELAN 4 device used for drilling and cutting bone during surgery and the JS series sterilization container used to store instruments in a sterile environment. B. Braun division, Aesculap Medical Systems of Central Valley, PA was the manufacturer of the devices and Mr. Stoll's employer.

As part of his illegal activities, Mr. Stoll created the false clearance letters using FDA letterhead and forged a digital signature of an FDA approving official. Stoll was responsible for shepherding two of the company's devices through FDA's 510(k) clearance process: the ELAN 4 Air Drill, a high-speed surgical drill used for bone cutting, sawing, and drilling, and the JS Series SterilContainer S2, a reusable sterilization container for medical instruments. Stoll additionally admitted that he never submitted any 510(k) clearance documents to FDA regarding either device. The acts by Mr. Stoll eventually resulted in the company selling and distributing

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many of these medical devices throughout the United States as officially cleared by FDA.

Once the fake FDA clearance letters were discovered, the company was required to issue urgent device recalls in 2017. The recall lasted two years and resulted in thousands of these devices being recalled from surgery centers.

C. Court Decision

Mr. Stoll entered his guilty plea on July 20, 2023, to one felony count of causing the introduction of misbranded and adulterated medical device into interstate commerce under 21 U.S.C. Sections 331(a) and 331(a)(2).

Mr. Stoll admitted through his plea in the Eastern District of Pennsylvania to on or about 2017 creating two false letters showing FDA clearance of two medical devices used in surgery. The sentencing was originally scheduled for November 7, 2023, and continued when, on January 24, 2024, DOJ announced as a result of his earlier plea Mr. Stoll was sentenced by U.S. District Judge Joseph Leeson to twelve months in prison and one year of supervised release.

Stoll had faced up to three years imprisonment and a fine of $250,000.

III. FUTURE IMPACT OF THE CASE

FDA's Office of Criminal Investigations (OCI) aggressively investigated this case against Mr. Stoll for his egregious intentional and fraudulent conduct as another example of the FDA and DOJ being willing to bring criminal prosecutions and hold lower-level life science company officials such as regulatory affairs specialists liable under the FDCA.

This case, which resulted in prison time, will likely further encourage FDA/OCI to pursue other lower-level individuals when this kind of fraudulent behavior is uncovered involving the sacred FDA approval and clearance process that patients and healthcare providers rely upon to ensure products are safe and effective prior to their use.

Missouri v. Murthy

BRIGID BONDOC & ATIQ CHOWDHURY*

WHY IT MADE THE LIST

At a time when the U.S. Food and Drug Administration's Commissioner Califf has made fighting "misinformation" online a key priority, *Missouri v. Murthy*[1] could have significant implications for how closely the federal government, including the FDA, can work with social media companies to combat inaccurate information about FDA-regulated products. Plaintiffs Missouri, Louisiana, and a group of social media users alleged government officials, including the President, the Surgeon General, the U.S. Department of Health and Human Services, the National Institutes of Health, the Centers for Disease Control and Prevention, and FDA,[2] "coerced" social media platforms to target their "conservative-leaning free speech" and censor their social media posts relating to a host of COVID-19 issues and election integrity in the 2020 presidential election, among other issues, thereby violating their First Amendment rights.[3] The federal government disagreed with plaintiffs' allegations of censorship, arguing that it worked cooperatively with the social media platforms and sought to "persuade" them to combat public health misinformation, all within the realm of permissible government speech.[4] After significant narrowing of the facts and circumstances at issue in the lower courts, the case is currently pending before the United States Supreme Court.

DISCUSSION

Factual and Procedural Background

In 2022, Missouri and Louisiana Attorneys General, together with several private plaintiffs,[5] filed suit in the U.S. District Court for the Western District of Louisiana

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1 The case was originally styled as *Missouri v. Biden*, but the President was not included in the injunction issued by the district court. This case has frequently been referred to as "the jawboning case."

2 FDA was not named in the initial complaint but was added, along with certain FDA officials, by the second amended complaint. FDA was not subject to the injunction issued by the district court.

3 Mem. Ruling on Req. for Prelim. Inj. at 4, 9, Missouri v. Biden, No. 3:22-CV-01213, Dkt. No. 293 (W.D. La. July 4, 2023).

4 *Id.* at 87, 90, 96.

5 The initial complaint was filed by Missouri and Louisiana's Attorneys General. Several individuals joined an amended complaint a few months later. These individuals included professors at prestigious medical schools that co-authored the Great Barrington Declaration, described in the complaint as "a statement criticizing government-mandated COVID restrictions, which was co-signed by over

alleging that the federal government and certain government officials violated the First Amendment by "collud[ing] with and/or coerc[ing] social-media platforms" to censor "conservative-leaning free speech" content on their platforms.[6] Specifically, plaintiffs asserted "that by using emails, public and private messages, [and] public and private meetings," defendants pressured social media platforms to target and suppress topics such as election integrity in the 2020 presidential election, the origin of COVID-19, and the "efficiency"[7] of COVID-19 vaccines, masks, and lockdowns, among other assertions.[8]

The district court's fact-finding focused on examples of high-level White House officials contacting firms like X (formerly known as Twitter), YouTube, Google, and Facebook/Meta to "partner" on goals like reducing viewership of "vaccine-hesitant content."[9] One email sent to Facebook suggested "'warning screens' before linking to domains known to promote vaccine misinformation."[10] Other emails from government officials sought to better understand what action the companies were taking to curb the spread of COVID-19 misinformation.

Based on these events, plaintiffs argued that "Defendants have threatened adverse consequences to social-media companies, such as reform of Section 230 immunity under the Communications Decency Act, antitrust scrutiny/enforcement, increased regulations, and other measures, if those companies refuse to increase censorship."[11] In response, defendants argued that they "never demanded the social-media companies to suppress postings or to change policies, and the changes were due to the social-media companies' own independent decisions."[12]

On July 4, 2023, the district court issued a preliminary injunction against certain defendants, not including FDA or its officials, finding they "likely 'jointly participated' with the social-media companies to such an extent that said defendants have become 'pervasively entwined' in the private companies' workings to such an extent as to blur the line between public and private action."[13] In other words, defendants "significantly encouraged" the social media companies to such an extent that their actions should be considered government actions.[14]

930,000 people, including over 62,000 scientists and healthcare professionals." Other plaintiffs included the founder of The Gateway Pundit, an online news website, and the co-director of Health Freedom Louisiana, a consumer and human rights advocacy organization. Each plaintiff alleged "extensive government-induced censorship of her speech on social media."

[6] Mem. Ruling on Req. for Prelim. Inj. at 2, 4, Missouri v. Biden, No. 3:22-CV-01213, Dkt. No. 293 (W.D. La. July 4, 2023).

[7] *Id.* at 4 ("In this case, Plaintiffs allege that Defendants suppressed conservative-leaning free speech, such as: . . . **(3) suppressing speech about the efficiency of masks and COVID-19 lockdowns; (4) suppressing speech about the efficiency of COVID-19 vaccines** . . . .") (emphasis added).

[8] *Id.* at 4, 9.

[9] *Id.* at 20.

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

[11] *Id.* at 8.

[12] *Id.* at 96.

[13] *Id.* at 117.

[14] *Id.* at 95.

The Fifth Circuit's Decision

On September 8, 2023, the Fifth Circuit vacated much of the district court's preliminary injunction, except for one prohibition, which was modified because it was "both vague and broader than necessary to remedy the plaintiffs' injuries."[15]

> Under the modified injunction, the enjoined Defendants cannot coerce or significantly encourage a platform's content-moderation decisions. Such conduct includes threats of adverse consequences—even if those threats are not verbalized and never materialize—so long as a reasonable person would construe a government's message as alluding to some form of punishment.[16]

The court determined/decided the plaintiffs had standing "because they have demonstrated ongoing harm from past social-media censorship and a likelihood of future censorship, both of which are injuries traceable to government-coerced enforcement of social-media platforms' content-moderation policies and redressable by an injunction against the government officials."[17]

When examining whether the defendants' statements to plaintiffs can "reasonably be construed" as threats of adverse consequences, the court used the Second Circuit's "four-factor test for distinguishing coercion from persuasion."[18] The court concluded the defendants' statements (specifically the White House, acting in concert with the Surgeon General's office) were coercive based on several factors including, but not limited to, the context and defendants' tone, and defendants' "express and implied references to adverse consequences" unless the plaintiffs complied.[19] The court also found the defendants "significantly encouraged the platforms to moderate content by exercising active, meaningful control over those decisions" and "entangled themselves in the platforms' decision-making processes, namely their moderation policies," rendering such decisions state actions likely violating the First Amendment.[20]

Lastly, the court agreed with the district court that the plaintiffs' "[d]eprivation of First Amendment rights, even for a short period, is sufficient to establish irreparable injury."[21] While the court acknowledged that "[i]t is true that the officials have an interest in engaging with social-media companies, including on issues such as

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[15] Published Op. at 66-71, *Missouri v. Biden*, No. 23-30445, Dkt. No. 238-1 (5th Cir. Sept. 8, 2023).

[16] *Id.* at 71.

[17] *Id.* at 27.

[18] *Id.* at 44. (Four-factor test reviews: "(1) the officials' word choice and tone; (2) the recipient's perception; (3) the presence of authority; and (4) whether the speaker refers to adverse consequences." *Nat'l Rifle Ass'n of Am. v. Vullo*, 49 F.4th 700, 715 (2d Cir. 2022)); *see also Kennedy v. Warren*, 66 F.4th 1199, 1207 (9th Cir. 2023).

[19] *Id.* at 51.

[20] *Id.* at 52 (quoting *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982)). The Fifth Circuit found the district court did not err finding the White House, the Surgeon General, the CDC, and the FBI, likely coerced or significantly encouraged social-media platforms to moderate content, but erred in enjoining the NIAID, the State Department, and CISA. *Id.* at 59-61.

[21] *Id.* at 63 (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976); *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020); *Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 295 (5th Cir. 2012)).

misinformation and election interference," the government "is not permitted to advance these interests to the extent that it engages in viewpoint suppression."[22]

Supreme Court

On October 20, 2023, the Supreme Court granted the federal government's application for a stay of the preliminary injunction by the district court as modified by the Fifth Circuit.[23] The Court also granted certiorari and will address the following questions: "(1) Whether respondents have Article III standing; (2) Whether the government's challenged conduct transformed private social-media companies' content-moderation decisions into state action and violated respondents' First Amendment rights; and (3) Whether the terms and breadth of the preliminary injunction are proper."[24]

A significant number of amicus briefs were filed in this case, representing a wide array of opinions. For example, the American Academy of Pediatrics argued the government has a "compelling interest" in "combatting vaccine misinformation" to "prevent factually incorrect statements from costing people their lives."[25] In contrast, the Association of American Physicians and Surgeons supported the right to disseminate vaccine criticism "especially when vaccination is administered without a risk-benefit analysis and informed consent" and "[t]he proper antidote to alleged false information is a stronger right to free speech, not a weaker one."[26]

During the oral arguments held on March 18, 2024, some of the Justices' questions suggested they may be leaning toward a decision on standing, which would obviate the need to address the merits. Specifically, some Justices expressed skepticism that plaintiffs' alleged harms could be traced to government action and that granting an injunction would redress those injuries.[27] On the merits, it appeared that most of the justices were skeptical that the communications from the federal government to social media firms amounted to coercion, citing examples of the government frequently "encouraging press to suppress their own speech" without violating the First Amendment.[28]

IMPACT OF THE CASE

There are competing interests at stake in defining the boundary between coercion and persuasion. On the one hand, governments have a compelling interest in ensuring that their citizens receive accurate information about public health issues; on the other hand, First Amendment jurisprudence is clear that the government may

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[22] *Id.* at 64 ("[i]njunctions protecting First Amendment freedoms are always in the public interest," the equities weigh in plaintiffs' favor. *Opulent Life Church*, 697 F.3d at 298) (quotation marks and citations omitted).

[23] Murthy v. Missouri, 601 U.S. ___ (2023) (No. 23A243).

[24] Appl. for a Stay at 40, Murthy v. Missouri, 601 U.S. ___ (Sept. 14, 2023).

[25] Brief for Am. Acad. of Pediatrics, et al. as Amici Curiae Supporting Petitioners at 4, Murthy v. Missouri, 601 U.S. ___ (Dec. 12, 2023).

[26] Brief for Ass'n of Am. Physicians and Surgeons as Amicus Curiae Supporting Respondents at 2–3, Murthy v. Missouri, 601 U.S. ___ (Feb. 7, 2024).

[27] Oral Arg. Tr. at 9–10, 13–14, 44–45, 102–04, 121–22, Murthy v. Missouri, 601 U.S. ___ (Mar. 18, 2024).

[28] *Id.* at 71.

not engage in viewpoint discrimination. While the plaintiffs in *Murthy v. Missouri* may not prevail in this case due to a lack of standing, the overall impact of the litigation may have a chilling effect on public health agencies' outreach efforts. Without clear guidance from the Court on the merits, the government may overcautiously and unnecessarily constrain its engagement with important platforms for sharing public health information.

Nonetheless, FDA, and Commissioner Califf in particular, has undertaken significant efforts to stop the spread of misinformation about FDA-regulated products. Recently, FDA published a website entitled "Rumor Control" in an effort to "provide facts" and "help stop the spread of false rumors."[29] Issues addressed by this website include, among other things, the importance of childhood vaccination, whether thermograms are an appropriate substitute for mammograms, and whether consumers can rely on marketing claims that a dietary supplement is "FDA Approved." The website even contains instructions for the public on how to report misinformation to various social media platforms. Commissioner Califf also recently co-authored an article in a prominent medical journal discussing the risks of misinformation about the safety of vaccines and the resulting trend of lower vaccine uptake.[30] While this type of communication by FDA and its officials may not constitute coercion, even under the plaintiffs' theory in *Murthy*, given the lack of FDA's direct interaction with social media platforms, other efforts to "coordinate" with social media could cross the line. If the Court reaches the merits, *Murthy* may provide guidance on where the line is between moderating public health misinformation and state action amounting to censorship.

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[29] *Rumor Control*, U.S. FOOD & DRUG ADMIN. (Apr. 3, 2024), https://www.fda.gov/news-events/rumor-control (last accessed Mar. 26, 2024).

[30] Peter Marks & Robert Califf, *Is Vaccination Approaching a Dangerous Tipping Point?*, JAMA (Jan. 5, 2024).

Apter v. Department of Health and Human Services

JONATHAN BERMAN & COLLEEN M. HEISEY*

You are not a horse, and FDA is not a physician.

I. WHY IT MADE THE LIST

FDA frequently issues statements and warnings about matters of public health. FDA was held to have exceeded its authority to do so in *Apter v. Department of Health and Human Services*.[1]

During the COVID pandemic, increasing numbers of people took drugs containing ivermectin—including drugs intended for livestock—to treat COVID. FDA advised against this, reminding us that "you are not a horse." The Fifth Circuit shot back: "FDA is not a physician."[2] The *Apter* court held that FDA did not have general authority to make pronouncements regarding public health, and that statements made without specific statutory authority were *ultra vires*, and unlawful. FDA can disseminate information, but not medical recommendations.

Case law is sparse regarding the limits of FDA's authority to comment on public health. *Apter* breaks new ground and provides a new avenue for challenging FDA.

II. DISCUSSION

A. Factual Background

Ivermectin is the active ingredient in a number of FDA-approved drugs. FDA has approved ivermectin-containing tablets, creams, and lotions for human use, as well as dozens of products intended for animals. Approved indications include the treatment and prevention of parasites—but not COVID-19.

Despite the lack of a COVID indication, ivermectin products became increasingly popular for the treatment or prevention of COVID. In response, FDA launched a

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[1] Apter v. U.S. Dep't of Health & Hum. Servs., 80 F.4th 579 (5th Cir. 2023).

[2] *Id.* at 595.

publicity campaign in an attempt to discourage this use. FDA viewed ivermectin as ineffective against COVID. Moreover, FDA identified that high doses of ivermectin, such as the doses found in products intended for livestock, are dangerous to humans.

FDA issued a number of statements on this subject. The punchiest, and the ones that gathered the greatest public attention, focused on the danger of taking drugs intended for livestock. FDA tweeted:

> "You are not a horse. You are not a cow. Seriously, y'all. Stop it."

This tweet is still on FDA's "X" account, where it has gathered 46,179 reposts and 105,892 "likes."[3] The tweet links to a long article on the FDA website titled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19."[4]

Similarly, FDA posted on Instagram: "You are not a horse. Stop it with the #Ivermectin. It's not authorized for treating #COVID."[5]

Three doctors who commonly prescribed ivermectin to treat COVID, including Dr. Robert Apter, sued FDA. They alleged that the above statements (and other similar social media postings) exceeded FDA's authority. They further alleged that these "Posts" interfered with their ability to practice medicine and caused pharmacies to refuse to fill ivermectin prescriptions. Additional alleged harms vary among the plaintiffs, but include harm to reputation, the loss of admitting privileges, and the loss of positions at a medical school and a hospital.[6]

The district court found that sovereign immunity barred these claims, and dismissed the lawsuit. While a government officer does not have sovereign immunity for *ultra vires* acts—acts taken "without any authority whatsoever, or without any colorable basis for the exercise of authority," the district court held that FDA had "at least a colorable basis in authority—and there is no statute saying otherwise."[7] The Administrative Procedure Act (APA) sometimes supplies a waiver of sovereign immunity, but the Posts were not "final agency action" within the meaning of the APA and were therefore not reviewable under that statute.[8] An appeal ensued.

B. The Fifth Circuit's Ruling

The Fifth Circuit reversed in part. It agreed with the district court that the Posts were not final agency action, and that therefore the plaintiffs failed to state a claim under the APA. However, the Fifth Circuit held that the Posts were *ultra vires*, and therefore actionable notwithstanding the assertion of sovereign immunity.[9]

FDA had argued that it had an inherent authority to speak on behalf of its statutory mission "to promote the public health."[10] FDA also cited to statutory authority to

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[3] https://twitter.com/US_FDA/status/1429050070243192839?lang=en (last visited March 6, 2024).

[4] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.

[5] https://www.instagram.com/fda/p/CS1giIfJ0sa/.

[6] *See Apter*, 80 F.4th at 585.

[7] Apter v. U.S. Dep't of Health & Hum. Servs., et al., 644 F.Supp.3d 361, 367, 369 (S.D. Tex. 2022).

[8] *Id.* at 369–72.

[9] *See Apter*, 80 F.4th.

[10] 21 U.S.C. §§ 393(b)(1), (b)(2)(B).

utilize publicity to "disseminate[] information regarding . . . drugs . . . in situations involving . . . imminent danger to health or gross deception of the consumer."[11]

The Fifth Circuit held that this authority was inapplicable to the Posts. The Posts "offer advice, not mere information."[12] "[A]ll six of the Posts contain syntax that is imperative rather than declaratory . . . ."[13] Although "FDA cites plenty of statutory authority allowing it to issue *information*, it never identifies even colorable authority allowing it to make medical *recommendations* . . . ."[14] In sum, the Fifth Circuit held:

> FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise. The [plaintiffs] have plausibly alleged that FDA's Posts fell on the wrong side of the line between telling *about* and telling *to*.[15]

III. IMPACT

The *Apter* decision is significant for several reasons.

First, the decision opens up a new (or at least seldom-used) pathway for challenging FDA's public statements: arguing that they are *ultra vires*.

Second, proceeding on an *ultra vires* theory potentially avoids an inquiry into the accuracy of the challenged statements. The *Apter* decision does not discuss whether patients should in fact use ivermectin as a COVID treatment, nor whether FDA is owed deference in a matter of scientific opinion. The apparent holding of *Apter* is that an *ultra vires* action is unlawful, pure and simple.

Third, FDA issues recommendations and warnings in any number of contexts, including where it discerns "imminent danger[s] to health or gross deception[s] of the consumer."[16] For example, FDA maintains on its website a page titled "Health Fraud Scams," designed to warn against "products that claim to prevent, treat, or cure diseases or other health conditions, but are not proven safe and effective for those uses."[17] *Apter* calls into question FDA's ability to issue these warnings, many of which arguably do not merely "inform," but also make medical recommendations, denounce, and advise.

An important question that was litigated in *Apter*, but expressly left unresolved,[18] is whether FDA violated a prohibition on interfering with the practice of medicine by advising against a specific off-label use of an approved medicine. A section of the Federal Food, Drug, and Cosmetic Act (FDCA) states that it shall not "be construed to limit or interfere with the authority of a . . . practitioner to prescribe or administer

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[11] 21 U.S.C. § 375(b). *See also* 42 U.S.C. § 242o(b) (permitting HHS to "issue information related to public health").

[12] *Apter*, 80 F.4th at 589.

[13] *Id.* at 588.

[14] *Id.* at 589 (emphasis original); *accord id.* ("Nothing in the [FDCA's] plain text authorizes FDA to issue medical advice or recommendations.").

[15] *Id.* at 595 (emphasis in original).

[16] 21 U.S.C. § 375(b).

[17] *Health Fraud Scams*, U.S. FOOD & DRUG ADMIN. (Feb. 6, 2024), https://www.fda.gov/consumers/health-fraud-scams.

[18] *Apter*, 80 F.4th at 589 & n. 31.

any legally marketed ***device*** . . . ."[19] The parties debated, but *Apter* did not resolve, whether the principle of noninterference extends to off-label prescriptions of ***drugs***.[20]

Nor did *Apter* resolve what it means to "interfere" with a practitioner's authority. FDA's Posts about ivermectin did not order anyone to do, or not do, anything: plaintiffs failed "to show that FDA's actions determined rights, produced obligations, or caused legal consequences."[21] But FDA certainly intended the real-world consequence of convincing people that treating COVID with ivermectin was bad medicine. And the plaintiffs alleged the real-world consequence of harm to their professional reputations and positions. Particularly in light of FDA's unique ability to influence debates on medical issues, does the principle of noninterference place a check on FDA's authority to do so?

We can expect continued litigation as courts more fully define the line between government overreach and FDA's power to inform the public.

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[19] 21 U.S.C. § 396 (emphasis added).

[20] There is no code section comparable to 21 U.S.C. § 396 that explicitly references drugs. However, it is commonly said that FDA does not regulate the practice of medicine, including with regard to off-label uses of drugs.

[21] *Apter*, 80 F.4th at 593.

Davis v. Disability Rights New Jersey

WILLIAM M. JANSSEN*

WHY IT MADE THE LIST

In the late 1950s and early 1960s, comedian Art Linkletter hosted a segment on his television program where he asked children questions about themselves, their families, and other life topics. The segment, entitled "Kids Say the Darnedest Things," was often hilarious, occasionally touching, and almost always innocently insightful.

As most practicing litigators can attest, judges can "say the darnedest" things, too. Consider one example. Chief Judge Joseph F. Anderson, Jr. of the federal district court in South Carolina published an opinion some years back summarizing several demoralizing, personal observations from umpiring civil discovery disputes over his long service on the bench. After recounting overreaching requests, stonewalling responses, hardball tactics, and towering costs, the Judge quoted approvingly from the exasperated sentiments of one of his fellow jurists: "If there is a hell to which disputatious, uncivil, vituperative lawyers go, let it be one in which the damned are eternally locked in discovery disputes with other lawyers of equally repugnant attributes."[1] Few would disagree with the Judge that pitched discovery disputes are among the most unwelcome events in most civil litigators' existences.[2]

It may be surprising, then, to learn that a discovery fight—especially one having nothing to do with food and drug law—was chosen as among the top food and drug cases of 2023. But there's a good reason why. The New Jersey Superior Court in *Davis v. Disability Rights New Jersey*[3] examined a question of first impression to that State which is of recurring importance for at least every tort lawyer, if not for all lawyers in most litigations in all jurisdictions: the discoverability of someone's social media activity. With the ubiquity of social media platforms, the regularity of social media posting, and the familiarity of these platforms to most factfinders, social media represents a great reservoir of potentially discoverable, admissible information. And, given the unchastened manner of how social media posts are made, the bounty of remarkably candid and pulverizingly relevant (perhaps even case-dispositive) information that can be mined there is daunting. The New Jersey

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1 Network Computing Servs. Corp. v. Cisco Sys., Inc., 223 F.R.D. 392, 395 (D.S.C. 2004) (quoting Oklahoma federal judge Wayne Alley, citation omitted).

2 *See generally* Sidney Schenkier, *Discovery Mud Fights: Why They Happen and How to Avoid Them*, ABA GROUPS—SOLO, SMALL FIRM, AND GENERAL PRACTICE DIVISION (Dec. 16, 2021), https://www.americanbar.org/groups/gpsolo/publications/gpsolo_ereport/2021/december-2021/discovery-mud-fights-why-they-happen-how-avoid-them/ ("Who among us went to law school with the idea that, wow, am I ever looking forward to spending untold hours duking it out with my opponents in nasty, name-calling, down-and-dirty discovery battles?").

3 291 A.3d 812, 816 (N.J. Super. Ct. App. Div. 2023), *appeal denied*, 254 N.J. 180 (N.J. 2023).

Superior Court navigated these issues well in *Davis*, setting out an analytical approach for social media discoverability that could well become the model for the nation.

DISCUSSION

Norma Davis had been employed as a senior staff attorney for Disability Rights New Jersey (DRNJ), an agency of the State of New Jersey charged "to protect and advocate for the human, civil, and legal rights of people with disabilities."[4] Davis alleged that she was wrongfully terminated from her employment due to her own medical conditions (lupus and cancer) which necessitated, she asserted, disability accommodations.[5] She filed suit in State court, seeking redress under the New Jersey Law Against Discrimination.[6] More specifically, she sought recompense for an array of injuries she contended DRNJ and her immediate supervisors had caused her: "personal hardships, including economic loss, physical and emotional distress, anxiety, pain and suffering, humiliation, [and] career, family, and social disruption."[7] Davis asserted that her emotional distress remained "ongoing," producing "physical manifestations" such as "terrible migraines, insomnia, worsening of her diabetes, [and] worsening blood pressure."[8]

Discovery of Social Media and Cell Phone Use

In discovery, the defendants (DRNJ and her supervisors) sought copies of Davis's social media posts and her cell phone records. When Davis refused to make the requested productions, defendants sought the trial court to compel discovery of all of Davis's social media content that concerned "any emotion, sentiment or feeling of [p]laintiff, as well as events that could reasonably be expected to evoke an emotion, sentiment, or feeling." Defendants also sought the court to compel discovery of Davis's cell phone records over a twenty-five-month span for the purpose of evidencing "her work performance" during that period.[9] Davis resisted both requests on several grounds: her privacy interests in both her social media activities and her cell phone use; the vague and overly broad sweep of the requests; the defendants' lack of a compelling need for the discovery; and the adequacy of her medical records and deposition testimony to validate her emotional distress.[10]

The trial court granted defendants' motion, with some narrowing. Davis was ordered to produce her social media "posts, profiles, or comments" regarding:

- her former employer;
- her lawsuit's allegations;

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[4] *Our Story*, DISABILITY RIGHTS NEW JERSEY, https://disabilityrightsnj.org/our-story/ (last visited Mar. 25, 2024). *See also Davis*, 291 A.3d at 816.

[5] *See id.*

[6] *See id.* at 815 (invoking N.J. STAT. ANN. §§ 10:5-1 to -50).

[7] *See id.* at 816.

[8] *See id.*

[9] *See id.* at 816–17.

[10] *See id.* at 821 ("According to plaintiff, defendants' discovery should be limited to her medical records and deposition testimony.").

- her expressions of an emotion ("such as 'I am happy that . . . ', 'It makes me angry when . . . ', or 'I am worried about . . . '", though "happy birthday" and political opinion posts were exempted);
- all mentions of "vacations, trips, parties, or celebrations";
- any discussions or mentions of "illness or worry about illness";
- mentions of work;
- pictures of herself (but exempting pictures of "trees, sunsets, landscapes, or pets" and pictures of other people).

The trial judge directed Davis to make this production within three weeks and, thereafter, to appear for deposition on topics that "reasonably flow from" this discovery.[11]

Davis was also ordered to produce to defendants her cell phone records, though she was permitted to redact entries that related to "non-work purposes" or that occurred "outside of normal business hours." However, an unredacted copy of those same records had to be delivered to the court, accompanied by a descriptive index and privilege log of redacted entries.[12]

Davis persisted in her objection to this discovery, seeking immediate appellate review of the discovery orders, which the New Jersey intermediate appellate court allowed. The appeals court consolidated the two challenges, using the opportunity to resolve this question of first impression for the State, noting "there is no New Jersey case law detailing the scope of discovery regarding a litigant's private social media posts."[13] Coming a bit late to the social media discovery party, the New Jersey appellate judges had the benefit of earlier rulings from other courts to help inform their decision.

Social Media Privacy Exists, But Tolerates Discovery

As a threshold matter, the appellate court agreed (and defendants had not contested[14]) that Davis enjoyed a legally protected privacy interest in her social media activities, an interest that emanated from several sources, including the federal Stored Communications Act[15] and New Jersey's Social Media Privacy Law.[16] But

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[11] *See id.* at 817.

[12] *See id.* at 817–18. The court ordered the production of a "*Vaughn* index," which it described as "a privilege log 'containing a 'relatively detailed' justification for the claim of privilege being asserted for each document," which, then, the presiding judge reviews "'to determine, on a document-by-document basis, whether each such claim of privilege should be accepted or rejected.'" Paff v. Div. of Law, 988 A.2d 1239, 1251 n.9 (N.J. Super. Ct. App. Div. 2010) (citing Vaughn v. Rosen, 484 F.2d 820, 826–28 (D.C. Cir.1973)).

[13] *See Davis*, 291 A.3d at 824.

[14] *See id.* at 819.

[15] *See* 18 U.S.C. § 2701 (establishing punishment for anyone who "intentionally accesses without authorization a facility through which an electronic communication service is provided" or, without authorization, "obtains . . . access to a wire or electronic communication while it is in electronic storage in such system").

[16] *See* N.J. Stat. Ann. § 34:6B-6 (forbidding employers to "require or request a current or prospective employee to provide or disclose any user name or password, or in any way provide the employer access to, a personal account through an electronic communications device").

finding a valid privacy interest to exist, ruled the court, was not dispositive of the question of discoverability: "there is no merit to plaintiff's assertion that her private social media posts are off limits from defendants' discovery requests based upon her [State law] emotional distress claims."[17]

The court ruled that none of the sources on which Davis based her privacy arguments afforded her an express or implied blanket discovery shield.[18] Nor did New Jersey's law of "privileges" extend to supply an immunity to social media posts marked private by the user.[19] A finding otherwise, the court posited, would undermine the liberal breadth of civil discovery, where "many types of privacy interests . . . must yield to discovery if the information sought is relevant"—citing personal financial information and medical records as examples of private data that may be discoverable.[20]

Rejecting Davis's pitch for a categorical denial of all social media discovery, however, did not mean that the appeals court was prepared to license an untargeted foraging through an adversary's social media activity. The court quoted approvingly from earlier federal rulings that "privacy concerns may be germane to the question of whether requested discovery is burdensome or oppressive and whether it has been sought for a proper purpose in the litigation."[21] Accordingly, the court embarked on a more nuanced assessment.

Discovery of Social Media-Posted "Emotions"

Like most courts, New Jersey construes its civil discovery rules "liberally in favor of broad pretrial discovery" so as to endeavor "to ensure that the ultimate outcome of litigation will depend on the merits in light of the available facts."[22] What is discoverable in New Jersey courts (also as in most courts) is unprivileged, relevant information—that is, information that possesses "a tendency in reason to prove or disprove any fact of consequence to the determination of the action."[23]

So, what meets this standard when a litigant is seeking damages for emotional distress and other psychic injuries? Are social media posts that exhibit emotions discoverable? In this important case of first impression, the unanimous three-judge panel of the Superior Court of New Jersey ruled "yes." The court's analysis in this case was thoughtful, comprehensive, and instructive.

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[17] *See Davis*, 291 A.3d at 819.

[18] *See id.* at 819–20.

[19] *See id.* at 820 (quoting Tompkins v. Detroit Metro. Airport, 278 F.R.D. 387, 388 (E.D. Mich. 2012) (ruling that private social media post is "generally not privileged, nor is it protected by common law or civil law notions of privacy")).

[20] *See id.* at 820.

[21] *See id.* at 820 (quoting E.E.O.C. v. Simply Storage Mgmt., LLC, 270 F.R.D. 430, 434 (S.D. Ind. 2010). *See also* Tompkins v. Detroit Metro. Airport, 278 F.R.D. 387, 388 (E.D. Mich. 2012) (opponent does not "have a generalized right to rummage at will through information that [the user] has limited from public view," but must make "threshold showing that the requested information is reasonably calculated to lead to the discovery of admissible evidence"; "Otherwise, the Defendant would be allowed to engage in the proverbial fishing expedition, in the hope that there *might* be something of relevance in Plaintiff's Facebook account.").

[22] *See Davis*, 291 A.3d at 823 (citations omitted).

[23] *See id.*

First, the court determined that Davis's private social media posts met the low relevance threshold for discoverability. While the defendants would not be granted "unabated access to [Davis's] private social networking history simply because she pursues a claim for emotional distress damages," the court determined that posts that involved "comments or images depicting [her] emotions, celebrations, vacations, employment, and health" were properly discoverable as they were "relevant to whether defendants' conduct caused her severe emotional distress."[24] Quoting from an earlier federal trial case, the court explained why:

> It is reasonable to expect severe emotional or mental injury to manifest itself in some [social media] content, and an examination of that content might reveal whether onset occurred, when, and the degree of distress. Further, information that evidences other stressors that could have produced the alleged emotional distress is also relevant.[25]

Second, the court was unpersuaded by the argument from Davis and her amici that whatever relevance social media activity might be thought to have should be discounted because some experts in this field believe such posts do not offer accurate, reliable, realistic insights into the poster's true life.[26] Such a contention, reasoned the court, might influence whether (or which) social media posts ought to be admissible before the factfinder, but it would not impact pretrial discoverability.[27] Perhaps, mused the court, at time of trial, the judge might allow the factfinder to consider such views via testifying experts (whose opinions could be tested on cross-examination), or perhaps such views might never be offered into evidence at all since they could tend to undermine the very reliability of a plaintiff's own testimony on the witness stand.[28] In any event, characterizing a social media user's posts as potentially "unrealistic portrayals" did not defeat discoverability.

Third, though the court agreed that privacy interests could tilt the discoverability balance, it found that social media posts were categorically unlike personal financial records in their privacy nature. Access to financial records is aggressively protected under the law; by contrast, nothing "prevent[s] an approved private recipient from sharing another's private [social media] posts, either verbally or by sending a screenshot to a non-private member."[29] Thus, the court decided, "[p]ersons who choose to post social media messages and photos necessarily assume the risk that

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[24] *See id.* at 824.

[25] *See Davis*, 291 A.3d at 824 (quoting E.E.O.C. v. Simply Storage Mgmt., LLC, 270 F.R.D. 430, 435 (S.D. Ind. 2010).

[26] *See id.* at 820–21 & n.4 (quoting law journal scholar who commented: "Because social networking websites enable users to craft a desired image to display to others, social scientists have posited that outside observers can misinterpret that impression," Kathryn R. Brown, *The Risks of Taking Facebook at Face Value: Why the Psychology of Social Networking Should Influence the Evidentiary Relevance of Facebook Photographs*, 14 VAND. J. ENT. & TECH. L. 357, 365 (2012)).

[27] *See id.* at 825.

[28] *See id.* (noting that "defendants could plausibly use the posts to attack plaintiff's credibility by arguing if private posts are not a true reflection of her thoughts, then why should a factfinder determine that her discovery responses and trial testimony are true").

[29] *See id.* The court emphasized this distinction: "A member of a private social media group may have a moral obligation not to share posted content, but the content does not have the contractual and lawful protections afforded to personal financial and tax records." *Id.*

intended recipients will share the information with others."[30] The illusion of privacy created by clicking the "private" button on a social media platform thus did not transform the vulnerability of posts made there.

Fourth, the court rejected Davis's assertion that the social media discovery was so overbroad and burdensome as to warrant exclusion. Davis had "the right to seek damages to her emotional well-being" alleged to have been caused by what she claimed to be her wrongful termination, just as defendants had "the right to pursue rational discovery . . . to oppose plaintiff's allegations."[31] The discovery the court permitted was not overbroad, ruled the appeals panel, because it was limited to a three-year period, restricted to emotion-laded posts, and subject to Davis's right to withhold posts she deemed to be nonresponsive (provided she provided a proper withholding log and understood the court's right to in camera confirmation).[32] Nor was the discovery unduly burdensome, in light of the frequency with which Davis posted on her social media accounts. Davis's "avid" social media use, concluded the court, "should not be a bar to defendants' legitimate discovery request given that her posts may be a window into her emotional state, which is in dispute."[33]

Discoverability of Cell Phone Records

Davis's cell phone records were sought because the defense contended that she was terminated for failing to complete her work assignments, which included communicating with clients. Evidently, Davis could not answer defendants' inquiries about her client contacts during those times when she was being paid to work from her home; she had responded to such inquiries by asserting that she could not remember that information. This prompted defendants to press that Davis's lack of recollection supplied them with "a particularized need" for the cell phone records.[34] The court agreed. Because the discovery request excluded cell phone use both outside of work hours and concerning non-work-related calls, the court found the discovery order reasonably tailored to the needs of the litigation, especially since—like the companion social media discovery order—Davis was permitted to withhold nonresponsive cell phone use data, subject to the same restrictions (the submission of a withholding list and the trial court's right to in camera review).[35]

IMPACT

Lawyers and their clients have been bemoaning about pretrial discovery in civil litigation for nearly two centuries (at least).

In the mid-19th Century, when frustration with "trial by ambush" prompted reformers such as David Dudley Field to pitch a tepid liberalization of pretrial information sharing (New York's "Field Code"), that innovation was met with both

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[30] *See id.*

[31] *See id.* at 825.

[32] *See id.* at 825–26.

[33] *See id.*

[34] *See id.* at 827.

[35] *See id.* at 826–27.

cheers and jeers.[36] A similar reception followed the unveiling of the new "Federal Rules of Civil Procedure" in 1938, where Charles E. Clark and Edson R. Sunderland championed an easily accessed, robust system of civil discovery.[37] Discovery innovation had its champions to be sure, but its critics were earnest and vocal.

Nonetheless, "American-style" discovery soon became the order of the realm, both in federal and State courts. Indeed, within a decade after the Federal Civil Rules took effect, the U.S. Supreme Court was extoling the new breadth of federal discovery: "No longer can the time-honored cry of 'fishing expedition' serve to preclude a party from inquiring into the facts underlying his opponent's case"; rather, "either party may compel the other to disgorge whatever facts he has in his possession" since "[m]utual knowledge of all the relevant facts gathered by both parties is essential to proper litigation."[38] There was visceral and practical appeal to this embrace of liberal discovery: there is much to be praised in a system of information exchange that allows litigants to arrive on the day of trial prepared for the battles about to ensue.[39] In the decades since they first arrived, the federal discovery rules have been amended many times, acquiring today an even further reach than they had originally.

But the fervor over striking the right balance between, on the one hand, facilitating fair pretrial preparation and, on the other hand, unfair intrusion, cost, and extortionate-like disruption has never really quieted.[40] If anything, the fervor has become only more shrill. The discovery fights during the first fifty years of liberal civil discovery often centered on exasperation with the chores of gathering, reviewing, producing, and inspecting boxes (or truckloads, or warehouses) filled with paper discovery. Today, the fights often center on electronically stored information. In retrospect, it might have seemed uncontroversial, in the dawning days of the computer age, to blithely conclude that discovery requests "aimed at the

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[36] *See generally* Stephen N. Subrin, *David Dudley Field and the Field Code: A Historical Analysis of an Earlier Procedural Vision*, 6 LAW & HIST. REV. 311, 312 (1988) (noting that Field Code "met resistance"); Stephen N. Subrin, *How Equity Conquered Common Law: The Federal Rules of Civil Procedure in Historical Perspective*, 135 U. PA. L. REV. 909, 963–64 (1987) (discussing Charles Clark's critiques of Field Code).

[37] *See generally* CHARLES ALAN WRIGHT, THE LAW OF FEDERAL COURTS § 81, at 540 (4th ed. 1983) (noting that "[t]he 'sporting theory of justice' was rejected," "surprise, dearly cherished by an earlier generation of trial lawyers, would be minimized or ended altogether," and victory would now "go to the party entitled to it, on all the facts, rather than to the side that best uses it wits"). *But see* Stephen N. Subrin, *Fishing Expeditions Allowed: The Historical Background of the 1938 Federal Discovery Rules*, 39 B.C. L. REV. 691, 727–34 (1998) (discussing critiques of new federal rules and their approach to civil discovery).

[38] Hickman v. Taylor, 329 U.S. 495, 507 (1947).

[39] *See* Shelak v. White Motor Co., 581 F.2d 1155, 1159 (5th Cir. 1978) (commenting how federal discovery rules were designed to prevent "trial by ambush").

[40] Internationally, "American-style" discovery leaves the United States as an outlier in our judicial approach to civil discovery. The rest of the world does not seem to share our appetite for broad, far-reaching pretrial information exchanges. *See, e.g.*, Heraeus Kulzer, GmbH v. Biomet, Inc., 633 F.3d 591, 596 (7th Cir. 2011) ("[T]he German legal system . . . does not authorize discovery in the sense of Rule 26 of the Federal Rules of Civil Procedure. A party to a German lawsuit cannot demand categories of documents from his opponent. All he can demand are documents that he is able to identify specifically—individually, not by category."); Ela Barda & Thomas Rouhette, *The French Blocking Statute and Cross-Border Discovery*, 84 DEF. COUN. J. 1 (2017) (describing the operation of France's discovery-blocking statute); David J. Karl, *Islamic Law in Saudi Arabia: What Foreign Attorneys Should Know*, 25 GEO. WASH. J. INT'L L. & ECON. 131 (1991) ("Saudi law does not have any procedures for pretrial discovery.").

production of records retained in some electronic form [are] no different, in principle, from a request for documents contained in an office file cabinet."[41] The reality of present-day discovery has revealed a more numbing reality: the almost unfathomable task posed by monster volumes of electronically stored data, sometimes numbering in gigabytes or terabytes.[42] Appeals to trial judges to rein in the sprawl of electronically stored information discovery through better managerial oversight has proved to be no panacea. In 2007, even the U.S. Supreme Court had to acknowledge that "the success of judicial supervision in checking discovery abuse has been on the modest side," with the specter of untenable discovery costs "push[ing] cost-conscious defendants to settle even anemic cases."[43]

From the beginning, and through the tornado of withering criticisms leveled against broad civil discovery, one irresistible retort has persisted: the information exchange model in our approach to civil discovery is an entitlement that runs in both directions. Indeed, this very attribute was cited by the Supreme Court (albeit in a footnote) back in 1947 as it praised the benefits of robust discovery and tried to defang critics: "One of the chief arguments against the 'fishing expedition' objection is the idea that discovery is mutual—that while a party may have to disclose his case, he can at the same time tie his opponent down to a definite position."[44]

Yet there is no denying: civil discovery is intrusive. Defendants frequently complain about the burdens imposed by sweeping, invasive discovery requests,[45] but this refrain is heard often from plaintiffs as well.[46] Such is the nature of fishing expeditions: "It is part and parcel of the discovery process for parties to make discovery requests without knowing what they will get, or indeed, whether they will get anything at all."[47]

This is not to suggest that judges are weaponless in controlling the discovery sprawl, or that discovery procedures impose no meaningful constraints. In federal court, for example, most motions to compel discovery may only be filed after the

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[41] Linnen v. A.H. Robins Co., 1999 WL 462015, at *6 (Mass. Super. Ct. June 16, 1999). Equally casual was the judicial empathy for the types of challenges electronic-stored information discovery would pose: "While the reality of the situation [created by electronically stored information] may require a different approach and more sophisticated equipment than a photocopier, there is nothing about the technological aspects involved which renders documents stored in an electronic media 'undiscoverable.'" *Id.*

[42] *See generally* Bernard Marr, *How Much Data Do We Create Every Day? The Mind-Blowing Stats Everyone Should Read*, FORBES (May 21, 2018), https://www.forbes.com/sites/bernardmarr/2018/05/21/how-much-data-do-we-create-every-day-the-mind-blowing-stats-everyone-should-read/?sh=5f02f39660ba.

[43] Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007).

[44] Hickman v. Taylor, 329 U.S. 495, 507 n.8 (1947) (quoting James A. Pike & John W. Willis, *Federal Discovery in Operation*, 7 U. CHICAGO L. REV. 297, 303 (1940)).

[45] *See, e.g.*, Linnen, 1999 WL 462015, at *4 (estimating costs to comply with discovery requests to be between $1.1 million and $1.75 million).

[46] *See, e.g.*, Allen v. G.D. Searle & Co., 122 F.R.D. 580, 581–82 (D. Or. 1988) (ordering Dalkon Shield plaintiffs to provide discovery on their "number of sexual partners, frequency of sexual activity, and age of first sexual activity," notwithstanding plaintiffs' contention that their personal lives did not expose them to such alternative injury-causation risks: "Searle [defendant] is not required to rely on the plaintiffs' assurances that there are no potential causes of the plaintiffs' [injuries] other than Searle's [Dalkon Shield] product, but is entitled to discovery sufficient to form its own opinion").

[47] *See* Whiteamire Clinic, P.A., Inc. v. Quill Corp., 2013 WL 5348377, at *6 (N.D.Ill. Sept. 24, 2013) (Schenkier, M.J.).

parties first attempt to negotiate their discovery disagreements with a good-faith conferral,[48] and the motion-losers stand exposed to having to reimburse their opponents for reasonable motion costs.[49] The discoverability relevance standard is concededly quite broad, but it, too, is not unconstrained: judges are still required to assess "how big a pond" the discovery seeker is "allowed to fish in" and what "the requesting party [may] fish for."[50] And it remains improper, in the memorable phrasing of one judge, to "drain the pond and collect the fish from the bottom," rather than "using rod and reel, or even a reasonably sized net."[51]

The decision in *Davis v. Disability Rights New Jersey* is a reminder that the benefits of a system of robust pretrial civil discovery comes with costs. As technology evolves and society confronts new types of discovery challenges, the same debate renews. How committed are we and our profession to the vision of broad information exchanges? Has the time come to reassess the value of that breadth, or recalibrate the balance it strikes? Liberal discovery in civil litigation was once defended on its mutuality: that it posed similar opportunities and detriments to all litigants. Has that remained true in our increasingly digital age, with nearly inconceivable volumes of information multiplying exponentially?

The New Jersey Superior Court in *Davis* stayed the course. Social media posting—an activity unknown until just before the turn of the 21st century—today presents a content-rich environment for discovery "fishing" that intrudes into highly private and personal electronic sharing. The court in *Davis* understood all that, and, for the first time in the State of New Jersey, set out a template for resolving future social media discovery challenges in a manner that honored the broad scope of "American-style" discoverability "relevance" while still endeavoring to safeguard social media posters against unreasonable rummaging through their private spaces. The unanimous appellate court's considered approach merits emulation.

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[48] *See* Fed. R. Civ. P. 37(a)(1).

[49] *See* Fed. R. Civ. P. 37(a)(5).

[50] *See* Whiteamire Clinic, P.A., Inc.,, 2013 WL 5348377, at *6 (Schenkier, M.J.). *See also* Myers v. Prudential Ins. Co. of Am., 581 F. Supp. 2d 904, 913 (E.D. Tenn. 2008) (Carter, M.J.) ("the Federal Rules of Civil Procedure allow the Courts to determine the pond, the type of lure, and how long the parties can leave their lines in the water").

[51] *See* In re IBM Peripheral EDP Devices Antitrust Litig., 77 F.R.D. 39, 42 (N.D. Cal. 1977) (Conti, J.).

Relentless, Inc. v. Dep't of Commerce

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WHY IT MADE THE LIST

The discerning reader will note two facts about this case that may give rise to questions as to the reason for its inclusion in this compendium. First, although *Relentless* relates to fish, the agency facing challenge is not the U.S. Food and Drug Administration (FDA). Second, the paramount decision in this case is still pending with SCOTUS (although the appellate court decision was handed down in 2023), so the potential impacts of the case are yet to be determined. However, one need only crack an administrative law textbook or look to the last four decades of agency litigation to see the outsized importance of the doctrine at the heart of this case—*Chevron* deference.

While the appellate-level decision presents a fairly rote application of the doctrine, the Supreme Court took up the case as an opportunity to reconsider whether *Chevron* should be ditched entirely. Accordingly, it is the potential sea change in administrative law and corresponding implications for administrative agencies, including FDA, that make this case worthy of inclusion in this year's tome.

DISCUSSION

Background: Chevron *Deference*

In 1984, the Supreme Court first articulated the *Chevron* doctrine, which generally holds that a court reviewing an agency action under the Administrative Procedure Act (APA) should defer to an administrative agency's interpretation of a statute if: 1) Congress has not "directly spoken to the precise the question at issue," and 2) the agency's interpretation is "based on a permissible construction of the statute."[1] Under *Chevron* "step one," courts are to "employ traditional tools of statutory construction" to determine whether Congress has addressed the question before the court.[2] If Congress has done so, courts must "give effect to the unambiguously expressed intent of Congress."[3] Under *Chevron* "step two," if Congress was instead silent or ambiguous on the issue, whether explicitly or implicitly leaving a gap for an agency to fill, courts are to defer to the agency interpretation if it is "permissible."[4]

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1 Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842–43 (1984).

2 *Id.* at 843.

3 *Id.*

4 *Id.* at 865.

Agency interpretations that are the result of formal adjudication or notice-and-comment rulemaking are more likely to receive *Chevron* deference as compared to informal agency interpretations.[5]

Undergirding this approach is the philosophy, espoused by the Court, that "[j]udges are not experts in the [technical] field, and are not part of either political branch of the Government."[6] Conversely, these technical, scientific, and/or specialized areas of regulation are arguably well suited for interpretation using an agency's expertise and experience. Executive branch administrative agencies make "policy choices—resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities."[7]

Over the past forty years since *Chevron* was handed down, trial courts have diligently applied the *Chevron* "two-step" framework as gospel, even while higher courts have restricted its applicability[8] and questioned its workability.[9] The *Chevron* doctrine has been viewed by some as a beacon of stability, while others believe it distorts the branches of government and bestows too much power on executive agencies. Despite all of this debate, the Court has not actually engaged in a *Chevron* analysis since 2016.[10]

Notably, while the *Chevron* framework is most relevant to *Relentless*, readers would be remiss to overlook other key legal doctrines that may inform the Court's reasoning in the instant case or how the Court's decision in *Relentless* may impact the future of *Chevron*. For instance, many have opined that the Major Questions Doctrine (MQD), which the Court first referred to by name in 2022,[11] foretold the future irrelevance of *Chevron* deference. Separately, where *Chevron* does not apply, courts may still afford agency actions some deference under the *Skidmore* doctrine, pursuant to which agency interpretations are entitled to respect to the extent they have the "power to persuade."[12]

Procedural History

While the subject of *Relentless*—Atlantic herring fishing—is not of particular relevance here, some factual background will be helpful in bringing the potential impacts of this case to life.

The Magnuson-Stevens Fishery Conservation and Management Act (the MSA)[13] created eight regional councils to manage the fisheries in their regions and charged

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[5] *See, e.g.*, Martin v. Occupational Safety & Health Rev. Comm'n, 499 U.S. 144, 157 (1991) (where the Court first suggested that *Chevron* does not apply to interpretative rules); Christensen v. Harris Cnty., 529 U.S. 576 (2000) (refusing to grant *Chevron* deference to a Department of Labor opinion letter).

[6] *Chevron*, 467 U.S. at 865.

[7] *Id.* at 865–66.

[8] *See, e.g.*, United States v. Mead Corp., 533 U.S. 218, 231–35 (2001).

[9] *See, e.g.*, Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 111 (2015) (Scalia, J., dissenting).

[10] *See* Encino Motorcars, LLC v. Navarro, 579 U.S. 211 (2016).

[11] This case, *West Virginia v. Env't Prot. Agency*, was also the subject of a chapter in last year's edition of FDLI's *Top Food and Drug Cases, 2022 & Cases to Watch, 2023*, available at https://www.fdli.org/2023/06/west-virginia-v-environmental-protection-agency/.

[12] Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

[13] 16 U.S.C. §§ 1801 et seq.

them with each promulgating fishery management plans that specify conservation measures "necessary and appropriate" to prevent overfishing and promote sustainability.[14] These plans (and any amendments) are subject to review by an administrative agency (the National Marine Fisheries Service, NMFS) for compliance with the MSA and notice and comment rulemaking. Since 2000, the fishery management plan in New England for Atlantic herring has included monitoring by government-funded observers to measure bycatch (fish unintentionally caught) on fishing trips. In 2020, the New England regional council amended its fishery management plan to provide for a monitoring program funded, at least in part, by industry.[15]

Plaintiffs in *Relentless* argued that their unique fishing style (involving longer trips in which they may not catch herring) rendered them disproportionately burdened by the amended plan and that the MSA did not authorize its issuance, among other statutory and constitutional violations.

The District Court for the District of Rhode Island and the U.S. Court of Appeals for the First Circuit upheld the rule codifying the amended plan by applying the *Chevron* doctrine. The district court granted NMFS' request for summary judgment, finding that NMFS reasonably interpreted the MSA to permit industry-funded monitoring.[16] On appeal, the First Circuit affirmed the district court's ruling, dutifully applying *Chevron* to find against the petitioners.[17] The First Circuit found that the MSA explicitly authorizes the placement of observers on fishing vessels and rejected petitioners' argument that because the MSA contains no language allowing NMFS to place the cost burden on industry, NMFS lacks the authority to do so.

The Supreme Court granted petitioner's writ of certiorari in October 2023 and expeditiously held oral arguments on January 17, 2024. While this timetable may seem more hurried than is typical for the Court's docket, the Justices sought to hold oral arguments for both *Relentless* and a case with nearly identical facts, *Loper Bright Enterprises, Inc. v. Raimondo*, which the Court agreed to review in May,[18] on the same date in the January 2024 argument session.

Arguments Before the Supreme Court

Following oral arguments, the Court appears poised to overturn or limit the application of the *Chevron* framework. At argument, the government emphasized the doctrine's "deep roots in this Court's jurisprudence" and the need for a "truly extraordinary justification" to overrule the Court's prior decision under the doctrine of stare decisis.[19] On the other hand, petitioners argued that application of the *Chevron* doctrine is "not consistent with the rule of law" given that it requires

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[14] 16 U.S.C. §§ 1852-1853.

[15] *See* Magnuson–Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Industry-Funded Monitoring, 85 Fed. Reg. 7414 (Feb. 7, 2020).

[16] *See* Relentless, Inc. v. U.S. Dep't of Comm., 561 F. Supp. 3d 226, 237–38 (D.R.I. 2021).

[17] *See* Relentless, Inc. v. U.S. Dep't of Comm., 62 F. 4th 621, 628–34 (1st. Cir. 2023).

[18] The Justices may have wished to consider both cases due, at least in part, to Justice Ketanji Brown Jackson's recusal from *Loper Bright*, as she sat on the D.C. Circuit panel that originally heard the case.

[19] Transcript of *Relentless* Oral Argument at 75 (Relentless Transcript), available at https://www.supremecourt.gov/oral_arguments/argument_transcripts/2023/22-1219_e2p3.pdf.

deference to an agency's interpretation so long as it is reasonable, even if all Justices agree that an opposing interpretation is better.[20]

Justices Kagan, Sotomayor, and Jackson appeared to remain in favor of upholding the doctrine. According to the three liberal Justices, federal agencies that have scientific and technical expertise are better positioned than courts to resolve statutory ambiguities. Justice Jackson expressed concern over her prediction that, absent *Chevron*, the courts may inappropriately make policy decisions when filling in statutory gaps left by Congress.

The potential for a *Chevron* reversal appeared less concerning to Justices conventionally identified as the Court's conservative bloc. For example, Justice Kavanaugh commented that *Chevron* deference enables "massive change[s]" to agency policy decisions every four or eight years with each new administration.[21] Separately, Justice Gorsuch expressed concern over *Chevron*'s impact on the "little guy" who is affected by the actions of federal agencies and often not protected by application of the doctrine.[22]

The petitioners and government also disagreed over the practical implications of overturning *Chevron*. The government warned that litigants would "come out of the woodwork" if the Court were to overrule its past precedent.[23] Instead, the government suggested that the Court could more narrowly rule in a way that "clarif[ies] and articulate[s] the limits of *Chevron* deference."[24] However, the petitioners adamantly maintained that "the fundamental problem is *Chevron* itself."[25] The Justices also sought engagement on what *Chevron*'s potential replacement would look like, which we discuss further in the next section.

IMPACT OF THE DECISION

For forty years, the *Chevron* doctrine has been a bedrock of administrative law and practice, providing a source of certainty for the agencies that apply it, frustration for litigants seeking to challenge agency action, and debate amongst judges and legal scholars.[26] But in its review of *Relentless*, the Court will re-engage with the question of how much leeway agencies should receive in interpreting and fulfilling their congressional mandates. In our attempt to read the tea leaves, the Court's forthcoming decision will likely meaningfully impact the contours of this doctrine, but the potential implications for FDA are more opaque.

Assessing the impact first requires understanding what the presence of *Chevron* deference *means*, in practical terms, to FDA. Many commenters have remarked on the "ossification" of agency rulemaking over the years—in that rulemaking efforts take longer, are more resource intensive, and accordingly, result in fewer completed

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[20] *Id.* at 5.

[21] *Id.* at 97.

[22] *See id.* at 134–35.

[23] *Id.* at 80–81.

[24] Transcript of *Loper Bright* Oral Argument at 49, available at https://www.supremecourt.gov/oral_arguments/argument_transcripts/2023/22-451_o7jp.pdf.

[25] Relentless Transcript, *supra* note 19, at 155.

[26] According to the Solicitor General, the Supreme Court has relied on the *Chevron* framework in "more than 70 cases . . . to sustain an agency's interpretation." *Id.* at 75–76.

rulemakings. The presence of the *Chevron* doctrine provides the agency a degree of certainty in rulemaking; specifically, provided that an agency's "official" interpretation of a statute does not stray too far from the authorities delegated by Congress, there is a presumption that a reviewing court will defer to the agency's interpretation of the statute rather than substitute its own.[27]

An agency, such as FDA, may be less willing to sink limited resources into multi-year rulemaking efforts if the fate of a final rule is less predictable in the event of challenge. Policymaking ambitions of executive agencies may be diminished, such that any rulemaking hews much closer to the actuating statutory text.[28]

However, it is important to note that the Court may choose to clarify, pare back, or limit the application of *Chevron* rather than eliminate it entirely. Illuminating here is the Court's 2019 decision in *Kisor v. Wilkie*, in which the Court elected to retain but restrict a parallel doctrine ("*Auer* deference") that instructs courts to defer to an agency's interpretation of its own rules.[29] The Court could "Kisor-ize" *Chevron* deference by restricting the circumstances in which a court could deploy the framework, although this has been criticized by certain members of the Court as a stay of execution rather than a solution.[30] Moreover, a decision by the Court that weakens the *Chevron* doctrine could bolster the MQD's prominence as a basis to side-step *Chevron* altogether. Under the MQD, courts may never reach "step one" of Chevron if faced with "extraordinary cases . . . in which the history and the breadth of the authority that [the agency] has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority."[31] That is, courts reticent to apply *Chevron* deference may more readily find that agency actions raise a "major question" demanding "clear congressional authorization." Even if such result would have minimal impact on the policymaking function of FDA, the agency would be less likely to receive deference in case of challenge.[32]

If *Chevron* deference is fully uprooted and cast aside, however, the potential impacts to FDA are unclear.

At oral argument, the government warned of a torrent of litigation seeking to reopen past decisions "not [on the grounds of] whether the agency's interpretation is reasonable and whether the regulation can be upheld on that basis, but how the statute should be interpreted without granting any deference to the agency's interpretation."[33] If this prediction is borne out, FDA's legal interpretations (both formal and informal) would likely be a target for greater scrutiny. This could implicate a broad swath of agency actions, ranging from standard-setting

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[27] This deference is not assured, as FDA has discovered. *See* Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) (considered by many to be the first invocation of the MQD).

[28] Of course, for the challengers in *Relentless* and others that view the current administrative state as overbroad, this appears to be the intended result.

[29] *See* Kisor v. Wilkie, 139 S. Ct. 2400, 2419–23 (2019) (citing Auer v. Robbins, 519 U.S. 452 (1997)).

[30] *See Kisor*, 139 S. Ct. at 2426.

[31] West Virginia v. EPA, 142 S. Ct. 2587, 2608 (2022) (internal quotations omitted).

[32] At oral argument, the government stated that lower courts granted *Auer* deference "far less frequently" following *Kisor*. *See* Relentless Transcript, *supra* note 19, at 91–92.

[33] *Id.* at 80–81.

rulemakings (for example, the definition of "adequate and well controlled investigation" in the context of drug approvals[34]) to interpretative guidance across all product areas.

This is not to say that FDA functions would grind to a halt. Even absent *Chevron* deference, FDA's scientific or technical determinations are likely to still receive a heightened degree of deference,[35] although some conservative-minded Justices on the Court seem to indicate that they would be open to judicial review of *every* agency interpretation with "all the traditional tools of statutory interpretation."[36] At oral argument, Justice Kagan pointedly questioned petitioners on the limits of this position, asking whether a court should be charged with assessing *de novo* if a new product designed to promote healthy cholesterol levels would be considered a drug or dietary supplement, noting that "sometimes the law runs out" and reliance on agency expertise is warranted.[37] Although it is likely that the status quo will be maintained for agency determinations which are obviously factual in nature, the majority of the Justices' seeming willingness to remove *Chevron* and blur the lines between factual determination and legal interpretation raises questions about how long such a regime would last.

Finally, if the Court disposes of *Chevron* deference, what remains? Agency interpretations of statutes would likely remain entitled to *Skidmore* deference, based on a 1944 decision that was resurfaced at the turn of this century by the Court.[38] Under *Skidmore*, a court is not constrained to find in favor of the agency if the statute at issue is ambiguous; rather, a court independently interprets the statute and may elect to give weight to an agency's interpretation as a factor in its analysis depending on the "thoroughness evident in its consideration, the validity of its reasoning, its consistency," and even then, "all those factors . . . give it power to persuade," not to "control."[39] Agency officials should take caution—as Justice Kavanaugh intimated, "deference" is a misnomer; in application, *Skidmore* is closer to *de novo* review.[40]

Ultimately, the impacts of *Chevron*'s demise (if it comes to pass) remain to be seen; whether there is a "flood" of litigation or a ripple largely depends on the contours of the Court's decision, expected later this year. Nevertheless and regardless of how the Court rules, given the prevailing winds, it seems likely that agencies such as FDA can expect an uphill battle in defending their interpretations in court.

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[34] *Id.* at 67; 21 C.F.R. § 314.126(a).

[35] Provided an agency's factual conclusions have a substantial basis in the record, a reviewing court should refrain from substituting its judgement for that of the agency. Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42, 43 (1983). This axiom is particularly true where the agency's determination is technical, "at the frontiers of science," or within the realm of the agency's expertise. Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc., 462 U.S. 87, 103 (1983).

[36] Relentless Transcript, *supra* note 19, at 82–83.

[37] *Id.* at 12–13.

[38] *See Christensen*, 529 U.S. 576 (citing *Skidmore*, 323 U.S.).

[39] *Skidmore*, 323 U.S. at 140.

[40] *See* Relentless Transcript, *supra* note 19, at 52.

State ex rel. Shikada v. Bristol-Myers Squibb Co.

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WHY IT MADE THE LIST

In *Shikada*,[1] the State of Hawaii sued two drug companies, alleging they violated state consumer protection law by misleading the public about the efficacy of the blood thinner Plavix. Specifically, the State claimed the companies failed, for many years, to disclose that people with certain genetic makeup can be "poor responders" to Plavix before finally adding it to the label in 2009.

Shikada made the list because although the Hawaii Supreme Court did not fully affirm the trial court's finding in favor of the State of Hawaii with an associated significant monetary penalty, it did recognize broad tort-like liability for drug manufacturers for failure to warn of risks specific to racial and ethnic groups, second-guessing the judgment of the FDA as to appropriate label content. The case, although factually specific, may set risky precedent, threatening manufacturers of products that comply with FDA requirements but are less effective for certain racial groups.

BACKGROUND

In 2014, the State of Hawaii filed suit alleging that BMS and Sanofi ("manufacturers") violated Hawaii's Unfair or Deceptive Acts or Practices law (UDAP) by misleading the public about the safety and efficacy of the widely used blood thinner, Plavix (clopidogrel). The complaint alleged that Plavix was less effective in patients who had certain liver-enzyme mutations (poor responders), including Asian Americans. It also claimed that the manufacturers violated UDAP in two ways: by failing to update the drug's warnings to inform the public of Plavix's poor responder issue and by intentionally keeping the poor responder issue under wraps and suppressing research.

Before trial, the State moved for partial summary judgment on its ***deceptive*** acts or practices UDAP theory. To prove a deceptive acts claim, the State had to show: 1) a representation, omission, or practice that 2) was likely to mislead consumers acting reasonably when 3) the representation, omission, or practice was material.[2] The State's motion for summary judgment focused on the third element—materiality. It argued that trial was unnecessary regarding ***materiality*** of information about Plavix's lower efficacy for poor responders because there was "no doubt that the information

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1 State *ex rel.* Shikada v. Bristol-Myers Squibb Co., 526 P.3d 395 (Haw. 2023).

2 *Id.* at 526.

contained on Plavix's federally mandated black box warning is material as a matter of law." The trial court, calling itself the "Ultimate Trier of Fact," agreed, and concluded it "need not resolve inferences in favor of the non-moving party," granting the State's partial summary judgment. As a result, the manufacturers were precluded from presenting trial evidence about the materiality of Plavix's black box warning, including evidence that prescribers and patients did not stop using Plavix when the poor responder issue was later added to the black box warning—a critical defense made in any prescription drug case.

A month-long bench trial focused on three issues: 1) whether the manufacturers omitted the poor responder issue from the Plavix label between 1998 and 2009, or whether the manufacturers were doing the best they could with conflicting research on Plavix and variability in users' responsiveness; 2) whether the manufacturers suppressed research into variability of users' response; and 3) whether the omissions of the poor responder information from Plavix's label hurt Hawaii consumers.

The trial court agreed with the State of Hawaii on all three issues, finding the manufacturers violated UDAP by engaging in deceptive *and* unfair acts and practices, imposing an $834 million penalty on the manufacturers.

On appeal, the Supreme Court for the State of Hawaii held the following: "procedural bars," including UDAP's safe harbor provision, statute of limitations, and preemption, did not prevent the State's claims; the trial court erred in granting summary judgment to the State on materiality because the court disregarded evidence that raised a genuine factual dispute, which in turn led to vacating the trial court's deceptive acts or practices finding; affirmed the trial court's unfair acts or practices finding; and vacated the trial court's penalty determination.

DISCUSSION

"Procedural" Challenges

The manufacturers made three failed arguments on appeal related to legal issues the court characterized as "procedural."

First, the manufacturers argued that because Plavix's label was FDA-approved, it was exempted as "conduct in compliance with" a federal agency under the UDAP's "safe harbor" provision.[3] The Hawaii Supreme Court disagreed, focusing on the manufacturers' ***conduct*** and approach to publicizing and investigating the poor responder issue, which was not covered by FDA's approval of Plavix's label.[4] According to the court, FDA's approval did not provide a "safe harbor" for suppressing research on the poor responder issue.

Second, the manufacturers argued the State's action was time-barred. But under Hawaii law, the State is not subject to any limitations period unless it is "specifically designated in such statute as subject to the limitation period contained therein."[5] Under the applicable statute of limitations, however, there was no specific designation that the State was subject to the limitations period. Thus, the Supreme Court rejected the statute of limitations argument.

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[3] State ex rel. Shikada v. Bristol-Myers Squibb Co., 526 P.3d 395, 413 (2023).

[4] *Id.* at 414.

[5] Haw. Rev. Stat. § 657-1.5.

Third, the manufacturers argued the State's UDAP claims were preempted by the Federal Food, Drug, and Cosmetic Act (FDCA) because it would be impossible for them to comply with both federal drug labeling requirements and the duties imposed by the State's UDAP claims. Under federal law, labeling for the drug must match FDA-approved labeling. Under FDA's "changes being effected" (CBE) regulation, however, manufacturers can change a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage or administration that is intended to increase the safe use of the drug."[6] Because of the CBE regulation, the *Shikada* court held that the manufacturers could only establish "impossibility preemption" if they could show "with clear evidence that the FDA would not have approved a change to [Plavix]" required by state law.[7] The court held that the manufacturers had not provided "clear evidence" that FDA would have rejected an earlier label-update proposal, so there was no preemption.

Summary Judgment Challenge

The manufacturers then challenged the trial court's granting of the partial motion for summary judgment on materiality, and the Hawaii Supreme Court agreed.

In opposing the motion for summary judgment, the manufacturers showed that Hawaii doctors had not changed their prescribing decisions once the poor responder issue was later added to Plavix's black box warning in 2010, which suggests that any omission was not "material." The trial court disagreed, finding that when information relates to safety and health, there is a presumption that it is material. The Hawaii Supreme Court rejected the trial court's logic, emphasizing that "the testimony of prescribing doctors [] cannot be completely written off" and the trial court "erred by shutting out this category of evidence entirely."[8] The Hawaii Supreme Court determined that the manufacturers' showing was enough to create a triable issue of material fact at the summary judgement stage, even if the trial court were "confident" it would have reached the same conclusion at trial.[9]

Deceptive Acts or Practices Challenge

The Hawaii Supreme Court vacated the trial court's deceptive acts or practices holding because the grant of summary judgment on materiality "reverberated" throughout trial on this issue.

Proving that the omission of the poor responder issue from Plavix's labeling was material information likely to mislead consumers was critical to the State's deceptive acts or practices challenge. If the State could show that adding the poor responder issue to Plavix's labeling would have made no difference in whether people in Hawaii took the drug, then that would not be material information. But because of the summary judgment ruling, the manufacturers were barred from presenting any evidence that Hawaii doctors continued to prescribe Plavix even once the poor responder issue was added to its label in 2010. Thus, the Hawaii Supreme Court

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6 *Wyeth v. Levine*, 555 U.S. 555, 568 (2009) (quoting 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)).

7 *Shikada*, 526 P.3d at 416.

8 *Id.* at 419.

9 *Id.* at 419.

vacated the deceptive acts or practices holding, because the manufacturers "did not have the chance to make their case fully at trial."[10]

Unfair Acts or Practices Challenge

The Hawaii Supreme Court, however, affirmed the trial court's holding that the manufacturers engaged in unfair acts or practices in violation of the UDAP. A practice is unfair if it 1) offends public policy; 2) is immoral, unethical, oppressive, or unscrupulous; ***or*** 3) substantially injures Hawaii consumers.[11] Focusing on the conduct of the manufacturers (and not what Plavix's labeling said), the Hawaii Supreme Court concluded that the State of Hawaii had proven that the manufacturers' conduct both offended public policy and was immoral.

First, the court discussed the trial court's public policy findings. The State of Hawaii, according to the trial court, proved that the manufacturers "suppress[ed] research and continuously and repeatedly failed to further investigate" the poor responder issue.[12] The trial court found that the manufacturers knew that Plavix was less effective for non-White populations but failed to disclose that information to FDA and avoided funding studies that might draw more attention to the poor responder issue. The Supreme Court pronounced that "preventing risks from becoming apparent for financial gain offends Hawaii public policy."[13]

Second, the Hawaii Supreme Court left undisturbed the trial court's finding that the manufacturers' conduct was immoral for reasons much like its public policy findings. The court determined that there was no clear error in the trial court's finding that the manufacturers "buried their heads in the sand about the problems with Plavix."

Ultimately, the Supreme Court concluded that the manufacturers' conduct was unrelated to the materiality of Plavix's label, so the trial court's error granting summary judgment did not impact its unfair acts or practices finding.

Penalties

The *Shikada* court determined that the trial court's summary judgment ruling on materiality impacted its $834 million penalty determination, which "heav[ily] relied" on its materiality determination.[14] Thus, the court vacated the penalty to be determined after the deceptive acts claim was re-tried.

IMPACT

This case will undoubtedly inspire additional efforts to use broad consumer protection statutes to attack products that have been approved (or cleared) by FDA, are safe, provide benefit to most of the public, but may be less effective for certain ethnic groups. State Attorneys General and consumer advocacy groups are likely to make similar claims as the State of Hawaii against drugs like Plavix. For example, a similar lawsuit has been filed in California against the manufacturers of pulse

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[10] *Id.* at 420.

[11] *Id.*

[12] *Id.* at 424.

[13] *Id.*

[14] *Id.*

oximeters. Although many pulse oximeters are cleared by FDA, a consumer advocacy group claims the manufacturers violated California consumer protection statutes because competing research suggests pulse oximeters may be less accurate for people with darker pigmented skin. Thus, a product that is authorized by FDA, manufactured properly, with a state-of-the-art design, and adequate warnings still may face liability under consumer protection statutes if it turns out that the product is less effective for a particular racial group and the manufacturer either fails to disclose such information and in particular if it actively avoids or suppresses research suggesting such a difference.

Gilead Tenofovir Cases

ANAND AGNESHWAR, JOCELYN WIESNER & TOMMY HUYNH*

WHY IT MADE THE LIST

Under traditional tort principles, if a manufacturer makes a prescription medication that is free from defects in its design, manufacture, and labeling, it should not be held liable for causing any warned-about side effects. In *Gilead Tenofovir Cases*,[1] the California Court of Appeal disagreed. There, the California Court of Appeal approved a novel theory of negligence liability based on the allegation that the pharmaceutical manufacturer knew that a *different* medication it invented to treat the same condition but which had not yet been approved by FDA had fewer side effects. Specifically, the court held that users of defendant Gilead's HIV/AIDS medication, tenofovir disoproxil fumarate (TDF), could assert a negligence claim—without proving any defect in TDF—based on Gilead's alleged decision to delay commercialization of a different medication, tenofovir alafenamide fumarate (TAF), once it allegedly acquired actual knowledge that TAF is safer than, and equally effective as, TDF.

Some believe *Gilead* will open the floodgates to lawsuits whenever a pharmaceutical manufacturer releases a new, improved medication. While those concerns are understandable, we believe *Gilead* is better read as an aberration from traditional tort principles that is limited to a particular set of facts. First, the court's finding of a duty of care is premised on a manufacturer having actual, rather than constructive, knowledge of a safer alternative medication. While the court did not slam the door on a constructive knowledge standard, it did signal skepticism. Second, Gilead and manufacturers in other cases may be able to significantly curtail potential liability if they can establish that such liability attaches only after the new, alternative medication has completed FDA Phase III clinical trials, which are designed to compare the safety and efficacy of a new medication to an existing one. Whatever the outcome, this case is one to watch.

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[1] 98 Cal. App. 5th 911 (2024).

THE FACTS

Gilead developed TDF as one of the first medications to treat HIV/AIDS.[2] While TDF is an effective treatment, as with any medication, it is not without risks. Accordingly, when FDA approved TDF in 2001, it did so with a label that warned about various side effects, including bone and kidney damage.[3] While Gilead was developing TDF, it discovered TAF, a similar, but chemically distinct, medication.[4] Plaintiffs allege that Gilead's early testing indicated preliminarily—but not definitively—that TAF might be as effective a treatment for HIV/AIDS as TDF but have fewer side effects than TDF. Gilead conducted Phase I and II clinical trials of TAF in 2002, but allegedly discontinued its development in 2004 to maximize TDF's profitability.[5] Gilead eventually resumed work on TAF in 2011, and conducted a Phase III study to compare TDF and TAF in 2013, which showed TAF had less impact than TDF on bone metabolism and kidney function.[6] FDA approved TAF in 2015.[7]

Over 24,000 TDF users sued Gilead in California state court.[8] While they originally filed claims for strict product liability, negligence, breach of warranty, and fraudulent concealment, plaintiffs ultimately dropped any claim that TDF is defective as designed and narrowed their case to two theories: 1) Gilead failed to disclose facts relating to TAF while it was under development; and 2) Gilead breached its duty of reasonable care by postponing TAF's development in 2004 despite knowing TAF is a safer alternative to TDF, thus depriving plaintiffs of the *choice* between TDF and TAF.[9]

Gilead moved for summary judgment on each of plaintiffs' remaining claims. Although Gilead disputed plaintiffs' assertions about its knowledge of the relative safety and efficacy of TAF as well as its alleged profit motives for "delaying" commercialization, its motion focused on threshold legal issues and not the factual disputes. As to the fraudulent concealment claim, Gilead argued "it had no duty to disclose facts relating to TAF when it had not been approved as an alternative to TDF."[10] As to plaintiffs' negligence claim, it argued there can be no such claim without proof of a defect. "The trial court denied the motion in its entirety."[11]

Gilead filed a writ petition in 2022 presenting two questions. First, as to fraudulent concealment, Gilead asked whether it had a duty "to disclose facts relating to TAF, which was not available as an alternative to TDF."[12] Second, for negligence, the question presented was "whether a drug manufacturer, having invented what it knows is a safer, and at least equally effective, alternative to a prescription drug that it is currently selling and that is not shown to be defective, has a duty of reasonable care to

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2 *Id.* at 916.

3 *Id.* at 918.

4 *Id.* at 916.

5 *Id.* at 918.

6 *Id.* at 919 n.1.

7 *Id.* at 916.

8 *Id.*

9 *Id.* at 919.

10 *Id.* at 917.

11 *Id.*

12 *Id.* at 948.

users of the current drug when making decisions about the commercialization of the alternative drug."[13]

ANALYSIS AND HOLDING

The court granted the writ as to the fraudulent concealment claim, agreeing that Gilead had no duty to disclose facts about a potential alternative product that was not yet available for use. According to the court, "information about a [medication] that was not available, and ***could not possibly*** become available as a treatment for many years as a result of the time-consuming FDA approval process, would not have been material" to patients deciding whether to take TDF.[14] In other words, the court recognized that it would be "irrational" to make treatment decisions based on a product that might never come to be.[15]

Yet, paradoxically, the court found that Gilead ***did*** have a duty to bring TAF to market without delay. In arguing before the Court of Appeal, Gilead focused on plaintiffs' decision to abandon any claim that TDF is defectively designed. According to Gilead, because a manufacturer satisfies its duty of reasonable care by making a product that is not defective, plaintiffs' abandonment was fatal to its negligence case.[16] While that argument has obvious appeal given the history of product liability, the court did not agree. After reviewing a series of California cases, the court concluded that while proof of product defect may be necessary for a strict liability claim, it is not for negligence.[17] "Rather, the critical question for plaintiffs' purposes is simply whether Gilead's years-long delay in bringing TAF to market, despite knowing its equivalent efficacy to TDF, breached a duty of reasonable care to users of TDF if the reason was solely to maximize Gilead's profits."[18]

Having concluded that plaintiffs did not need to prove a design defect, the court analyzed plaintiffs' theory of liability under California's duty of care statute, Civil Code 1714(a), which imposes a general duty of "ordinary care or skill in the management of [] property or person." It held that Gilead bore the burden of showing that the *Rowland* factors—a set of foreseeability and public policy factors stemming from *Rowland v. Christian*, 69 Cal. 2d 108 (1968)—justified an ***exception*** to its duty of care. Although Gilead disputed plaintiffs' allegations, the court accepted—for purposes of its analysis—that Gilead both had actual knowledge that TAF was a safer alternative to TDF ***and*** that it delayed commercialization of TAF "solely to maximize Gilead's profits."

Gilead first argued that there is a categorical exception for FDA-approved drugs accompanied by adequate warnings that are not shown to be defective.[19] Alternatively, Gilead proposed a narrower exception that plaintiffs could "assert a claim for negligence without proof of a defect, but only as to decisions the . . . manufacturer made after obtaining the results of Phase III clinical trials of the alternative"

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[13] *Id.* at 922.

[14] *Id.* at 948–50 (emphasis added).

[15] *Id.* at 950.

[16] *Id.* at 922.

[17] *Id.* at 927.

[18] *Id.* at 933.

[19] *Id.* at 917.

medication.[20] In other words, the narrower exception proposed that "the amount of knowledge necessary to trigger the imposition of a duty of care cannot exist before the manufacturer has the results of Phase III trials of the alternative drug."[21]

The court first considered the proposed categorical exception under *Rowland*. The first three *Rowland* factors, or the foreseeability factors, are: foreseeability of injury, degree of certainty that plaintiffs suffered injury, and closeness of the connection between the defendant's conduct and the injury.[22] The court found these factors weighed against the exception. According to the court, it was foreseeable that Gilead's delay in commercializing TAF would "cause some users to suffer injury they could have avoided had the new drug been available."[23] While the court recognized that there may be differences in the relative safety and efficacy between two drugs that could impact the "extent of harm"—and thus foreseeability—it found that this did not justify an exception where (as it assumed here) the new drug "is ***at least equally*** effective ***and*** poses a lower risk of side effects."[24] Likewise, the court acknowledged that "there is often considerable uncertainty associated with" FDA approval and cautioned against "hindsight bias."[25] But it was "not persuaded that the need for FDA approval necessarily . . . sever[ed] what would otherwise be a close connection" because in its view, there necessarily comes a point in time when a drug manufacturer can assess the likelihood of FDA approval.[26] Here, it believed approval was "far less uncertain than might otherwise be" for TAF because it had accepted the premise that Gilead ***knew*** TAF "to be as effective as, and safer than," TDF based on its Phase I/II testing.[27]

The remaining four *Rowland* factors, or the public policy factors, that the court evaluated were: moral blame, policy of preventing future harm, the burden to the defendant and consequences to the community, and availability and cost of insurance.[28] Among other things, the court stated that the most important factor is the prevention of foreseeable harm, which weighed against the exception because finding a "duty would prevent manufacturers from delaying the development of safer treatments."[29] The court accepted plaintiffs' allegations that Gilead acted to gain financial benefit. While it did not find that this "***precise*** conduct" was a factual prerequisite, it did confirm that there must be some showing of negligence: "our task is to evaluate the degree of moral blame that attaches to *negligence* in a drug manufacturer's decisions about commercializing a safer drug, not to potential non-negligent reasons for its actions."[30]

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[20] *Id.* Phase III trials "'consist of wide-scale studies on patients with the disease for which the drug is intended and evaluate the overall risks and benefits of the drug'" and "are the final stage in the process required to obtain approval of a new drug." *Id.* at 945 (citation omitted).

[21] *Id.* at 946.

[22] *Id.* at 938.

[23] *Id.*

[24] *Id.* (emphases added).

[25] *Id.* at 940.

[26] *Id.*

[27] *Id.*

[28] *Id.* at 941.

[29] *Id.* at 945.

[30] *Id.* at 942 (emphasis in original).

Second, the court left open whether Gilead's proposed narrower exception—that a duty attaches only after a Phase III trial—for another day. Gilead for its part argued that a manufacturer would not be able to foresee with sufficient confidence that a new drug would have an improved safety and efficacy profile until the conclusion of Phase III trials—wide-scale studies in patients which form the basis of FDA approval.[31] Plaintiffs argued that Phase I and II trials can provide significant information and the level of knowledge will vary based on the facts at hand.[32] The court, explaining that the record on these questions had not been developed in the trial court and thus it did "not know, for example, how often or under what circumstances a drug's apparent promise after Phase II is undermined by unexpected results in Phase III," held that Gilead had not established that such an exception was appropriate.[33] But the court nonetheless recognized the "potential availability" of such an exception and allowed Gilead to further develop the record before seeking the narrower exception from either the trial court or on appeal.[34]

THE IMPACT

Gilead will undoubtedly be a cause for concern for many pharmaceutical manufacturers worried about increased product liability exposure. We think, however, that plaintiffs will have difficulty expanding *Gilead* beyond the particular facts at issue here.

First, the *Gilead* holding is premised on an "actual knowledge" requirement, meaning that, to impose a duty, a manufacturer must actually possess knowledge that an alternative medication is safer than, and equally effective as, an existing medication.[35] Gilead did not contest that it knew TAF was safer and as effective as TDF for purposes of its petition, and thus the court assumed that actual knowledge had been established.[36] The court was clear, however, that its conclusion did not prevent Gilead from further developing the factual record in the trial court—or, if necessary, on appeal—to contest the basic allegations underpinning its analysis.

Admittedly, the court did not foreclose the possibility that these or other plaintiffs could show a duty that is premised on the less-stringent constructive knowledge standard (i.e., what the manufacturer ***should have*** known), which could expand potentially liability.[37] But the court also cautioned that liability without actual knowledge would be difficult because "actual knowledge appears to be necessary to the motivation plaintiffs attribute to Gilead's decision."[38] The court also explained that a different *Rowland* analysis would be required because "among other things, a constructive knowledge standard would be more susceptible to hindsight bias by the

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[31] *Id.* at 945–46.

[32] *Id.* at 946.

[33] *Id.* at 946–47.

[34] *Id.* at 948.

[35] *Id.* at 921–22, 937.

[36] *Id.* at 921–22.

[37] *Id.* at 922 n.5 ("we take no position on whether plaintiffs should be permitted to include a constructive knowledge theory on remand").

[38] *Id.*

jury and therefore present more challenging policy issues."[39] And assuming actual knowledge is required—which we think it will—plaintiffs could face substantial hurdles in surviving even the pleading stage because California is a fact-pleading state that would require specific factual allegations demonstrating actual knowledge.

Second, the court left the door open for Gilead to develop the factual record on its clinical trial program and re-argue for the narrower exception tied to Phase III clinical trials. Because the court put the burden on Gilead to prove the exception applies, it is unclear whether the court would endorse a categorical exception for ***all*** manufacturers based on the record Gilead develops—e.g., "any meaningful generalizations about what can reasonably be known after Phase II trials as compared to Phase III trials, and what those generalizations would be"[40]—or would instead require ***each*** manufacturer to prove the exception on a case-by-case basis, potentially necessitating costly discovery before resolution. Either way, the argument for the exception to apply has legs to stand on. Unlike Phase II clinical trials that merely test whether a new medication works for a certain type of disease, "Phase III clinical trials compare the safety and effectiveness of the new [medication] against the current standard [medication]."[41] Assuming courts reject a constructive knowledge standard, it may be hard for plaintiffs to show a manufacturer actually knew the new medication is safer than the current medication without first completing Phase III trials specifically designed to make such a comparison.

Viewing the decision with a glass-half-full outlook, *Gilead* as it currently stands applies only to the seemingly rare situation where a manufacturer developed both the existing and alternative medications, actually knew the alternative is safer than, and provides the same benefits as, the existing medication, and acted negligently in delaying the commercialization of the alternative medication. Indeed, the court went out of its way to say that it was creating a narrow duty that did not apply to "improved" products or require manufacturers to take steps to perfect their products. The way the court put it likely holds some truth: "if this situation were common, the claim likely would have arisen long ago."[42]

We will have to wait to see how the case plays out, as the California Supreme Court, in a rare move, granted Gilead's petition for review on May 1, 2024. Briefing before the Court will likely close by October 2024, but the Court might not issue a decision until late 2025. In the meantime, in-house counsel should keep abreast of the results of any clinical testing for "improved" medications in the pipeline and any decisions regarding their commercialization.

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[39] *Id.* at 937.

[40] *Id.* at 946.

[41] *Types and Phases of Clinical Trials*, AM. CANCER SOC'Y (Aug. 18, 2020), https://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/clinical-trials/what-you-need-to-know/phases-of-clinical-trials.html.

[42] *Gilead*, 98 Cal. App. 5th at 944.

Horti v. Nestle Healthcare Nutrition, Inc.

RENE BEFURT, ANNE CAI, SEAN FLANAGAN & TOM RAHR*

WHY IT MADE THE LIST

To assess "reasonable" consumers' interpretations of a packaging claim, numerous product labeling cases have emphasized the importance of considering the context in which consumers encounter the claims. For instance, in *Horti v. Nestle*, the district court and the appellate court agreed generally on the relevance of marketplace context, such as the section of brick-and-mortar and online retail stores in which a product is placed, in assessing whether claims are deceptive to target consumers. In particular, the appellate court found that the at-issue "products' placement in stores alongside legitimate diabetes treatments may create a 'contextual inference[]' that the product may have a positive effect on the regulation of blood sugar,"[1] and the district court agreed that "[t]he context in which products are marketed and sold is indeed relevant to the assessment of whether product labels are deceptive."[2]

However, critically, the district court and the appellate court in this case disagreed on whether categorization or placement of the products relative to others in the marketplace were relevant to the litigation and Nestle's liability. Specifically, the district court dismissed Plaintiffs' Third Amended Complaint in part because Plaintiffs did not demonstrate that the physical or digital placement of the at-issue products in the marketplace is within Nestle's control. In contrast, the United States Court of Appeals for the Ninth Circuit reversed the district court's dismissal, noting that it is important to consider whether reasonable consumers may make a

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[1] Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832, at 4 (9th Cir. Dec. 13, 2023) (citing Moore v. Trader Joe's Co., 4 F.4th 874, 882 (9th Cir. July 15, 2021)).

[2] Horti v. Nestle Healthcare Nutrition, Inc., No. 21-cv-09812-PJH, at 5 (N.D. Cal. Nov. 7, 2022).

"contextual inference" based upon the placement of the product in certain categories or in proximity to other products.

These rulings in *Horti v. Nestle* demonstrate the importance of considering whether marketplace context beyond the product label itself, such as shelf placement, can be relevant to consumers' understanding and decision-making. Further, such contextual inferences—as with consumer perceptions more broadly—can be different for the relevant target consumers with particular knowledge and experience than for the general consuming public. Future stages of this matter and other matters regarding product labeling claims may benefit from survey-based empirical assessments of the perceptions and behavior of reasonable consumers in the relevant target population, with inclusion of marketplace elements that could potentially be used by target consumers to draw contextual inferences beyond the product label itself.

DISCUSSION

Procedural Background and Ruling of the District Court

In August 2022, Plaintiffs Bruce Horti, Sandra George, and Jeanette Craig filed an amended complaint in a class action lawsuit against Nestle Healthcare Nutrition, Inc. The lawsuit concerned Nestle's BOOST Glucose Control protein drinks that are sold by brick-and-mortar and online retailers such as Amazon, Walmart, Target, and CVS, as well as on Nestle's own website.[3] Plaintiffs took issue, for example, with the statement on the bottle reading "designed for people with diabetes" and alleged that Nestle's BOOST Glucose Control products presented claims that were false and deceptive and "misleadingly represent that they were designed for people with diabetes and control and manage blood glucose."[4] Specifically, Plaintiffs alleged that the name of the products themselves, "BOOST Glucose Control," along with the bottle packaging claims that the products "help[] manage blood sugar" and are "designed for people with diabetes," deceived consumers into believing that the products "would have some affirmatively therapeutic impact on their blood glucose levels, or otherwise mitigate, treat, or prevent prediabetes or diabetes."[5] Pointing to a clinical trial commissioned by Nestle and discussed on its website, Plaintiffs alleged that Nestle's BOOST Glucose Control products' only beneficial impact on consumers' blood sugar levels is that they "were only associated with a lesser rise in glucose levels as compared to one other nutritional drink that was unidentified in the study and . . . this is only because Boost Glucose Control drinks have less sugar[.]"[6]

In addition to allegations regarding the packaging claims specifically, Plaintiffs also alleged that the placement of Nestle's BOOST Glucose Control on physical store shelves and in categories of online stores further misled consumers. In particular, Plaintiffs alleged that Nestle's BOOST Glucose Control products are "sold in the health and nutritional supplement sections [of stores and websites], which [in physical retail stores] adjoin aisles selling over-the-counter medications,

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[3] Horti v. Nestle Healthcare Nutrition, Inc., No. 21-cv-09812-PJH, at ¶¶ 1–3, 7–10 (N.D. Cal. Aug. 1, 2022) (Dkt. 29, Third Amended Class Action Complaint).

[4] *Id.* ¶¶ 1–5, 49.

[5] *Id.* ¶¶ 3, 5.

[6] *Id.* ¶¶ 5, 53.

and other FDA-approved treatments, and diabetes diagnostic tests."[7] They further alleged that "Nestle's chosen placement of the [BOOST Glucose Control products] in stores and on websites enforces the conclusion Nestle and/or the retailers selling the [p]roducts view the products as treating health conditions, and that this is what they want consumers to believe."[8]

Nestle filed a motion to dismiss Plaintiffs' amended complaint at the end of August 2022.[9] In November 2022, the district court sided with Nestle and dismissed Plaintiffs' amended complaint with prejudice. The district court ruled that Plaintiffs failed to establish that "a reasonable consumer would be misled by the Boost labels," stating that the "clear designations of the nutritional contents on the front of the label, along with the description as nutritional drinks, demonstrate that the products are a food that will necessarily impact glucose levels, not a health supplement or a drug that would treat the chronic disease." The court further found that "this is particularly true for the targeted consumer group, persons with diabetes and prediabetes, who are aware of the relation between consuming sugar and blood glucose levels."[10] Additionally, the court found that "[t]he context in which products are marketed and sold is indeed relevant to the assessment of whether product labels are deceptive, but plaintiffs fail to plausibly allege that Nestle held control over placement of the products. The placement of the products thus does not sway the assessment."[11]

The district court also ruled that because Plaintiffs "[did] not allege facts that relate to their particular purchases . . . [they] simply [did] not provide enough detail beyond the barest descriptions of their injury to support standing."[12]

Plaintiffs appealed the decision in April 2023, and the United States Court of Appeals for the Ninth Circuit issued its opinion in December 2023.[13]

Ruling and Reasoning of the Appellate Court

The appellate court reversed the district court's ruling and remanded the case back to the district court. The appellate court found that the Plaintiffs did "sufficiently allege[] that the representations on the BOOST Glucose Control label are likely to mislead a reasonable consumer" at the pleading stage.[14] The appellate court noted that although Nestle offered interpretations of the product labels contrary to those offered by Plaintiffs, "that disagreement is not appropriate for resolution on a motion to dismiss." The appellate court further acknowledged that, consistent with Plaintiffs' allegations, the at-issue "products' placement in stores alongside

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[7] *Id.* ¶ 48.

[8] *Id.* ¶ 45.

[9] Horti v. Nestle Healthcare Nutrition, Inc., No. 21-cv-09812-PJH (N.D. Cal. Aug. 29, 2022) (Dkt. 32, Motion to Dismiss Third Amended Class Action Complaint).

[10] Horti v. Nestle Healthcare Nutrition, Inc., No. 21-cv-09812-PJH, at 4–5 (N.D. Cal. Nov. 7, 2022).

[11] *Id.* at 5.

[12] *Id.* at 6.

[13] Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832 (9th Cir. Apr. 7, 2023) (Plaintiffs-Appellants' Opening Brief); Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832 (9th Cir. Dec. 13, 2023).

[14] Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832, at 3 (9th Cir. Dec. 13, 2023).

legitimate diabetes treatments may create a 'contextual inference[]' that the product may have a positive effect on the regulation of blood sugar."[15]

The appellate court further disagreed with the district court's ruling regarding Plaintiffs' allegations of economic harm. While the district court found that Plaintiffs "[did] not provide enough detail" to support their standing,[16] the appellate court found that Plaintiffs' allegations that "they purchased a product they otherwise would not have bought but for defendant's alleged misrepresentations" are sufficient at the pleading stage to show they suffered harm.[17] Moreover, the appellate court ruled that, despite not offering the explicit amounts Plaintiffs paid for the at-issue products, "Plaintiffs fairly alleged that BOOST Glucose Control has a higher price than other comparable products and that plaintiffs chose to pay the premium based on Nestle's alleged misrepresentations."[18]

Horti v. Nestle was consolidated with another case, *Owens v. Nestle*, and Plaintiffs submitted their consolidated class action complaint in February 2024.[19] Nestle filed its answer to the consolidated complaint in March.[20]

IMPACT

In both the district court's dismissal of Plaintiffs' amended complaint and the appellate court's reversal, the courts assessed how a "reasonable consumer" could interpret the at-issue claims. In the appellate court's order, the court found that, at the pleading stage, Plaintiffs' arguments were "sufficient to show that a reasonable consumer could expect the product to exert some benefit on the control and regulation of blood sugar."[21] The appellate court found that, while this was sufficient for the pleading stage, the reasonable consumer test would require Plaintiffs to address the "probability 'that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.'"[22]

Later stages of the consolidated case may benefit from empirical evidence that addresses to what extent, if any, the at-issue representations were interpreted by consumers as alleged, and whether those at-issue representations affected consumers' purchase decisions. As the district court and appellate court recognized, several factors may affect consumers' perceptions of the at-issue claims and their ultimate purchase decisions. These factors matter at different stages of the purchase funnel—keeping in mind that consumers' purchase journeys do not typically start with evaluating the product packaging in isolation at the point of purchase, and

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[15] *Id.* at 4 (citing Moore v. Trader Joe's Co., 4 F.4th 874, 882 (9th Cir. July 15, 2021)).

[16] Horti v. Nestle Healthcare Nutrition, Inc., No. 21-cv-09812-PJH, at 6 (N.D. Cal. Nov. 7, 2022).

[17] Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832, at 2 (9th Cir. Dec. 13, 2023).

[18] *Id.* at 2–3.

[19] *In re* Nestle Boost Nutritional Drink Litig., No. 21-cv-09812-PJH (N.D. Cal. Feb. 20, 2024) (Dkt. 57, Order Granting Motion for Consolidation and Appointment of Interim Co-Lead Class Counsel); *In re* Nestle Boost Nutritional Drink Litig., No. 21-cv-09812-PJH (N.D. Cal. Feb. 29, 2024) (Dkt. 59, Consolidated Class Action Complaint).

[20] *In re* Nestle Boost Nutritional Drink Litig., No. 21-cv-09812-PJH (N.D. Cal. Mar. 21, 2024) (Dkt. 63, Answer to Consolidated Complaint).

[21] Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832, at 3 (9th Cir. Dec. 13, 2023).

[22] *Id.* at 3 (citing Ebner v. Fresh, Inc. 838 F.3d 958, 965 (9th Cir. 2016)).

instead include multiple phases: Consumers identify a need, collect information on available products to meet that need, evaluate the products they identify, decide on and purchase a product, and then experience the product in the post-purchase process.[23] Of particular relevance for this case, the information consumers are exposed to and the other products they consider in their purchase process may inform their understanding of and reaction to different marketing claims.

Many methods are available to assess consumer perceptions and behavior, including gathering empirical evidence through well-designed consumer surveys. Consumer surveys, assuming they are designed and conducted to produce valid and reliable data, have the advantage of addressing highly specific aspects of consumer behavior—a benefit that sales data or other data sources often cannot offer. In this case, surveys could examine factors related to the reasonable consumer's perceptions, beliefs, and purchase motivations about which the district court and the appellate court appear to disagree.

Relevant Population—Who is the Reasonable Consumer?

In the context of this case, the district court expressed concerns regarding Plaintiffs' theory as to how certain consumers would be misled by the at-issue claims. In their dismissal of Plaintiffs' Third Amended Complaint, the court concluded that deception was particularly unlikely "for the targeted consumer group, persons with diabetes and prediabetes, who are aware of the relation between consuming sugar and blood glucose levels."[24] When the district court's decision was overturned, the appellate court did not comment specifically on the at-issue products' target population, finding generally that a "reasonable consumer could understand these [at-issue] representations to indicate that the product[s] will have a positive effect on diabetes and blood sugar levels."[25] The two courts' disagreement on a "reasonable" consumer's interpretation of the at-issue representation thus sparks the questions of which type of consumer is targeted by Nestle's BOOST Glucose Control protein drinks, and subsequently, how those targeted consumers understand the at-issue claims.

Determining the target customer is an important consideration in an analysis regarding the reasonable consumer standard because the purchase process, and especially the sophistication and knowledge based on which buyers examine a product, may vary substantially between those who have purchased or would consider purchasing the at-issue product, and those who are not in the market for the at-issue product. In general, during the information search phase of the consumer buying process, consumers may conduct their own research, learn from professionals (such as physicians), receive information from friends or family, or recall their experience with the same or similar products.[26] The information that different consumers consider could impact how they interpret and act on marketing claims—if they do so at all. Because the perceptions and behavior of those who belong to a population of interest may differ systematically from those who do not, it is

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

[24] Horti v. Nestle Healthcare Nutrition, Inc., No. 21-cv-09812-PJH, at 5 (N.D. Cal. Nov. 7, 2022).

[25] Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832, at 3–4 (9th Cir. Dec. 13, 2023).

[26] KOTLER & KELLER, *supra* note 23, at 196.

important to carefully consider the target population of research aimed at assessing these issues.[27]

Marketplace Context—Does the Presentation of the Products Influence Consumer Behavior?

In its decision, the appellate court found that "the [at-issue] products' placement in stores alongside legitimate diabetes treatments may create a 'contextual inference[]' that the product may have a positive effect on the regulation of blood sugar."[28] Plaintiffs also reference the positioning of the at-issue products under the "Diabetes Care" section of the CVS website as contextual information that may lead consumers to interpret the at-issue claims as alleged. In contrast, in its dismissal of Plaintiffs' Third Amended Complaint, the district court found that "[t]he context in which products are marketed and sold is indeed relevant to the assessment of whether product labels are deceptive, but plaintiffs fail to plausibly allege that Nestle held control over placement of the products."[29] Irrespective of whether shelf placement of the at-issue product was in Nestle's control, it is reasonable to hypothesize that marketplace context may sway consumer behavior in this case. A well-designed survey could be informative in assessing the extent, if any, to which consumers interpreted the at-issue claims as alleged, in the context of their presentation in the marketplace.

Surveys can provide valuable insights into the ways in which consumers interpret and respond to the information presented to them by emulating—at least to a certain degree—how consumers experience contextual cues in the marketplace.[30] Accordingly, a guide on survey research conducted for litigation states that "a primary criterion for assessing the reliability of surveys . . . is based on the degree to which they alter the fundamental conditions in which the marks or terms at issue are encountered by buyers in reality."[31] In this matter, the marketplace context to consider when designing a survey may include the channels through which consumers search for the at-issue products, which other products may appear alongside the at-issue products on store shelves (or online), and in which section of brick-and-mortar stores or online retailer websites the at-issue product can be found.

Well-constructed surveys whose designs carefully consider the appropriate target population, realistic stimuli, and the marketplace context described above can provide evidence on the effect (if any) of particular marketing representations on consumers' perceptions and behavior that other data sources cannot directly address. In the *Nestle Boost Nutritional Drink Litigation*, survey research may help the courts to sharpen their view of the reasonable consumer by eliciting to what extent, if any, actual and prospective purchasers of the at-issue products interpret the at-issue

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[27] Shari Seidman Diamond, *Reference Guide on Survey Research*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 376–77 (3d ed. The National Academies Press 2011).

[28] Horti v. Nestle Healthcare Nutrition, Inc., No. 22-16832, at 4 (9th Cir. Dec. 13, 2023) (citing Moore v. Trader Joe's Co., 4 F.4th 874, 882 (9th Cir. July 15, 2021)).

[29] Horti v. Nestle Healthcare Nutrition, Inc., No. 21-cv-09812-PJH, at 5 (N.D. Cal. Nov. 7, 2022).

[30] *See, e.g.*, James R. Bettman, Mary Frances Luce & John W. Payne, *Constructive Consumer Choice Processes*, 25 J. CONSUMER RSCH. 187 (1998).

[31] Itamar Simonson & Ran Kivetz, *Demand Effects in Likelihood of Confusion Surveys: The Importance of Marketplace Conditions*, *in* TRADEMARK AND DECEPTIVE ADVERTISING SURVEYS: LAW, SCIENCE, AND DESIGN 259 (1st ed. American Bar Association 2012).

claims in the marketplace context as alleged, and if the alleged misrepresentations are material to consumers' purchase decisions.

McGinity v. The Procter & Gamble Co.

MITAL PATEL*

WHY IT MADE THE LIST

The filing of mass-produced class action suits targeting allegedly misleading product labels continued unabated in 2023. Though the trend shows no hint of slowing down, courts across the country continued to critically assess the allegations of these proposed class actions. California courts have long been a preferred venue for class action litigation, and this year, the Ninth Circuit provided much needed clarity to consumer companies that routinely face false advertising litigation by resolving an issue that had split district courts in the circuit.

In a panel decision, the Ninth Circuit held that when "a front label is ambiguous, the ambiguity can be resolved by reference to the back label."[1] The decision also warned that consumer surveys require the "utmost care."[2] Prior to this decision, the district courts in the Ninth Circuit were split as to whether and when a reasonable consumer can be expected to rely on the back label to clarify content on the front label. *McGinity* provided consumer products companies with necessary guidance on labeling practices and consumers with the assurance that an unambiguously deceptive front label of a product cannot be cured by the back label.

Though prolific plaintiffs' attorneys are continuing to file putative class actions targeting the food and beverage industry at high speeds, the Ninth Circuit is sending clear messages to the plaintiffs' bar. In 2023, the Ninth Circuit also affirmed the dismissal of *Vitort v. Kroger Co.*, another putative class action targeting a spreadable fruit product, "Just Fruit," sold by Kroger supermarkets.[3] In an unpublished decision, a three-judge panel agreed with the lower court that a reasonable consumer is unlikely to be misled especially because spreadable fruit products usually contain added sugars.[4]

Other circuit and district courts around the country are undoubtedly taking note of the Ninth Circuit's skepticism of complaints based on front label claims alone. Whether these decisions slow down the plaintiffs' bar has yet to be determined.

DECISION AND BACKGROUND

The *McGinity* case concerned "Pantene Pro-V Nature Fusion" shampoo and conditioner with "Nature Fusion" labels appearing in bold, capitalized text with an

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1 McGinity v. Procter & Gamble Co., 63 F.4d 1093, 1099 (9th Cir. June 9, 2023).

2 *Id.* at 1100.

3 No. 22-35185, 2023 U.S. App. LEXIS 10410 (9th Cir. Apr. 28, 2023).

4 *Id.*

image of an avocado on a green leaf on the front label.[5] Plaintiffs filed a putative class action complaint in the Northern District of California against Procter & Gamble Co. (P&G) alleging the front labels of these shampoos and conditioners were misleading and violated California consumer protection laws because the labels conveyed the products are natural when they purportedly "contain nonnatural and synthetic ingredients, harsh and potentially harmful ingredients, and are substantially unnatural."[6]

In support of his allegations that the labels were misleading, McGinity relied on a survey of over 400 consumers commissioned by his counsel. This consumer survey purported to show that about 75% of consumers thought the products contained more natural than synthetic/artificial ingredients; 52.6% of consumers thought the phrase "Nature Fusion" meant that the product did not contain synthetic ingredients; 49.1% of consumers thought that the phrase "Nature Fusion" meant that the product contained only natural ingredients; and 69.2% thought that the phrase "Nature Fusion" meant that the product contained both natural and synthetic ingredients.[7]

McGinity's survey only showed the survey respondents the products' front labels.[8] Plaintiff alleged the back labels were irrelevant because according to Plaintiff, information on the back of a product cannot be used to "clarify" a deceptive label on the front.[9]

After the district court dismissed plaintiff's second amended complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), he appealed the decision to the Ninth Circuit.[10] Plaintiff contended that he purchased the products and paid a premium for them because he wanted "natural" personal care products, but these products contained non-natural and synthetic ingredients and were substantially unnatural. The Ninth Circuit, applying the reasonable consumer standard, affirmed the district court's dismissal of the complaint for failure to state a claim.[11]

Pointing to the plaintiff's own survey, the Ninth Circuit panel found that there was ambiguity as to what "Nature Fusion" meant in the context of the product packaging. As the court noted, "[l]ooking only at the front label, survey respondents were split nearly 50/50 on the question of whether the products contain a mixture of natural and non-natural ingredients, or if they instead contain all or substantially all natural ingredients."[12] As in *Moore v. Trader Joe's*,[13] where the court found a manuka honey product label stating "100% New Zealand Manuka Honey" was ambiguous as to whether the Manuka flower was the only source of the honey, this ambiguity regarding "Nature Fusion" meant that the court needed to consider what additional

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5 63 F.4d 1093.

6 McGinity v. Procter & Gamble Co., No. 4:20-cv-08164, 2021 U.S. Dist. LEXIS 165001 (N.D. Cal. Aug. 31, 2021).

7 *McGinity*, 2021 U.S. Dist. LEXIS 165001, at *6; *see also McGinity*, 69 F.4th at 1096.

8 *McGinity*, 69 F.4th at 1099.

9 *Id.*

10 *McGinity*, 69 F.4th.

11 *Id.*

12 *Id.* at 1099.

13 4 F.4th 874, 876–77 (9th Cir. 2021).

information other than the front label was available to consumers.[14] Judge Gould, who authored the panel decision, noted that "[g]iven that ambiguity, the survey is not informative as to whether the labeling of the products is misleading as a whole . . . . Had the survey participants had access to the products' back labels, they would have had an immediate answer to this question—they could see that the products contain avocado oil, a natural ingredient, as well as many synthetic ingredients."[15]

Citing *Moore v. Mars Petcare U.S., Inc*., the court held that when, as here, a front label is ambiguous, the ambiguity can be resolved by reference to the back label.[16] These products' back labels contained representations that made clear that "Nature Fusion" referred to the use of natural avocado oil in the products and the ingredient lists dispelled any confusion on the part of a reasonable consumer as to whether each of the ingredients were natural or synthetic. With the entire product in hand, no reasonable consumer would think that the products were either completely or substantially natural. The court therefore affirmed the decision of the district court dismissing plaintiff's claims for failure to state a claim under F.R.C.P. 12(b)(6).[17]

Concurring in his own opinion, Judge Gould, joined by Judge Berzon, wrote separately expressing some discomfort and opining that although the labeling at issue was not deceptive as a matter of law, the labeling nonetheless reflected an increasingly common practice known as "greenwashing," in which the positive environmental impact or attributes of a product are publicly misrepresented or exaggerated.[18]

Two months prior to the *McGinity* decision, the Ninth Circuit also affirmed the District Court of Oregon's dismissal in *Vitort*.[19] In *Vitort*, the plaintiff claimed that Kroger marketed its spreadable fruit product as "Just Fruit" in order to capitalize on consumer demand for minimally processed foods that avoid unhealthy added sugars despite including "significant added sugar, well beyond the sugar occurring naturally in the fruit," including additives such as pectin, calcium citrate, apple juice concentrate, and citrus acid.[20]

In an unpublished opinion, the Ninth Circuit panel agreed with the lower court's conclusion that the product's label "Just Fruit" was not objectively false in the context of spreadable fruit products.[21] Plaintiff's allegation that the pectin, fruit syrup, calcium citrate, apple juice concentrate, and citric acid are not fruit because they don't appear in a form that exists in nature was unpersuasive to the court.[22] The court noted that "spreadable fruit" is also not found in nature and, unlike many other spreadable fruit products that do contain non-fruit ingredients such as flavor extracts, non-fruit sugar, food coloring, or animal gelatin, each ingredient in Kroger's "Just Fruit" product is actually derived from fruit.[23] The court concluded that because each

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[14] *McGinity*, 69 F.4th at 1097.

[15] *Id.* at 1099.

[16] *McGinity*, 69 F.4th at 1093.

[17] 69 F.4th 1093, 1099–1100.

[18] *McGinity*, 69 F.4th at 1100 (Gould, J., concurring).

[19] 2023 U.S. App. LEXIS 10410.

[20] *Id.*

[21] *Id.* at *2.

[22] *Id.* at *3.

[23] *Id.*

of the ingredients on the label was derived from fruit, the label was not objectively false.

The Ninth Circuit further agreed with the lower court's determination that a reasonable consumer would not be misled by the "Just Fruit" label.[24] The court found that the label does not imply or expressly state anything about the sugar content of the product, and a reasonable consumer would not interpret it as doing so because spreadable fruit products also tend to contain added sugars.[25]

IMPLICATIONS AND IMPACT

This recent pair of decisions suggests a growing skepticism by courts of challenges to front label claims. The decisions reinforce a growing trend of cases holding that while a back-label disclosure cannot correct a plainly false or deceptive representation, the back label, including the ingredient list, would set reasonable consumers straight when the challenged statements on the front pack are merely ambiguous. This is a welcomed decision for false advertising defendants that have had difficulty convincing district courts to review the entirety of a package with allegedly misleading front-of-pack representations. Going forward, it will be more difficult for plaintiffs to argue that a reasonable consumer should solely rely on a product's front label. To do so, plaintiffs will face the burden of plausibly alleging that the front label is plainly false or deceptive, rather than merely ambiguous. If relying on a survey to show whether a front label is deceptive or merely just ambiguous, it must be designed with the utmost care.

Notably, the *McGinity* decision has already had a positive impact on defendants facing false labeling consumer class action suits. For instance, after the *McGinity* decision, the U.S. District Court for the Central District of California granted defendant's motion for reconsideration and dismissed with prejudice the Consumer Legal Remedies Act and express warranty claims in *Scruggs v. Mars Inc*.[26] In its prior motion to dismiss, the court—citing *Williams v. Gerber Prods. Co.*[27]—found that "the placement, color and font size of 'Artificially Flavored' compared to the word 'CINNAMON' [on an Altoids container] and the depiction of cinnamon sticks, could cause a reasonable consumer to find the meaning [of the front label] ambiguous."[28] In light of *McGinity*, on reconsideration the court determined that the front label of the product was ambiguous and therefore, "a reasonable consumer would be expected to review and consider the back label in determining the actual ingredients of the Product."[29] The *Scruggs* decision highlights the welcomed impact *McGinity* will continue to have on false labeling consumer class actions.

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[24] *Id.* at *4.

[25] *Id.*

[26] No. 22-cv-05617 JAK, 2023 U.S. Dist. LEXIS 212597, at *2 (C.D. Cal. Nov. 9, 2023).

[27] 552 F.3d 934, 939 (9th Cir. 2008).

[28] Scruggs v. Mars, Inc., 2023 U.S. Dist. LEXIS 96022, *19–*20 (C.D. Cal. May 22, 2023).

[29] *Scruggs*, 2023 U.S. Dist. LEXIS 212597 at *19.

Eli Lilly v. Novartis (Kisqali)

MELISSA C. BROWN*

I. WHY IT MADE THE LIST

On June 3, 2022, Novartis released the results of its latest clinical trial for its breast cancer treatment, Kisqali. The headline read:

> **New CDK4/6i data at ASCO reinforce Novartis Kisqali as only drug in class with consistently proven overall survival benefit in HR+/HER2- metastatic breast cancer.**

The announcement had special resonance in the industry as the following day, Pfizer announced that the results of the most recent trial of its competing drug Ibrance, although promising, did not reach statistical significance. On the back of the announcement, Novartis launched a broad national advertising campaign directed to both health care providers and consumers, including a television commercial which aired on several major networks, website advertising, and physician brochures, fliers and conference presentations touting the results of it studies. The following month, after a brief and unsuccessful round of correspondence with Novartis, competitor Eli Lilly filed a challenge with the National Advertising Division of BBB National Programs (NAD), alleging that Novartis' advertising made false and misleading claims about its Kisqali drug.

The decision that issued at the end of that year is notable as a casebook study of the challenges of substantiating health benefit claims and the limitations of cross-trial comparisons submitted for that purpose. It is also a striking illustration of how an advertising claim directed to health care professionals can convey a distinctly different message to the lay public and goes to the heart of the issues that arise in advertising prescription drugs—especially sophisticated treatment drugs—directly to consumers.

II. DISCUSSION

Metastatic breast cancer, or stage IV breast cancer, is cancer that has spread beyond the breast to other parts of the body. Roughly 20–30% of persons diagnosed with early breast cancer will develop metastatic breast cancer, the most common form of which is HR+, HER2 breast cancer. Metastatic breast cancer is presently incurable, but current treatments can reduce the spread of cancer to other parts of the body, consequently extending time without disease progression and enabling patients to live longer—an outcome referred to as "overall survival." Kisqali belongs to a class of treatments known as CDK 4/6 inhibitors. CDK 4/6 inhibitors block proteins

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of the same name found in both healthy and cancer cells and which, in breast cancer, can become overactive and cause the cells to grow and divide uncontrollably and precipitate tumor growth. In the United States, there are currently three CDK4/6 inhibitors that have been approved by the FDA to treat HR+, HER2 breast cancer: Pfizer's *Ibrance*, Lilly's *Verzenio* and Novartis' *Kisqali*. Each drug has been the subject of several significant phase III clinical trials with overall survival as a key clinical endpoint. The test groups in each study received the target drug in combination with an adjuvant therapy (usually an endocrine therapy), and survival outcomes were compared against the placebo group taking the same therapy alone.

Both parties submitted data as to their clinical trials.[1] In addition, Novartis introduced a meta-analysis of global CDK4/6 research to date. That analysis indicated that no other CDK4/6 treatment had achieved statistical significance in three phase III trials. The claims at issue in *Novartis* were grounded in this clinical landscape.

Specifically, Lilly challenged the headline claim in the press release and several variations of the express claim "KISQALI – the longest median overall survival ever reported in HR+/HER2 mBC,"[2] along with the implied claims that Kisqali provided superior survival benefits over competing treatments and that patients taking Kisqali would live longer than patients taking any other comparable drug. During the course of the proceedings, Novartis informed NAD that it was permanently discontinuing all but one of the challenged express claims—a result not uncommon in response to an NAD challenge—as well as the implied claims alleged to flow therefrom. Novartis also withdrew the commercial in which those claims appeared. Remaining for NAD's review was the claim "The only drug in class with consistently proven overall survival benefit in HR+/HER2- metastatic breast cancer," (the "only drug in class" claim).

Lilly argued that the remaining claim was undeniably comparative and went beyond merely reporting the results of Novartis' MONALEESA trials and conveyed the message that Kisqali provides superior survival benefits as to other available treatments, including Verzenio—a message that was unsupported in the absence of head-to-head testing of Kisqali against the market. Lilly also emphasized that Novartis' advertising targeted a vulnerable population grappling with an incurable

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[1] Lilly's first published trial, MONARCH-2, studied Verzenio in combination with fulvestrant and yielded a statistically significant improvement in overall survival as compared to the placebo. Its latest study, MONARCH-3 combining Verzenio with an NSAI, is ongoing, and results have not yet reached statistical significance. Novartis has published three clinical trials, MONALEESA-7, in combination with goserelin and either an NSAI or tamoxifen; MONALEESA-3, Kisqali with fulvestrant; and MONALEESA-2, Kisqali with letrozole. In all three trials, Kisqali demonstrated a statistically significant survival benefit over the placebo. Separately, public records indicate that Pfizer had published two clinical trials, PALOMA-3, in combination with fulvestrant, and PALOMA-2, in combination with letrozole. In both trials, although patients in the Ibrance group demonstrated a longer overall survival than patients in the placebo, neither trial had achieved results that were statistically significant.

[2] The other challenged claims were:

"Live Longer with KISQALI - The Longest Overall Survival Data Ever Reported in HR+, HER2- mBC";

"The longest survival data ever reported in HR+, HER2- mBC";

"Kisqali has the longest median overall survival ever reported in HR+/HER2- metastatic breast cancer."

disease. Novartis argued that its claim was not a superiority claim and at best a parity claim that was fully supported by current clinical data.

In an NAD proceeding, the advertiser bears the burden of proof and is responsible for all messages reasonably conveyed by the advertising, not merely those it intended to convey. Moreover, although NAD false advertising analysis often evaluates advertising from the perspective of the reasonable consumer, NAD has recognized that the takeaways by discerning professionals may be critically distinct from the interpretations of that same advertising by the lay consumer. NAD therefore evaluated the challenged claim through the lens of each of the target audiences.

i. Consumer-Directed Advertising

As a threshold matter, NAD determined that the claim, "only drug in class with consistently proven overall survival benefit in HR+/HER2 metastatic breast cancer across three phase III trials," is inherently comparative. By virtue of the phrase "only drug in class", the claim pits Kisqali against all other CDK4/6 inhibitors and posits it has an attribute that the others do not have—here, a consistently proven survival benefit across three clinical trials.[3] NAD noted that to a lay consumer, a reasonable conclusion from the statement that a drug has been consistently—and more often—proven to achieve a statistically significant survival benefit is that that product is more effective.[4] NAD noted further that as used here, the term "consistently" implies that the results of trials of competing drugs have been *inconsistent*—a message that, without qualification, was open to negative inferences beyond the mere absence of regularly achieving a statistically significant result. As such, NAD found that, to the lay audience, Novartis' quantitative claim could convey a qualitative message. NAD also agreed with Lilly that the target audience here would be especially susceptible to claims of improved survival.

NAD reasoned that most consumers do not have the medical knowledge or experience to understand the nuances of clinical trials. They may not appreciate that the results of a clinical trial may be influenced by a variety of factors apart from the quality and efficacy of the tested drug, such as trial design, patient population characteristics, interactions and nature of adjuvant drugs, etc., and as such, they will not understand that outcomes across trials are difficult to compare. NAD reasoned further that the lay consumer will not understand that achieving statistical significance across three clinical trials does not in and of itself establish superior efficacy to other drugs that have proven effective in a smaller number of trials.

Novartis argued that because Kisqali is a prescription drug, it cannot be obtained directly by the patient, and the oncologist could correct any possible misleading messages conveyed by the challenged claim. However, NAD determined that the fact

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[3] Novartis informed NAD that the claim would replace the discontinued "longest survival" claims on the patient-facing section of the Kisqali website.

[4] See *i-Health (Culturelle)*, Report #6196, NAD/CARU Case Reports (January 2018), involving a challenge to a series of clinically proven claims for i-Health's Culturelle probiotic supplement, including the claims: "LGG is the most clinically proven effective strain*" "*Based on the studies of a range of benefits throughout the lifespan*"; "LGG is the most proven effective strain*" "**Based on the number of Lactobacillus rhamnosus GG clinical studies, as of May 2017."* NAD determined that one message reasonably conveyed by the advertiser's "most proven effective" claims was that the strain of probiotic in Culturelle had been proven to be more effective than competing strains in providing the benefits associated with probiotics.

that a consumer cannot purchase Kisqali by herself or that an oncologist may correct any misinterpretation of Novartis' advertising did not remove the initial impression of the claim. Nor did it absolve Novartis of its obligations to ensure that the initial impression of its advertising was not misleading.

In sum, NAD concluded that one message reasonably conveyed to consumers by the "only drug in class" claim is that Kisqali is more effective and provides superior survival benefits to other drugs in its class, including Verzenio, and that patients taking Kisqali will live longer than when taking any other CDK4/6 treatment. NAD also concluded that Novartis' evidence did not support such a claim. NAD noted first that clinically proven health claims are held to a very a high standard of proof and that where express or implied superiority claims are at issue, head-to-head testing is the most reliable form of substantiation. NAD also noted that data accumulated from different tests cannot be reliably compared unless it is established that the data resulted from tests that were "essentially identical or all of the variables are accounted for."[5]

NAD found that the clinical data presented by Novartis did not allow for meaningful assessment or comparison. Although that evidence established that Kisqali had achieved the longest median overall survival outcome in a published clinical trial of CDK4/6 inhibitors, Novartis presented no evidence that the methodologies in the studies it had submitted were similar enough to allow NAD to properly compare the reported overall survival data, nor any statistical analysis of those results. Additionally, Novartis did not provide any details as to the patient populations enrolled in each trial or other critical elements of the trials being compared (such as study design, period of follow-up, etc.). Further, as Lilly pointed out, the comparator arms (endocrine therapy combinations) were not the same between the studies relied on by Novartis and submitted to the record. There were also important differences even as between the Lilly and Novartis studies evaluating Verzenio and Kisqali in combination with fulvestrant, especially as to the patient populations enrolled in each trial. For example, MONALEESA-3 enrolled a higher proportion of patients with advanced or metastatic breast cancer who had never

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[5] *See, e.g.*, *Colgate-Palmolive Co. (Colgate Optic White Toothpaste)* Report #5490, NAD/CARU Case Reports (July 2012) (disallowing comparison of results of clinical testing on advertiser's toothpaste to results of testing on challenger's product where "studies were conducted at different sites, using different protocols, and using different criteria for participation, with different baselines); *Unilever US, Inc. (Vaseline Sheer Infusion*) Report #5262, NAD/CARU Case Reports (Dec. 2010) (rejecting combination of advertiser's monadic sensory testing and statistical PCA (Principal Component Analysis) data to support claim advertiser's product had a "silkier feel" over other lotions); *Novus International, Inc. (Mintrex and MAAC Organic Copper Supplements for Livestock)*, Report #5597, NAD/CARU Case Reports (May 2013) (rejecting series of studies on bovine liver copper values to support superiority claim in the absence of statistical analysis of performance of copper supplements as compared to each other and not to placebo); *Procter & Gamble (Crest White Strips)* Report #3918, NAD Case Reports (June 2002) (rejecting cross study comparison because of the "many differences between the [two] studies" submitted); *Den-Mat Corp. (Rembrandt Plus Superior Bleaching system and Dazzling White Tooth Bleaching Value Kit)* Report #3814, NAD Case Reports (Sept. 2001) (disallowing comparison of data from advertiser's product to multiple tests of challenger's Crest Whitestrips where "the methodology varied with respect to the number of people being evaluated, the accompanying dentifrice that was used by test participants and inclusion or omission of pre-test prophylaxis . . . made a comparison of the resulting data untenable"); *Ecofibers, Inc. (d/b/a Precision Fibers) (Hydroseeding Mulch)* Report #3905, NAD/CARU Case Reports (May 2002) (disallowing comparison of results of two separate studies due to differences in methodologies).

received endocrine therapy as treatment for breast cancer (endocrine naïve), while MONARCH-2 excluded these patients from the intent-to-treat population. Additionally, MONARCH-2 enrolled more patients with clinical features suggestive of endocrine resistant disease.

For all these reasons, NAD concluded that the implied superiority messages in the "only drug in class claim" were not supported and recommended that Novartis discontinue the claim in patient-facing advertising and refrain from making any claims that implied that Kisqali provides superior survival benefits to other comparable drugs or that patients taking Kisqali would live longer than patients taking any other available treatment.

ii. Physician-Directed Advertising

NAD reached a different conclusion with respect to Novartis' physician-directed advertising claim: "The only CDK4/6 inhibitor with statistically significant overall survival proven across 3 phase III trials." The claim appears in a context surrounded by data, including the parameters of all three of the MONALEESA studies, follow up times, confidence bounds, patient subgroups tested, extensive drug and safety information, and additional notes on toxicities, adverse reactions, lab abnormalities, footnote references, and a graph of MONALEESA-2 data as the study progressed. NAD determined that the target audience—primarily oncologists—would discern that the comparative claim related to clinical data points and did not convey a broader message of relative efficacy. First, NAD reasoned that the oncologist audience would be well versed with the science in this area and familiar with the intricacies of breast cancer research and as such, would be fully equipped to appreciate both the significance *and* the limitations of the reported data, especially when provided with sufficient detail as to the trials' design and findings. For the same reasons, NAD determined that the professional audience would understand that, although the achievement of a statistically significant survival outcome in more trials than its competitors is a promising result, it is not conclusive that Kisqali provides superior survival benefits to other comparable drugs or superior survival benefits to all classes of patients with HR+/HER2 metastatic breast cancer.

NAD concluded that clinical experience and the context provided in the HCP advertising would both inform the physician takeaway and limit it to the recited facts, and that this audience would interpret the comparative claim here simply as reporting that Kisqali is unique in achieving a statistically significant overall survival benefit across Novartis' three phase III clinical trials. NAD also found that this message was amply supported by the advertiser's evidence.

Novartis agreed to comply with NAD's recommendations. On the patient section of its redesigned website for Kisqali, the claim now reads: **"Proven to Extend Lives in 3 Large Clinical Trials."**

III. IMPACT

First and foremost, *Novartis* was a resounding win for consumers, and misleading claims targeting a vulnerable population were removed from the marketplace in a matter of months. Indeed, to patients with terminal cancer, Novartis' survival claim was the ultimate health benefit claim. Second, *Novartis* was an affirmation for self-regulation, and a high-stakes dispute was resolved quickly, efficiently, and with limited expenditure of resources. Third, the decision offers important guidance for advertisers seeking to make comparative clinical effect claims or comparative health

benefit claims generally. More broadly, NAD has no discretion to reject challenges brought before it and is regularly tasked with addressing novel issues. Thus, although NAD review relies heavily on FTC rulings and guidance—and where regulated products are at issue, seeks to harmonize its decisions with federal regulation—it is often called upon to fill in the gaps of agency rules and guidance.

Finally, and perhaps most critically, *Novartis* is an example of how NAD can look at claims—especially implied claims that may not rise to the level of priorities of the FDA. Further, for example, Lilly noted in its challenge that in fiscal year 2021, the FDA's Office of Prescription Drug Promotion received over 145,000 unique submissions through the Form 2253 process. As the decision illustrates, NAD can take a deep dive into these claims and the full spectrum of contexts in which they appear. Clearly, the risks of overstatement in comparative health benefit claims are not limited to prescription medications. However in this arena, with claims about a penultimate health benefit, the stakes can be much, much higher.

ABOUT THE NATIONAL ADVERTISING DIVISION

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.

In 2023, approximately 25% of NAD cases involved products regulated in whole or in part by the FDA, and every quarter, NAD submits a report of its decisions of cases involving FDA regulated products to various division of that agency. As a coda to the *Novartis* case, in January of this year, the FDA issued a warning letter to Novartis for a new television commercial making a compound claim that Kisqali helped patients with metastatic breast cancer both live longer and live well.

2023 FDA Regulatory Developments

AUGUST T. HORVATH

The year 2023 saw several significant regulatory developments and policy initiatives involving FDA. Here is a brief selection of the regulatory "greatest hits" from the past year.

FOOD AND DRUG OMNIBUS REFORM ACT

At the end of 2022 (December 29), President Biden signed into law the Food and Drug Omnibus Reform Act (FDORA), which amended the Federal Food, Drug, and Cosmetic Act (FDCA) to give FDA new authority and mandates. The legislation reformed the process of accelerated marketing approval for products whose release is deemed urgent by FDA. FDA can now require the sponsor to have confirmatory trials underway before being granted accelerated approval, and provides for expedited withdrawal of a previously granted approval if the confirmatory trials fail to confirm a clinical benefit. The law also provided for the establishment of an inter-agency Accelerated Approval Council, which was convened in 2023 and included representatives of the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Oncology Center of Excellence. The council's activities in 2023 were limited to two meetings concerned with agenda-setting and high-level policy discussion.[1]

FDORA also gave FDA new authority to mandate diversity of race, gender, ethnicity, and socioeconomic status in clinical trials, a subject that has been the subject of growing industry consensus for some years. Under the new law, sponsors must submit a diversity action plan for any Stage 3 clinical trial, including goals for enrollment and a plan for meeting them. As also required by the law, FDA held its first public workshop, in association with the Clinical Trials Transformation Initiative, by videoconference on November 29–30, 2023.[2]

Several provisions of FDORA sought to update drug reform to take account of the rise of biologics. One provision, paralleling those already in place for drugs, required biologics license holders to submit marketing status reports to FDA by June 27, 2023, confirming that their products' Purple Book listings are accurate, and to notify FDA when a biological product is withdrawn from the market. Another provision extended the Qualified Infectious Disease Product program, heretofore available only to conventional chemical drugs, to biologics. The effect of these and other biologics-related provisions of FDORA is to normalize the regulatory treatment of biologics under a regime similar to that in place for drugs.

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[1] U.S. FOOD & DRUG ADMIN., ACCELERATED APPROVAL COUNCIL ACTIVITIES REPORT, CY 2023, https://www.fda.gov/media/174154/download.

[2] Recordings and slide decks from the workshop are available at the Clinical Trials Transformation Initiative web site. *Virtual Public Workshop to Enhance Clinical Study Diversity (FDORA)*, CLINICAL TRIALS TRANSFORMATION INITIATIVE (Nov. 29–30, 2023), https://ctti-clinicaltrials.org/virtual-public-workshop-to-enhance-clinical-study-diversity/.

MODERNIZATION OF COSMETICS REFORM ACT

Along with FDORA, the government enacted long-awaited reform of the federal regulatory regime for cosmetics, in the form of the Modernization of Cosmetics Regulation Act (MoCRA), which went into effect on December 29, 2023, the first anniversary of its enactment. This law imposes new requirements on manufacturers and distributors of cosmetics (defined by the FDCA as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance," and therefore including many products that might commonly be considered cleansers or personal care products), including registration of facilities, reporting of product listings, reporting serious adverse health events, and fragrance allergen labeling. These requirements are patterned after ones that exist for drugs, which therefore are being relied upon for guidance in the absence of detailed implementing regulations and enforcement precedent for these nascent requirements.

CANNABIDIOL (CBD) REGULATION

Early in 2023, FDA announced that it had concluded that "existing regulatory frameworks for foods and supplements are not appropriate for cannabidiol" and that it will work with Congress to establish a new regulatory paradigm for CBD products.[3] This statement coincided with the denial of three citizen petitions requesting that FDA regulate CBD products under the existing dietary supplement regime. FDA cited special safety concerns purportedly associated with CBD and stated that it will continue to issue warning letters regarding clear violations of the FDCA while it works with Congress on comprehensive regulation. Since the 2018 Farm Bill removed cannabis from the Controlled Substances Act, CBD occupied a regulatory no-man's-land between food, drug, and supplement categories, limiting FDA's regulatory authority while it spent the intervening years contemplating which category, if any, it would regulate CBD under.

FDA GUIDANCE ON CLINICAL TRIALS

FDA issued several guidance documents on best practices for clinical trials in 2023. This guidance addressed not only research practices going to the validity of clinical trials, but also ethical concerns such as informed patient consent.

Good Clinical Practice E6(R3) Draft Guideline

On May 19, FDA issued draft guidance intended to bring U.S. practice and regulation into conformance with Good Clinical Practice, described as "an international, ethical, scientific and quality standard for the conduct of trials that involve human participants."[4] By its terms, this extensive set of principles applies to

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[3] Press Release, Statement from Janet Woodcock, U.S. Food & Drug Admin., FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward (Jan. 26, 2023), https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol.

[4] U.S. FOOD & DRUG ADMIN., E6(R3) GOOD CLINICAL PRACTICE (GCP) DRAFT GUIDELINE 1 (May 19, 2023), https://www.fda.gov/media/169090/download.

"interventional clinical trials of investigational products that are intended to be submitted to regulatory authorities," but they may also have more general applicability to drug-related clinical research. The guideline includes protections for the well-being, privacy, and safety of participants, as well as for diverse participant enrollment. Most principals are worded generally, as the guideline seeks to be flexible to accommodate the wide variety of clinical trial methodologies.

Final Guidance on Informed Consent

In August, FDA issued its final guidance "to assist institutional review boards (IRBs), clinical investigators, and sponsors in complying with FDA's informed consent regulations for clinical investigations."[5] The guidance supersedes prior guidance issued in 1998 and finalizes a draft form of the guidance issued in 2014, and "first present[s] general guidance on FDA's regulatory requirements for informed consent and a discussion of the roles of IRBs, clinical investigators, sponsors, and FDA related to informed consent, followed by a series of frequently asked questions."[6]

Electronic Systems and Signatures Draft Guidance

FDA issued draft guidance on the use of electronic systems, records, and signatures in clinical trials for foods, medical products, tobacco products, and animal drugs in March.[7] "The guidance provides recommendations regarding the requirements, including the requirements under 21 CFR part 11, under which FDA considers electronic systems, electronic records, and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper."[8] The bulk of the guidance is in question-and-answer format, and it seeks to clarify record-keeping and data submission requirements relating to clinical trial patient information and research data.

Draft Guidance on Single-Study Substantial Evidence of Effectiveness

In September, FDA released draft guidance regarding what it may consider to be substantial evidence of clinical effectiveness based on one randomized controlled trial plus other confirmatory evidence, as opposed to the two randomized controlled trials which have been the default standard.[9] FDA noted that this alternative has existed since 1997, when Congress amended Section 505(d) of the FDCA to give FDA discretion to consider such evidence. The bulk of this document discusses the types of confirmatory evidence that could support effectiveness when combined with

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[5] U.S. FOOD & DRUG ADMIN., INFORMED CONSENT—GUIDANCE FOR IRBS, CLINICAL INVESTIGATORS, AND SPONSORS (Aug. 2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent.

[6] *Id.*

[7] U.S. FOOD & DRUG ADMIN., ELECTRONIC SYSTEMS, ELECTRONIC RECORDS, AND ELECTRONIC SIGNATURES IN CLINICAL INVESTIGATIONS: QUESTIONS AND ANSWERS—GUIDANCE FOR INDUSTRY (Mar. 2023), https://www.fda.gov/media/166215/download.

[8] *Id.* at 1–2.

[9] U.S. FOOD & DRUG ADMIN., DEMONSTRATING SUBSTANTIAL EVIDENCE OF EFFECTIVENESS WITH ONE ADEQUATE AND WELL-CONTROLLED CLINICAL INVESTIGATION AND CONFIRMATORY EVIDENCE—GUIDANCE FOR INDUSTRY (Sept. 2023), https://www.fda.gov/media/172166/download.

a single clinical trial, including clinical trials of the same product from a related indication, mechanistic or pharmacodynamic evidence, evidence from relevant animal models, evidence from related products, and various kinds of real-world experience.

ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PROGRAM GUIDANCE

FDA closed out the year by issuing draft guidance on "advanced manufacturing technologies" (AMT), which it defines as "an innovative pharmaceutical manufacturing technology or approach that has the potential to improve the reliability and robustness of the manufacturing process and supply chain and increase timely access to quality medicines for the American public."[10] The impetus for this guidance was FDORA, which included amendments to FDCA § 506L requiring the establishment of such a program. FDA encourages the development of such technologies and issued its draft guidance for comment. The draft guidance concerns the criteria for formulating and submitting a request for AMT designation, as well as the proposed benefits associated with successfully obtaining such a designation. These proposed benefits include prioritized interaction with FDA, such as "timely advice and . . . additional communication, in the form of written correspondence or meetings" with AMT designation holders and other parties working with them.

[10] U.S. FOOD & DRUG ADMIN., ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PROGRAM— GUIDANCE FOR INDUSTRY (Dec. 2023), https://www.fda.gov/media/174651/download.

Food and Drug Cases to Watch in 2024

THE CONTRIBUTORS

As always, our panel of contributors has assembled some key ongoing cases to keep an eye on for the balance of the year 2024.

TAKAHASHI-MENDOZA V. COOP. REGIONS OF ORGANIC PRODUCER POOLS

The plaintiff in the putative class action *Takahashi-Mendoza v. Coop. Regions of Organic Produce Pools* alleges that Organic Valley, an organic dairy seller, falsely claims that its products are made with the highest standards of animal care practices, despite engaging in allegedly inhumane treatment of dairy cows.[1] The defendant's primary argument in its motion to dismiss was that the challenged packaging statements were non-substantive romance copy that is puffery and communicates no actionable claims. Judge Jon Tigar of the Northern District of California dismissed some claims, but found that claims that the defendant was "committed to the highest organic standards and animal care practices" were not puffery and were actionable. The parties have started discovery in this case and are preparing for a summer mediation. It will be interesting to see what happens in this case as it could greatly impact ESG food and beverage litigation.

UNITED STATES V. VEPURI

As reported in FDLI's *Food and Drug Law Journal*, the Third Circuit Court of Appeals in 2023 decided a case that "potentially allows any firm manufacturing a copycat drug to market it without FDA approval and without fear of FDA enforcement action under 21 U.S.C. § 355(a), provided the copycat has the same chemical composition and labeling as a drug specifically approved by FDA pursuant to a new drug application (NDA) or an abbreviated new drug application (ANDA)."[2] The court overturned the criminal convictions of a drug company and its executives for defrauding FDA in connection with its unauthorized substitution of a supplier of the active ingredient in its product from a facility not listed in the company's ANDAs or otherwise approved by FDA. At issue was the interpretation of FDCA § 355(a), which prohibits the introduction of a "new drug" into interstate commerce without a current application. The basis for the Third Circuit's decision was its conclusion that a drug does not become a "new drug" with a new "composition" merely because the source of the active ingredient is changed. Although this case was dismissed in April 2024 pursuant to the Third Circuit's ruling, commentators are

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[1] No. 22-cv-5086-JST (N.D. Cal.).

[2] 74 F.4th 141 (3d Cir. 2023); *see* Donald Ashley, Kalah Auchincloss & Elizabeth Oestreich, *Implications of Recent Third Circuit Court of Appeals Decision for FDA Drug Approval Framework*, 78 FOOD & DRUG L.J. 257 (2023), https://www.fdli.org/2023/12/implications-of-recent-third-circuit-court-of-appeals-decision-for-fda-drug-approval-framework-open-access/.

closely watching the government's next move to attempt to close the loophole created by the decision.

VANDA PHARMACEUTICALS V. UNITED STATES

In January of this year, the U.S. Court of Federal Claims granted in part and denied in part a motion to dismiss a case brought against FDA by Vanda, alleging a Fifth Amendment taking and a breach of implied-in-fact contract based on FDA's alleged disclosure of trade secrets and confidential information of Vanda during the approval process for generic drug equivalents of Vanda's product.[3] Vanda alleged that FDA had disclosed proprietary information about dissolution specifications, impurities analysis, and micronization to four generic drug companies that had filed ANDAs seeking to make generic versions of Vanda's Fanapt and Hetlioz branded drugs for treatment of schizophrenia and sleep disorders, respectively. The Fifth Amendment count survived the motion to dismiss, and the continuing case will be watched closely for its implications for FDA and other government agencies.

WINKELBAUER V. WELCH FOODS INC. & PROMOTION IN MOTION, INC.

Winkelbauer v. Welch Foods Inc. and Promotion in Motion, Inc. is a putative class action filed in the Northern District of California, alleging that Welch Foods misrepresents fruit snacks as containing no preservatives although the ingredient statement discloses the presence of citric and lactic acids.[4] This is one of many recent cases in which acids and other additives in foods, which are acknowledged potentially to serve multiple functions in the food, are alleged to be serving one particular function in contradiction of some labeling claim—most often either "no preservatives" or "no artificial flavors." Someday down the line, plaintiffs presumably would bear the burden of proving that the additive actually serves that function in the product. For purposes of a motion to dismiss, however, many courts require little more of plaintiffs than to allege that the ingredient *could* serve the alleged purpose or that it sometimes does so in other foods. *Winkelbauer* is one such case, and having survived a motion to dismiss in May 2023, it is currently in the process of litigating a motion for class certification. The case has been relatively hotly litigated, with the defendants succeeding in dismissing one named plaintiff who refused to show up for a deposition, and with motions to strike allegedly late-produced factual evidence and expert testimony before the court for hearing in June.

ALLIANCE FOR HIPPOCRATIC MEDICINE V. U.S. FOOD & DRUG ADMINISTRATION

We would be remiss in not mentioning the widely watched mifepristone case, whose appeal is styled FDA v. Alliance for Hippocratic Medicine, argued before the Supreme Court on March 26, 2024.[5] In this case, anti-abortion groups challenged

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[3] No. 23-629C (Ct. Fed. Claims).

[4] No. 3:22-cv-7028-JD (N.D. Cal.).

[5] No. 23-235 (S.Ct.).

FDA's approval of expanded access in 2016 and 2021 to drugs commonly used in medication abortions, as well as the drugs' original approvals in 2000. The appeal is from the Fifth Circuit, which upheld the plaintiffs' restrictions relating to the 2016 and 2021 FDA actions. The Justices' questioning during argument focused on Article III standing, including the sufficiency of the alleged underlying injury. They also expressed concern whether the nationwide injunction against the drugs would be an appropriate remedy, even if FDA's actions were found to be arbitrary and capricious in violation of the Administrative Procedure Act. Attention will continue to be focused on this case, given both its legal significance and political sensitivity.