Top Food and Drug Cases, 2021, & Cases to Watch, 2022

Edited by August T. Horvath

FDLI
Food and Drug Law Institute

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Introduction

AUGUST T. HORVATH*

Greetings again, readers! Any comment about the continuing COVID-19 pandemic and its impact on this volume would be trite by now. Suffice it to say, the original plan was to return to a paper publication to be distributed at the 2022 FDLI Annual Conference, but with the decision to make the conference only semi-in-person, it made sense to revert to an ebook again for our 2021–2022 edition of Top Food and Drug cases.

What this edition lacks in tree by-products, it makes up for in quality of content. This year we have fourteen chapters on top cases or clusters of cases, more than we have had for the past few years, perhaps reflecting something of a return to business as usual in both litigation and regulatory enforcement. As always, we span all aspects of the food, drug, and medical device sectors, and even cover developments outside the food and drug realm where our authors decided that they have important implications for the food and drug community. All of our contributors hope that FDLI's members continue to find our volume informative, interesting, and worth archiving for future reference. As always, we deliver a heads-up on Cases to Watch at the end of the book, to alert you to potential developments in the latter half of 2022 and beyond.

Several of our cases always cover developments at FDA. This year, Sara Koblitz covers the *Catalyst v. FDA* case, an important development in Orphan Drug Act approval. The team of Véronique Li, Faraz Siddiqui, and Jeff Gibbs tells us about a key case regarding FDA's ban on shock treatment devices for mental conditions. Naomi Igra writes about an important circuit court decision regarding FDA's stem cell procedure approval process. Jackie Chan and Dan Logan have written up an important case about FDA's Generally Recognized as Safe (GRAS) rules.

Two of our cases this year relate to another key agency, the Federal Trade Commission (FTC), and the implications of recent developments there for the food and drug sectors. Bryant Godfrey and Tina Papagiannopoulos discuss developments in the wild, high-profile tale of "pharma bro" Martin Shkreli, with its consequences for competition and other enforcement in the prescription drug sector. Lynn Tyler covers a key FTC matter involving FTC's authority to seek monetary recovery as a consumer protection remedy that, while not a food or drug case, has broad implications for any industry sector in which FTC is active. In addition, Jonathan Havens discusses the overall state of regulation of cannabis products.

Our other chapters address private litigation. Ginger Pigott and Michael Goodman cover an important development in the learned intermediary doctrine in failure-to-warn product liability cases. Mital Patel and Francisco Cabrera Lopez discuss a key appellate decision and its implications for the adequacy of pleading in the current

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significant wave of false labeling cases involving food products. I weigh in on an important constitutional challenge to the tide of litigation in California to enforce the state's mandated Proposition 65 warnings as they apply to acrylamide in foods. Bill Janssen reviews a key case relating to the pleading standard in product liability cases. James Beck summarizes an important Oklahoma Supreme Court decision, and related developments, on the ability of state Attorneys General to apply public nuisance and other laws to hold pharmaceutical companies liable for America's opioid abuse epidemic. Genna Liu, Rene Befurt, and Rebecca Kirk Fair discuss another important food labeling precedent relating to the interpretation of labels by courts in false advertising cases. Finally, from outside the food and drug area, Anand Agneshwar, Anna Thompson, and Jocelyn Wiesner reports on the implications of a major case on personal jurisdiction over out-of-state defendants.

As usual, we include two composite chapters summarizing types of developments that don't necessarily generate "cases" or court decisions. Lauren Farruggia again describes important regulatory and enforcement developments from the past year, and Justine Lenehan covers significant settlements between federal enforcement agencies and their targets over the course of 2021. For our final chapter, several authors nominated in-progress cases that we think are worth watching for the balance of 2022. As always, there is more than a little to interest any active practitioner in the food, drug, and related spaces in these pages.

I and FDLI sincerely appreciate the contributions of all of our authors, many of whom have been faithful contributors for several years. We hope this summary of important 2021 and early 2022 matters in the food and drug area provides you with the same education and enjoyment as our previous volumes. On behalf of the entire Top Cases team, we wish our audience a happy, healthy, and safe year.

Catalyst Pharmaceuticals, Inc. v. Becerra

SARA W. KOBLITZ*

WHY IT MADE THE LIST

The Orphan Drug Act of 1983 (the "Orphan Drug Act") provides incentives to encourage development of treatments for rare diseases affecting less than 200,000 patients in the United States.[1] Chief among those incentives is a seven-year period of market exclusivity awarded upon approval of a drug designated for the treatment of a rare disease or condition ("orphan condition") by the U.S. Food and Drug Administration (FDA).[2] By statute, this exclusivity precludes FDA from approving another application "for the same drug for the same disease or condition" for seven years after approval of the orphan-designated drug.[3] For thirty years, FDA has interpreted the language "same disease or condition" in the context of orphan drug exclusivity as the indication for which the designated drug was actually approved.[4] Consequently, the scope of orphan drug exclusivity has been narrow, protecting against competition from the "same drug" for only the same "use or indication," rather than the more expansive "disease or condition."[5]

In *Catalyst v. Becerra*, the Eleventh Circuit upended this nearly thirty year practice when it determined that FDA's interpretation of the phrase "same disease or condition" as same "use or indication" contravened the plain language of the Orphan Drug Act.[6] In September 2021, the Eleventh Circuit reversed a Southern District of Florida decision holding that the statutory phrase "same disease or condition" in the Orphan Drug Act is ambiguous and overturned its consequent deference to FDA's interpretation of the phrase to mean "use or indication" to define the scope of orphan drug exclusivity.[7] Accordingly, the Eleventh Circuit held that FDA's narrow interpretation of the scope of orphan drug exclusivity must be set aside, and along with it FDA's approval of the drug at issue in this case, as it is "the same drug" for the

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1 Orphan Drug Act of 1983, Pub. L. No. 97–414, 96 Stat 2049 (Jan. 4, 1983).

2 21 U.S.C. § 360cc(a).

3 *Id.*

4 *See* 21 C.F.R. § 316.3(b)(12) (Dec. 29, 1992); *see also* Orphan Drug Regulations, 56 Fed. Reg. 3,338 (explaining that the Orphan Drug Act "provides conditions under which a sponsor of an approved orphan drug enjoys exclusive approval for that drug for the orphan indication for 7 years following the date of the drug's approval for marketing") (Jan. 29, 1991).

5 *See id.*; Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299, 1307 (11th Cir. 2021).

6 *Catalyst*, 14 F.4th at 1307.

7 *Id.* at 1306.

"same disease or condition" as an orphan-protected drug but for a different "use or indication"[8]

Effectively, the *Catalyst v. Becerra* decision expands the scope of orphan drug exclusivity but, depending on how FDA implements it, could also limit its availability as FDA adjusts to the new interpretation of the Orphan Drug Act's exclusivity provisions. Barring any legislative action, *Catalyst v. Becerra* will force FDA to revisit its approach to orphan drug designation and exclusivity regulations.

DISCUSSION

Legal Background

Enacted in 1983, the Orphan Drug Act amended the Federal Food, Drug, and Cosmetic Act (FDCA) to encourage the development of drugs for rare diseases and conditions.[9] Because so few patients are affected by any given rare disease or condition, Congress recognized that a sponsor would incur financial loss in developing a drug for such a limited patient population, which would discourage innovation in this area.[10] To reduce the costs of development and encourage investment in orphan drugs, Congress adopted the Orphan Drug Act. [11]

The Orphan Drug Act provides a variety of benefits to sponsors of drugs intended to treat rare diseases or conditions. In addition to grants and tax credits for developing treatments for orphan conditions, the Orphan Drug Act awards a period of seven years of marketing exclusivity upon approval of an orphan drug during which FDA cannot approve another version of the "same drug for the same disease or condition" ("orphan drug exclusivity").[12] Eligibility for these incentives hinges on designation as an orphan drug early in the drug development process.[13] To receive such a designation, a manufacturer or sponsor submits a written request for designation to FDA demonstrating that a drug treats a "rare disease or condition" (i.e., an "orphan drug"), which is defined by statute as a condition that "affects less than 200,000 persons in the United States" or "affects more than 200,000 persons in the United States" but "for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug."[14] Assuming that the sponsor establishes a medically plausible hypothesis of effectiveness in a demonstrably orphan condition, FDA will designate the drug as an orphan drug for that specific disease or condition.[15]

Once FDA approves a marketing application for an orphan-designated drug, the agency may not approve another company's version of the "same drug" for the "same

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[8] *Id.* at 1312–13.

[9] Orphan Drug Act of 1983, Pub. L. 97-414, 96 Stat. 2049 (codified as amended at 21 U.S.C. §§ 360aa–360ee) (Jan. 4, 1983).

[10] *Id.* at § 1.

[11] *Id.*

[12] 21 U.S.C. § 360cc(a).

[13] *Id.* at § 360bb.

[14] *Id.* at § 360bb (a)(2).

[15] 21 C.F.R. § 316.20(b)(4).

disease or condition" for seven years.[16] There are, however, three narrow exceptions to this exclusivity bar: 1) FDA may only approve another sponsor's drug if there is not enough of the initially approved orphan product to supply the market; 2) if the sponsor of the drug protected by orphan drug exclusivity consents; or 3) if the subsequent drug is "different" from the approved orphan drug.[17] A drug is "different" from an approved orphan drug if it is chemically or structurally distinct from an approved orphan drug. However, even a drug that is structurally "the same" as an approved orphan drug may be approved for the same condition if it is "clinically superior" to the approved orphan drug. Sponsors must prove that the drug is clinically superior to overcome (or "break") orphan drug exclusivity.[18]

Factual Background

Long used to treat Lambert-Eaton myasthenic syndrome (LEMS), a condition affecting roughly 950 to 1,300 adult patients and a "couple dozen" pediatric patients in the United States, FDA granted amifampridine orphan drug designation for use in LEMS first in 1990 upon request by Jacobus Pharmaceutical Company, Inc. ("Jacobus"), and again upon request by Catalyst Pharmaceuticals, Inc. ("Catalyst") in 2009.[19] The two companies raced for approval with each submitting its New Drug Application (NDA) in early 2018.[20] Catalyst won the race for approval, and FDA approved Catalyst's orphan-designated drug product, called Firdapse (amifampridine), in November 2018 for the treatment of LEMS in adults. Firdapse was awarded seven years of orphan drug exclusivity pursuant to the Orphan Drug Act.[21]

Notwithstanding the orphan drug exclusivity barring FDA from approving another amifampridine product for the treatment of LEMS, FDA did just that when it approved Jacobus's NDA in 2019.[22] Rather than adult patients, however, Jacobus's amifampridine product, called Ruzurgi, was approved only for use in the very small group of pediatric LEMS patients.[23]

The path to approval for Ruzurgi was unusual. After FDA approved Catalyst's Firdapse, much concern was raised about pricing.[24] Senators "investigated" the price of Firdapse and urged FDA to enable access to more affordable versions of amifampridine;[25] more affordable versions of amifampridine included Ruzurgi, which Jacobus had been giving away for free for many years under an expanded access program.[26] FDA's hands were tied, though: due to the Firdapse orphan drug exclusivity, FDA could not approve the "same drug for the same disease or condition"

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[16] *Id.* at § 360cc(a).

[17] *Id.* at § 360cc(b).

[18] *Id.*

[19] Catalyst Pharms., Inc. v. Becerra, 14 F.4th at 1304 (11th Cir. 2021).

[20] *Id.*

[21] *Id.*

[22] *Id.* at 1304–05.

[23] *Id.*

[24] Press Release, Sen. Bernie Sanders, Sanders Investigates a $375,000 Price Spike on Old Drug (Feb. 4, 2019).

[25] *Id.*; Br. Appellant Catalyst, Catalyst Pharms., Inc. v. Alex Azar et al., Docket No. 20-13922 at 14–15 (S.D. Fla. Nov. 13, 2020).

[26] *Catalyst*, 14 F.4th at 1304.

as Firdapse, and thus could not approve Ruzurgi for the treatment of adult LEMS patients.[27]

FDA, of its own volition, administratively divided the Ruzurgi NDA into two parts—one for the treatment of LEMS in pediatric patients and the other for adult patients—"to allow for independent action in these populations" even though Jacobus's Ruzurgi NDA sought approval for all LEMS patients.[28] Approval for pediatric patients would not be blocked by orphan drug exclusivity, FDA determined, because treatment of the pediatric population constituted a different "use or indication" from Firdapse's indication of LEMS in adult patients, and thus fell outside of the scope of the orphan drug exclusivity applicable to Firdapse.[29] With this reasoning, FDA approved Ruzurgi for the treatment of pediatric LEMS in May 2019.[30] Approval was based on clinical data solely in adults as Jacobus had never performed studies in pediatric patients, and pediatric safety was based on data from Jacobus's expanded access program.[31]

Court Decision

Catalyst sued FDA in the Southern District of Florida alleging that the approval of Ruzurgi violated the Administrative Procedure Act (APA) and demanded that the court vacate FDA's approval of Ruzurgi.[32] Catalyst argued that, under the plain language of the Orphan Drug Act, FDA could not approve Ruzurgi because it is the "same drug" for the "same disease or condition" as Firdapse.[33] Catalyst also argued that the Ruzurgi labeling is false or misleading because it suggests that Ruzurgi can be used in adults—the patient population for which Firdapse has exclusivity—notwithstanding the fact that Ruzurgi obtained approval only for pediatric patients.[34] Jacobus intervened.[35]

All parties agreed that Firdapse and Ruzurgi meet the definition of "same drug" under the Orphan Drug Act and even agreed that LEMS is a single disease rather than two distinct conditions—one in pediatric patients and one in adult patients.[36] The parties, however, disagreed as to whether FDA's interpretation of the phrase "same disease or condition" in the Orphan Drug Act as same "use or indication" was reasonable.[37] A magistrate judge found that the plain language in the Orphan Drug Act is ambiguous, as the Orphan Drug Act is "unclear whether ["same disease or condition"] refers to the use for which the drug is approved after it submits its NDA."[38] The magistrate judge then concluded that FDA's interpretation was reasonable and

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[27] *Id.* at 1304–05.

[28] *Id.*

[29] *Id.* at 1305.

[30] *Id.* at 1304–05.

[31] *Id.* at 1305.

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.* at 1306.

[37] *Id.*

[38] *Id.*

should be afforded deference and recommended granting summary judgement to FDA.[39] The district court agreed, adopted the magistrate's recommendation in full, and dismissed the case.[40]

Catalyst appealed the district court's decision, and the Eleventh Circuit reviewed Catalyst's challenge to the agency action *de novo*.[41] On appeal, Catalyst argued that the district court erred in finding the plain language of the "same disease and condition" ambiguous; even if that language is ambiguous, Catalyst argued that FDA's interpretation limiting that phrase to "use or indications" was unreasonable.[42] Finally, Catalyst reiterated its argument that the Ruzurgi labeling violated the FDCA's labeling requirements.[43] Ultimately, the court addressed only the statutory argument, as the court determined that FDA's interpretation clearly violated the plain language of the statutory text and reversed the district court.[44]

Evaluating the term "same drug or condition" under the well-established canons of statutory interpretation, the court analyzed the plain and usual meaning of the term in the context of the Orphan Drug Act.[45] The word "same" in the Act, the court explained, is used to mean "the one under discussion or already referred to."[46] The only "disease or condition" already referred to in the exclusivity provision of the Orphan Drug Act as codified at 21 U.S.C. § 360cc(a) is the "rare disease or condition" for which the drug was "designated" pursuant to the Act's provisions codified in 21 U.S.C. § 360bb.[47] Thus, the court concluded, the "same drug or condition" in the exclusivity provision can be read only in one way: the "same disease or condition" for purposes of awarding exclusivity under 21 U.S.C. § 360cc refers specifically to the "rare disease or condition" designated under § 360bb.[48] Consequently, the court explained, the scope of the orphan drug exclusivity applies to the entire rare disease or condition—not just the "use or indication" for which the product is approved.[49]

Applying the plain language of the term "same disease or condition" to analyze the scope of the orphan drug exclusivity protecting Firdapse, the court reasoned that if, as all parties agreed, LEMS is a single condition—rather than two separate conditions in pediatric patients and adults—then *any* amifampridine used for LEMS is blocked by the Firdapse exclusivity, regardless of patient age.[50] Under the statute, therefore, FDA should not have approved Ruzurgi for any LEMS patient population until the expiration of the Firdapse exclusivity.[51] Thus, FDA's approval of Ruzurgi contradicted the unambiguous language of the Orphan Drug Act, and as a result, "FDA's agency

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[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.* at 1307.

[46] *Id.* at 1308.

[47] *Id.*

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] *Id.*

action was arbitrary, capricious, and not in accordance with the law" in violation of the APA.[52]

IMPACT OF THE DECISION

The court's ruling here upsets FDA's decades-long interpretation of the scope of orphan drug exclusivity. FDA had, since 1992, interpreted "same drug" in the context of exclusivity as limited to the "indication or use" for which the orphan drug product was approved and codified that longstanding interpretation in 2013.[53] The intent of this approach was to "permit multiple orphan-drug exclusive approvals for multiple subsets of the same underlying orphan disease or condition," which the agency believed "is consistent with the purpose of the Orphan Drug Act because it provides an important incentive for one or more sponsors to develop, or to continue to develop, a potentially promising drug for use in all persons affected by a rare disease or condition, rather than in just a subset of that orphan population, even after the drug has been approved for a different subset of the population with the disease or condition."[54] But under this decision, that approach contravenes the plain language of the Orphan Drug Act and violates the APA.

This decision undoubtedly increases the value of orphan drug exclusivity. With the significant expansion of the scope of orphan drug exclusivity to include the entire disease or condition—rather than the indication alone—such exclusivity would block approval of the same drug even if the exclusivity-protected orphan drug does not treat a given subpopulation. Such expansive market protection would preserve the intended incentive and impede maneuvers to circumvent orphan exclusivity through subsets and carve-outs. In turn, the expansive orphan drug exclusivity interpretation would provide more assurances that an orphan drug sponsor could recoup its investment in an otherwise (likely) unprofitable drug, which would thereby increase incentives to develop products for underserved patients. It would also serve to discourage FDA from deliberately undermining existing exclusivity by artificially subsetting a patient population in response to congressional pressure, as Catalyst alleged the agency did here.

However, the expansion of orphan drug exclusivity to block approval of the entire designated disease or condition could also limit treatment options for patients where few exist. Patients that cannot be treated by a drug that is protected by orphan exclusivity—if, for example, the drug is unsafe or ineffective in that orphan subset (i.e., the patient can't metabolize an oral drug)—but could be treated by another dosage form or salt would not have those options until the expiration of the orphan drug exclusivity. This scenario would encourage the use off-label or compounded formulations if no other treatments are available. Off-label use and compounded formulations provide no safety assurances, raising risks for already-vulnerable patients.[55]

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[52] *Id.* at 1312–13.

[53] *See* 76 Fed. Reg. 64,868, 64,870–71 (Oct. 19, 2011) ("The scope of orphan exclusive approval for a designated drug is limited to the approved indication or use, even if the underlying orphan designation is broader."); 21 C.F.R. § 316.31(b).

[54] 76 Fed. Reg. at 64,871.

[55] CONG. RSCH. SERV., R45792, OFF-LABEL USE OF PRESCRIPTION DRUGS (Feb. 23, 2021), https://sgp.fas.org/crs/misc/R45792.pdf; U.S. FOOD & DRUG ADMIN., MEMORANDUM, PUBLIC HEALTH

Importantly, the impact does not only affect orphan drug *exclusivity*; it also affects orphan drug *designation*. This may seem like a distinction without a difference, but it is the designation that provides tax credits, grants, user fee exemptions, and FDA development assistance.[56] Facilitating access to these benefits, orphan drug designation was intended to be granted liberally,[57] but expansion of exclusivity could cause FDA to scrutinize requests for designation more heavily, as the designated condition now determines the scope of exclusivity. FDA could do this simply by raising the burden of proof required to demonstrate a scientific rationale that the proposed product will treat the broader orphan condition rather than a subset.[58] And, in so doing, FDA effectively would limit access to important drug development resources.

Further, to limit overbroad exclusivity, FDA could subdivide a given condition into multiple conditions. This approach also raises policy concerns, as it could encourage further attempts to subtype (known as "salami slicing") conditions to obtain exclusivity where it has already been exhausted.[59] Such salami slicing concerns have raised concerns about "gaming" the orphan drug process with critics pointing to several instances in which FDA has granted multiple periods of orphan drug exclusivity to the same drug where the drug's sponsor obtains serial approvals for either different segments (i.e., indications) of the designated rare disease or condition, or where a drug's indication evolves into something new, shedding and subsuming the previous indication statement (e.g., different disease stages or different lines of therapy).

Finally, the court's decision in *Catalyst v. Becerra* could also lead to a slew of new Orphan Drug Act litigation. In some cases, particularly where drugs were designated and approved prior to this case, orphan drug exclusivity may now extend significantly farther than the approved indication for a product; another marketing application for the same drug for a different indication related to the same rare disease or condition may be subject to a legal challenge or, like here, rescission of approval. In other cases, however, there may be challenges to FDA's award of multiple periods of orphan drug exclusivity for the same drug for different indications of the same rare disease or

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INTERESTS AND FIRST AMENDMENT CONSIDERATIONS RELATED TO MANUFACTURER COMMUNICATIONS REGARDING UNAPPROVED USES OF APPROVED OR CLEARED MEDICAL PRODUCTS (Jan. 2017), https://www.regulations.gov/document?D=FDA-2016-N-1149-0040.

[56] Orphan Drug Regulations, 56 Fed. Reg. 3,338, 3,339 (Jan. 29, 1991); *Designating an Orphan Product: Drugs and Biological Products*, U.S. FOOD & DRUG ADMIN. (Sept. 7, 2021), https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products.

[57] 56 Fed. Reg. at 3,340 ("FDA decided on a liberal designation policy, however, because the agency wants to encourage research whose aim is to produce safer and more effective drugs, even if FDA believes that the prospects are dim . . . for eventual marketing approval.") (Sept. 7, 2021).

[58] *See* 21 C.F.R. § 316.10(b) (requiring an explanation to support the rationale of use of a proposed drug in the relevant orphan condition).

[59] Michael Mezher, *FDA Analyst Counters Critiques of Orphan Drug Act*, RAPS (Oct. 18, 2017), https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/10/fda-analyst-counters-critiques-of-orphan-drug-act.

condition because the court's decision supports a "one and done" approach to orphan drug exclusivity.[60]

As a result of the court's decision in *Catalyst v. Becerra*, FDA likely will revisit its approach to orphan drug exclusivity and designation. However, the agency has, in the past, refused to capitulate to courts with respect to the Orphan Drug Act and continued to enforce its violative interpretation notwithstanding a court decision.[61] Further, FDA previously has been successful in legislatively overriding similar decisions through an act of Congress.[62] Both of these options remain. How exactly FDA will address or change its practices in response to this decision is unknown.

As of the time of submission, FDA has not appealed, but Jacobus has filed a Petition for Certiorari to the Supreme Court.[63]

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[60] *See* Kurt R. Karst, *Orphan Drugs: The Current Firestorm, a Real Evergreening Issue, and a Possible Solution*, FDA LAW BLOG (Mar. 12, 2017), https://www.thefdalawblog.com/2017/03/orphan-drugs-the-current-firestorm-a-real-evergreening-issue-and-a-possible-solution-/.

[61] *See* Policy on Orphan-Drug Exclusivity; Clarification, 79 Fed. Reg. 76,888 (Dec. 23, 2014) (limiting the "clinical superiority" decision in *Depomed Inc. v. HHS et al*., Civil Action No. 12–1592 (Sept. 5, 2014) only to Gralise, the product at issue in that case).

[62] *See* Food and Drug Administration Reauthorization Act, Pub. L. 115-52 § 709, 131 Stat. 1005, 1067 (enacting legislation to overturn *Depomed Inc. v. HHS et al.*) (Aug. 18, 2017).

[63] Petition for Writ of Certiorari, *Jacobus v. Catalyst*, No. 21- , (U.S. April 7, 2022).

Judge Rotenberg Educational Center v. U.S. Food and Drug Administration

VÉRONIQUE LI, FARAZ SIDDIQUI & JEFF GIBBS*

WHY IT MADE THE LIST

The U.S. Food and Drug Administration (FDA) had only exercised its authority to ban medical devices twice by the time it finalized its ban on electrical stimulation devices (ESDs) for patients with self-injurious behavior (SIB) and aggressive behavior (AB). ESDs are aversive conditioning devices that deliver electrical shocks via electrodes attached to a person's skin. They are intended to limit or stop targeted behavior, such as nail biting or smoking. Patients with severe SIB and AB engage in extreme behaviors that can cause harm to themselves or others. This case represented FDA's first attempt to use this authority to ban a device for a particular use while allowing other uses, and the first time a device ban was challenged in court.[1] Plaintiffs, the Judge Rotenberg Center (JRC) and the parents and guardians of patients using ESDs for SIB/AB, sued FDA on multiple grounds, including for violating the practice of medicine exception. The Circuit Court of the District of Columbia agreed with plaintiffs that FDA could not ban a device for a particular use because doing so would "limit or interfere" with a physician's authority to prescribe or administer a "legally marketed device."

DISCUSSION

Legal Background

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (FDCA) grants FDA authority to ban medical devices under 21 U.S.C. § 360f. This section reads:

> Whenever the Secretary finds . . . that (1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and (2) in the case [this deception or risk] could be corrected or eliminated by labeling or change in labeling and with respect

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[1] Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food & Drug Admin., 3 F.4th 390 (D.C. Cir. 2021).

> to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period; he may initiate a proceeding to promulgate a regulation to make such device a banned device.[2]

Banned devices manufactured or introduced into interstate commerce are adulterated and subject to FDA's civil and criminal enforcement authority.[3] In this case, JRC challenged FDA's ban to use ESDs for patients with SIB/AB as an agency action that "limits and interferes" with the practice of medicine. Congress had stated on multiple occasions that FDA lacked jurisdiction over the practice of medicine, and FDA itself had acknowledged that it could not regulate the practice of medicine. Congress codified this so-called "practice of medicine exception" in the Food and Drug Modernization Act of 1997 under FDCA § 396:

> Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations.[4]

Courts have affirmed that regulating the off-label use of a medical device by a physician is "not the province of the FDA."[5] Over the years, the practice of medicine exception has allowed healthcare practitioners the flexibility to prescribe or administer legally marketed drugs or medical devices not just for the approved use, but for any off-label condition or disease.

FDA contended that § 396 in no way constrained its invocation of § 360f. FDA argued that a banned device would not, by definition, be a legally marketed device, and therefore § 396 was not applicable. FDA also argued that that it would be a peculiar construction of the statute if the statute authorized it to ban a device completely, but prohibited the agency from tailoring a ban to those particular intended uses which FDA believed presented a substantial risk.

Factual Background

JRC is a Massachusetts treatment facility offering treatment to patients who exhibit self-injurious behavior and aggressive behavior. To treat refractory (i.e., treatment-resistant) SIB/AB in certain adult patients, JRC uses an ESD called the Graduated Electronic Decelerator (GED) device for aversive conditioning. JRC is the only facility in the country using ESDs for this purpose.

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2 21 U.S.C. § 360f(a).

3 21 U.S.C. §§ 331(a) and (g), 333, 334(a)(1), 351(g).

4 21 U.S.C. § 396.

5 *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 395 (quoting Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1344 (10th Cir. 2015) (alterations omitted)).

Aversive conditioning devices were on the market prior to the passage of the Medical Device Amendments on May 28, 1976. In 1979, they were classified as Class II devices and regulated under the premarket notification (510(k)) process. JRC obtained clearance from FDA for its ESD via the 510(k) process in 1994 for "treatment of patients . . . who exhibit self-injurious behavior of sufficient intensity and frequency to cause serious damage to themselves. The device should be used only on patients where alternate forms of therapy have been attempted and failed."[6]

The GED consists of a stimulus generator, electrodes, and a remote monitor. Upon recognition of SIB/AB in a patient, a trained practitioner can send a signal via the remote monitor to the generator. The generator then triggers a two-second low voltage electrical current to the patient via the electrodes to reduce or stop observed SIB/AB.

JRC has used GED devices for over twenty-five years with hundreds of clients. For a patient to be admitted to JRC, a Massachusetts law requires that a licensed doctoral-level clinician document a comprehensive Applied Behavior Analysis (ABA) plan for that individual. The plan prescribes the GED and discusses how alternative treatments have been attempted and failed. A peer-review committee and a human rights committee must sign off on the treatment plan. The patient or their parent(s)/guardian must provide written informed consent. Additionally, a Massachusetts Probate and Family Court judge must also review the patient consent to the proposed GED treatment; here, the patient is represented by separate counsel. Finally, JRC must collect extensive data regarding treatment and each instance of therapy delivered to the patient.

Over the years, the use of the GED has become increasingly controversial, attracting the attention of multiple groups that were opposed to aversive therapy. FDA inspected JRC in 2000 and "did not observe any indications that the patients/clients were at risk." JRC was also inspected in 2010 and 2012 and each inspection resulted in no "reportable" incidents related to GED use. Nevertheless, in December 2012, FDA issued a warning letter asserting that the models of the GEDs then in use were modified from the originally cleared GED device, thus requiring a new 510(k). In the letter, FDA acknowledged that it had scheduled a meeting in January 2013 to discuss JRC's proposed 510(k) submission and to discuss a transition plan for those patients currently using devices. The meeting was canceled by FDA shortly before it was to be held.

On April 24, 2014, FDA held a meeting of the Neurological Devices Panel, which evaluated the merits of issuing a ban on ESDs for aversive conditioning devices "used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics."[7] The Panel was closely divided on whether to ban the device, but unanimously agreed that there was a subpopulation of SIB/AB patients who could not be adequately treated with existing therapies.

On April 25, 2016, FDA issued a proposed ban. In proposing the ban, FDA asserted a variety of risks, including psychological distress, pain, and burning. The agency also said that there was no evidence that GEDs provided any meaningful benefits. After receiving over 1,000 comments—many of which were form comments supporting the ban—FDA published a final rule on March 4, 2020 to ban ESDs, but only when used to treat SIB/AB. In the final rule, FDA asserted that new or updated device labeling

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[6] K911820.

[7] 21 C.F.R. § 882.5235.

could not address the risks from ESDs. The ban did not include other uses of ESDs (e.g., nail biting or smoking).

DECISION SUMMARY

In March 2020, JRC and the parents and guardians of patients that used or sought to use ESDs petitioned the U.S. Circuit Court of the District of Columbia to review the final rule. (While the case was pending, FDA granted a stay of the ban for patients already using the GED.) Though the petitioners raised multiple issues with FDA's ban, the court decided the case on a single question: whether FDA had the legal authority to ban an otherwise-legal device from a particular use. Writing for the court's 2-1 majority, Judge Katsas answered this question by analyzing the interplay of two statutes: 21 U.S.C. § 360f, which authorizes FDA to ban medical devices, and 21 U.S.C. § 396, which prohibits FDA from regulating the practice of medicine.

JRC argued that the use of § 360f to ban a medical device for a particular purpose constitutes the regulation of the practice of medicine and violates the plain text of § 396. According to JRC, banning ESDs for SIB/AB but not for other uses, such as nail biting and smoking, was an intrusion into the practice of medicine that was inconsistent with § 396.

FDA contended that § 396 has no applicability over § 360f. According to FDA, § 396 only prohibited the agency from limiting the authority of practitioners from prescribing or administering "legally marketed devices"—and a banned device would not, by definition, be a legally marketed device. FDA reasoned that devices are, after all, defined by their intended use, so banning devices with reference to particular uses would be appropriate.[8] FDA also argued that if the agency could completely ban a device, it necessarily has the power to ban specific uses of the same device.

The court found the statutes to be unambiguous. Noting that FDA did not argue otherwise, the court proceeded to analyze the competing statutes and their competing interpretations without employing the *Chevron* framework.[9] Starting with § 360f, the court found that Congress only allowed FDA to ban a device, not ban it "in some uses," potentially supporting JRC. Yet, Congress also required FDA to evaluate the "reasonableness" of a device's risks—presumably in light of its benefits—to ban a device. Because each use of a device has its own benefit–risk profile, the court noted the reasonableness language may support FDA's argument that bans may be tailored only to circumstances that FDA finds unreasonable.

The court then analyzed how § 396 restricted the use of § 360f: would an ESD ban for SIB/AB "limit or interfere" with a practitioner's authority to prescribe or administer a device, and was a device that FDA has attempted to ban "legally marketed?" The court held that a use-specific ban does "limit or interfere" how a practitioner could use the device in the ordinary sense of these words. A device ban would limit ("restrict" and "curtail") and interfere ("hinder" and "impede") with a physician's ability to prescribe or administer the device. The court also held that a device is "legally marketed" if it is lawful for a manufacturer to sell it or for a practitioner to prescribe or administer it. Therefore, banning a device for a particular use will still result in a device that is legally marketed for its other uses. Therefore,

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[8] *See* 21 U.S.C. § 321(h)(1) (defining devices as articles that are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . .").

[9] Chevron USA, Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).

banning ESDs for SIB/AB would interfere with a practitioner's ability to administer or prescribe ESDs based on their own medical judgment for certain conditions while the device is still available for other conditions.

The court also rejected FDA's reasoning that a device is defined as a pairing of a particular instrument with a particular use. According to the court, if it endorsed this position, it would follow that ESDs are not "legally marketed" as soon as FDA bans them for SIB/AB. FDA was essentially asking the court to read into "legally marketed" "a limitation that the device must be marketed for the particular use for which the practitioner wants to utilize the device," which would "eviscerate the statute's protection of off-label use."[10] Finally, in rebuffing FDA's argument that the power to ban a device necessarily includes the power to ban certain uses of that device, the court cited precedents that possession of a "greater" power does not imply the existence of a "lesser" power.[11]

Chief Judge Srinivasan dissented from the decision. In his opinion, the statute was not an "all-or-nothing banning power" and instead gave FDA the power to tailor a ban. Applying *Chevron* to interpret "legally marketed device," Judge Srinivasan concluded that § 396 does not unambiguously foreclose FDA's position, and therefore the court must defer to FDA's interpretation if it was reasonable and consistent with the statute's purpose. Judge Srinivasan found a tailored ban "eminently reasonable" given that Congress already allows a complete ban.

FDA sought rehearing en banc of the decision. On November 22, 2021, this request was denied.

IMPACT OF THE DECISION

This case represented the first ever challenge to an FDA ban on medical devices. FDA had previously banned two devices, but neither ban had been challenged.

The D.C. Circuit Court of Appeals found that in issuing the ban on ESDs for SIB/AB, and not nail biting or smoking or other behaviors, FDA overstepped its authority. Citing § 396's language that "nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease,"[12] the court held that FDA could not interfere with the practice of medicine by proscribing a particular intended use. While the specific legal issue of the intersection of the practice of medicine exemption and FDA's authority to ban may be narrow, this unequivocal support for the practice of medicine exemption may have implications for other situations in which FDA seeks to curb the authority of physicians.

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[10] *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 397. The court noted that Congress may indeed have contemplated such an interpretation based on legislative history, but ultimately dismissed that interpretation based both on the definition of a device and because of how it would nullify the practice of medicine exception. *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 397. The court also noted that FDA's actions that impinge on the practice of medicine implicate the Tenth Amendment of the Constitution because they attempt to regulate the practice of medicine, an unenumerated power that was not delegated to FDA and therefore has always resided with the state. *Id.* at 399.

[11] *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 398.

[12] 21 U.S.C. § 396.

United States v. U.S. Stem Cell Clinic, LLC

NAOMI IGRA & EMILY MARDEN*

WHY IT MADE THE LIST

U.S. Stem Cell Clinic[1] made the list because it validates the Food and Drug Administration's (FDA's) view of its authority in the expanding field of regenerative medicine therapies. The defendant clinic offered a procedure involving the extraction and isolation of stromal and vascular cells ("stromal-vascular fraction" or "SVF") from a patient's body fat for reinjection back into the patient. It marketed the procedure as a treatment for medical conditions ranging from diabetes to osteoarthritis. In FDA's view, this rendered the clinic's SVF product a "drug" under the Federal Food, Drug, and Cosmetic Act (FDCA), as well as a "biological product" under the Public Health Service Act (PHSA). The clinic responded that FDA had no authority to regulate its SVF product because it fell within an exception to the regulation of human cells, tissues, and cellular and tissue-based products (HCT/Ps). In affirming summary judgment for the government, the Eleventh Circuit determined that the claimed exception did not apply and that the SVF product was subject to FDA's regulatory authority.

The court's decision will likely support FDA's campaign against what it views as similar unapproved, adulterated, or misbranded products, including many stem cell and exosome therapies.[2] The timing of the decision is also significant because it followed immediately after the expiration of a grace period FDA offered for the developers of HCT/Ps to consider whether they need to file Investigational New Drug (IND) or marketing applications for their products.[3] Taken together with recent FDA warning letters and consumer alerts, the Eleventh Circuit's decision signals that

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1 United States v U.S. Stem Cell Clinic, LLC, 998 F.3d 1302 (11th Cir. 2021).

2 FDA has sometimes grouped these regenerative medicine therapies together with SVF therapy in its consumer alerts. *E.g.*, U.S. FOOD & DRUG ADMIN., IMPORTANT PATIENT AND CONSUMER INFORMATION ABOUT REGENERATIVE MEDICINE THERAPIES (June 3, 2021), https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies.

3 FDA ended its policy of enforcement discretion on May 31, 2021. It now "expects all establishments that manufacture HCT/Ps regulated as drugs or biological products to have an approved biologics license application (BLA) or an investigational new drug application (IND) in effect." U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS REGARDING THE END OF THE COMPLIANCE AND ENFORCEMENT POLICY FOR CERTAIN HUMAN CELLS, TISSUES, OR CELLULAR OR TISSUE-BASED PRODUCTS (HCT/PS) (July 9, 2021), https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/questions-and-answers-regarding-end-compliance-and-enforcement-policy-certain-human-cells-tissues-or.

purveyors of unapproved regenerative therapies should prepare for increased scrutiny and enforcement activity.

DISCUSSION

Regulatory Background

FDA generally regulates stem cell therapies as HCT/Ps, which are "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient."[4] An HCT/P may be a "drug" under the FDCA if it is intended to "diagnose, cure, treat, mitigate or prevent diseases, or [is] intended to affect human bodily function or structure."[5] It may also be a "biological product" under the PHSA.[6] An HCT/P that is a drug and/or a biological product is subject to statutory approval requirements; in addition, the FDCA prohibits the marketing of adulterated or misbranded drugs. However, if an HCT/P meets certain criteria outlined in FDA regulations, it may qualify for more limited regulatory oversight under Section 361 of the PHSA.

Among other requirements, a "Section 361 HCT/P" must be "intended for homologous use only."[7] "Homologous use" is the "repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the *same basic function* or functions in the recipient as in the donor."[8] For example, a heart valve transplant may involve homologous use. If an HCT/P meets the homologous use requirement and other regulatory criteria, it is subject only to the requirements under Section 361 of the PHSA.

HCT/Ps may also be exempt from FDA regulations under the "same surgical procedure exception."[9] Under that exception, an establishment does not have to comply with FDA regulations pertaining to HCT/Ps if it "removes HCT/Ps from an individual and implants such HCT/Ps into the same individual during the same surgical procedure."[10] A common example is a skin graft whereby healthy skin is removed from one part of a patient's body to treat a severe burn to another region of the same patient's body.

In November 2017, FDA issued guidance on "homologous use" and the "same surgical procedure exception" as part of a comprehensive regenerative medicine policy framework. In announcing the framework, then-FDA Commissioner Scott Gottlieb characterized cell-based regenerative therapies as a "a paradigm shift in the practice of medicine."[11] At the same time, he warned of "unscrupulous actors" making

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4 21 C.F.R. § 1271.3(d).

5 21 U.S.C. § 321(g)(1).

6 42 U.S.C. § 262(i)(1).

7 21 C.F.R. § 1271.10(a)(2).

8 *Id.* § 1271.3(c) (emphasis added).

9 *Id.* § 1271.15(b).

10 *Id.*

11 U.S. FOOD & DRUG ADMIN., STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D. ON FDA'S COMPREHENSIVE NEW POLICY APPROACH TO FACILITATING THE DEVELOPMENT OF INNOVATIVE REGENERATIVE MEDICINE PRODUCTS TO IMPROVE HUMAN HEALTH (Nov. 15, 2017), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-comprehensive-new-policy-approach-facilitating.

"deceptive claims to patients about unproven, and in some cases, dangerous products."[12] To balance the interests of innovation and public health, FDA adopted a "risk-based approach" to enforcement actions for novel cellular therapies.[13] It generally gave manufacturers of cell and tissue-based products thirty-six months to comply with FDA pre-market review regulations but emphasized that it would not exercise enforcement discretion for products that pose a safety concern.

Factual and Procedural Background

U.S. Stem Cell Clinic, LLC ("the Clinic") is a Florida business that advertises itself as offering the "latest and most exclusive regenerative therapies."[14] The therapy FDA challenged involves the removal of adipose tissue, which is composed primarily of fat cells and collagen fibers but also contains stromal and vascular cells (SVF), some of which are stem cells. The Clinic used a five-step process to isolate the SVF from the adipose tissue, then injected it back into the patient suspended in saline solution or in platelet-rich plasma.[15] The Clinic marketed its SVF procedure as a treatment for a wide range of autoimmune, neurological, and degenerative conditions.[16]

FDA inspected the Clinic in 2015 and 2017. During the inspections, FDA reviewed records of adverse events and observed multiple violations of FDA's current good manufacturing practices (cGMP). The Clinic responded to FDA's observations and a subsequent warning letter by arguing that it was exempt from FDA oversight.[17]

FDA filed suit against the Clinic in the Southern District of Florida in 2018. The complaint characterized the Clinic as "experimenting on patients with adulterated and misbranded drugs."[18] FDA alleged that the Clinic's SVF product was a "drug" under the FDCA and a "biological product" under the PHSA. FDA then explained why the SVF product did not fall within any exception to FDA's regulatory authority. It followed that the SVF product was "adulterated" because it was not manufactured in compliance with cGMP, and "misbranded" because it lacked adequate directions for use.[19]

FDA moved for summary judgment arguing that the court could decide as a matter of law that no exceptions apply and the SVF is an adulterated and/or misbranded drug under the FDCA. The Clinic cross-moved for summary judgement arguing that the court could decide as a matter of law that the same surgical procedure in fact applied and FDA had no authority to regulate the SVF product under the FDCA.[20] The district

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[12] *Id.*

[13] U.S. FOOD & DRUG ADMIN., FDA ANNOUNCES COMPREHENSIVE REGENERATIVE MEDICINE POLICY FRAMEWORK (Nov. 15, 2017), https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regenerative-medicine-policy-framework.

[14] U.S. STEM CELL CLINIC, https://usstemcellclinic.com/ (last visited June 9, 2022).

[15] United States v U.S. Stem Cell Clinic, LLC, 998 F.3d 1302, 1306 (11th Cir. 2021).

[16] *Id.* at 1305.

[17] United States v. U.S. Stem Cell Clinic, LLC, Case No.: 18-CV-61047 (S.D. Fla. May 9, 2018), Dkt. #1 ("Complaint" or "Compl.") at ¶¶ 42–52; *see also Warning Letter, US Stem Cell Clinic, LLC*, U.S. FOOD & DRUG ADMIN. (Aug. 24, 2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-stem-cell-clinic-llc-524470-08242017.

[18] *Id.* at ¶ 1.

[19] *Id.* at ¶¶ 33–46.

[20] United States v. U.S. Stem Cell Clinic, LLC, 403 F. Supp. 3d 1279, 1287 (S.D. Fla. 2019).

court ultimately agreed with FDA's view and entered an injunction in favor of the government.

The Eleventh Circuit's Decision

The Eleventh Circuit affirmed the district court's judgment, focusing on the core issues of whether the SVF product was outside the scope of the FDCA's adulteration and misbranding provisions under the same surgical procedure exception or as a "Section 361 HCT/P."

First, the court examined the text of the same surgical procedure exception. The central question was whether the Clinic qualified as an establishment that removes HCT/Ps from a patient and then implants "such HCT/Ps" into the same patient.[21] The Clinic argued that it satisfied this requirement because its procedure removed SVF from a patent for reinjection into the same patient. FDA responded that the phrase "such HCT/P" means the that HCT/P removed must be the same as the HCT/P implanted; "[i]f significant processing steps expose the HCT/Ps to foreign substances and alter their form prior to reimplementation, then the HCT/Ps cease to be the same as they were at the time of removal."[22] The Eleventh Circuit agreed with FDA's reasoning, concluding that "[b]y the time the [SVF] is reinjected, it is no longer 'such HCT/P' as the adipose tissue removed from the patient."[23]

The court then turned to the question of whether the Clinic's SVF product satisfied the criteria for a "Section 361 HCT/P." The dispositive issue was whether the Clinic intended the SVF solely for "homologous use" in the sense that it intended the reinjected SVF to "perform the same basic function" as the SVF removed from the adipose tissue. The Eleventh Circuit emphasized that its analysis turned on the Clinic's "objective intent," which could be discerned from the Clinic's own marketing materials. It concluded that the Clinic marketed SVF to treat a "plethora of conditions," which is not the same "basic function" the Clinic alleged SVF performed in the adipose tissue.[24]

Because the SVF product did not satisfy the criteria for the same surgical procedure exception or a "Section 361 HCT/P," the Eleventh Circuit affirmed the judgment of the district court.

IMPACT OF THE CASE

The Eleventh Circuit's decision was a critical victory for FDA. In the words of Peter Marks, Director of the Center for Biologics Evaluation and Research, the decision is "an endorsement of the FDA's work to stop stem cell clinics that place patients at risk."[25]

At the same time, the decision spotlights a similar case pending in the Central District of California against another clinic offering SVF therapy. In that case, Judge Bernal denied the government's motion for summary judgment, concluding that same

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[21] *Id.* at 1296, 1298–1301.

[22] United States v U.S. Stem Cell Clinic, LLC, 998 F.3d 1302, 1308–09 (11th Cir. 2021).

[23] *Id.* at 1310.

[24] *Id.* at 1311.

[25] U.S. FOOD & DRUG ADMIN., INNOVATIVE REGENERATIVE MEDICINE THERAPIES—PATIENT SAFETY COMES FIRST (June 3, 2021), https://www.fda.gov/news-events/fda-voices/innovative-regenerative-medicine-therapies-patient-safety-comes-first.

surgical procedure exception could apply if the SVF cells remain "unaltered" during the course of the SVF procedure. That issue presented a question of fact that precluded summary judgment.[26] The parties proceeded to trial and are still awaiting a decision. Despite the force of the Eleventh Circuit's ruling, providers of stem cell therapies may doubt the scope of FDA's authority as long as the issue remains open before Judge Bernal.

Indeed, stem cell clinics have proliferated notwithstanding FDA's efforts. FDA does not have the resources to bring injunctive actions against the hundreds of stem cell clinics offering procedures like SVF. Moreover, stem cell clinics may just shift to other unapproved therapies that have not been tested in the courts.[27]

Ultimately, the Eleventh Circuit's decision may be most powerful in lending momentum to the efforts of other stakeholders like the Federal Trade Commission and state attorneys general who have stepped up their enforcement activities against stem cell clinics in recent years. In all events, stem cell clinics are sure to be under increased scrutiny in 2022 and beyond. Purveyors of other regenerative medicine therapies would be wise to ensure their products fall within a recognized exception or comply with all FDA regulations that may apply.

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[26] United States v. Cal. Stem Cell Treatment Ctr., Inc., 2020 WL 1289543, at *9 (C.D. Cal. Jan 27, 2020).

[27] *See, e.g.*, William Wan, *Stem Cell Clinics Likely to Flourish Despite Judge's Rebuke*, WASH. POST (June 7, 2019).

Center for Food Safety v. Becerra

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WHY IT MADE THE LIST

Occasionally, important cases are those that maintain, rather than alter, the status quo. This case[1] is included in this volume because it does just that: it maintains the voluntary notification procedure, created by the Food and Drug Administration (FDA), under which a manufacturer may inform FDA that a substance is generally recognized as safe (GRAS) for its intended use and therefore may be added to food, and declines to make the notification mandatory. This voluntary notification procedure has been unchanged for two decades, partially because, for much of that time, the procedure was set forth as policy (in a proposed rule) rather than in a final rule. In 2016, after FDA promulgated a final rule, it was promptly challenged by plaintiffs. This case presents the first instance in which a court considered, and affirmed, FDA's voluntary GRAS notification process.

BACKGROUND

A food additive is defined, in part, as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[2] As part of the 1958 Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress required "food additives" to undergo a premarket approval process.[3] This premarket approval process consists of a sponsor-submitted petition that "proposes the issuance of a regulation prescribing the conditions under which such additive may be safely used,"[4] and may result in FDA proposing a food additive regulation for the specific substance and intended use.

Ostensibly recognizing that certain substances should not be required to undergo a fulsome premarket review, Congress provided for an exception to the definition of "food additive" for substances that are:

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1 Ctr. for Food Safety v. Becerra, No. 17-CV-3833 (VSB), 2021 WL 4504472 (S.D.N.Y. Sept. 30, 2021).

2 21 U.S.C. § 321(s).

3 21 U.S.C. § 348(b)–(g).

4 21 U.S.C. § 348(b)(1).

> generally recognized, among experts qualified by scientific training and experience to evaluate their safety . . . as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of their intended use.[5]

The use of a substance falling under such exclusion because it is GRAS is not subject to the premarket review process for "food additives."

Since the passage of the Food Additives Amendments, FDA has implemented various approaches to identify those substances that are GRAS, including publication of a "GRAS list" by regulation,[6] which itself notes the impracticality of listing all substances that are GRAS for an intended use.[7] FDA initially issued non-binding (and generally private) "opinion letters"[8] and later progressed to a GRAS affirmation process, which included FDA review of safety and functionality data, a public notice-and-comment period, and FDA publication of the substance as either GRAS or not.[9] If FDA affirmed a substance to be GRAS, the agency added the substance to its list of GRAS substances, codified in 21 C.F.R. Parts 184 and 186.[10]

Importantly, from 1958 on, the focus of FDA's regulation of GRAS substances was on defining the scientific and legal standards that such substances had to meet, and these standards were tested in various court decisions. FDA recognized that, if a substance qualified as GRAS, then it was exempt from the food additive definition and FDA had no premarket authority over it. As such, FDA considered any procedure under which industry reported GRAS determinations to FDA to be voluntary; the agency has never tried to implement a mandatory GRAS reporting procedure.

Ultimately, in April 1997, FDA promulgated a proposed rule that, when implemented, would replace the GRAS affirmation procedure with a "notification procedure whereby any person may notify [FDA] of a conclusion that a particular use of a substance is GRAS."[11] However, FDA did not move to finalize the GRAS rule until 2016. During the intervening nineteen years, the agency effectively operated under the policy set forth in the proposed rule, allowing a manufacturer to voluntarily notify FDA of its determination that a substance is GRAS for a particular use. Following a 2010 U.S. Government Accountability Office (GAO) report that criticized FDA for failing to finalize its GRAS notification procedure, which "potentially detract[s] from the program's credibility,"[12] the agency issued the 2016 final rule (GRAS rule) that is the target of this litigation.

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[5] Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,963 (Aug. 17, 2016) (citing 21 U.S.C. § 321(s)).

[6] 21 C.F.R. Part 182.

[7] 21 C.F.R. § 182.1(a).

[8] 81 Fed. Reg. at 54,693.

[9] 81 Fed. Reg. at 54,693.

[10] 81 Fed. Reg. at 54,693–94.

[11] *Id.* (citing Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (Apr. 17, 1997) (proposed rule), https://www.govinfo.gov/content/pkg/FR-1997-04-17/pdf/97-9706.pdf).

[12] U.S. GOV'T ACCOUNTABILITY OFF., GAO-10-246, FOOD SAFETY: FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) (Feb. 2010), https://www.gao.gov/assets/gao-10-246.pdf [hereinafter GAO REPORT].

Under the GRAS rule, persons may voluntarily "notify FDA of a view that a substance is not subject to the premarket approval requirements [applicable to food additives] based on that person's conclusion that the substance is GRAS under the conditions of its intended use."[13] A GRAS notice must be supported by evidence of "general recognition of safety," based on the views of qualified experts and "generally available and accepted scientific data, information, and methods."[14] Following FDA review of the submission, the agency will publicly respond by letter and state that 1) it has "no questions" regarding the GRAS conclusion, 2) the submitter has provided an insufficient basis for a GRAS conclusion, or 3) it ceased to evaluate the notice on the submitter's request.[15]

It is important to note that under the policy set forth by the 1997 proposed rule, as formalized by the 2016 final rule, a manufacturer is not *required* to notify FDA of a GRAS conclusion.[16] Rather, entities may opt to make an "independent conclusion" of a substance's GRAS status and keep such determination proprietary.[17] In fact, food manufacturers had been "self-affirming" GRAS determinations in this way for many years, guided by the scientific standards in FDA's regulations. The notification process that FDA established in 1997 was an attempt to encourage manufacturers to voluntarily notify FDA of their self-affirmed GRAS determinations. The 1997 policy did not distinguish between a GRAS determination submitted to FDA and one that is not—the same content requirements applied to both[18]—but it did offer submitters the potential benefit of a "no questions" letter from FDA, which could make their new food formulations easier to sell in the marketplace.

DISCUSSION

In this case, Plaintiffs, all non-profit advocacy organizations,[19] alleged that the GRAS rule "allows FDA to abdicate its core duty under the FDCA . . . to be responsible for the safety of the food supply."[20] Specifically, Plaintiffs argued that, because the rule permits entities to reach independent GRAS conclusions without notifying FDA or keeping and retaining records regarding the basis of such determination, in effect, it permits "potentially unsafe chemical substances to be added

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[13] 21 C.F.R. § 170.205.

[14] 21 C.F.R. § 170.30(a)–(c).

[15] *About the GRAS Notification Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/generally-recognized-safe-gras/about-gras-notification-program (updated Jan. 4, 2018).

[16] 62 Fed. Reg. at 18,941–42.

[17] 81 Fed. Reg. at 54,984.

[18] 81 Fed. Reg. at 54,984.

[19] Plaintiffs were the Center for Food Safety, Breast Cancer Prevention Partners, Center for Science in the Public Interest, Environmental Defense Fund, and Environmental Working Group. The court subsequently dismissed the claims of Plaintiffs Breast Cancer Prevention Partners, Center for Science in the Public Interest, and Environmental Working Group for lack of standing. *See* Ctr. for Food Safety v. Becerra, No. 17-CV-3833 (VSB), Docket #44.

[20] Complaint at 2, Ctr. for Food Safety v. Becerra, No. 17-CV-3833 (VSB) (filed May 22, 2017), http://www.centerforfoodsafety.org/files/1-complaint-2017-5-22_69110.pdf.

to food based on conclusions by self-interested food . . . manufacturers . . . without FDA's oversight or knowledge."[21]

Plaintiffs sought a declaratory judgment that the GRAS rule: "(1) unlawfully subdelegates FDA's duty to ensure food safety in violation of the Constitution, the [Administrative Procedure Act (APA)], and the FDCA; (2) exceeds FDA's statutory authority and constitutes arbitrary and capricious agency action in violation of the FDCA and APA; and (3) conflicts with the FDCA."[22] The trial court considered, and rejected, each of these arguments in turn.

First, the court explained that the FDCA does not require manufacturers to submit GRAS conclusions, nor does it mandate that FDA review GRAS conclusions prior to marketing.[23] In contrast with the FDCA's premarket approval scheme for food additives, FDA's controls over GRAS determinations are entirely postmarket, and the agency retains discretion to pursue enforcement action if it does not agree with a manufacturer's conclusion that a substance is GRAS for a particular use.

It appears that the court was receptive to FDA's argument that the GRAS rule had no effect on its longstanding framework, and that even if FDA had not finalized the GRAS rule, manufacturers still could reach a self-affirmed GRAS determination on their own responsibility, without notifying the agency, and at the risk of enforcement in case FDA were to disagree. Although it found merit in Plaintiffs' concerns that the lack of public scrutiny and potential conflicts of interest on private GRAS expert panels (as noted by the 2010 GAO Report)[24] undercut the ability of FDA and the public at large to scrutinize decisions about chemical substances added to foods, the court ultimately disagreed that the public's inability to challenge private GRAS determinations rose to the level of a constitutionally unlawful subdelegation of powers.[25]

Second, the court concluded that the GRAS rule was a reasonable interpretation of the FDCA under the APA and the typical two-step *Chevron* analysis.[26] At the outset, Plaintiffs primarily argued that the FDCA plainly contradicts the GRAS rule because the Food Additives Amendment requires FDA, in making determinations of food additive safety, to consider the "cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet."[27] In Plaintiffs' view, permitting entities to make internal GRAS determinations frustrates this responsibility because the agency does not have full knowledge of all substances added to food. The court rejected this argument outright, noting that "it is dubious to think that Congress used such language to require manufactures to inform FDA of GRAS determinations without saying so."[28]

That said, the court found that the statutory text of the FDCA does not indicate that Congress clearly spoke to the precise question at issue: whether GRAS notifications

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[21] *Id.* at *2–3.

[22] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *5.

[23] *Id.* at *7.

[24] GAO REPORT, *supra* note 14, at 14.

[25] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *7–8.

[26] *Id.* at 8 (citing Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842 (1984)).

[27] 21 U.S.C. § 348(c)(5)(B).

[28] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *9.

must be mandatory.[29] Although the court recognized that the FDCA broadly requires FDA to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled," the court also (repeatedly) highlighted Congress's express exemption of GRAS substances from the FDCA's rigorous statutory scheme for approving food additives. Given that the FDCA did not speak directly to this question, the court turned to *Chevron*'s step two.

At *Chevron*'s second step, the court determined that FDA's interpretation of the FDCA (set forth in the GRAS rule) was reasonable. In reaching this conclusion, it pointed to the following: 1) the FDCA does not specify that a GRAS notification must be mandatory; 2) the number of submitted GRAS notices actually increased during the time that the rule was pending; 3) FDA has a "long-standing record" of excluding GRAS substances from premarket review under the FDCA; and 4) mandatory GRAS submissions would require FDA to divert limited resources from other food safety activities.[30] In addition to the FDCA's silence on the issue of whether GRAS notifications must be mandatory, the court found particularly compelling that, again, Congress specifically exempted GRAS substances from premarket review and that Congress "remained silent for more than sixty years on whether GRAS submissions should be voluntary, and has amended the statute at issue when a voluntary system was in place."[31]

The court further noted that Plaintiffs' counterarguments could be distilled to one basic point: "if GRAS notifications were mandatory, FDA could obtain all of the information it needs to make food safety determinations before ingredients are placed into food."[32] In dismissing this argument, the court explained that, as recognized by FDA and GAO, it is unclear whether the FDCA even grants FDA the authority to make GRAS notifications mandatory in the first instance.[33]

Finally, the court considered, and rejected, Plaintiffs' claim that the GRAS rule unlawfully contradicts the FDCA criteria for determination of GRAS status. Notably, Plaintiffs argued that the GRAS rule fails to ensure that data, information, and methods used to support a GRAS conclusion are "generally recognized,"[34] specifically, the rule does not prohibit the use of unpublished information in support of a GRAS conclusion. Again, the court disagreed, explaining that unpublished material is just "one potential part of the GRAS determination," and in any case, the use of such material is not prohibited by the FDCA.[35] Moreover, the court similarly disagreed with Plaintiffs' contention that the GRAS rule runs afoul of the Delaney Clause,[36] explaining that such clause is applicable to food additives, not GRAS substances, and that in any case, the

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[29] *Id.* at *9–10.

[30] *Id.* at *11.

[31] *Id.* at *11–12.

[32] *Id.* at *12.

[33] *Id.* at *13.

[34] *Id.* at *14.

[35] *Id.* at *15.

[36] 21 U.S.C. § 348(c)(3)(A) (prohibiting FDA from approving food additives shown to cause cancer).

requirements for a GRAS determination would preclude a conclusion that such substance is GRAS.[37]

IMPACT OF THE DECISION

For twenty years, the FDA policy permitting manufacturers to voluntarily notify self-affirmed GRAS determinations went judicially untested and unreviewed; the court's blessing of this policy provides a degree of certainty and long-term stability to the current rule. However, even in a victory for FDA, the court appeared to give some credence to the Plaintiffs' concerns. For instance, it noted that Plaintiffs' concerns regarding potential conflicts of interest on GRAS panels were "valid," and repeated conclusions from a study cited by Plaintiffs showing that in "more than 450 GRAS determinations voluntarily reported to FDA, every determination was made by experts with financial ties to the manufacturer of the substance at issue."[38] Thus, there is still room for improvement (and FDA has issued guidance to reduce the risks posed by conflicts of interest). Moreover, the court's dicta may provide additional ammunition for proponents of mandatory GRAS notification with which to lobby Congress for statutory change.

As a practical matter, however, the GRAS notification program is a success in the sense that it has established a system that food companies can and do rely on when sourcing new ingredients. A "successful" GRAS notification can provide at least some assurance that a new ingredient meets acceptable safety standards. This promotes a stable supply chain: as the U.S. food ingredient supply chain grows ever more global, U.S. food companies seeking to ensure that ingredients used in their U.S.-marketed food products are lawful can rely—at least in part—on FDA's GRAS notification procedure.

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[37] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *15–16 (citing to 21 C.F.R. § 170.30(a) ("General recognition of safety requires common knowledge throughout the scientific community . . . that there is a reasonable certainty that the substance is not harmful under the conditions of its intended use.")).

[38] *Id.* at *15. Note that FDA has published draft guidance regarding best practices for convening a GRAS panel. U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: BEST PRACTICES FOR CONVENING A GRAS PANEL (Nov. 2017), https://www.fda.gov/media/109006/download.

Federal Trade Commission v. Martin Shkreli

BRYANT GODFREY & TINA PAPAGIANNOPOULOS*

WHY IT MADE THE LIST

The Federal Trade Commission (FTC) has been investigating and enforcing against potential anticompetitive conduct in the pharmaceutical industry for decades. The complexity of the regulatory framework under the Federal Food, Drug, and Cosmetic Act (FDCA), however, makes antitrust enforcement over certain practices in the pharmaceutical industry all the more challenging. The intense congressional debate over drug pricing over the past several years has started to focus on legislative solutions that would make it more difficult for pharmaceutical companies to manipulate or take advantage of the regulatory scheme in order to block or delay competition. This case provides some examples of the type of conduct that is at the heart of these concerns.

Within days of acquiring the rights to market a life-saving drug in the United States, "Pharma Bro" Martin Shkreli directed his company, Vyera Pharmaceuticals, LLC, to implement a drastic price hike that caught the nation's attention and prompted a congressional hearing on pharmaceutical pricing. FTC, along with several states, subsequently brought a civil action against Shkreli, Vyera, and others alleging a web of anticompetitive agreements that delayed generic competition by obscuring the profitability of the drug and by making it virtually impossible for generic entrants to complete the steps necessary to obtain regulatory approval from the Food and Drug Administration (FDA). As a witness in this case put it, the price hike was "the poster child of everything that is considered wrong about the pharmaceutical industry."[1]

The court agreed and banned Shkreli from ever working in the pharmaceutical industry again and held him jointly and severally liable with the other defendants for $64.4 million in consumer redress. Consumer redress was possible despite the Supreme Court's decision in *AMG Capital Management v. FTC*[2] because this remedy was available under state law. Pursuant to a consent order entered into shortly before the trial, Vyera and its parent company were also required to make Daraprim available to any potential generic competitor at the list price and to provide prior notification of any planned pharmaceutical transaction valued at $25 million or more.

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1 FTC v. Shkreli, No. 20cv00707, 2022 U.S. Dist. LEXIS 7715, at *29 (S.D.N.Y. Jan. 14, 2022).

2 AMG Cap. Mgmt., LLC v. Fed. Trade Comm'n, 141 S. Ct. 1341, 1352 (2021).

These orders send the message that pharmaceutical companies engaging in anticompetitive exclusionary conduct could face severe monetary remedies under state law. In light of the strong public policy favoring generic competition, brand companies could also become subject to a duty to deal on certain terms with generic companies. The message is also clear that pharmaceutical executives can be held personally liable for conduct that delays generic competition and may even face a permanent injunction under certain circumstances.

DISCUSSION

The Federal Trade Commission (FTC) and the Attorneys General for seven states[3] (collectively, "the Government") filed an antitrust action in the U.S. District Court for the Southern District of New York against Martin Shkreli; Vyera Pharmaceuticals, LLC; its parent company, Phoenixus AG (collectively "Vyera"); and Kevin Mulleady, the former Vyera CEO, due to conduct involving the sale and distribution of Daraprim. Shkreli was the founder of Phoenixus and Vyera, the largest shareholder and former chairman of the board of Phoenixus, and the former CEO of Vyera. Mulleady and the corporate defendants entered into a consent order settling the claims against them shortly before trial. The case against Shkreli proceeded to trial and is the subject of the court's Opinion.[4]

Daraprim has been approved by FDA for the treatment of toxoplasmosis, a parasitic infection that can cause severe disease and death, since1958. The infection principally impacts immunosuppressed and immunocompromised individuals (e.g., patients who are HIV positive or are recipients of organ transplants). The most common and acute presentation of the disease among immunosuppressed patients is toxoplasma encephalitis. Patients that are diagnosed with toxoplasma encephalitis could die within twelve to twenty-four hours and there is a risk of severe brain damage in those who survive.

Pyrimethamine, the active pharmaceutical ingredient (API) in Daraprim, remains the only drug approved by FDA for the treatment of toxoplasmosis and is a key component in a treatment regimen that is highly recommended by clinical practice guidelines for acute toxoplasmosis. Until the entry of a generic pyrimethamine product in 2020, Daraprim was the only FDA-approved pyrimethamine product available in the United States.

For more than sixty years, Daraprim had been sold as an affordable, life-saving treatment for toxoplasmosis. In 2015, however, Vyera Pharmaceuticals, LLC acquired the U.S. rights to Daraprim from the only existing supplier and raised the wholesale acquisition cost (WAC) of the drug from $17.50 to $750 per tablet—an increase of more than 4,000%—within days of the acquisition. (After subtracting discounts, chargebacks, and rebates from the WAC, the average net price of Daraprim ranged between $228 and $305 per tablet from 2016 to 2019.) This caught the attention of health care providers, patients, and Congress.

According to the Government, Vyera was able to maintain these prices by implementing a strategy that involved a web of anticompetitive restrictions that delayed generic entry for years. First, Vyera implemented a closed distribution scheme

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[3] New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia.

[4] *Shkreli*, 2022 U.S. Dist. LEXIS 7715.

that prevented potential generic entrants from obtaining samples of the drug needed for bioequivalence testing. Vyera also restricted access to the API by entering into exclusivity agreements with the API suppliers that prevented them from supplying generic potential competitors. Vyera also entered into agreements with two distributors to prevent them from releasing Daraprim sales data that would have revealed the true size of the market opportunity for generic competition.

DELAY OF GENERIC ENTRY

Background on Generic Entry Requirements

Several generic companies sought to obtain marketing authorization from FDA for a generic version of Daraprim pursuant to the abbreviated new drug application (ANDA) pathway under Section 505(j) of the FDCA.[5] An ANDA application must provide information to show, among other things, that the active ingredient(s), as well as the route of administration, dosage form, strength, and conditions of use of the new drug are the same as those of the previously approved drug (the "reference listed drug" or "RLD") and that the new drug is bioequivalent to the reference listed drug.[6] "Bioequivalence" is defined in the regulations as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives become available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."[7] In other words, the generic version must demonstrate that it delivers the same amount of active ingredients into a patient's bloodstream in the same amount of time as the reference listed drug. In order to demonstrate bioequivalence, a company needs to perform bioequivalence testing comparing the two products using "the most accurate, sensitive and reproducible approach available," which can include a variety of in vivo and/or in vitro methods.[8] A generic company needs to be able to access sufficient quantities of the brand product to complete bioequivalence testing and to fulfill other relevant testing requirements (such as tests necessary to establish appropriate dissolution specifications) and/or regulatory requirements (such as requirements to retain reserve samples).

An ANDA submission also must include a section on the chemistry, manufacturing, and controls (CMC) established for the generic product which provides information related to the manufacture of the API. This section of the ANDA must include details about all intermediate and final drug substance manufacturing facilities as well as all research and development manufacturing and testing sites that generated data to support the application.[9]

As the court explained, the defendants entered into agreements with other parties or otherwise engaged in activities that created obstacles for the generic companies to fulfill these essential ANDA requirements and therefore delayed the entry of generic competition.

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[5] 21 U.S.C. § 355(j).

[6] 21 U.S.C. § 355(j).

[7] 21 C.F.R. § 314.3.

[8] 21 C.F.R. § 320.24.

[9] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, ANDA SUBMISSIONS—CONTENT AND FORMAT (June 2019), https://www.fda.gov/media/128127/download.

Vyera Blocked Access to the Distribution of Daraprim Needed for Bioequivalence Testing

Before Vyera's rights to market Daraprim were even finalized, the company converted the distribution of the drug from a retail model (which had been used for decades) into a closed distribution system and imposed restrictions in its distribution contracts to limit the types of customers who could buy the drug to government customers, hospitals, specialty pharmacies, and other specialized entities. Essentially, a distributor could not sell Daraprim to a retail pharmacy or a generic drug company without Vyera's approval.[10] Vyera's agreements with hospitals required the hospitals to limit their use of Daraprim to their own use and not resell the drug.[11] Vyera also imposed limits on the number of Daraprim bottles that a single customer could purchase at a time without Vyera's approval.[12] As the court pointed out, these restrictions were not required by FDA; they were not necessary for safety purposes; and the product did not require any special shipping, handling, storage, or administration.[13]

FDA will, under certain circumstances, require prescription drugs and biologics to develop and implement a Risk Evaluation and Mitigation Strategy (REMS), which may include distribution restrictions as an element to assure safe use (ETASU) of the product. In determining whether a REMS is necessary to ensure that the benefits of the drug outweigh its risks, FDA applies a number of factors set forth in Section 505-1 of the FDCA, which include (among other factors) the seriousness of any known or potential adverse events that may be related to the drug, the seriousness of the disease or condition that is to be treated with the drug, and the expected benefit of the drug.[14]

Some generic companies have initiated antitrust lawsuits alleging that brand companies were using a REMS distribution restriction as a pretext for restricting access to samples of the branded drug needed to conduct bioequivalence testing. Brand companies, in turn, have argued that they were under no duty to deal with their potential competitors. FTC has taken the position that a monopolist's refusal to sell to its potential competitors may, under certain circumstances, violate Section 2 of the Sherman Act and that the regulatory framework designed to encourage the introduction of generics could not function as Congress intended if generics were unable to access samples of brand products to conduct bioequivalence testing.[15]

Congress stepped in with the CREATES Act, which was enacted in December 2019 as part of the Further Consolidated Appropriations Act of 2020.[16] The CREATES Act established a private right of action for a generic company against a brand company that refuses to provide sufficient quantities of the product on "commercially

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[10] FTC v. Shkreli, No. 20cv00707, 2022 U.S. Dist. LEXIS 7715, at *31–37 (S.D.N.Y. Jan. 14, 2022).

[11] *Id.* at *34.

[12] *Id.* at *34–37.

[13] *Id.* at *32.

[14] Section 505-1(a)(1) of the FDCA (21 U.S.C. § 355-1(a)(1)).

[15] *See, e.g.*, Mylan Pharms., Inc. v. Celgene Corp., Federal Trade Commission's Brief as Amicus Curia, Case No. 2:14-CV-2094-ES-MAH (D. N.J. June 17, 2014); Actelion Pharms. Ltd. v. Apotex Inc., Federal Trade Commission's Brief as Amicus Curiae, Case No. 1:12-cv-05743-NLH-AMD (D. N.J. March 11, 2013).

[16] Further Consolidated Appropriations Act, 2020, P.L. 116-94 § 610, 133 STAT 3130 (Dec. 20, 2019), 21 U.S.C. 355-2.

reasonable, market-based terms."[17] If the covered product is subject to a REMS with ETASU, the generic company must first obtain an authorization from FDA to obtain sufficient quantities of the product, referred to as a "Covered Product Authorization (CPA)," and request the samples from the brand company before bringing an action.[18] A generic company does not need to obtain a CPA before requesting samples of a product that is not subject to a REMS. In addition to obtaining access to the samples, a generic company that prevails in litigation under the CREATES Act may be entitled to attorneys' fees, litigation costs, and civil monetary penalties.

In this case, Vyera was not subject to a REMS, but it instituted the closed distribution system and other distribution restraints expressly in order to delay generic entry. For example, Vyera's Director of Patient Access admitted that the quantity limits were imposed to make it harder for generics to obtain enough Daraprim "in order to copy the drug and compete with it."[19] Moreover, the company actively monitored the distribution of the product, investigated larger orders, and intercepted the distribution of the drug in instances where it seemed likely that the units would end up in the hands of a generic company. Mulleady at one point met with a pharmacy owner in a parking lot to repurchase bottles that were destined for a distribution company that supplies reference listed products for bioequivalence and clinical trials at twice the price the pharmacy paid for the bottles.[20]

Vyera Blocked Access to the API

Vyera also frustrated generic development by blocking access to the two most important manufacturers of the pyrimethamine API, Fukuzyu Pharmaceutical Company and RL Fine, through exclusive supply agreements. Fukuzyu had a drug master file (DMF) registered in the United States and was the API manufacturer that was referenced in Daraprim's new drug application (NDA). A DMF allows the holder to authorize one or more applicants or sponsors of an NDA or ANDA to incorporate by reference proprietary information contained in the DMF without having to disclose that information to the applicants or sponsors.[21] FDA customarily reviews the technical contents of DMFs only in connection with the review of applications that reference them. RL Fine had a DMF registered in Europe, but it had not yet filed a DMF in the United States for pyrimethamine.[22]

In 2017, Vyera entered into an exclusive contract with Fukuzyu for the purchase of pyrimethamine in the United States. The contract did not ensure that Vyera would have a reliable supply of the API or even require Fukuzyu to fill a single Vyera order, but rather the contract acted to bar Fukuzyu from selling the API to another company for the use, sale, or distribution of the product in the United States.[23]

Vyera also executed two contracts with RL Fine in 2017. Vyera entered into a Distribution and Supply Agreement that "gave Vyera 'the exclusive right to sell, distribute, and market' RL Fine's pyrimethamine for five years and limited RL Fine

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[17] *Id.* at § 610(b)(2)(A).

[18] *Id.* at § 610(b)(2)(B).

[19] FTC v. Shkreli, No. 20cv00707, 2022 U.S. Dist. LEXIS 7715, at *35 (S.D.N.Y. Jan. 14, 2022).

[20] *Id.* at *38–39.

[21] 21 C.F.R. § 314.420.

[22] *Shkreli*, 2022 U.S. Dist. LEXIS 7715, at *46.

[23] *Id.* at *44–45.

to selling pyrimethamine for use outside India only 'with the consent' of Vyera."[24] The Supply Agreement included a royalty payment to RL Fine of 7.5% of net revenues on Verya's sales of Daraprim, with a guaranteed minimum payment of $3 million. Vyera's obligation to make royalty payments above the guaranteed amount would terminate upon the entry of a generic pyrimethamine product in the U.S. market.[25]

In addition, Vyera entered into a Product Collaboration Agreement with RL Fine, whereby Vyera paid RL Fine $1 million towards expenses for research and development and preparation of a DMF. Vyera had previously estimated that the cost for RL Fine to prepare a DMF for pyrimethamine was less than $100,000.[26] Neither of these agreements required RL Fine to file a DMF with FDA or conditioned the payment on any milestones necessary to file a DMF, and RL Fine did not take any steps toward filing a DMF with FDA for pyrimethamine.[27] Vyera likewise never tried to obtain FDA approval to use RL Fine's API in Daraprim as a backup supplier.[28] According to the court, "In sum, Vyera received nothing in return for the millions of dollars it paid to RL Fine except the foreclosure of generic competitors' access to RL Fine's pyrimethamine."[29] Indeed, once it signed the Supply Agreement, RL Fine stopped supplying pyrimethamine to two generic drug manufacturers.[30]

Vyera Blocked Access to Sales Data

The court's opinion describes in detail how the two types of vertical restraints described above "exploited features of the FDA approval process for generic drug products by unreasonably and unlawfully restricting the markets for RLD and API" and effectively delayed the entry of generic Daraprim.[31] The Government also proved at trial that data-blocking provisions in Vyera's contracts with its distributors prevented generic companies from receiving accurate information about Daraprim sales.[32] According to the complaint, the purpose of these provisions was to "prevent generic companies from accurately assessing the market opportunity for a generic Daraprim product and thereby deter them from even pursuing development of a generic product."[33] The court, however, did not explore this element of the Government's claim in depth because it found that the lack of data did not actually impede the eventual entry of two generic companies.[34]

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[24] *Id.* at *49.

[25] *Id.* at *49–51.

[26] *Id.* at *46–49.

[27] *Id.* at *50.

[28] *Id.*

[29] *Id.*

[30] *Id.* at *49.

[31] *Id.* at *98–99.

[32] *Id.* at *98 n. 35.

[33] Redacted Amended Complaint for Injunctive and Other Equitable Relief, FTC v. Shkreli, No. 20cv00707 (S.D.N.Y. Apr. 16, 2020), ECF No. 91, at ¶7.

[34] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *98 n.35.

VIOLATION OF ANTITRUST LAWS

The court found Shkreli liable for Vyera's unreasonable restraint of trade and monopolization of the FDA-approved pyrimethamine market in violation of Sections 1 and 2 of the Sherman Act and that his conduct also violated the competition laws of each of the plaintiff states.[35]

The restrictive distribution contracts for Daraprim and exclusive supply agreements for the API constituted unreasonable restraints of trade in violation of Section 1, which prohibits "every contract, combination . . . , or conspiracy, in restraint of trade or commerce among the several States."[36] Most vertical restraints of trade are analyzed under the rule of reason, which requires an analysis of any procompetitive benefits of the restraint and the competitive characteristics of the relevant market. Exclusive dealing arrangements can implicate Section 1 when they exclude competitors or new entrants from a necessary input or when they allow a supplier to deprive other suppliers of a market for their goods.[37] For exclusive dealing to violate Section 1, the agreement must exclude "a significant fraction of buyers or sellers from the market."[38] The court found Shkreli's proffered justifications for these distribution and supply agreements pretextual.

The court also found that through these agreements, Shkreli and Vyera unlawfully and willfully maintained a monopoly in the relevant market through anticompetitive conduct in violation of Section 2 of the Sherman Act, which makes it unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States."[39] A claim under Section 2 requires a plaintiff to establish "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[40] The court had no trouble concluding that Vyera had a monopoly in the market for FDA-approved pyrimethamine market, as evidenced by the company's ability to raise the price to an astronomical level, and that it maintained that monopoly power through the absence of competition and not because it possessed a superior product or business acumen.[41]

Shkreli was found to be personally liable for Vyera's conduct due to the control he exercised over the company. The court characterized Shkreli as the "prime mover in this anticompetitive scheme," which the court explained was Shkreli's "brainchild" that he drove "each step of the way."[42] The opinion describes several instances where Shkreli specifically directed the activities at issue in the case, even in the midst of serving a prison sentence for an unrelated violation of the Securities and Exchange

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[35] *Id.* at *98.

[36] 15 U.S.C. § 1.

[37] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *89, citing Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc., 386 F.3d 485, 508 (2d Cir. 2004).

[38] *Id.*

[39] 15 U.S.C. § 2.

[40] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *90, citing United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd., 11 F.4th 118, 137 (2d Cir. 2021) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570–71, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (1966)).

[41] *Id.* at *99–108.

[42] *Id.* at *133.

Act. Shkreli was also described as being the mastermind of the scheme, having launched Vyera with a plan to "acquire sole-source drugs that were the gold standard treatment option for life-threatening diseases with a small patient population and inferior alternative treatments, with the intent to raise their prices, block generic competition, and reap extraordinary profits."[43] According to the court, Shkreli "road-tested" the strategy of acquiring sole source orphan drugs, creating a closed distribution system, and raising the drugs' prices at his previous firm, Retrophin, and later touted this experience to Vyera investors.[44]

REMEDIES

The consent order requires Vyera and Phoenixus to pay up to $40 million total in equitable monetary relief and to make Daraprim available to any potential generic competitor at list price. The companies must also provide FTC with prior notification of any planned pharmaceutical transaction valued at $25 million or more.[45] The consent order also subjects Mulleady to a suspended judgment of $250,000 in equitable monetary relief and prohibits him from engaging in certain activities on behalf of a pharmaceutical company for seven years. Mulleady, Vyera, and Phoenixus also are prohibited for ten years from entering into any contract that, with certain exceptions, restricts the ability of 1) any purchaser to provide a drug product to a generic company for the purpose of developing a generic version of that product; 2) any manufacturer or distributor of an API to sell or provide that API to a pharmaceutical company; or 3) any distributor, wholesaler, pharmacy, or group purchasing organization to provide sales or distribution data to a data aggregator.

Personal Liability for Shkreli

The court order against Shkreli bans him for life from the pharmaceutical industry. While the court acknowledged that banning an individual from an entire industry is a serious remedy, the court found that "Shkreli's egregious, deliberate, repetitive, long-running, and ultimately dangerous illegal conduct warrants imposition of an injunction of this scope."[46] The court pointed to Shkreli's pattern of conduct at Retrophin and Vyera and his utter lack of remorse, characterizing the Daraprim scheme as "particularly heartless and coercive," since the drug must be administered within hours to patients with acute toxoplasma encephalitis.[47]

The order against Shkreli also awards disgorgement to the states in the amount of $64.6 million, which it calculated by determining the excess profits based upon the hypothetical dates on which two generic drug companies would have entered the market but for Vyera's anticompetitive conduct. The court estimated that the defendants' actions caused one of the generic companies a thirty-month delay and the other company a twenty-four-month delay. Because Shkreli was the person principally responsible for the conduct, the court found him jointly and severally liable for the full

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[43] *Id.* at *23.

[44] *Id.* at *20–25.

[45] Joint Motion for Entry of Stipulated Order for Permanent Injunction, FTC v. Shkreli, No. 20cv00707 (S.D.N.Y. Dec. 7, 2021), ECF No. 753.

[46] *Shkreli*, 2022 U.S. Dist. LEXIS 7715 at *124–25.

[47] *Id.* at *125–26.

amount of the disgorgement, to be offset by any amounts paid by the settling defendants.[48]

IMPACT

The case illustrates that restrictive pharmaceutical distribution systems, particularly in the absence of any safety risk, can be considered anticompetitive if they are intended to delay the entry of generic products. The strong public policy favoring generic competition may create a duty to deal in this industry that is far more compelling than the general presumption in antitrust doctrine that a company has no duty to deal with its competitors. Even when the distribution system is restricted as a REMS element due to a legitimate safety risk, FTC has argued, and Congress has made clear, that a reference listed drug product must still make its drug available to a prospective generic entrant on commercially reasonable terms for the purpose of conducting the necessary testing to support an ANDA.

This case also provides a prime example of FTC's ability to coordinate with state enforcers to maximize the relief available to consumers. The cooperation among the federal and state enforcers allowed the agencies to obtain disgorgement relief despite the Supreme Court's ruling in the *AMG Capital Management* case. As a result, disgorgement is still on the table as a potential remedy when there is a joint enforcement action involving certain states.

Finally, this case should serve as a reminder that pharmaceutical executives can and will be held personally liable for their company's actions, particularly when they direct or control the anticompetitive conduct at issue in the case. To be sure, Shkreli's brazen conduct and the egregiousness of the price hike sealed his fate. While few would dare to act as shamelessly as Shkreli did, the prospect of personal liability should deter executives from directing companies under their control to engage in exclusionary conduct, especially if such conduct would result in supracompetitive pricing of a critical therapy.

[48] *Id.* at *128–35.

AMG Capital Management, LLC v. Federal Trade Commission: No Money for You! Supreme Court Holds FTC Cannot Obtain Equitable Monetary Relief Without First Going Through Its Administrative Adjudication Process

LYNN C. TYLER*

In *AMG Capital Mgmt., LLC v. FTC*, 141 S. Ct. 1341 (2021) ("*AMG Capital*"), the Supreme Court held that the Federal Trade Commission (FTC) cannot obtain equitable monetary relief, such as disgorgement or restitution, when it pursues district court litigation directly under § 13(b) of the Federal Trade Commission Act (FTC Act or the Act). Rather, to obtain such relief, FTC must first follow its administrative adjudication procedures under § 5 of the Act.

WHY IT MADE THE LIST

AMG Capital directly applies to several categories of Food and Drug Administration (FDA)-regulated entities because § 12 of the FTC Act, 15 U.S.C. § 52, makes it unlawful to disseminate false advertising about cosmetics, drugs, food, and medical devices. Further, the Court's analysis and reasoning appear to apply with equal force to civil litigation brought by the FDA (through the Department of Justice) under § 302 of the Federal Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. § 332.

DISCUSSION

Question Presented

Justice Breyer wrote the opinion for the unanimous Court. He began by noting that § 13(b) of the Act authorizes FTC to obtain, "in proper cases," a "permanent injunction" in federal court against "any person, partnership, or corporation" that it believes "is violating, or is about to violate, any provision of law" that the Commission enforces. He then stated the question presented as whether this statutory language authorizes FTC to seek, and a court to award, equitable monetary relief such as disgorgement or restitution.

Factual and Procedural Background

Scott Tucker controlled several companies in the short-term payday lending business. When the companies explained the terms of their loans, they misled many customers. The companies' written explanations appeared to say that customers could repay a loan by making a single payment. When doing so, a person who, for example,

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had borrowed $300 would owe an extra $90, for a total of $390. In fine print, however, the loan agreements said that the loans would automatically renew unless the customer took affirmative steps to opt out. Thus, unless the customer who borrowed $300 was aware of the fine print and actively prevented the loan's automatic renewal, he or she could end up having to pay $975, not $390. Between 2008 and 2012, Tucker's businesses made more than 5 million payday loans, resulting in more than $1.3 billion in deceptive charges.

In 2012, FTC filed suit and claimed that Tucker and his companies were engaging in "unfair or deceptive acts or practices in or affecting commerce," in violation of § 5(a) of the Act, 15 U.S.C. § 45(a)(1). FTC did not first use its own administrative proceedings to assert that Tucker's practices were likely to mislead consumers. Rather, it filed a complaint against Tucker directly in federal court, pursuant to § 13(b), and asked the court to issue a permanent injunction to prevent Tucker from committing future violations of the Act. Relying on the same provision, FTC also asked the court to order monetary relief, in particular, disgorgement and restitution. The district court granted a motion for summary judgment filed by FTC, granted its request for an injunction, and directed Tucker to pay $1.27 billion in disgorgement and restitution.

Congress added § 13(b) to the FTC Act in 1973. Section 13(b) permits FTC to proceed directly to court (prior to issuing a cease and desist order) to obtain a "temporary restraining order or a preliminary injunction," and also allows FTC to obtain a court-ordered permanent injunction. In the same legislation, Congress also amended § 5(l) of the Act to authorize district courts to award civil penalties against respondents who violate final cease and desist orders and to "grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission." Two years later, Congress authorized district courts to grant "such relief as the court finds necessary to redress injury to consumers," including through the "refund of money or return of property." Congress specified, however, that the consumer redress could be sought only against those who have "engage[d] in any unfair or deceptive act or practice . . . with respect to which the Commission has issued a final cease and desist order which is applicable to such person."

Court's Analysis

Justice Breyer wrote that several considerations convinced the Court that § 13(b)'s "permanent injunction" language does not authorize FTC directly to obtain monetary relief. First, the language refers only to injunctions. It says, "in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent *injunction*." It does not mention monetary relief. Further, the language and structure of § 13(b), taken as a whole, focuses upon relief that is prospective, not retrospective. Those words are buried in a lengthy provision that focuses upon purely injunctive, not monetary, relief.

Moreover, the Court found that the structure of the Act beyond § 13(b) confirms this conclusion. In §§ 5(l) and 19, Congress gave district courts the authority to impose limited monetary penalties and to award monetary relief in cases where FTC has *issued cease and desist orders*, i.e., where FTC has engaged in administrative proceedings. Because Congress explicitly provided in these provisions for "other and further equitable relief," 15 U. S. C. § 45(l), and for the "refund of money or return of property," § 57b(b), it likely did not intend for § 13(b)'s narrower "permanent injunction" language to have similarly broad scope.

The Court also found that to read § 13(b) to mean what it says, as authorizing injunctive but not monetary relief, produces a coherent enforcement scheme. FTC may obtain monetary relief by invoking its administrative procedures first and then § 19's redress provisions (which include limitations). In addition, FTC may use § 13(b) to obtain injunctive relief while administrative proceedings are foreseen or in progress, or when it seeks only injunctive relief. By contrast, FTC's broad reading of § 13(b) would allow it to use that section as a substitute for §§ 5 and 19. Referencing the venerable maxim that "Congress does not hide elephants in mouseholes," the Court concluded that could not have been Congress' intent.

In short, based on the language of § 13(b) itself, and the overall language and structure of the FTC Act, the Court unanimously concluded that § 13(b) does not authorize FTC to recover equitable monetary relief, such as disgorgement and restitution. Rather, if FTC wants such relief, it must first complete its administrative adjudication proceedings and issue a cease and desist order and then seek enforcement in a district court.

It is now time to consider how *AMG Capital* applies to FDA. Section 302 of the FDCA, 21 U.S.C. § 332, states: "The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of section 301 of this title, except paragraphs (h), (i), and (j)." As most FDLI members are likely aware, § 301 of the FDCA includes a lengthy list of prohibited acts. In other words, just as § 13(b) of the FTC Act authorizes FTC to seek permanent injunctions, § 302 of the FDCA authorizes the FDA to seek injunctions "to restrain violations of section 301." And just as § 13(b) of the FTC Act is silent about monetary relief, equitable or otherwise, so is § 302 of the FDCA. So far, the applicability of *AMG Capital* to FDA is clear.

AMG Capital's application to FDA becomes even clearer when one considers other provisions of the FDCA. Section 303 of the FDCA includes several subsections that authorize a court to impose criminal fines or civil penalties for violations of various provisions. Section 518 of the FDCA authorizes FDA to order refunds or reimbursements to people who have been damaged by a recall of a medical device. Just as the Court found in *AMG Capital* that the fact Congress explicitly provided monetary relief in other sections of the FTC Act meant that it likely did not intend for § 13(b)'s narrower "permanent injunction" language to have similarly broad scope, the Court would likely find that the FDCA's express provision of monetary relief in §§ 303 and 518 means that § 302 does not authorize such relief.

Overall, the conclusion that *AMG Capital* precludes FDA from seeking monetary relief, equitable or otherwise, under § 302 is compelling.

IMPACT

The author's research has not uncovered any express and official public reaction to *AMG Capital* by FDA. It seems likely FDA is less-than-thrilled by it because, beginning in the 1990s, FDA and DOJ began pursuing disgorgement and/or restitution in certain consent decrees. The agencies argued that disgorgement and restitution are equitable remedies that may be imposed in equitable proceedings like injunctions. Over the years, they have had considerable success, including some nine-figure recoveries. They were also successful in persuading some courts of appeals to affirm awards of disgorgement and restitution. Going forward, they may no longer be able to achieve these results, reducing their own recoveries and those for consumers. In some

cases, FDA and DOJ may be able to continue recovering monetary relief for the government and consumers by joining claims under the FDCA with claims under other laws, such as the False Claims Act.

In appropriate cases, the agencies may be able to pursue monetary relief under the various provisions of § 303 of the FDCA, generally discussed above. For the criminal fines made available under § 303, the agencies will have to satisfy the highest burden of proof, beyond a reasonable doubt, rather that the preponderance of the evidence standard applicable in civil matters. Presumably, that will lessen the number of such cases they can pursue under that section. Further, both the criminal fines and civil penalties available under § 303 are subject to various limitations and may not compare to disgorgement or restitution. Although § 518 provides for reimbursement to certain parties in the distribution chain, including consumers, it is limited to medical devices.

In sum, *AMG Capital* is likely to hamper severely FDA's ability to recover equitable monetary relief, specifically disgorgement and restitution, for violations of the FDCA, absent congressional action. Congress is certainly aware of *AMG Capital* given that the Senate Commerce Committee held a hearing the day before the Supreme Court's decision was handed down during which it discussed the case and its potential impact on FTC's ability to obtain monetary relief for consumers. After the decision, remedial legislation has been considered, but so far not adopted. It is anyone's guess if and when Congress will be able to agree on amendments to the FTC Act, FDCA, and potentially other statutes authorizing litigation by other federal agencies, that address the issue.

2021 Cannabis Review and 2022 Outlook: States Will Continue to Lead the Charge, Possibility of Federal Landscape Shift, Plus Other Drugs

JONATHAN HAVENS, SETH GITNER & ADAM FAYNE*

Despite federal cannabis reform stalling in 2021, states showed no signs of slowing down in establishing or expanding medical and/or adult-use (i.e., recreational) cannabis programs. At last count, thirty-seven states have medical cannabis laws on their books, with eighteen of those states also permitting adult use. After the November 2020 elections, trade (and several mainstream) press headlines said the same thing: Weed wins big at the ballot box.[1] Voters in five states approved medical and/or adult-use cannabis. More specifically:

- Arizona voters approved an adult-use measure;
- Mississippi voters approved a medical-use measure;
- Montana voters approved an adult-use measure;
- New Jersey voters approved an adult-use measure; and
- South Dakota voters approved both medical-use and adult-use measures (becoming the first state to do so at the same time).

While there were successful legal challenges to Mississippi's medical initiative and South Dakota's adult-use measure, the South Dakota legislature could in 2022 enact through legislation the reforms that voters approved in 2020. Mississippi's legislature already did so, and Governor Tate Reeves signed a medical cannabis measure (SB 2095) into law in February 2022.

Beyond acknowledging the significant impact November 2020 had on cannabis reform, it is worth discussing state activity in response to the same. For example, Connecticut enacted an adult-use law in June 2021, no doubt in response to both New Jersey voters approving adult-use, which is expected to launch this year (possibly as

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[1] *See* Jonathan Havens & Marc Adesso, *Cannabis 2021 Year in Review, and the Road Ahead*, CANNABIS BUS. EXEC. (Dec. 15, 2021), https://www.cannabisbusinessexecutive.com/2021/12/cannabis-2021-year-in-review-and-the-road-ahead/.

soon as April 2022),[2] and New York enacting an adult-use law earlier in 2021. Now, all eyes are on states in the region that already have medical cannabis programs—Delaware, Maryland,[3] and Pennsylvania—as they could adopt adult-use measures this year or next.

Regardless of strong public opinion polling, there are still pockets of the country (both in traditional "blue" and "red" states) that oppose legalization. However, given the drastic expansion of state cannabis programs in the last several years, slow-adopter states risk losing out on significant tax revenue to their regional neighbors if they don't follow suit in enacting cannabis reform. Beyond the Mid-Atlantic, states in the mid-west, central, and south could add some color to the cannabis legalization map. Arkansas, Florida, Missouri, Ohio, and Oklahoma could take up adult-use this year, and Nebraska and Wyoming could consider medical-use measures. For more information on these and other measures, we refer the reader to the *Cannabis Business Times*' piece on state activity in 2022.[4] Speaking of the south, we are monitoring developments in Alabama and Georgia, as both look to roll out medical programs this year, as well as in Virginia, especially with Governor Glenn Youngkin (R) taking office. Virginia enacted adult-use last year, and it is not clear how, if at all, Youngkin will impact the timing or implementation of that law.

For now, it's state expansion or bust given the low prospect of sweeping federal reform, at least given the current makeup of the U.S. Senate. Congress's upper chamber has become a bit of a legislative graveyard, stalling movement of even some key policy measures. While the 50-50 split in the Senate has caused headaches for stakeholders in a number of industries, there could be change on the horizon: Majority Leader Chuck Schumer (D-NY) signaled recently that the Senate could soon take up filibuster reform. It is unclear whether the Senate will actually consider such a measure, let alone approve it. Even if filibuster reform is adopted, it is also not clear whether all fifty Senate Democrats would support ending the federal prohibition on cannabis. Yet another variable is the impact the 2022 midterm elections will have on control of Congress. Although beyond the scope of this piece, it is feasible that Republicans could win control of the House, and given the 50-50 Senate split, they would only need a net plus one seat to gain control of the Senate.

It is also possible that if Republicans gain control of one or both houses of Congress, cannabis reform (either incremental or sweeping) could occur. Cannabis polls very well, and it is wrong to assume that only liberal Democrats support it. One stumbling block that has prevented incremental reform like the Secure and Fair Enforcement (SAFE) Banking Act from passing the Senate—even though it's passed the House multiple times—is that Senators Schumer and Cory Booker (D-NJ), sponsors of the Cannabis Administration and Opportunity Act (CAOA), along with Senator Ron Wyden (D-Ore), have opposed piecemeal reform, opting instead for a comprehensive

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[2] Tracey Tully, *Legal Marijuana Sales Expected to Start Within Weeks in New Jersey*, N.Y. TIMES (Mar. 11, 2022), https://www.nytimes.com/2022/04/11/nyregion/marijuana-sales-nj.html.

[3] *See* Kyle Jaeger, *Maryland Lawmakers Officially Put Marijuana Legalization on the Ballot, Also Sending Implementation Bill to Governor*, MARIJUANA MOMENT (Apr. 1, 2022), https://www.marijuanamoment.net/maryland-lawmakers-officially-put-marijuana-legalization-on-the-ballot-also-sending-implementation-bill-to-governor/.

[4] Tony Lange, Andriana Ruscitto, Eric Sandy & Melissa Schiller, *15 States That Could Legalize Cannabis in 2022*, CANNABIS BUS. TIMES (Oct. 27, 2021), https://www.cannabisbusinesstimes.com/article/states-likely-legalize-cannabis-2022/.

measure that includes social justice reform. Perhaps with a flip of the Senate, Republicans could advance a measure like the States Reform Act (SRA) introduced by Representative Nancy Mace (R-SC). The SRA could be more palatable to Republicans and moderate Democrats, as it contains the fundamentals of CAOA with more narrowly tailored social justice measures.

Turning away from Congress, the U.S. Senate recently confirmed Dr. Robert Califf, President Biden's pick to lead the U.S. Food and Drug Administration (FDA). Califf is a cardiologist who previously served as FDA Commissioner and Deputy Commissioner under President Obama. Little is known about how a Califf-led FDA will impact cannabis and cannabis-derived products, although it has been reported that Califf recommended some cannabis-derived drug products to patients while in private practice. We should not read too much into that, other than to say that he realizes that any drug, whether it is cannabis-derived or otherwise, when well-researched and considered safe and effective, can and should be used to treat patients. We do not expect Califf to be any more or less active in the cannabis space than his predecessors. As others have done before him, he will let science inform FDA's decisions around which drug products it approves. Regarding hemp-derived cannabidiol (CBD), we do not see Califf departing from FDA's previously articulated stance regarding the illegality of CBD as a dietary ingredient unless Congress forces the agency's hand through legislation.

Speaking of cannabinoids, another issue we are monitoring this year is treatment of newer or lesser-known ones, such as delta-8 tetrahydrocannabinol (THC), delta-10 THC, THC-O acetate (THC-O), cannabigerol (CBG), and cannabinol (CBN). Particularly with regard to the THC cannabinoids in this list, there has been an increased amount of attention from industry and regulatory stakeholders, especially about the legality of products containing them. While a number of states have banned delta-8 THC, for example, it is still widely available, and federal enforcement is virtually non-existent.

Last, but certainly not least, while this section largely addresses cannabis, we have been receiving an increasing number of questions around psychedelics, both with regard to federal and state regulation of the same. We are seeing similarities between how the psychedelics space is developing now with how the cannabis space really started to take shape several years ago. The science around the potential effectiveness of methylenedioxymethamphetamine (MDMA), psilocybin (i.e., mushrooms), and lysergic acid diethylamide (LSD) to treat depression, post-traumatic stress disorder (PTSD), and more, is impressive.[5] Regulators and policymakers, especially at the state level, seem to be taking note of the same.

While much of the psychedelics policy movement has occurred at the local level (e.g., the City of Denver was the first municipality to decriminalize psilocybin in 2019), Oregonians voted in 2020 to legalize psilocybin for therapeutic purposes. A great overview of many of these policies from across the country is available in this piece from Marijuana Moment.[6] Although there is some way to go in opening up access to psychedelics, the U.S. Drug Enforcement Administration (DEA) and the

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[5] Paul Tullis, *How Ecstasy and Psilocybin are Shaking up Psychiatry*, NATURE (Jan. 27, 2021), https://www.nature.com/articles/d41586-021-00187-9.

[6] Kyle Jaeger, *Psychedelics Decriminalization Advancing in Three More Cities, Spanning from Coast to Coast*, MARIJUANA MOMENT (Aug. 3, 2021), https://www.marijuanamoment.net/psychedelics-decriminalization-advancing-in-three-more-cities-spanning-from-coast-to-coast/.

National Institute on Drug Abuse (NIDA) have indicated in testimony to Congress their support for streamlining the process of researching certain schedule I drugs (e.g., cannabis, some psychedelics), which is an important step.

We will be monitoring developments regarding these issues and more in 2022.

Salinero v. Johnson & Johnson et al.

GINGER PIGOTT & MICHAEL GOODMAN*

WHY IT MADE THE LIST

The term "learned intermediary" originated in the Eighth Circuit decision of *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966)[1] and today is applied in most U.S. jurisdictions to define the warning obligations for prescription drug and device manufacturers. In broad terms, this doctrine stands for the proposition that a manufacturer fulfills its duty of care when it provides all necessary information to a "learned intermediary" who then interacts with the consumer of a product. Where the learned intermediary doctrine applies, the duty to warn and adequacy of warnings are more easily defended against failure-to-warn claims. Over the last fifty-six years, plaintiffs consistently have attempted to avoid the learned intermediary doctrine and pursue failure-to-warn claims without having to deal with the doctrine's limiting effect.

Prior to *Salinero v. Johnson & Johnson*, no Florida court had specifically addressed whether a physician's financial relationship with a manufacturer could alter the doctrine.[2] As in other places, in Florida, where prescription drugs and devices are accompanied by an adequate set of warnings in the Instructions for Use (IFU) to the physician, failure-to-warn claims fail against their manufacturers. The Eleventh Circuit has found the learned intermediary doctrine still applies, even where a physician has a financial relationship with the manufacturer.

DISCUSSION

Legal Background

Failure-to-warn claims in a prescription product context are almost universally adjudicated by application of the learned intermediary doctrine and frequently at an earlier stage in the litigation, depending on various factors and most often after a physician's testimony. Under the doctrine, courts evaluate the adequacy of product labeling by reference to the understanding of the prescriber rather than the patient. While some failure-to-warn claims are barred by application of other dispositive legal

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[1] Carole A. Cheney, *Not Just for Doctors: Applying the Learned Intermediary Doctrine to the Relationship between Chemical Manufacturers, Industrial Employers and Employees*, 85 NW. U. L. REV. 562, 581 n. 127 (1991).

[2] Salinero v. Johnson & Johnson et al., 995 F.3d 959, 961 (11th Cir. 2021) (The Eleventh Circuit recognized that the "Salineros asked [the district court] to create a 'financial bias' exception to the learned intermediary doctrine, [but] the Florida courts [had] never recognized—much less discussed—one.").

defenses (primarily preemption), when prescription product cases get to the point of evaluation, the key from a warning perspective is often the testimony of the prescribing physician.

The Restatement (Second) of Torts expresses the basic requirements for a plaintiff to plead and prove a failure-to-warn claim. A plaintiff must allege and establish 1) the manufacturer either knew, or should have known, of dangers inherent in the use of the product, yet adequate warnings were not given; and 2) if adequate warnings had been provided, the harm would have been avoided.[3] Thus, the first point of dispute is almost always whether the product is "properly prepared, and accompanied by proper directions and warnings."[4] In the prescription product context, the manufacturer must make adequate warnings available to the patient's doctor—not to the patient—since physicians are in a better position to understand the risks and also initiate the decision for the patient to use the prescription product.[5] Here, the physician is the learned intermediary.[6]

The second part is the causation element, asking whether different warnings would have resulted in a different outcome. Proximate cause is essential for survival of failure-to-warn claims. If the learned intermediary does not read the label, plaintiff cannot show proximate cause, and the warning claim fails.[7] For example, a patient's widow alleged her husband's prescription antidepressants did not adequately warn his physician of the associated side effects. Because the physician admitted he had not read the label, the widow failed to show that the alleged inadequate warnings proximately caused her husband's death.[8] So ended the failure-to-warn claim, regardless of the warning's contents.

What has not been addressed uniformly is whether a plaintiff can successfully diminish the value of the learned intermediary doctrine and create a question of fact for the jury by showing evidence that the manufacturer incentivized the physician to ignore the warnings and stay the course with the allegedly "dangerous device." *Salinero v. Johnson & Johnson et al*. refuses to expand Florida law to accommodate this proposed exception following the logic of other jurisdictions considering similar arguments.

Factual Background

Ethicon's Artisyn® pelvic mesh is a prescription device indicated to treat pelvic organ prolapse. The Food and Drug Administration cleared Ethicon's premarket notification for Artisyn® pelvic mesh as a Class II medical device in June 2012.[9]

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[3] Restatement (Second) of Torts § 402A cmt. j.

[4] Restatement (Second) of Torts § 402A cmt. k.

[5] Reyes v. Wyeth Labs., Inc., 498 F.2d 1264, 1276 (5th Cir. 1974) ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers[.]").

[6] *See id.*

[7] *E.g.*, Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659 (9th Cir. 2004).

[8] *Id.* at 661.

[9] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., K113205, ETHICON 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION (June 12, 2012), https://www.accessdata.fda.gov/cdrh_docs/pdf11/K113205.pdf.

A. Court Decision

In *Salinero v. Johnson & Johnson et al.*, plaintiff Charlotte Salinero sued Johnson & Johnson and its subsidiary, Ethicon, on September 6, 2018, in the U.S. District Court for the Southern District of Florida for alleged injuries from Ethicon's Artisyn® pelvic mesh.[10] She alleged the Artisyn® pelvic mesh Dr. Jaime Sepulveda implanted in 2012 had to be removed five years later because of fistulas, fecal incontinence, and severe pain.

Plaintiff alleged Ethicon was liable under theories of negligence, strict liability based on manufacturing defect, strict liability based on design defect, failure-to-warn, false information negligently supplied for guidance of others, negligent infliction of emotional distress, gross negligence, and loss of consortium.

Like many past failure-to-warn claims in the prescription device space, Salinero's failure-to-warn claim fell short upon application of Florida's learned intermediary doctrine. But it was Salinero's novel "financial bias" argument that drove the Southern District of Florida to take a harder look at Salinero's failure-to-warn claim.

Ethicon argued the learned intermediary doctrine barred Salinero's failure-to-warn claim. In his deposition, Dr. Sepulveda testified that he mainly relies on his experience and training when choosing an appropriate implantable device. He also testified that he was aware of the potential risks with Ethicon's Artisyn® pelvic mesh but considered the risks to be highly infrequent. And at some point prior to its use, Dr. Sepulveda read the Instructions for Use and determined that Ethicon's Artisyn® pelvic mesh was still the best option for Salinero. When a physician testifies to reading the IFU of a challenged medical device, and where the IFU warns of the risk alleged, the link between a manufacturer and plaintiff is fractured.

Salinero attempted to sidestep the learned intermediary doctrine by arguing that it does not apply when the manufacturer financially incentivizes the physician to disregard the dangers and stay the course. She specifically relied on *Aubin v. Union Carbide Corp*., 177 So. 3d 489, 514 (Fla. 2015), contending that Dr. Sepulveda's judgment was clouded by his significant financial relation with Ethicon and the fact that Ethicon had long used him as an expert witness and consultant, thus wrongfully casting aside Artisyn®'s risks of failure.

The plaintiff in *Aubin* claimed the manufacturer failed to warn its retailers of the significant harm attached to its asbestos. The Florida Supreme Court viewed the manufacturers warnings in light of the product's degree of danger: the greater the harm the end user would face if the manufacturer did not give proper warnings, the less reasonable a manufacturer would be in relying on an intermediary to ensure the warnings were fully and adequately communicated to the end user.[11] The degree of harm and reasonability of the manufacturer's reliance on the retailers created a question of fact left to the jury, thus escaping dismissal as a question of law.

But the Florida Supreme Court in *Aubin* passively—and seemingly tangentially to the facts—provided that "a manufacturer may not be able to reasonably rely on an intermediary to provide warnings if the manufacturer knows that the necessary warnings would render the product less valuable and *provide an incentive* to the

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[10] Johnson & Johnson was dismissed from the case leaving Ethicon as the sole defendant.

[11] Salinero v. Johnson & Johnson et al., 400 F. Supp. 3d 1334, 1346 (S.D. Fla. 2019), *aff'd*, 995 F.3d 959 (11th Cir. 2021) (citing Aubin v. Union Carbide Corp., 177 So. 3d 489, 515–16 (Fla. 2015)).

intermediary to withhold the necessary information from the consumer."[12] Salinero read this to mean the Florida courts adopted "financial bias" as a reason to cast aside the learned intermediary doctrine, but the Southern District of Florida declined to adopt her medical device comparison to *Aubin*'s asbestos suit. Thus, the district court dismissed Salinero's failure-to-warn claim.[13]

After a trial in January 2020—in which the jury rejected all of Salinero's remaining claims against Ethicon—Salinero sought to revive her case by appealing the U.S. District of Florida's dismissal of the failure-to-warn claim. She argued that Dr. Sepulveda's undisclosed financial relationship with Ethicon pierced Ethicon's defense that it did not have a duty to warn her directly. Stated another way, plaintiff argued the district court had erred when it applied the learned intermediary doctrine to dismiss the failure-to-warn claim.

The Eleventh Circuit reviewed the judgment as a matter of law de novo, evaluating Salinero's novel financial bias argument.[14] Emphatically, the Eleventh Circuit held that Florida courts have never recognized a "financial bias" exception to the learned intermediary doctrine on prescription drug or medical devices used by a physician, and the Eleventh Circuit was not willing to create new doctrine out of whole cloth.[15]

While *Aubin* created an exception to the learned intermediary doctrine, it did not implicate the physician–patient relationship, nor did the Florida Supreme Court borrow from Florida's medical learned intermediary cases in reaching its decision.[16] The Eleventh Circuit further differentiated the physician's degree of sophistication from that of an asbestos manufacturer:

> [A] physician who has significant education and training and understands the complexity of a medical drug or device is in a profoundly different position than an intermediary manufacturer of construction materials that include asbestos.[17]

Salinero's failure-to-warn claim could not succeed because Dr. Sepulveda testified he knew the risks posed by Ethicon's Artisyn® pelvic mesh but still chose it over other options.[18] Because Dr. Sepulveda knew the risks the prescription device posed, the Eleventh Circuit denied Salinero's effort to rewrite the learned intermediary doctrine, rejecting her "financial bias" argument and dismissing her failure-to-warn claim.

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[12] *Aubin*, 177 So. 3d at 515 (emphasis added).

[13] *Salinero*, 400 F. Supp. at 1347.

[14] Salinero v. Johnson & Johnson et al., 995 F.3d 959, 964 (11th Cir. 2021).

[15] *Id.* at 967.

[16] *Id.* at 967–68.

[17] *Id.* at 968.

[18] *Id.* at 965–66 (upholding summary judgment where doctor testified that different warning would not have changed his decision to implant the device); *In re* DePuy Orthopaedics, Inc., 888 F.3d 753, 775 (5th Cir. 2018) (testimony of treating physician must show that different warning would have changed prescribing decision); Higgins v. Ethicon, No. 2:12-CV-01365, 2017 WL 2813144, at *3 (S.D. W. Va. Mar. 30, 2017) (summary judgment where no evidence that different warning would have changed prescriber's decision); Twombly v. Bos. Sci. Corp., No. 2:13-CV-23829, 2016 WL 1737118, at *6 (S.D. W. Va. May 2, 2016) (same).

IMPACT OF THE DECISION

Salinero underscores the Eleventh Circuit's understanding of the rationale behind the learned intermediary doctrine:

> [A] physician who has significant education and training and understands the complexity of a medical drug or device is in a profoundly different position than an intermediary manufacturer of construction materials that include asbestos.[19]

In other words, the financial interests of the physician should not overcome the dispositive impact of the learned intermediary doctrine. The court left open the question of whether certain extraordinary circumstances might keep a court from granting summary judgment based on the doctrine or whether certain influence might be deemed to take away that independent medical judgment. Unlike professionals in some other industries, physicians are well-educated, highly trained, and have a great deal of supervision over their patients and are oath-bound to act in the best interests of such patients based on their medical needs. At the same time, a manufacturer most often has little opportunity to provide direct warnings and certainly does not have or provide the necessary medical judgment to apply to a patient's particular case. While plaintiffs will likely continue to test the learned intermediary doctrine and explore whether some financial relationship evidences undue influence, the financial interests of the physician alone may never outweigh the longstanding precedent of the learned intermediary doctrine.

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[19] *Salinero*, 995 F.3d at 968.

Bell v. Publix Super Mkts., Inc.

FRANCISCO CABRERA LOPEZ & MITAL PATEL*

WHY IT MADE THE LIST

Class action litigation over labeling on food products continues unabated as courts across the nation face a steady stream of cases from plaintiffs alleging that they are misled by product labels. Courts are left with the difficult task of determining whether an ambiguous label is misleading to a reasonable consumer. All courts consistently hold that claims on a product label must be analyzed in the context of the entire packaging and other contextual references, with some explicitly holding that reasonable consumers should look to the product's ingredient statement to dispel any possible ambiguities that could be identified on a food label.

The Seventh Circuit's decision in *Bell v. Publix Super Mkts., Inc.*,[1] however, has created a great deal of confusion regarding the role ingredient statements should play when assessing the reasonableness of a plaintiff's interpretation of an arguably ambiguous food label. In *Bell*, the plaintiff had contended that she was deceived into buying a cheese product because it had prominently claimed on its label that it was "100% Grated Parmesan Cheese."[2] The ambiguity of this claim was in whether it meant that the product was 100% parmesan cheese or that the parmesan cheese in the product was 100% pure. Reviewing the district court's finding that "100%" parmesan cheese was ambiguous and that a reasonable consumer would have clarified any such ambiguity by consulting the cheese product's ingredient statement, the Seventh Circuit reversed and held that it "joins [the First, Second, and Ninth Circuits] in holding that an accurate fine-print list of ingredients does not foreclose as a matter of law a claim that an ambiguous front label deceives reasonable consumers."[3]

This decision marked the Seventh's Circuit rejection of what it called the "ambiguity rule," which generally posited that if a food product's front label is ambiguous, then a reasonable consumer should look to the ingredient statement on the back of the product to dispel any such ambiguity. The *Bell* court held that "an accurate fine-print list of ingredients does not foreclose as a matter of law a claim that an ambiguous front label deceives consumers."[4] The court's rejection of the rule was based predominately over concerns of establishing a precedent that would validate highly deceptive food advertising on the basis that the ingredient statement could validate at least one reasonable interpretation of the label.

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1 982 F.3d 468, 473 (7th Cir. 2020).

2 *Bell*, 982 F.3d at 474.

3 *Id.*

4 *Id.* at 476.

But the *Bell* court's ruling, as many well-intentioned acts do, ended up creating distortions in false advertising jurisprudence that are as problematic as the problems it sought to prevent. The court's rejection of the ambiguity rule was premised on a mistaken interpretation of the First, Second, and Ninth Circuit case law it relied upon for its decision. It missed a crucial factor in that case law—those cases held that an accurate ingredient list would not foreclose as a matter of law the deceptiveness of an *unambiguously or clearly misleading* claim on a front label, not arguably ambiguous ones. The *Bell* court expanded the rationale of those cases beyond their respective factual backgrounds and applied them to any case involving an arguably ambiguous label. Other circuits do hold that an accurate ingredient list can foreclose a finding that an ambiguous front label is misleading as a matter of law as long as there's nothing unambiguously deceptive about the label. The *Bell* decision's expansion of the rationale in false advertising case law relating to ambiguous labels runs against the well-established legal principle that claims on food packaging need to be viewed in the context of the entire package and other contextual references. Its ruling over what it called the ambiguity rule was not necessary to resolve the matter it had before it and resulted in distortions in applicable jurisprudence that can only serve to breathe life into otherwise spurious class action lawsuits.

DECISION AND BACKGROUND

Plaintiffs filed five consolidated class action complaints in the Northern District of Illinois against multiple defendants, described as "purveyors of grated parmesan cheese products with labels stating '100% Grated Parmesan Cheese' or some variation thereof."[5] The complaints alleged 1) that labeling the product as "100% Grated Parmesan Cheese" was misleading because the product contained cellulose; and 2) that the ingredient list on the back of the canister was misleading because it described cellulose as an anti-caking agent when, in fact, the cellulose also acted as a simple filler.[6]

In 2018, the district court dismissed plaintiffs' claims based on the phrase "100% Grated Parmesan Cheese." To support their position that a reasonable consumer could believe that a "100% cheese" product could exist unrefrigerated on a supermarket shelf, plaintiffs submitted consumer survey evidence, reports from linguistic professors regarding the meaning of "100% Grated Parmesan Cheese," and a Kraft patent stating that fully cured parmesan cheese "keeps almost indefinitely." Regardless, the district court found this "evidence" unpersuasive and stated that "given the context provided by the ingredient lists and the products' placement on unrefrigerated shelves, no reasonable consumer could be misled by the '100% Grated Parmesan Cheese' labels into thinking that the products were 100% cheese."[7]

Also in 2018 and 2019, the district court narrowed the scope of plaintiffs' "anti-caking" claims.[8] Following Parmesan II, the dispute headed to the Seventh Circuit

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[5] *In re* 100% Grated Parmesan Cheese Mktg. and Sales Practices Litig., 348 F. Supp. 3d 797, 801 (N.D. Ill. 2018) [hereinafter "Parmesan I"].

[6] *Id.* at 802.

[7] *Id.* at 804.

[8] Parmesan I, *supra* note 5, at 806–18; *see also In re* 100% Grated Parmesan Cheese Mktg. and Sales Practices Litig., 393 F. Supp. 3d 745, 756–66 (N.D. Ill. 2019) [hereinafter "Parmesan II"].

Court of Appeals. On September 17, 2020, the Seventh Circuit held oral argument *Bell v. Publix Super Markets, Inc.*[9]

The Seventh Circuit resolved the appeal in the consumers' favor, holding that—notwithstanding the product's ingredient list and placement alongside other nonperishables on store shelves—their "nothing-but-cheese" interpretation of the labeling claim was not unreasonable as a matter of law. The court reasoned that "an accurate fine-print list of ingredients does not foreclose as a matter of law a claim that an ambiguous front label deceives reasonable consumers."[10] The Seventh Circuit refused to endorse the "ambiguity rule." The panel claimed that "[u]nder the district court's [approach], as a matter of law, a front label cannot be deceptive if there is any way to read it that accurately align[s] with the back label"—"even if the label actually deceived most consumers, and even if it had been carefully designed to deceive them."

The court cited examples from other circuits in concluding that the reasonable consumer standard does not necessarily presume that consumers will examine the ingredient list on the back to dispel front label confusion, especially when purchasing "low-priced, everyday items."[11] The circuit court relied on *Dumont v. Reily Foods Co.*,[12] *Mantikas v. Kellogg Co*.,[13] and *Williams v. Gerber Products Co.*[14]

IMPLICATIONS AND IMPACT

The *Bell* court's ruling was based on a misinterpretation of the case law it cited and unnecessarily distorted the general principle that product label elements must be viewed within the context of the whole package and other contextual references. The rationale in *Bell* sows confusion as to what role an ingredient statement—arguably one of the most important components of every food label—should play when analyzing whether a reasonable consumer would be misled by a certain claim on the label.

However, the cases from other circuits that *Bell* relied on in making the above holding, *Mantikas v. Kellogg*, *Williams v. Gerber*, and *Dumont v. Reily Foods*, involved products that made explicit, unambiguous ingredient claims that were directly and wholly contradicted by their ingredient statements. The product in *Mantikas* was a box of crackers which displayed the ingredient claims "WHOLE GRAIN" and "Made with WHOLE GRAIN" in large bold type on the front of the box, which in reality was overwhelmingly made with enriched white flour.[15] The product in *Williams* was a fruit juice primarily comprised of white grape juice from concentrate despite having a label with the words "Fruit Juice" prominently juxtaposed with images of oranges, peaches, strawberries, and cherries.[16] The product in *Dumont* involved a coffee product labeled "Hazelnut Crème," which actually contained no

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[9] 982 F.3d 468 (7th Cir. 2020).

[10] *Id.* at 476. Nor did the court find compelling the district court's determination that "common sense" would solve this problem given the non-refrigerated placement of the product in stores. And finally, the court rejected the manufacturers' argument that the buyers' state law claims were, in any event, preempted.

[11] *Id.* at 477, 479.

[12] 934 F.3d 35 (1st Cir. 2019).

[13] 910 F.3d 633 (2d Cir. 2018).

[14] 552 F.3d 934 (9th Cir. 2008).

[15] 910 F.3d at 637.

[16] 552 F.3d at 936.

hazelnut.[17] In all of these cases, there was no ambiguity about the ingredient being claimed, but only about whether it was actually present in the product or was present in the amount implied by the label. The naming of a specific, unambiguous ingredient and an ingredient statement directly contradicting that ingredient claim were central to the holdings of all of these cases. *Mantikas* and *Williams* both held that reasonable consumers "should not be expected to look beyond ***misleading*** representations on the front of the box to discover that the ingredient list actually contradicts the prominent ingredient claims being made on the label."[18] The *Dumont* court noted, "[a]fter all, if there is nothing in the package other than coffee, what does Hazelnut Créme mean to say?"[19] It is only when the label makes an unambiguous, misleading claim that is directly contradicted by the ingredient statement that an ingredient statement will not foreclose such a finding.

The Second and Ninth Circuits have been consistent in holding that an ingredient statement can foreclose a finding that a front label is misleading as a matter of law[20] and the rule remains good law in the First Circuit as well.[21] While the *Bell* court clarified that it "stand[s] by the general principle that deceptive advertising claims should take into account all the information available to consumers and the context in which that information is provided and used," its misinterpretation of the case law it relied on effectively eroded that principle. It is precisely when a plaintiff's case turns entirely on an ambiguous label that the context of the entire food label becomes crucial to assessing the reasonableness of a plaintiff's claim. Even if the *Bell* court would have preferred not placing any affirmative duty on a reasonable consumer to verify the ingredient list to clarify a potentially ambiguous label, it did not need to issue a ruling on the lower court's "ambiguity rule." The court could have just held that the claim "100% parmesan cheese" was too capable of misleading a substantial number of

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[17] 934 F.3d at 37.

[18] *Id.* (quoting *Williams*, 552 F.3d at 939) (emphasis added).

[19] 934 F.3d 35 at 41.

[20] *See* Freeman v. Time, Inc., 68 F.3d 285, 289–90 (9th Cir. 1995) ("Any ambiguity that Freeman would read into any particular statement is dispelled by the promotion as a whole."); Locklin v. StriVectin Operating Co., No. 21-cv-07967-VC, 2022 U.S. Dist. LEXIS 52461, at *8–9 (N.D. Cal. Mar. 23, 2022) ("'[I]nformation available to a consumer is not limited to the physical label and may involve contextual inferences regarding the product itself and its packaging.' And asterisks might cabin sweeping claims or further define ambiguous language. But a company can't say something misleading on the front of a label and escape liability by stating 'that's not actually what we mean' in fine print on the back.") (citing Moore v. Trader Joe's Co., 4 F.4th 874, 882 (9th Cir. 2021)); Fink v. Time Warner Cable, 714 F.3d 739, 742 (2d Cir. 2013) ("[U]nder certain circumstances, the presence of a disclaimer or similar clarifying language may defeat a claim of deception."); Solak v. Hain Celestial Grp., Inc., 3:17-CV-0704 (LEKJDEP), 2018 U.S. Dist. LEXIS 64270, 2018 WL 1870474, at *5 (N.D.N.Y. Apr. 17, 2018) (holding that consumers can resolve any potential ambiguity associated with the product's front label, which emphasizes certain ingredients, by [looking at] the back panel of the products, which list[s] all ingredients in the order of predominance) (internal quotations omitted); Brown v. Kellogg Sales Co., No. 1:20-CV-7283-ALC, 2022 U.S. Dist. LEXIS 60748, at *15–16 (S.D.N.Y. Mar. 31, 2022) ("To the extent the label contains any ambiguity about the presence or amount of strawberries in the Product, in the Second Circuit, courts are to consider 'disclaimers and qualifying language.' Here, the reasonable consumer would overcome any confusion by referring to the unambiguous ingredient list on the packaging. The ingredients list does not 'contradict,' but rather 'confirm[s] . . . representations on the front of the box.'") (citing *Mantikas*, 910 F.3d at 636–37).

[21] Lima v. Post Consumer Brands, LLC, Civil Action No. 1:18-cv-12100-ADB, 2019 U.S. Dist. LEXIS 136549, at *19 (D. Mass. Aug. 13, 2019) ("[C]onsumers who are presented with images or information that would be recognized as ambiguous by a reasonable consumer are generally expected to resolve such an ambiguity by referring to other information on a product's packaging.").

reasonable consumers to be saved by an accurate disclosure of the ingredient list. Regardless of what one thinks about that specific claim, such a ruling would have at least fallen in line with the case law it cited and not created a precedent obfuscating a set of legal principles in favor of others.[22] This obfuscation only provides articulable legal arguments to plaintiffs in the kind of class action lawsuit that food manufacturers have been facing over the years. It provides an added lifeline to claims that would otherwise would easily be dismissed at the pleading stage. Ironically, the Seventh Circuit's concern over highly deceptive advertising has led it to issue a decision that breathes life into highly deceptive lawsuits. The Seventh Circuit should clarify its jurisprudence to bring it more in line with the case law it agreed with in *Bell* to stop robbing Peter to pay Paul.

[22] There are examples of courts making the same misinterpretations based on the Seventh Circuit's decision in *Bell*. *See, e.g.*, Pierre v. Healthy Bev., LLC, No. 20-4934, 2022 U.S. Dist. LEXIS 35109, at *28 n.10 (E.D. Pa. Feb. 28, 2022) (holding that the First, Second, and Ninth Circuits repudiated the rule distinguishing claims based on labels that are unambiguous and misleading from claims aimed at ambiguous labels though the ambiguity can be resolved by a nutrition facts panel or ingredient list).

California Chamber of Commerce v. Becerra

AUGUST T. HORVATH*

An aphorism often misattributed to Mark Twain goes, "It ain't what people don't know that causes trouble, it's what they know that ain't so." Knowing something that isn't so (or, at least, isn't proven) caused trouble for the State of California in its Proposition 65 enforcement campaign against the chemical acrylamide in 2022, courtesy of the California courts, in *California Chamber of Commerce v. Becerra*, 529 F. Supp. 3d 1099 (E.D. Cal. 2021), *aff'd sub nom California Chamber of Commerce v. Council for Education and Research on Toxics*, No. 21-15745 (9th Cir. Mar. 17, 2022).

WHY IT MADE THE LIST

If you have spent any time waiting for your car to be serviced or performing any of countless other errands in the State of California, your bored case will at some point have fallen on a prominent sign advising you, "WARNING: Entering this area can expose you to chemicals known to the State of California to cause [cancer/birth defects/reproductive harm], including [name of one or more chemicals], from [name of one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov."[1] We owe these depressing reminders of the perils of modern life to a 1986 ballot referendum, Proposition 65, which inaugurated a state regulatory regime requiring such warnings whenever a person may be exposed to an annually updated list of more than 900 chemicals, both naturally occurring and synthetic.[2]

Of particular importance to food and beverage practitioners, Prop 65 requires that food and beverage products display similar warnings, a duty that falls not only on the manufacturers of such products but, under certain circumstances, also on downstream distributors and retailers. The warning requirement is triggered whenever the food or beverage product contains one of the over 900 chemicals on an annually updated list maintained by the California Environmental Protection Agency.

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[1] The precise language of the warning is not mandated, but the government issues "model" warnings that are widely followed and considered risky to deviate from. Those who have not spent time in California lately may be more familiar with the previous, slightly less dire formulation: "WARNING. This facility contains one or more chemicals known to the state of California to cause cancer, birth defects, or reproductive harm." This was replaced in 2018 by the current version emphasizing that the hapless reader is being personally exposed and specifically naming at least one disease, chemical, and source of exposure. *See Notice of Adoption of Article 6: Clear and Reasonable Warnings*, CAL. OFF. OF ENV'T HEALTH HAZARD ASSESSMENT (Dec. 13, 2016), https://oehha.ca.gov/proposition-65/crnr/notice-adoption-article-6-clear-and-reasonable-warnings.

[2] Proposition 65 is also known by its codified name, The Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code ch. 6.6, § 25249.5 to 25249.14.

The Prop 65 warning requirement may be enforced either by the State of California or by private actors. Private plaintiffs need allege only a violation of the law, not any harm, injury, or damage to themselves personally, to the population generally, or to the environment. Defendants have the burden of showing, if one of the listed chemicals is present in their products, that the amount is not significant, does not pose a significant cancer risk, or will have no observable effect on reproductive health in the concentration that exists in the product—a nigh impossible "proving the negative" scientific task. Penalties for non-compliance are up to $2,500 per day, per violation. Sellers of food and beverages generally enter into settlements, rather than having to litigate issues such as what "per violation" means in the context of a mass marketed consumer product. Private enforcers of the statute recover a bounty of 25% of the penalties or settlement amount, plus attorney fees and costs.

With the odds thus stacked against any food or beverage company that doesn't print a frightening warning on its own products, as Joseph Heller might say, "That's some proposition, that Proposition 65." The result has been a burgeoning industry in private enforcement, with bounty-hunting law firms turning out boilerplate enforcement complaints, often in the guise of what appear to be public interest organizations that are actually appendages of the law firms, and capturing over $20 million annually. Indeed, most of the money paid by companies as a result of Prop 65 enforcement lines the pockets of plaintiffs' law firms, and of course the manufacturers also incur the expense of their own counsel.

AT THE DISTRICT COURT

Acrylamide is a naturally occurring chemical that forms when many types of foods are cooked at high temperatures or otherwise heat-processed. It occurs in bread, cereals, coffee, crackers, fried and baked snack foods, grilled or roasted vegetables, fruits, and nuts. If you enjoyed toast this morning, you created acrylamide, and you ingested more acrylamide that was already in the bread before you toasted it and in the coffee you drank with it. Some studies indicate that acrylamide, in massive dosages, causes cancer in animals, and on the basis of these studies, acrylamide was added to the Prop 65 list in 1990, although at that time only high-concentration workplace exposure was contemplated, as the chemical had not yet been detected in food products. Acrylamide in baked and fried processed snack foods has been one of the primary targets of bounty-hunting Prop 65 private enforcement actions in recent years, with several hundred of the required pre-suit sixty-day notices having been issued. Prior to this action, all such cases (whether publicly or privately initiated) resulted in settlements, with the underlying issue of whether acrylamide actually causes cancer never being litigated.

The California Chamber of Commerce ("CalChamber") in 2019 sued the State of California, in the person of then-Attorney General Xavier Becerra,[3] for a declaratory judgment that the mandated Prop 65 warnings, as applied to acrylamide in foods, are unconstitutional compelled speech under the First Amendment. CalChamber's complaint alleged that no reliable evidence links acrylamide with elevated cancer risk in humans, and that the available evidence appears to show no cancer risk from acrylamide at normal dietary concentrations. Therefore, CalChamber alleged, the

[3] Becerra left the California Attorney General's post in 2021 when appointed Secretary of the Department of Health and Human Services by the Biden Administration.

warnings themselves were "false, misleading, and highly controversial statements" that harm consumers by deterring them from consuming products that have no cancer risk, and that in some instances have even been linked to reduced cancer risk. The warnings were alleged to be false, in short, because they assert that acrylamide is "***known*** to the State of California to cause cancer" in humans, when in fact, CalChamber argued, California knows no such thing. CalChamber sought an injunction of public and private enforcement of the state-mandated warning requirement.

An intervenor–defendant soon stepped in to assist, in the form of the Council for Education and Research on Toxins (CERT), one of those putative public interest organizations actually controlled by a plaintiff's law firm. CERT sought to have the case dismissed not only on the merits, but also because it assertedly violated the Noerr-Pennington doctrine and infringed CERT's right to petition by filing Proposition 65 enforcement actions. The district court denied this motion and on March 30, 2021, granted CalChamber's motion for a preliminary injunction on all new public and private enforcement actions for acrylamide.

The court analyzed CalChamber's likelihood of success on the constitutional merits under the standard of *Zauderer v. Office of Disciplinary Counsel*, which held that "the government may compel truthful disclosure in commercial speech as long as the compelled disclosure is 'reasonably related' to a substantial governmental interest."[4] The required disclosure must be "limited to 'purely factual and uncontroversial information.'"[5] The court found that the Prop 65 cancer warning for dietary acrylamide is not purely factual, but "is controversial because it elevates one side of a legitimately unresolved scientific debate about whether eating foods and drinks containing acrylamide increases the risk of cancer."[6] In addition, "[b]y asserting vaguely that consuming a product can 'expose' a person to acrylamide—a chemical most people have likely never used in preparing food or even heard of—the warning implies incorrectly that acrylamide is an additive or ingredient," as opposed to a naturally occurring by-product of a cooking process.[7]

Part of CERT's reaction to the district court decision was to attack the judge who issued it. CERT moved to disqualify Judge Kimberly J. Mueller on the grounds of financial conflicts of interest, citing family investments in an almond ranch and indirect ties to the California Chamber of Commerce through family business interests. CERT subpoenaed the judge's family members and exposed personal information in filings, in what the judge called "uncommonly aggressive, scorched earth efforts" that may have sought to put her and her family's safety at risk. Even so, and despite declaring that there was no legitimate basis for her recusal, Judge Mueller recused herself from the case in September 2021.

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[4] California Chamber of Commerce v. Becerra, 529 F. Supp. 3d 1099, 1116–17 (E.D. Cal. 2021), *aff'd sub nom.* California Chamber of Commerce v. Council for Education & Research on Toxics, No. 21-15745 (9th Cir. Mar. 17, 2022) (quoting CTIA—The Wireless Ass'n v. City of Berkeley, Cal., 928 F.3d 832, 845 (9th Cir.), *cert. denied*, _ U.S. _, 140 S. Ct. 658, 205 L.Ed.2d 387 (2019) (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651, 105 S.Ct. 2265, 85 L.Ed.2d 652 (1985))).

[5] *Id.* (quoting Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2372 (2018) (quoting *Zauderer*, 471 U.S. at 651)).

[6] 529 F. Supp. 3d at 1117–18 (citing *CTIA*, 928 F.3d at 845).

[7] *Id.* at 1117.

AT THE NINTH CIRCUIT

Intervenor–defendant CERT (but not the State of California) appealed the preliminary injunction ruling to the Ninth Circuit. On May 27, 2021, a divided motions panel of the Ninth Circuit granted CERT's motion for an emergency stay of the preliminary injunction pending appeal, but only as to private enforcement. Then, on March 17, 2022, the Ninth Circuit affirmed the district court's preliminary injunction order, finding that the court "used the correct framework for determining whether Prop. 65's warning requirement was a constitutionally compelled disclosure" and "dutifully followed" this legal framework.[8] The Ninth Circuit ruled that "[h]owever controversial is defined, the acrylamide Prop. 65 warning easily meets the definition because of the scientific debate."[9]

Part of the Ninth Circuit's consideration of the case involved what it means for something to be "known" in the language of the warning. California had argued at the district court level that "known" as used in the warning is effectively a legal term of art, referencing the statutory procedure for how a chemical gets added to the Prop 65 list, and not necessarily "known" as used in common parlance. The Ninth Circuit held, "use of the word 'known' is misleading . . . . Even the State of California has stipulated that it 'does not know that acrylamide causes cancer in humans, and is not required to make any finding to that effect in order to list the chemical under Proposition 65.'"[10]

CERT filed a petition for rehearing *en banc*, which is pending. It also has sought to have Judge Mueller's injunction vacated, notwithstanding that it was affirmed by the Ninth Circuit, on the grounds that she was "disqualified" and her prior rulings should now be nullified. CalChamber has opposed the motion on several grounds, including that (1) it is not the law that all rulings of a disqualified judge must be nullified, and in any event, (2) the judge, having been doxxed and harassed into recusing herself, is not quite the same as being "disqualified." Given the Ninth Circuit panel's unanimous and unequivocal endorsement of Judge Mueller's reasoning, the motion to vacate seems unlikely to succeed.

IMPACT

This is not the first successful constitutional challenge to a Prop 65 warning requirement. In 2020, an Eastern District of California court enjoined the enforcement of Prop 65 as to another chemical, glyphosate as used in fertilizers, on the same grounds as in the acrylamide case.[11] This injunction was a major contributor to the rise of acrylamide cases, as Prop 65 plaintiffs' firms pivoted to a new target to sustain their bounty-hunting operations. The state's response, while simultaneously appealing to the Ninth Circuit, was to rewrite the Prop 65 regulations specifically as to glyphosate. The special glyphosate warning would require, in an effort to pass constitutional muster, that manufacturers disclose that while the International Agency for Research on Cancer classifies glyphosate as "probably carcinogenic to humans," other

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[8] California Chamber of Commerce v. Council for Education & Research on Toxics, No. 21-15745, _ F.4th _ (9th Cir. Mar. 17, 2022), slip op. at 16, 21.

[9] *Id.* at 18–19 n. 10.

[10] *Id.* at 19.

[11] Nat'l Ass'n of Wheat Growers v. Becerra, 468 F. Supp. 3d 1247 (E.D. Cal. 2020).

authorities, including the Environmental Protection Agency, have determined that glyphosate is unlikely to cause cancer, or that the evidence is inconclusive. The new warning would add, "A wide variety of factors affect your personal cancer risk, including the level and duration of exposure to the chemical."[12] The appeal of the case is held in abeyance pending this rulemaking process.

Would California employ this same chemical-specific warning for acrylamide—or for any other Prop 65-listed chemical that courts have found are not really "known" to California to cause cancer, birth defects, or other reproductive harm? They might, but there is no guarantee that such warnings would pass constitutional muster, either. The currently proposed alternative glyphosate warning is seventy-seven words long, must still meet an "undue burden" prong under *Zauderer*, and may still imply more risks to consumers than are justified by the evidence, or may simply confuse them. And as shown by the 2018 amendment to the general required disclosure, California's initiative over the years has been to make the Prop 65 warnings more direct, specific, and disturbing, not less so.

Entities like the California Chamber of Commerce advocate for reform of Prop 65, which would include, at a minimum, reevaluation of its listed chemicals to include only those actually known by the State of California to pose the types of hazards stated or implied by the required warning. Such reform might also entail making the law less of a Plaintiff's Lawyer Full Employment Act by adjusting burdens of proof such that a plaintiff challenging the presence of a chemical in a food or beverage should have to furnish at least minimal evidence that it is harmful in the concentrations detected. Advocates of Prop 65 reform contend that relaxing the law as to chemicals not shown to be harmful will increase its effectiveness in warning consumers against the risks posed by chemicals that actually do pose a health hazard. The question is how many times will this "knowing what ain't so" objection have to be litigated as to individual chemicals before California follows a piece of advice that Twain actually *did* say: "Always do right. This will gratify some people and astonish the rest."[13]

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[12] *See Extension of Comment Period for Proposed Modification of Text and Addition of Documents to Rulemaking File for Glyphosate Warning Regulation*, CAL. OFF. OF ENV'T HEALTH HAZARD ASSESSMENT (Apr. 22, 2022), https://oehha.ca.gov/proposition-65/crnr/extension-comment-period-proposed-modification-text-and-addition-documents.

[13] Mark Twain, Note to the Young People's Society, Greenpoint Presbyterian Church, 1901.

Black v. DJO Global, Inc.

WILLIAM M. JANSSEN*

WHY IT MADE THE LIST

One sign that an author has risen from fame to legend is when the author's works are so widely known and remembered that they shift from stories to symbols, tales to metaphors. Hans Christian Andersen's *The Emperor's New Clothes* is a case in point. Published in Copenhagen in 1837 as a short, thirty-five paragraph children's fairy tale, this iconic story has been entertaining youngsters and adults the world over for nearly two centuries.

It tells of two swindlers who one day come into an emperor's town and spread word that they are great weavers, able to make "uncommonly fine" fabrics that are invisible to those "unfit" for public office or "unusually stupid." Enticed by how handy such a fabric could be in culling the unfit from his government, the emperor commissions the swindlers to weave him a garment from this special fabric. He is persuaded to supply the swindlers with all manner of expensive silks and threads, which they steal, all the while working in plain sight, night and day, on empty looms pretending to weave. The emperor's emissaries inspect the progress and, fearful of being revealed as "unfit" or "unusually stupid," verify that the cloth, its patterns, and its colors left them "spellbound." When he is finally dressed in his new, nonexistent garments, the emperor's own self-doubt overtakes him and he, too, pronounces the clothes "magnificent." In a procession through the streets in his new outfit, the townsfolk fall in with the delusion: "Oh, how fine are the Emperor's new clothes! Don't they fit him to perfection?" And on it went. Until a little child shouted out: "But he hasn't got anything on!" Nonplussed, the emperor kept parading.[1]

Among the countless messages imparted by this disarming little parable is about the insidious nature of willful ignorance. Inertial forces have often led minds to choose to go along with what is untrue or wrongheaded simply because it was widely championed or emphatically pitched. As Hans Christian Andersen cautioned, it takes the innocence of an unencumbered mind or the confidence of sound convictions to resist that tide.

Resistance was at issue in *Black v. DJO Global, Inc.*[2] The litigation involved a products liability claim for manufacturing defect. There was no corroborating expert opinion. Instead, the plaintiff proposed to rely on the seductive-sounding "malfunction theory" to carry her proof burden. Her injury (second-degree burn from a medical device) was indisputable. But a skin burn was a known, labeled risk of this medical

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[1] *See* Jean Hersholt, *The Emperor's New Clothes—A Translation of Hans Christian Andersen's Keiserens Nye Klæder*, THE HANS CHRISTIAN ANDERSEN CENTRE, https://andersen.sdu.dk/vaerk/hersholt/TheEmperorsNewClothes_e.html.

[2] 488 P.3d 1283 (Idaho 2021).

product. Could the "malfunction theory" still play a role in that sort of case—to prove that the product had, indeed, malfunctioned and consequently had to have been defectively assembled? The Idaho Supreme Court's unanimous ruling addressing that query ranks it among the top food and drug cases of 2021.

DISCUSSION

Linda Black suffered second-degree burns while a licensed physical therapist was performing electrical stimulation therapy on her back. That treatment had been intended to offer her pain relief, reduce inflammation, increase blood flow, and aid in tissue healing. Ms. Black alleged that her burns occurred due to a defect in the self-adhesive carbon electrode pads used during this electrical stimulation treatment. The source for that allegation was her treating physical therapist. He testified that Ms. Black had received the same electrical stimulation therapy three prior times without incident, that he had performed this type of therapy uneventfully many thousands of times before doing so on Ms. Black, and that on only three earlier occasions had he observed treatment burns and those all involved electrode pads made by the same manufacturer and drawn from the same production batch.[3] A products liability lawsuit was filed against the manufacturer, DJO Global, Inc., in Idaho State Court. Ms. Black's litigating theory was that something went awry during the manufacture of this particular batch of electrode pads, and that snafu had introduced what turned out to be an injury-causing product defect.

Discovery followed, including interrogatories, production requests, and the depositions of both Ms. Black and the treating therapist.[4] It was learned that the very same electrode pads that had been used uneventfully on Ms. Black during her three prior therapies were the ones also now accused of being defective.[5] Those pads had been thrown away by the therapist's office staff and, thus, were not available to be inspected by either the manufacturer or a technical expert.[6] It was also learned that the treating physical therapist lacked the experience or knowledge needed to opine as to the proper design or manufacture of self-adhesive carbon electrode pads.[7] The therapist had, however, been trained on how to visually inspect electrode pads for defectiveness ("the wire starts to become pulled out of the carbon portion of the pad and kind of puckers and dimples"); he observed none of those visual irregularities with Ms. Black's pads.[8]

The therapist described the manner of Ms. Black's injury-triggering therapy session. After satisfying himself that the patient's back was "clean and ready for treatment," the therapist applied the electrode pads directly to Ms. Black's skin—without placing a "moistened interface," like a cloth or sponge, between the electrode

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3 *See id.* at 1284–87.

4 *See* Brief for Appellee at 7, Black v. DJO Global, Inc., 488 P.3d 1283 (Idaho 2021) (No. 47812-2020), 2020 WL 5625637, at 4 [hereinafter, "Appellee Brief"].

5 *See* Brief for Appellant at 7, Black v. DJO Global, Inc., 488 P.3d 1283 (Idaho 2021) (No. 47812-2020), 2020 WL 4195938, at 4.

6 *See Black*, 488 P.3d at 1287.

7 *See* Appellee Brief, *supra* note 4, at 6 & 10.

8 *See id.* at 10–12.

pads and the patient's skin.[9] The user's manual for the electrotherapy device had specifically instructed otherwise ("When using carbon electrodes with any Rich-Mar stimulator, a moistened interface (cloth or sponge) MUST be utilized between these electrodes and patient *to avoid skin irritation and/or electrical burns*.").[10] The therapist also recalled setting the electrotherapy device to its highest current setting, 50 milliamperes (mA), for Ms. Black's last therapy session—which also, counseled the user's manual, required heightened care and occasional repositioning of the pad locations ("When using this device at current outputs above 40mA, extra caution should be observed *to avoid burns* by using an adequate conductive medium and by frequently using an alternate electrode placement.").[11] The user's manual had also noted that "skin irritation and burns beneath the electrodes have been reported with the use of muscle stimulators."[12]

Towards the end of the treatment session, the therapist noticed a white spot on the patient's back which, to the therapist, appeared to be a burn. Because Ms. Black reported no preexisting issues with her skin and seemed unconcerned with what the therapist was observing, the therapy session continued on, finished, and Ms. Black departed. When her skin became red and inflamed two hours later, Ms. Black returned to the therapist and was directed to seek a physician's care. She was subsequently diagnosed with second-degree burns to her back.[13]

Ms. Black first proposed to have her therapist offer an expert opinion that the burns were caused by a manufacturing defect in the electrode pads. That proffer was refused; the trial judge ruled that the therapist lacked the foundation necessary to render such an expert opinion. Ms. Black offered no other, independent expert to corroborate the therapist's surmise, perhaps because the essential evidence needed to construct that opinion (i.e., the pad used with Ms. Black) had been thrown away.

Left without expert proofs, Ms. Black proposed instead to invoke Idaho's "malfunction theory," which should, she insisted, create a prima facie manufacturing defect case solely on the basis of the therapist's recounting of events and his long, prior burn-free history of performing this type of electrical stimulation therapy. The Idaho Supreme Court described its state's "malfunction theory" as an indirect, circumstantial path for proving a product's defectiveness—it requires evidence that the product in question malfunctioned, combined with a lack of evidence of any reasonable, secondary cause for the claimed injury (such as abnormal use or some other cause that could exculpate the product supplier).[14] The court explained that, under those conditions, the "malfunction theory" can fairly carry the burden of circumstantially establishing a manufacturing defect in a product because "a product

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9 *See Black*, 488 P.3d at 1284.

10 *See* Appellee Brief, *supra* note 4, at 12–14 (capitalization in original; italics added).

11 *See id.* (italics added).

12 *See Black*, 488 P.3d at 1288.

13 *See id.* at 1284–85.

14 *See id.* at 1287. This formulation aligns with the one crafted for the Third Restatement of Torts. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 3 (1998) ("It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff: (a) was of a kind that ordinarily occurs as a result of product defect; and (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.").

will not ordinarily malfunction within the reasonable contemplation of the consumer in the absence of a defect."[15]

Both the trial judge and, later, the Idaho Supreme Court rejected Ms. Black's attempted use of the "malfunction theory." That theory, wrote the unanimous Supreme Court, is "a common sense rule that enables plaintiffs to bring a claim for a product defect where the product is no longer available or a specific defect cannot be identified." But applying it in Ms. Black's case, explained the court, "would stretch the theory to its logical breaking point" because the injury she suffered was "the precise type of injury" known to result from electrical stimulation theory. "This fact precludes a jury from inferring that 'an injury would not have occurred . . . had there not been a defect attributable to the manufacturer.'"[16]

IMPACT

The arc of products liability is fascinating. Setting aside its fits and starts, the progress and the regressions, from antiquity through the medieval period,[17] products liability by the early 1600s seemed sadly mired in buyer-beware. The law charged the consumer to inspect thoroughly before buying a product, and if the consumer failed to check, failed to check thoroughly, or failed to uncover the product's flaws, he or she was just plain out of luck if injured later (absent proof of a breach of an express warranty or scienter-based deceit).[18] During this age, it did not matter how insistently the product purveyor had promoted the goods, or how undiscoverably the product's defect had lurked: "An affirmation, no matter how many holy saints were invoked, fell short of a warranty; latent defects, however impervious to ordinary vision, were the purchaser's own lookout."[19]

Rightful dissatisfaction with this state of affairs coaxed product theory away from its twin anchors in contract and intentional tort, and into the sphere of ordinary care. But even there, problems of proof and trailing vestiges of warranty principles encumbered the field. In an influential concurrence in a case that allowed a waitress to recover when a bottle of Coke exploded in her hand, then-California associate justice Roger Traynor mused that even negligence seemed too constraining a requirement and ought to be replaced by "absolute liability" when a product injures a consumer.[20]

"Absolute" liability? Yikes. Backyard barbeques need to be hot to cook, knives need to be sharp to cut, and unpopped kernels are always a tooth-chipping threat in your family room. Peanuts and milk are actually deadly to those with peanut allergies and severe lactose intolerance. Even water, an essential ingredient to life, can leave you drowned. Berkeley Law's dean and tort scholar William Prosser made the point sprightly: "A good many individuals are allergic to strawberries and eggs. That doesn't

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15 *See Black*, 488 P.3d at 1287.

16 *See id.* at 1288.

17 Which is not to say that this epoch of the arc is uninteresting. *See generally* DAVID G. OWEN, PRODUCTS LIABILITY LAW § 1.2 (3d ed. 2015).

18 *See id.*

19 *Id.* at 15–16 (quoting Walton H. Hamilton, *The Ancient Maxim Caveat Emptor*, 40 YALE L.J. 1133, 1169 (1931)).

20 Escola v. Coca Cola Bottling Co., 150 P.2d 436, 461 (Cal. 1944) (Traynor, J., concurring).

mean that there is anything wrong with the food. There is something wrong with the individual."[21] Thus, product + injury = liability was too facile an equation.

From this revelation emerged the notion of "defectiveness" as a necessary prerequisite for product-based liability.[22] Liability follows only upon proof of defectiveness, or, adopting Dean Prosser's memorable phrasing, there needs to be "something wrong" with the product. And from here, strict liability's Section 402A and "defective-condition-unreasonably-dangerous-to-the-user" principles arrived.[23] Even California's trend-setting Justice (soon-to-be Chief Justice) Traynor was persuaded: "A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, *proves to have a defect* that causes injury to a human being."[24] Liability was to be "strict," but only when the product proved to have a "defect." The law had thus journeyed far from "buyer-beware" to nearly its polar opposite.

But practical, sometimes insurmountable hurdles continued to vex the injured consumer. What if the defectively mounted steering column in the car had been destroyed in the ensuing crash? What if the poorly seated rubber gasket on the gas heater had been incinerated in the ensuing fire? What if the shattered fragments of the exploded Coke bottle were swept up and tossed in the garbage? What if it is impossible to know what failed, how it failed, and what caused it to fail?

Solving for these challenges was to be the role of the "malfunction theory." When a product had malfunctioned (e.g., the car stopped steering, the heater's leaking gas detonated, the bottle disintegrated while being lifted onto a grocer's shelf), a manufacturing defect might be presumable from the very fact of the malfunction.[25] Assuming misuse and other possible causes could be ruled out, there *had to have been* something wrong during the product's manufacture because, as designed, a car will steer, a heater's gas will stay contained, and a bottle will be lifted without incident. If those things didn't happen, it plainly was not a problem with the product's design. Something went wrong during production. We might not know what, but a latent defect of some sort had been introduced into that particular car, that particular heater,

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[21] *See* DAVID G. OWEN & MARY J. DAVIS, PRODUCTS LIABILITY AND SAFETY 267 (8th ed. 2020) (quoting 38 ALI PROCEEDINGS 55 (1961)).

[22] Absent the obvious historic exceptions of breach of warranty or fraud.

[23] *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965).

[24] Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 900 (Cal. 1963) (italics added). *See also id.* at 901 ("To establish the manufacturer's liability it was sufficient that plaintiff proved that he was injured while using the Shopsmith in a way it was intended to be used *as a result of a defect* in design and manufacture of which plaintiff was not aware that made the Shopsmith unsafe for its intended use.") (italics added).

[25] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 3 cmt. b (1998) ("When a product unit contains [a manufacturing defect], and the defect affects product performance so as to cause a harmful incident, in most instances it will cause the product to malfunction in such a way that the inference of product defect is clear. From this perspective, manufacturing defects cause products to fail to perform their manifestly intended functions.").

or that particular bottle.[26] And, as between the product's purveyor and the consumer, the former ought to bear the risk of the resulting loss.[27]

The "malfunction theory" hinges irreducibly on a malfunction occurring. That's more than just the theory's namesake; it is its logical bedrock. A malfunction of a product supplies proof of the "something wrong" essential to product liability *because* that malfunction is only explainable in a properly used, properly designed product if some snafu occurred during production (e.g., some bolt wasn't completely tightened, some tube wasn't securely attached, some flap wasn't totally glued down).[28] "[T]he very purpose of the malfunction doctrine is to allow a plaintiff to prove a case by circumstantial evidence when a product *clearly fails* but there simply is no direct evidence of precisely how or why it did so."[29] Put another way, for the "malfunction theory" to work, the product must have provably failed.

Were the self-adhesive carbon electrode pads used on Ms. Black on the day of her burn injury defectively manufactured? Did those pads "fail"? No one can know for certain. They were thrown out and could not be inspected. Ms. Black offered no expert to opine on defective manufacture: no medical analysis of the type, shape, size, prominence, or severity of her burn; no testing of this batch and that batch of electrode pads to assess their uniformity; no laboratory attempt to recreate the injury choreography. Instead, Ms. Black rested her claim on the inference of defectiveness that the law allows to arise once a product is proven to have malfunctioned. Ms. Black's problem, however, was lack of proof of a malfunction.

Three attributes make *Black v. DJO Global* especially noteworthy. First, Ms. Black's litigating position shows how incanting "malfunction theory" can almost subliminally invite the law to skip past that theory's indispensable first element—the happening of a malfunction. Suffering a burn while undergoing electrical stimulation therapy is indisputable proof of an injury. On first glance, that might seem like enough. After all, a patient should not get burned during a therapy session, right? Similarly alluring is the suggestion, expressed or implied, that the "malfunction theory" can somehow be used to prove (or infer) the happening of a malfunction. (A bit like trusting in beautifully weaved, but oddly invisible "clothes.")

Both are legal errors. Proof of injury is not also proof of malfunction.[30] Conflating the two turns *strict* products liability into *absolute* products liability, something the law has steadfastly rejected. Similarly, the "malfunction theory" cannot be invoked to raise an inference of malfunction. To the contrary, a product's malfunction is the

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[26] *See id.* at cmt. c ("The inference of defect may be drawn under [the "malfunction theory"] without proof of the specific defect. Furthermore, quite apart from the question of what type of defect was involved, the plaintiff need not explain specifically what constituent part of the product failed.").

[27] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. a (1998) (rationale for strict liability in manufacturing defect cases). *See generally Greenman*, 377 P.2d at 901 ("The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves.").

[28] *See* Farmer v. Int'l Harvester Co., 553 P.2d 1306, 1312 (Idaho 1976) ("Proof of malfunction is circumstantial evidence of a defect in a product since a product will not ordinarily malfunction within the reasonable contemplation of a consumer in the absence of a defect."). *See also* Sochanski v. Sears, Roebuck & Co., 689 F.2d 45, 50 (3d Cir. 1982) ("A malfunction is evidence that a defect existed . . . .").

[29] OWEN, *supra* note 17, at 450–51 (italics added).

[30] *Cf. id.* at 454 (3d ed. 2015) ("it is hornbook law that proof of a product *accident* alone proves neither defectiveness nor causation").

irreducible prerequisite for, not the analytical output from, the "malfunction theory."[31] Both of these errors are easy to make in the obfuscating clutter of a careless invocation of the "malfunction theory." Simply put, no matter how enticing or empathy-arousing a case's facts might be (and Ms. Black's story surely qualifies), every "malfunction theory" analysis must always begin with proof of a product malfunction—that is, the product must have provably "failed." If that is absent, so too is the "malfunction theory."

The second attribute of *Black v. DJO Global* that merits notice is how a careful, disciplined application of the "malfunction theory" readily exposes when it is appropriate and when it is not. The Idaho Supreme Court made short work of Ms. Black's "malfunction theory" contention, concluding that the simple fact that the injury she suffered was "the precise type of injury" known to result from electrical stimulation theory "precludes a jury from inferring that 'an injury would not have occurred . . . had there not been a defect attributable to the manufacturer.'"[32] The conclusion is so obvious because the court returned the discussion back to first principles of "malfunction theory" analysis. Because the "malfunction theory" is merely a substitute path for proving a product's defectiveness when direct, affirmative proof is unavailable, the inference it permits follows only from (a) proof of a malfunction (the product "failing"), and (b) the absence of proof of any reasonable, other cause for the claimant's injury.[33] Put another way, no inference is possible if malfunction remains unproved or if reasonable, other causes for injury are obvious. That principled clarity doomed Ms. Black's claim. A skin burn from an electrode pad wasn't a malfunction of this product. It was a known and disclosed risk one encounters when using this product. Could that risk have been reduced or avoided by a better product design? Maybe, but that's not a defect in manufacturing. Could that risk have been warned about in a better way? Maybe, but that's also not a defect in manufacturing. A defect in manufacturing exists when the product "departs from its intended design."[34] The intended design of this product was to generate electrical stimulation, and that intended function, the user was told, posed a risk of burns. In short, this product behaved in a way both the manufacturer and the therapist understood it might behave. That is not a *mal*-function. Properly understood, the "malfunction theory" is thus quite easy to apply correctly.

The third important attribute of *Black v. DJO Global* is one the opinion did not confront directly but which inescapably underlies its conclusion—the consequence had the ruling been otherwise. When properly applied, the "malfunction theory" will create an inference of defectiveness, but that inference is neither conclusive nor binding. The claimant still always retains the burden of proof to ultimately persuade the factfinder by a preponderance of the evidence that the inferred product defect existed and that its existence caused the injury.[35] Had Ms. Black been permitted to use

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[31] *See id.* at 453–54 ("The doctrine presents a seductive but faulty shelter for plaintiffs with insufficient proof of defect and causation, and the law reports brim with decisions that recite the propriety of the doctrine as a general proposition but hold it inapplicable to the facts.").

[32] *See* Black v. DJO Global, Inc., 488 P.3d 1283, 1288 (Idaho 2021).

[33] *See id.* at 1287.

[34] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(a) (1998).

[35] *See* OWEN, *supra* note 17, at 456–57. *See also* Sochanski v. Sears, Roebuck & Co., 689 F.2d 45, 50 (3d Cir. 1982) ("Evidence of a malfunction . . . is not a substitute for the need to establish that the product was defective. A malfunction is evidence that a defect existed and eliminates only the need to identify a

the "malfunction theory" to infer a defect in the electrode pads in this case (or, more alarmingly, to infer a malfunction of those electrode pads), where would the jury have been left? Self-adhesive carbon electrode pads are known to result in skin burns on occasion. That's why special care in their use at high current levels was advised. Did that anticipated, conveyed risk cause Ms. Black's burns? Or had there really been a wiring problem or a pad adhesion issue that triggered those burns? No one will know, least of all the jury. What would result is factfinder speculation based on a guess resting on missing evidence, something the law cannot permit.[36] The mischief of such an improper use of the "malfunction theory" is obvious.[37]

The "malfunction theory" plays an important role in litigating claims over injuries thought to have occurred as a result of a defect introduced during the manufacture of a product. It is a shortcut to proof of liability. That shortcut is fair and, sometimes, irreplaceable. But that shortcut is also dependent upon proof that a malfunction actually occurred. Without that threshold proof, the "malfunction theory" can have no proper place in products liability litigation, as the Idaho Supreme Court in *Black v. DJO Global* correctly reminded us.

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specific failure . . . . [E]ven when a case is tried under a malfunction theory, recovery rests on a finding that a defect did exist.").

[36] *See* OWEN, *supra* note 17, at 454 ("[W]hile the malfunction doctrine provides a method for plaintiffs in proper cases to establish defectiveness and causation, the law will not allow plaintiffs or juries to rely on guess, conjecture, or speculation.").

[37] But in case it isn't, the indomitable Bexis (James M. Beck) once recounted the "ooey gooey" path a misapplication of the "malfunction theory" can travel. *See* Bexis, *Ooey Gooey*, DRUG & DEVICE LAW BLOG (July 20, 2011), https://www.druganddevicelawblog.com/2011/07/ooee-gooey.html ($18 million verdict without proof of malfunction).

State ex rel. Hunter v. Johnson & Johnson[1]

JAMES M. BECK*

WHY IT MADE THE LIST

The public nuisance tort cause of action is attractive to plaintiffs because it "elude[s] precise definition,"[2] and thus is so notoriously broad and vague so that public nuisance potentially could be "applied indiscriminately to everything."[3]

> There is perhaps no more impenetrable jungle in the entire law than that which surrounds the word "nuisance." It has meant all things to all people, and has been applied indiscriminately to everything from an alarming advertisement to a cockroach baked in a pie. There is general agreement that it is incapable of any exact or comprehensive definition."[4]

Plaintiffs have been pounding the square peg of "public nuisance" into the round hole of product liability since the 1990s, when governments claiming asbestos property damage first attempted to raise this theory.[5] They failed, but other plaintiffs suing over other products kept trying.

Since the right to "abate" a public nuisance is a governmental function, product liability-based nuisance actions are inherently permeated by politics. Waves of public nuisance litigation have tended to target products that are politically unpopular in the jurisdictions acting as plaintiffs. This phenomenon was particularly apparent with the wave of public nuisance suits targeting firearms that occurred around the turn of the century. In that litigation, plaintiffs expressly advocated the public nuisance tort as a judicial avenue to stricter governmental control of firearms, notwithstanding the refusal of the political branches to enact such measures.[6] The majority of public

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1 499 P.3d 719 (Okla. 2021) ("*Hunter*").

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2 City of Chicago v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1110 (Ill. 2004).

3 City of San Diego v. U.S. Gypsum, 35 Cal. Rptr.2d 876, 882 (Cal. App. 1994).

4 W. PAGE KEETON, PROSSER AND KEETON ON TORTS § 86, at 616 (5th ed. 1984). Quoted in, e.g., State v. Lead Indus. Ass'n, Inc., 951 A.2d 428, 456 n.17 (R.I. 2008); *Beretta*, 821 N.E.2d at 1110; *In re* Firearm Cases, 24 Cal. Rptr.3d 659, 679 n.22 (Cal. App. 2005); City of Chicago v. Am. Cyanamid Co., 823 N.E.2d 126, 130 (Ill. App. 2005).

5 *E.g.*, Tioga Public School Dist. v. U.S. Gypsum Co., 984 F.2d 915, 921 (8th Cir. 1993) (public nuisance would "become a monster that would devour in one gulp the entire law of tort"); Detroit Bd. of Educ. v. Celotex Corp., 493 N.W.2d 513, 521 (Mich. App. 1992); City of Manchester v. Nat'l Gypsum Co., 637 F. Supp. 646, 656 (D.R.I. 1986); Town of Hooksett Sch. Dist. v. W.R. Grace & Co., 617 F. Supp. 126, 133 (D.N.H. 1984); County of Johnson v. U.S. Gypsum Co., 580 F. Supp. 284, 294 (E.D. Tenn. 1984).

6 *See* David Kairys, *The Governmental Handgun Cases and the Elements and Underlying Policies of Public Nuisance Law*, 32 CONN. L. REV. 1175, 1187 (2000) (advocating product-based public nuisance as a means to combat "the proliferation of guns that has for so long defied contrary public policies, common sense, and overwhelming public opinion"). *See Beretta*, 821 N.E.2d at 1122 (pointing out that Mr. Kairys also served as counsel for plaintiffs). Product-related public nuisance litigation has been described as

nuisance lawsuits involving firearms failed.[7] But enough of these suits survived[8] that Congress, and occasional states, prohibited them statutorily.[9] Attempts to employ public nuisance against other politically disfavored products, such as tobacco products,[10] lead paint,[11] and chemicals,[12] as well as subprime lending[13] and climate change,[14] followed.

FDA-regulated prescription medical product manufacturers have also been targeted by litigants claiming that their federally approved and marketed products nonetheless amounted to public nuisances under state law. The first such claim—alleging that the defendants' over-the-counter cold and allergy medications contained ephedrine or pseudoephedrine, which contributed to a "methamphetamine epidemic"—failed

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"enlisting the judiciary to do the work that the other two branches of government cannot or will not do." City of San Francisco v. Exxon Mobil Corp., 2020 WL 3969558, at *20 (Tex. App. June 18, 2020).

[7] District of Columbia v. Beretta U.S.A. Corp., 872 A.2d 633, 650–51 (D.C. 2005); *Beretta*, 821 N.E.2d at 1125–27; Young v. Bryco Arms, 821 N.E.2d 1078, 1084–85 (Ill. 2004); Ganim v. Smith & Wesson Corp., 780 A.2d 98, 131–33 (Conn. 2001); *In re* Firearm Cases, 24 Cal. Rptr. at 679–80; People *ex rel.* Spitzer v. Sturm, Ruger & Co., 761 N.Y.S.2d 192, 194–99 (N.Y. App. Div. 2003); Penelas v. Arms Tech., Inc., 778 So.2d 1042, 1045 (Fla. App. 2001); City of Philadelphia v. Beretta U.S.A. Corp., 277 F.3d 415 (3d. Cir. 2002); Camden Cnty. Bd. of Chosen Freeholders v. Beretta U.S.A. Corp., 273 F.3d 536, 540 (3d Cir. 2001); Prescott v. Slide Fire Sols., LP, 410 F. Supp.3d 1123, 1144 (D. Nev. 2019); Sills v. Smith & Wesson Corp., 2000 WL 33113806, at *7 (Del. Super. Dec. 1, 2000).

[8] Cincinnati v. Beretta U.S.A. Corp., 768 N.E.2d 1136, 1142–44 (Ohio 2002); Gary v. Smith & Wesson Corp., 801 N.E.2d 1222, 1229 (Ind. 2003); Ileto v. Glock, Inc., 349 F.3d 1191, 1211–15 (9th Cir. 2003); James v. Arms Tech., Inc., 820 A.2d 27, 51–53 (N.J. Super. App. Div. 2003); City of Boston v. Smith & Wesson Corp., 2000 WL 1473568, at *14 (Mass. Super. July 13, 2000).

[9] *See* Protection of Lawful Commerce in Arms Act, 15 U.S.C.A. §§ 7901–03 (banning nuisance actions against gunmakers); Ohio Rev. Code § 2307.71(B) (subjecting public nuisance claims to state product liability statute).

[10] Ass'n of Washington Pub. Hosp. Dists. v. Philip Morris, Inc., 241 F.3d 696, 707 (9th Cir. 2001) (rejected); Allegheny Gen. Hosp. v. Philip Morris, Inc., 28 F.3d 429, 446 (3d Cir. 2000) (rejected); *In re* JUUL Labs, Inc., Marketing, Sales Practices, & Products Liability Litigation, 533 F. Supp.3d 858, 877 (N.D. Cal. 2021) (allowed); *In re* JUUL Labs, Inc., Marketing, Sales Practices, & Products Liability Litigation, 497 F. Supp. 3d 552, 649 (N.D. Cal. 2020) (allowed); Texas v. Am. Tobacco Co., 14 F. Supp.2d 956, 972–73 (E.D. Tex. 1997) (rejected); State v. Juul Labs, Inc., 2021 WL 2692131, at *4–5 (Minn. Dist. June 21, 2021) (allowed); State v. Juul Labs, Inc., 2020 WL 8257333, at *3–5 (Colo. Dist. Dec. 14, 2020) (rejected); Evans v. Lorillard Tobacco Co., 2007 WL 796175, at *18–19 (Mass. Super. Feb. 7, 2007) (allowed).

[11] State v. Lead Indus. Ass'n, Inc., 951 A.2d 428, 454–56 (R.I. 2008) (rejected); *In re* Lead Paint Litigation, 924 A.2d 484, 502–03 (N.J. 2007) (rejected); City of St. Louis v. Benjamin Moore & Co., 226 S.W.3d 110, 116 (Mo. 2007) (rejected); Cnty. of Santa Clara v. Atlantic Richfield Co., 40 Cal. Rptr. 3d 313, 330 (Cal. App. 2006) (allowed); City of Chicago v. Am. Cyanamid Co., 823 N.E.2d 126, 133–37 (Ill. App. 2005) (rejected); Lewis v. Lead Indus. Ass'n, Inc., 793 N.E.2d 869, 878 (Ill. App. 2003) (rejected); Cnty. of Cook v. Philip Morris, Inc., 817 N.E.2d 1039, 1046–48 (Ill. App. 2004) (rejected).

[12] City of Bloomington, Ind. v. Westinghouse Elec. Corp., 891 F.2d 611, 614 (7th Cir. 1989) (rejected); Sample v. Monsanto Co., 283 F. Supp. 2d 1088, 1092–94 (E.D. Mo. 2003) (rejected); *In re* StarLink Corn Prod. Liab. Litig., 212 F. Supp. 2d 828, 847 (N.D. Ill. 2002) (allowed); Town of Westport v. Monsanto Co., 2015 WL 1321466, at *3 (D. Mass. March 24, 2015) (rejected).

[13] City of Cleveland v. Ameriquest Mortg. Sec., Inc., 615 F.3d 496, 503 (6th Cir. 2010) (rejected); Cleveland v. JP Morgan Chase Bank, N.A., 2013 WL 1183332, at *3–6 (Ohio App. March 21, 2013) (rejected); City of Cincinnati v. Deutsche Bank Nat'l Tr. Co., 897 F. Supp. 2d 633, 640–41 (S.D. Ohio 2012) (rejected).

[14] Mayor & City Council of Baltimore v. BP P.L.C., ___ F.4th ___, 2022 WL 1039685, at *13 (4th Cir. Apr. 7, 2022) (noting, but not deciding claim); City of New York v. Chevron Corp., 993 F.3d 81, 96 (2d Cir. 2021) (rejected); Native Village of Kivalina v. ExxonMobil Corp., 696 F.3d 849, 857 (9th Cir. 2012) (rejected).

because the novel cause of action lacked sufficient causal nexus to the damages claimed by the governmental entity:

> [W]e are very reluctant to open Pandora's box to the avalanche of actions that would follow if we found this case to state a cause of action . . . . And what of the liability of manufacturers in other industries that, if stretched far enough, can be linked to other societal problems? Proximate cause seems an appropriate avenue for limiting liability in this context . . . "where an effect may be a proliferation of lawsuits . . . to address a myriad of societal problems regardless of the distance between the 'causes' of the 'problems' and their alleged consequences."[15]

While the claimed "methamphetamine epidemic" in *Ashley* proved insufficient to allow the camel's nose of public nuisance into the tent of FDA-regulated products, subsequent claims of an "opioid epidemic" succeeded in generating a wave of public nuisance claims against various alleged manufacturers and distributors of prescription opioids in both federal and state courts. Given the number of claims filed, the federal litigation became subject to multidistrict litigation.[16] Notwithstanding federalism concerns that weigh against recognition of novel state-law causes of action by federal courts sitting in diversity jurisdiction,[17] federal district courts considering public nuisance claims involving opioids allowed most of these claims to survive and to be litigated.[18] State trial courts have also generally been allowing opioid-related public nuisance claims.[19]

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[15] Ashley County, Arkansas v. Pfizer, Inc., 552 F.3d 659, 671–72 (8th Cir. 2009) (quoting District of Columbia v. Beretta, 872 A.2d at 651).

[16] *In re* Nat'l Prescription Opiate Litig., 290 F. Supp. 3d 1375 (U.S. Jud. Pan. M.D.L. 2017).

[17] Gasperini v. Ctr. for Humanities, Inc., 518 U.S. 415, 426 (1996) (diversity jurisdiction "does not carry with it generation of rules of substantive law"); Hicks v. Feiock, 485 U.S. 624, 630 n.3 (1988) ("a federal court is not free to apply a different rule however desirable it may believe it to be, and even though it may think that the state Supreme Court may establish a different rule in some future litigation"); Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975) (federal courts are "not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits"); Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938) (federal judges may not "brush[] aside the law of a state in conflict with their views").

[18] *In re* Nat'l Prescription Opiate Litig., 2022 WL 671219, at *17–18 (N.D. Ohio March 7, 2022); *In re* Nat'l Prescription Opiate Litig., 2022 WL 668434, at *28 (N.D. Ohio March 7, 2022); City of Chicago v. Purdue Pharma L.P., 2021 WL 1208971, at *13 (N.D. Ill. March 31, 2021); City & County of San Francisco v. Purdue Pharma L.P., 491 F. Supp. 3d 610, 669, 672–77 (N.D. Cal. 2020); *In re* Nat'l Prescription Opiate Litig., 458 F. Supp. 3d 665, 691–92 (N.D. Ohio 2020), *certification for appeal denied*, 2020 WL 3547011 (N.D. Ohio June 30, 2020); *In re* Nat'l Prescription Opiate Litig., 440 F. Supp. 3d 773, 805–08 (N.D. Ohio 2020), *certification for appeal denied*, 2020 WL 2128450 (N.D. Ohio May 5, 2020), and 2020 WL 2128462 (N.D. Ohio May 5, 2020); *In re* Nat'l Prescription Opiate Litig., 406 F. Supp. 3d 672, 676 (N.D. Ohio 2019); *In re* Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2018 WL 6628898, at *15–18 (N.D. Ohio Dec. 19, 2018).

[19] State v. McKesson Corp., 2021 WL 6297481, at *2 (Wash. Super. Sept. 1, 2021); City of Boston v. Purdue Pharma, L.P., 2020 WL 977056, at *5 (Mass. Super. Jan. 31, 2020); City of Boston v. Purdue Pharma, LP, 2020 WL 416406, at *8 (Mass. Super. Jan. 3, 2020); Commonwealth v. Purdue Pharma, L.P., 2019 WL 5495866, at *4–5 (Mass. Super. Sept. 17, 2019); State v. Purdue Pharma L.P., 2019 WL 3991963, at *9–10 (R.I. Super. Aug. 16, 2019); *In re* Opioid Litig., 2019 WL 2996570, at *8 (N.Y. Sup. June 21, 2019); State v. Purdue Pharma L.P., 2019 WL 1590064, at *3–4 (Ark. Cir. Apr. 5, 2019); State v. Purdue Pharma L.P., 2019 WL 2331282, at *5 (Tenn. Cir. Feb. 22, 2019); State v. Purdue Pharma L.P., 2019 WL 11729023, at *4 (Minn. Dist. Jan. 4, 2019); Brooke Cnty. Comm'n v. Purdue Pharma L.P., 2018 WL 11242293, at *7 (W. Va. Cir. Dec. 28, 2018); State v. Purdue Pharma Inc., 2018 WL 4566129, at *13 (N.H. Super. Sept. 18, 2018); State, *ex rel.* Dewine v. Purdue Pharma L.P., 2018 WL 4080052, at *4 (Ohio Com.

State ex rel. Hunter v. Johnson & Johnson, the decision discussed here, is the first appellate decision to address whether the public nuisance claims against manufacturers of prescription opioids are valid state-law causes of action. Billions of dollars of potential liability rest on the judicial response to that question. In *Hunter*, the defendants endured a thirty-three-day opioid bench trial in Oklahoma's Cleveland County.[20] That trial resulted in a $465 million verdict against the defendants.[21] Further raising the stakes, "[t]he State cross-appealed contending that [defendant] should be responsible to pay . . . approximately $9.3 billion to fund government programs."[22] In *Hunter*, the Oklahoma Supreme Court held that common-law public nuisance claims could not lie against the product manufacturers of FDA-approved prescription medical products.

DISCUSSION OF THE FACTS, HOLDING, AND RATIONALE

Beginning in the mid-1990s, defendants[23] produced and marketed two FDA-approved opioid analgesic medications.[24] Both drugs were controlled substances classified as "Schedule II" due to their "high potential for abuse."[25] Allegedly, defendants "used branded and unbranded marketing" that "promoted the concept that physicians were undertreating pain."[26] Defendants' marketing allegedly "overstated the benefits of opioid use, downplayed the dangers, and failed to disclose the lack of evidence supporting long-term use."[27]

However, by the time the State of Oklahoma brought suit in 2017, defendants no longer marketed or sold these products.[28] Defendants' share of the Oklahoma market was tiny—defendants' two drugs "amounted to less than 1% of all Oklahoma opioid prescriptions," and defendants "sold only 3% of all prescription opioids statewide."[29]

Pl. Aug. 22, 2018); *In re* Opioid Litig., 2018 WL 4827862, at *10–11 (N.Y. Sup. July 17, 2018); State v. Purdue Pharma L.P., 2018 WL 4468439, at *4 (Alaska Super. July 12, 2018); Commonwealth v. Endo Health Sols. Inc., 2018 WL 3635765, at *6 (Ky. Cir. July 10, 2018); *In re* Opioid Litig., 2018 WL 3115102, at *21 (N.Y. Sup. June 18, 2018); State v. Purdue Pharma L.P., 2018 WL 7892618, at *2 (Wash. Super. May 14, 2018). *But see* People v. Purdue Pharma L.P., 2021 WL 5227329, at *4–9 (Cal. Super. Nov. 1, 2021); State v. Purdue Pharma, L.P., 2021 WL 5873046, at *7–8 (S.D. Cir. Jan. 13, 2021); People v. Johnson & Johnson, 2021 WL 7160515, at *6–7 (Ill. Cir. Jan. 8, 2021); State *ex rel.* Stenehjem v. Perdue Pharma L.P., 2019 WL 224573, at *10–12 (N.D. Dist. May 10, 2019); State *ex rel.* Jennings v. Purdue Pharma L.P., 2019 WL 446382, at *12 (Del. Super. Feb. 4, 2019); Grewal v. Purdue Pharma L.P., 2018 WL 4829660, at *17 (N.J. Super. Ch. Div. Oct. 2, 2018) (all rejecting public nuisance claims in opioid cases).

[20] *Hunter*, 499 P.3d at 722.

[21] State of Oklahoma v. Purdue Pharma L.P., 2019 WL 9241510, at *21 (Okla. Dist. Nov. 15, 2019), *rev'd*, 499 P.3d 719 (Okla. 2021).

[22] *Hunter*, 499 P.3d at 723.

[23] A wholly owned Johnson & Johnson subsidiary was the actual manufacturer. *Id.* at 721. *Hunter* does not distinguish between the defendants.

[24] *Id.*

[25] *Id.* at 721 & n.3.

[26] *Id.* at 721.

[27] *Id.*

[28] *Id.* at 722 (defendants ceased promoting one of the products in 2007, and the second in 2015).

[29] *Id.*

The State of Oklahoma sued defendants in 2017, along with two other, unaffiliated opioid manufacturers. During the litigation, the unaffiliated manufacturers settled for several hundred million dollars, rather than face potential multi-billion-dollar liability.[30] Before trial, the state also "dismissed all claims against J&J except public nuisance."[31] Because public nuisance in Oklahoma "is equitable in nature," doing so deprived the defendants of a jury trial.[32]

Oklahoma's century-old public nuisance statute provided:

> A nuisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either: First. Annoys, injures or endangers the comfort, repose, health, or safety of others; or Second. Offends decency; or Third. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake or navigable river, stream, canal or basin, or any public park, square, street or highway; or Fourth. In any way renders other persons insecure in life, or in the use of property. . . .[33]

A thirty-three-day trial ensued, with the sole legal question "being whether [defendants were] responsible for creating a public nuisance in the marketing and selling of its opioid products."[34] The judge held defendants liable and ordered them to "abate" the nuisance by paying "$465 million to fund one year of the State's Abatement Plan, which consisted of the district court appropriating money to 21 government programs for services to combat opioid abuse."[35] Defendants' nuisance liability was joint, without regard to their small Oklahoma market share:

> The amount of the judgment against [defendants] was not based on [their] percentage of prescription opioids sold. The district court also did not take into consideration or grant [them] a set-off for the settlements the State had entered into with the other opioid manufacturers. Instead, the district court held [defendants] responsible to abate alleged harms done by all opioids, not just opioids manufactured and sold by [them].[36]

The trial court held defendants liable under Oklahoma public-nuisance statute for "false, misleading, and dangerous marketing campaigns" in opioid marketing.[37] That court held that public nuisance liability in Oklahoma was not "limit[ed]" to activities "that affect property."[38] Alternatively, the court held that defendants "used real and personal property" while creating the nuisance, as their sales representatives "trained in their Oklahoma homes" and "used company cars traveling on State and county roads to disseminate . . . misleading messages."[39]

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[30] *Id.* at 722 & n.11.

[31] *Id.* at 722.

[32] *Id.* at 723; *see id.* at 733 (dissenting, but agreeing that defendants were entitled to a jury trial).

[33] 50 Okla. Stat. §1 (enacted 1910), *quoted* 499 P.3d at 724.

[34] *Hunter*, 499 P.3d at 722.

[35] *Id.* Precise allocations to each specific program are listed, *id*. at n.12.

[36] *Id.* at 722–23.

[37] State of Oklahoma v. Purdue Pharma L.P., 2019 WL 9241510, at *12 (Okla. Dist. Nov. 15, 2019), *rev'd sub nom.* State *ex rel.* Hunter v. Johnson & Johnson, 499 P.3d 719 (Okla. 2021).

[38] *Id.* at *11.

[39] *Id.* at *12 (citations omitted).

In addition, defendants were the "cause-in-fact" and proximate cause of the nuisance—the claimed opioid epidemic in Oklahoma—because "acting in concert with others, [they] embarked on a major campaign to disseminate the messages that pain was being undertreated and 'there was a low risk of abuse and a low danger' of prescribing opioids to treat chronic, non-malignant pain and overstating the efficacy of opioids as a class of drug."[40] The opinion did not specify who those "others" were.[41]

Although the trial court found "the general contours" of the state's abatement plan "reasonable and necessary," it determined that "the State did not present sufficient evidence of the amount of time and costs necessary, beyond year one, to abate the Opioid Crisis."[42] The court refused to grant defendants any credit for the other defendants' settlements—which exceeded half the amount of the judgment—because "there has been no finding of fault entered against any other potential tortfeasor."[43]

On appeal, in opposition to the verdict, defendants argued that the trial court had "improperly expanded nuisance liability" beyond its traditional restriction "to property disputes and a limited class of recognized nuisances 'per se.'"[44] Instead, "the district court transformed this statutory cause of action into an all-purpose regulatory instrument—one that permits judges to singlehandedly enact government programs to combat harms the State attributes to commercial activity."[45] Defendants contended that in Oklahoma public nuisance, both statutory and common-law, "does not regulate the marketing of goods."[46] No Oklahoma precedent had ever extended public nuisance to product-related hazards.[47]

Defendants further argued that appellate precedent throughout the nation supported these traditional limits to public nuisance liability.[48] Precluding public as a product liability theory of liability preserved the element of individualized causation, the learned intermediary doctrine, and reliance, thus "incorporat[ing] protections against arbitrary liability."[49] Liability under Oklahoma's "standardless," century-old nuisance statute risked "creating a form of regulation administered through the courts at odds with the democratic process."[50] Almost any societal ill—climate change, obesity, oceanic plastic pollution—could be characterized as a "public nuisance, and given the

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[40] *Id.* at *4 (citations omitted), 14.

[41] The trial court also rejected defendants' First Amendment defense that their scientific and policy advocacy was protected speech. Not identifying any particular statements, the court found that all "the speech at issue here was clearly commercial in nature," and that twenty years of defendants' speech, from a large number of speakers, was false or misleading. *Id.* at *13–14.

[42] *Id.* at *15.

[43] *Id.* at * 21

[44] Appellants' Brief in Chief, State *ex rel.* Hunter v. Johnson & Johnson, No. 118,474, 2020 WL 7011964, at *15 (Okla., filed Oct. 8, 2020).

[45] *Id.* at *15–16.

[46] *Id.* at *16.

[47] *Id.* at *17–18 (*citing* State *ex rel.* Wood v. State Capital Co., 103 P. 1021 (Okla. 1909) (holding that allegedly illegal liquor advertising did not qualify as a public nuisance).

[48] *Id.* at *19.

[49] *Id.* at *19–20.

[50] *Id.* at *20 (citation and quotation marks omitted).

lack of any statute of limitations, such litigation could attack conduct that occurred decades ago.[51]

Defendants also raised several constitutional arguments. They argued that the Oklahoma statute was constitutionally void for vagueness, since "[t]he concept of nuisance is elusive," making the statute a sort of "legal garbage can" that "meant all things to all people."[52] Nor did the trial court's strained connection between the defendants' conduct and incidental "use" real property, such as roads and houses, satisfy public nuisance standards that required obstruction of others' use of such property.[53] Further, the "abatement" remedy—judicially ordered "creat[ion] and funding [of] new government programs"—violated the separation of powers recognized by Oklahoma's constitution.[54] Specifically:

> The judgment enacts a public-policy agenda and orders a private actor to fund it. The Oklahoma Constitution, however, commits policymaking and fiscal authority to the Legislature. . . . The Legislature's policymaking and fiscal authority are exclusive. . . . Here, the district court exercised policymaking and fiscal authority reserved for the Legislature by ordering nearly half a billion dollars in targeted government spending.[55]

In addition, defendants argued that what the state called "marketing" was actually First Amendment-protected scientific speech that did not fit within the "narrow" exception for "commercial speech" that merely "proposes a commercial transaction."[56]

Defendants also challenged the trial court's "causation" findings that held them liable for the entire "opioid epidemic," despite their minimal market share. Since that "crisis stemmed from multiple potential causes," including "economic and social changes," "criminal black markets," and "rampant diversion and abuse of" opioid drugs that these defendants had nothing to do with, the state's case failed Oklahoma's "but for" causation standard—"the event would not have occurred but for that conduct."[57] Indeed, the state failed to establish that even "a single Oklahoma physician or patient saw [defendants' marketing] materials."[58] As a result, defendants argued, the state improperly held them liable for the "entire" opioid crisis:

> The State's asserted injury, the opioid-abuse crisis, is not a single, indivisible injury in any sense. It encompasses individual cases of addiction, abuse, and overdose—each with its own causes—that occurred in different places and involved different actors over more than two

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[51] *Id.* at *20–21.

[52] *Id.* at *22 (citations and quotation marks omitted).

[53] *Id.* at *23–24.

[54] *Id.* at *24–28.

[55] *Id.* at *27–28 (citations omitted).

[56] *Id.* at *32–38. Defendants also asserted constitutional arguments based on preemption, excessive fines, and right to a jury trial. *Id.* at *28–29, 39, 46–50.

[57] *Id.* at *29–31.

[58] *Id.* at *30.

> decades. Courts routinely subject such injuries to individualized causation analysis.[59]

Nor could the state hold defendants liable for damages caused by "criminal actors" when it did not even contend that defendants "acted in concert" with them.[60] Similarly, defendants contended that, at minimum, they were entitled to a credit for settlements reached by other parties that the state actually did sue.[61]

In unanimously reversing the district court,[62] the Oklahoma Supreme Court refused to allow product liability-based public nuisance. Nor did it allow tort liability to assume the role of taxation as a response to societal problems.[63] Unlike traditional tort law, the state's claim for "abatement" of a "public nuisance" did not purport to limit the defendants' liability to injuries actually caused by their products:

> The amount of the judgment against [defendants] was not based on [their] percentage of prescription opioids sold. The district court also did not take into consideration or grant [defendants] a set-off for the settlements the State had entered into with the other opioid manufacturers. Instead, the district court held [defendants] responsible to abate alleged harms done by all opioids, not just opioids manufactured and sold by [them].[64]

This disconnect between products, causation, and damages was fatal. The supposed "nuisance" could not be abated since "[t]he abatement is not the opioids themselves," nor was it their promotion and marketing.[65]

> It is instead an award to the State to fund multiple governmental programs for medical treatment and preventive services for opioid abuse, investigatory and regulatory activities, and prosecutions for violations of Oklahoma law regarding opioid distribution and use—activities over which [defendants] ha[ve] no control.[66]

Never had any Oklahoma court "allowed the State to collect a cash payment from a defendant that the district court line-item apportioned to address social, health, and criminal issues arising from conduct alleged to be a nuisance."[67]

Nor did *Hunter* believe that manufacturers of legal products, with no inherent defects, should be liable for damages caused by misuse of their products. "[A] public right to be free from the threat that others may misuse or abuse . . . a lawful product[] would hold manufacturers, distributors, and prescribers potentially liable for all types

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[59] *Id.* at *42 (citations omitted).

[60] *Id.* at *39–40.

[61] *Id.* at *44–46.

[62] The single justice who would have permitted any public nuisance recovery agreed that the district court erred in not limiting recovery to injuries directly caused by the defendant's products. 499 P.3d at 732, 747–48 (Edmondson, J., dissenting).

[63] 499 P.3d at 722 (describing the judgment as "the district court appropriating money to 21 government programs for services to combat opioid abuse") (footnote omitted).

[64] *Id.* at 722–23.

[65] *Id.* at 729.

[66] *Id.*

[67] *Id.*

of use and misuse of prescription medications."[68] Nor did "[a] manufacturer . . . have a duty to people who use other manufacturers' products."[69]

Also key in *Hunter* was the defendants' lack of control over the alleged harm-causing conduct—an essential element of public nuisance. Unlike pollution cases or inappropriate uses of property interfering with their neighbors, product manufacturers do not "control" how others use—or misuse—their products after sale.

> The State asks this Court to broadly extend the application of the nuisance statute . . . to a situation where a manufacturer sold a product (for over 20 years) that was later alleged to constitute a nuisance. A product manufacturer's responsibility is to put a lawful, non-defective product into the market. There is no common law tort duty to monitor how a consumer uses or misuses a product after it is sold. Without control, a manufacturer also cannot remove or abate the nuisance—which is the remedy the State seeks from [defendants] in this case.[70]

Without control, there cannot be causation. "[T]he alleged nuisance in this case is several times removed from [defendants'] initial manufacture and distribution" of their products.[71] Prescription drugs, and particularly controlled substances, are not only legal, but "highly regulated."[72]

> Multiple agencies and boards across different jurisdictions oversee and enforce statutes and regulations that control the developing, testing, producing, manufacturing, distributing, labeling, advertising, prescribing, selling, possessing, and reselling of prescription opioids.[73]

The distribution of these products was set by "legislation governing prescription opioids over which [defendants] ha[ve] no control."[74] Even less could the defendants "control how individuals used other pharmaceutical companies' [products]."[75] The public nuisance theory that *Hunter* repudiated was worse than even market liability, since the state sought to make these defendants pay for "alleged losses caused by" other manufacturers' products comprising some 97% of the market, and for illegal drug sales beyond that.[76]

The Oklahoma Supreme Court in *Hunter* thus refused to supplant existing product liability limitations with the state's unprecedented public nuisance theory. It recognized that "[e]xtending public nuisance law to the manufacturing, marketing, and selling of products . . . would allow consumers to convert almost every products liability action into a public nuisance claim."[77] *Hunter* followed extensive precedent from "[o]ther jurisdictions [that] have refused to allow products-based public nuisance

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[68] *Id.* at 727.

[69] *Id.* at 729 (footnote omitted).

[70] *Id.* at 728 (citation and footnote omitted).

[71] *Id.*

[72] *Id.*

[73] *Id.*

[74] *Id.*

[75] *Id.* at 729.

[76] *Id.*

[77] *Id.* at 730 (citation and quotation marks omitted).

claims," finding "a clear national trend to limit public nuisance to land or property use."[78] Significantly, the decision also quoted extensively from the Third Restatement of Torts, which explicitly disapproves of public nuisance as a product-related tort:

> Tort suits seeking to recover for public nuisance have occasionally been brought against the makers of products that have caused harm, such as tobacco, firearms, and lead paint. These cases vary in the theory of damages on which they seek recovery, but often involve claims for economic losses the plaintiffs have suffered on account of the defendant's activities. . . . Liability on such theories has been rejected by most courts, and **is excluded by this Section, because the common law of public nuisance is an inapt vehicle for addressing the conduct at issue**. Mass harms caused by dangerous products are better addressed through the law of products liability, which has been developed and refined with sensitivity to the various policies at stake.[79]

Hunter is the first appellate court to cite this section of the Third Restatement.[80] The current restatement thus confirmed that "[p]ublic nuisance and product-related liability are two distinct causes of action, each with boundaries that are not intended to overlap."[81] *Hunter* thus concluded that, as a legal theory, "[p]ublic nuisance is fundamentally ill-suited to resolve claims against product manufacturers."[82]

Nor was *Hunter* willing to countenance "perpetual" liability to governmental units against which the statute of limitations did not run.

> Nuisance claims against products manufacturers sidestep any statute of limitations. In this case, the district court held J&J responsible for products that entered the stream of commerce more than 20 years ago, shifting the wrong from the manufacturing, marketing, or selling of a product to its continuing presence in the marketplace.[83]

"Oklahoma law has rejected such endless liability in all other traditional tort law theories. We again reject perpetual liability here."[84]

The Oklahoma Supreme closed in *Hunter* with a forceful rejection of the idea that courts, through litigation, can and should endeavor to solve societal problems:

> The State presented us with a novel theory—public nuisance liability for the marketing and selling of a legal product, based upon the acts not of one manufacturer, but an industry. However, we are unconvinced that such actions amount to a public nuisance under Oklahoma law. . . . The

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[78] *Id.* (citations and quotation marks omitted).

[79] *Id.* at 725–26 (quoting and following Restatement (Third) of Torts: Liability for Economic Harm § 8, comment g (ALI 2020) (emphasis added).

[80] By contrast, *Nat'l Prescription Opiate* dismissed defense reliance on this comment as "misplaced" because that section supposedly "applies only to claims for economic loss brought by a private party." 2022 WL 671219, at *25. The Reporters Notes to comment g refute that distinction, citing several state high court decisions with state or municipal plaintiffs as "representative": State v. Lead Industries, Ass'n, Inc., 951 A.2d 428; *Lead Paint*, 924 A.2d 484; Chicago v. Beretta, 821 N.E.2d 1099; and *Ganim*, 780 A.2d 98.

[81] 499 P.3d at 725 (citation omitted).

[82] *Id.* at 726.

[83] *Id.* at 729 (citation omitted).

[84] *Id.* (footnote omitted).

> district court's expansion of public nuisance law allows courts to manage public policy matters that should be dealt with by the legislative and executive branches; the branches that are more capable than courts to balance the competing interests at play in societal problems. Further, [a judge] stepping into the shoes of the Legislature by creating and funding government programs designed to address social and health issues goes too far. This Court defers the policy-making to the legislative and executive branches and rejects the unprecedented expansion of public nuisance law.[85]

IMPACT

The dynamic of opioid litigation, and of governmentally prosecuted product liability-based public nuisance claims generally, makes any option other than settlement extremely perilous. The sheer amount of potential liability—over $9 billion in *Hunter*—discourages defendants from obtaining appellate review of trial court decisions permitting such claims to proceed. Governmental plaintiffs in such litigation chose where to file suit, and thus influenced who the trial judges deciding that question in the first instance would be. Before *Hunter*, every decision allowing such public nuisance in opioid litigation was non-appealable, and none of the judges entering those orders saw fit to certify any of their opinions for interlocutory appeal. Settlement pressure on opioid defendants is strong, since claims brought by governmental units seek recovery of damages for the entire citizenry, as *Hunter* exemplifies. It is not surprising that the successful appellant in *Hunter* was Johnson & Johnson, the largest pharmaceutical company in the world, and thus the defendant least susceptible to this existential settlement pressure.

Hunter powerfully demonstrates that the precedential and policy bases for product liability-based public nuisance litigation are weak and not terribly persuasive. Public nuisance, as defined in the Second Restatement, is widely recognized as a legal morass; and the Third Restatement explicitly rejects product risks as a valid basis for imposition of nuisance-based liability. Oklahoma has joined seven other states with high-court precedent rejecting public nuisance as a "blunt and capricious method of regulation."[86] Only two state high courts have ever embraced public nuisance in the product liability context, and in one of those states (Ohio) the state legislature abolished the claim.[87] Probably influenced by Supreme Court precedent that federal courts should not predict novel expansion of state tort law,[88] only one federal appellate court has ever predicted that a state (California) would recognize product liability-based public nuisance as a state-law cause of action, and it was proven wrong.[89] Provided that defendants in opioid litigation can withstand intense settlement pressure, *Hunter* demonstrates that the chances are good that appellate courts will continue to

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[85] *Id.* at 731.

[86] *Firearm Cases*, 24 Cal. Rptr.3d at 682.

[87] *See supra*, note 10 (citing Ohio statute).

[88] *See supra* note 18.

[89] Two years after the Ninth Circuit predicted California would allow public nuisance against firearms manufacturers in *Ileto*, 349 F.3d at 1211–15, a California appellate court rejected the same theory against the same products. *Firearm Cases*, 24 Cal. Rptr.3d at 679-80.

reject public nuisance as a liability theory against manufacturers of FDA-approved prescription medical products.

Moore v. Trader Joe's Co.

GENNA LIU, RENE BEFURT & REBECCA KIRK FAIR*

WHY IT MADE THE LIST

What information may be relevant when evaluating whether a reasonable consumer would be misled by a product's labeling? In *Moore v. Trader Joe's Co.*, the United States Court of Appeals for the Ninth Circuit reinforced the importance of contextual clues beyond the at-issue product label to determine whether a reasonable consumer would hold what the court described as an "unreasonable or fanciful" interpretation of Trader Joe's manuka honey product label.[1] The court of appeals affirmed the district court's ruling that based on other readily available information, a reasonable consumer would interpret Trader Joe's "100% New Zealand Manuka Honey" label to mean a product whose *chief* floral source is the manuka plant, rather than a product that is 100% derived from the manuka plant.

In light of the court of appeals' guidance to inspect information beyond the product label, the case demonstrates the importance of additional contextual information in determining whether a reasonable consumer would be misled by a product label. Specifically, the court of appeals highlighted the need to consider consumers' background knowledge, the product's price point, and the product type.

DISCUSSIONS

Background: FDA's Guidance on the Labeling of Honey

The Food and Drug Administration (FDA) provides nonbinding recommendations on the proper labeling of honey products.[2] FDA's Honey Guidelines notes that as a

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[1] Moore v. Trader Joe's Co., 4 F.4th 874, 883 (9th Cir. 2021).

[2] U.S. FOOD & DRUG ADMIN., PROPER LABELING OF HONEY AND HONEY PRODUCTS: GUIDANCE FOR INDUSTRY (2018), https://www.fda.gov/media/110846/download.

single ingredient food, honey may be labeled with "the name of the plant or blossom if [there is] information to support the conclusion that the plant or blossom designated on the label is the chief floral source of the honey." While FDA does not specifically define "chief floral source," the Ninth Circuit interpreted the phrase to mean the principal source of the honey.[3]

Procedural Background and Ruling of the District Court

In July 2018, plaintiffs Lynn Moore, Shanque King, and Jeffrey Akwei filed a class-action lawsuit against Trader Joe's for allegedly misrepresenting its manuka honey product.[4] Specifically, plaintiffs alleged that Trader Joe's deceived consumers by labeling its manuka honey products as "100% New Zealand Manuka Honey" and listing "manuka honey" as its sole ingredient, even though only around 60% of the pollen in the honey product is derived from the manuka plant. In the complaint, plaintiffs mainly relied on conclusions from GNS Science, a research laboratory, on the manuka content of Trader Joe's manuka honey product. While the test showed that between 57.3% to 62.6% of Trader Joe's manuka honey product was manuka content, it provided no insights on how a reasonable consumer would interpret Trader Joe's product label. Plaintiffs offered no support from consumer behavior research to assert that the at-issue product label would be material to consumers' purchase decisions.

Trader Joe's filed a motion to dismiss plaintiffs' complaint in January 2019. In June 2019, the District Court of the Northern District of California sided with Trader Joe's and granted its motion to dismiss plaintiffs' complaint. The district court ruled that plaintiffs cannot allege adulteration, since their theory of adulteration is premised on the bees visiting different floral sources, which does not constitute adulteration, rather than the manufacturer purposefully mixing manuka honey with non-manuka honey. In addition, the district court concluded that Trader Joe's label is not misleading. In particular, given that honey is a single ingredient food, and the chief floral source of Trader Joe's manuka honey product is manuka, Trader Joe's product label is an accurate description of its product.

Plaintiffs appealed the district court's ruling, and the Court of Appeals for the Ninth Circuit issued its opinion in July 2021.

Ruling and Reasoning of the Appellate Court

The court of appeals affirmed the district court's decision, noting that although there is some ambiguity in the meaning of "100%" in Trader Joe's "100% New Zealand Manuka Honey" label, a reasonable consumer would quickly be dissuaded from the belief that Trader Joe's manuka honey was derived from 100% manuka flower nectar when the label is considered in the context of other readily available information.[5]

The court of appeals cited three main reasons why a reasonable consumer would not be misled by Trader Joe's product label. First, a reasonable honey consumer would know that it is impossible to make honey that is 100% derived from one floral source, given the foraging nature of bees. This knowledge is particularly accessible to a

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[3] 4 F.4th at 881.

[4] Moore v. Trader Joe's Co., Case 4:18-cv-04418-KAW (N.D. Cal. June 24, 2019) (order granting defendant's motion to dismiss).

[5] 4 F.4th 874.

consumer of a niche specialty product like manuka honey, because they would exhibit a higher standard of care when purchasing a manuka honey product.

Second, the inexpensive cost of Trader Joe's manuka honey product would signal to a reasonable consumer that the product has a relatively lower concentration of honey derived from manuka flower nectar. A jar of Trader Joe's manuka honey product costs approximately $13.99 ($1.59 per ounce), while a jar of honey that is 92% derived from manuka flower nectar costs around $266 ($21.55 per ounce). A reasonable consumer of manuka honey would be well aware of the varying concentration of manuka in different products, and would not expect a jar of honey that is 100% derived from manuka flower nectar to cost only $13.99.

Third, the "10+" label on Trader Joe's manuka honey product represents a rating on the Unique Manuka Factor grading system, which signals the product's quality. Reasonable consumers of manuka honey would routinely encounter such ratings and would thus understand that Trader Joe's manuka honey is on the lower end of the "purity scale," which ranges from 5+ to 26+, as opposed to having a high concentration of manuka flower nectar.

The court of appeals concluded that other available information about Trader Joe's manuka honey product would quickly dissuade a reasonable consumer from plaintiffs' "unreasonable or fanciful" interpretation of "100% New Zealand Manuka Honey."

Furthermore, the court of appeals affirmed the district court's ruling that Trader Joe's representation of "manuka honey" as the product's sole ingredient was not misleading, since the product is made of honey whose chief floral source is the manuka plant. The court noted that reasonable consumers would understand that by listing manuka honey as its sole ingredient, Trader Joe's is noting that there are no additives or other honeys present in the product, not that it is exclusively derived from the manuka plant. In other words, since Trader Joe's manuka honey product "*entirely* consists of Manuka Honey," the ingredients statement does not "display any affirmative misrepresentations" that would mislead a reasonable consumer.[6]

IMPACT

The court of appeals decision emphasized the importance of considering all accessible information when evaluating whether a reasonable consumer would be misled by a product label.[7] Plaintiffs unreasonably assumed that a reasonable consumer would be materially deceived by Trader Joe's product label by claiming that consumers "care a great deal about the purity of the manuka honey they purchase."[8]

Rather than viewing a product label in isolation as the plaintiffs suggested, consumers often go through a multistage buying process when purchasing a product. In this buying process, consumers recognize a problem, search for information, evaluate alternatives, make a purchase decision, and use and experience the product in the post-purchase stage.[9] During this process, consumers may gather information about the product category, brands, and specific feature sets—often relying on a

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[6] 4 F.4th at 886.

[7] For example, *Bell v. Publix Super Markets Inc.*, 982 F.3d 468 (7th Cir. 2020) left undisturbed "the general principle that deceptive advertising claims should take into account all the information available to consumers and the context in which that information is provided and used."

[8] Complaint at ¶ 36, Moore v. Trader Joe's Co., Case 4:18-cv-04418-KAW (N.D. Cal. July 20, 2018).

[9] PHILIP KOTLER & KEVIN LANE KELLER, MARKETING MANAGEMENT 173 (Pearson, 15th ed. 2016).

variety of sources that shape the set of information upon which a consumer relies when ultimately selecting a specific honey from a variety of potential offerings.

During this purchase process, consumers may come into contact with a variety of information that they may rely on when viewing individual product labels, including:

- Price point. Companies frequently use different price points to indicate quality, and consumers use price as an indicator of quality. For example, brands and products like Starbucks and BMW are positioned and perceived as an affordable luxury that offers high quality for premium prices. When comparing products, consumers may have a lower price threshold, below which prices signal lower-than-preferred quality to them.[10] In this case, the court of appeals highlighted the difference between the price of Trader Joe's manuka honey product and a jar of honey that is 92% derived from manuka plant to illustrate the difference in consumers' inferred quality.
- External information. In addition to receiving information about a product through sources such as Trader Joe's label, consumers may also learn about a product through public, personal, or experiential sources.[11] In fact, sources such as word of mouth can be the main information that drives a purchasing decision. In this matter, honey consumers may gather information from family, friends, and neighbors, and give the product label little attention and weight. Similarly, consumers' purchasing decisions may be driven by handling, examining, and using the product. For example, numerous repeat purchases may be based on a main characteristic of consumable products such as honey: its taste. Lastly, consumers may also glean information from public sources like mass media or consumer-rating organizations. In this case, honey consumers may learn that it is impossible to produce honey made exclusively from a single floral source. Moreover, manuka honey consumers, especially those who "care a great deal about the purity of the manuka honey they purchase," may have encountered the Unique Manuka Factor scale while researching on an informational website or talking with a family member.[12] When evaluating a product, consumers may also bring in external information rather than relying solely on a specific claim on the product label.
- Other considered products. Before purchasing a product, many consumers frequently browse and consider different competing brands and products. They may start with a "total set" of available brands, then narrow to a subset called "awareness set." Only products that meet certain buying criteria, such as fitting a specific price point or providing certain benefits, would then be filtered to a "consideration set," from which consumers make a final choice. For example, highly involved honey consumers may create a

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[10] *Id.* at 465–69.

[11] *Id.* at 174.

[12] Complaint at ¶ 36, Moore v. Trader Joe's Co., Case 4:18-cv-04418-KAW (N.D. Cal. July 20, 2018).

consideration set of manuka honey products with a high manuka concentration if they are interested in honey with strong wound healing properties and are willing to pay a higher price; whereas consumers for whom the purchase of honey is a low involvement decision would be inclined to pick a honey based on price, presentation, and placement on the shelf relative to competing products (eye-level vs. low level), or based on convenience and availability.

- Product type. Consumers may extract contextual information based on the product type. The court held in *Becerra* that because the at-issue product is soda, consumers would understand the word "diet" on a soda label to mean a claim about the product's caloric content relative to regular soda, not that the soda promotes weight loss generally. Similarly, although "100%" in "100% New Zealand Manuka Honey" can be interpreted in different ways, the implausibility of a honey product derived 100% from a single source renders plaintiffs' interpretation unreasonable.

Various methods have been used to study consumers' multidimensional decision-making process, including survey research. Well-constructed survey experiments can provide empirical insights into how consumers interpret a product label, what factors are important in their purchase decisions, and whether a product label is material to consumers' decisions. In this case, a survey experiment could have assisted the plaintiffs in assessing how honey consumers interpret Trader Joe's product label and whether Trader Joe's product label was material to their purchase decisions.

Ford Motor Co. v. Montana Eighth Judicial District Court: The Supreme Court Revisits Specific Personal Jurisdiction

ANAND AGNESHWAR, ANNA K. THOMPSON & JOCELYN WIESNER*

WHY IT MADE THE LIST

Last year, the U.S. Supreme Court yet again weighed in on personal jurisdiction. Since 2011, the Court has redefined all-purpose jurisdiction, concluding in no uncertain terms that a corporate defendant is subject to general jurisdiction only where it is "at home."[1] But with respect to case-linked or specific jurisdiction, the Court has been much less clear. After years of reining in jurisdiction in *J. McIntyre Machinery, Ltd. v. Nicastro*,[2] *Walden v. Fiore*,[3] and *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*,[4] a unanimous Court affirmed the exercise of specific jurisdiction over out-of-state defendant Ford Motor Company. In *Ford Motor Co. v. Montana Eighth Judicial District Court*,[5] the Supreme Court put a new gloss on the "relatedness" prong for specific jurisdiction, explaining that a strict causal connection between the claim and defendant's forum contacts is not required.

In the few months since *Ford*, plaintiffs alleging injuries from drugs and medical devices are already using the decision to re-instate sprawling theories of jurisdiction. For example, plaintiffs who purchased and used medical devices outside the forum are citing *Ford* to suggest that in-state business activities other than a defendant's manufacture and sale of a product can support jurisdiction.[6] Plaintiffs suing brand-name manufacturers for alleged injuries caused by generic drugs are saying that, by

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1 *See generally* Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. 915 (2011); Daimler AG v. Bauman, 571 U.S. 117 (2014); BNSF Ry. Co. v. Tyrrell, 137 S. Ct. 1549 (2017).

2 564 U.S. 873 (2011).

3 571 U.S. 277 (2014).

4 137 S. Ct. 1773 (2017).

5 141 S. Ct. 1017 (2021).

6 *See, e.g.*, Kingston v. AngioDynamics, Inc., No. 21-cv-10234-DJC, 2021 WL 3022320, at *8 (D. Mass. July 16, 2021); Simmons v. Cardinal Health, Inc., No. 20-2174, 2021 WL 1577843, at *4 (E.D. La. Apr. 22, 2021).

rejecting a strict "but-for" causation for relatedness, *Ford* means a court can properly exercise jurisdiction over innovator liability claims.[7] Drug and medical device manufacturers should therefore expect plaintiffs to argue that *Ford* has loosened the requirements for specific personal jurisdiction, bolstering theories such as innovator liability to sue defendants in states even when there is no direct link between their in-state conduct and the alleged injury.

DISCUSSION

The Facts

The Supreme Court's decision in *Ford* arose from two personal injury cases. In one, the decedent—a Montana resident—was driving her car in Montana when the tread separated from the rear tire, causing her to crash.[8] The decedent's estate sued Ford in Montana state court for design defect, failure to warn, and negligence.[9] In the second, the plaintiff—a Minnesota resident—suffered severe brain damage after his passenger-side airbag failed to deploy during a car crash in Minnesota.[10] The plaintiff sued Ford in Minnesota state court, asserting products liability, negligence, and breach of warranty claims.[11]

Ford—a Delaware corporation headquartered in Michigan—moved to dismiss for lack of personal jurisdiction.[12] Because Ford was not "at home" in Montana or Minnesota, it argued that neither state could exercise general jurisdiction.[13] And because Ford did not manufacture or sell the cars involved in the accidents in the forum states, it argued that there was no specific jurisdiction either.[14] The cars were designed in Michigan, manufactured in Kentucky and Canada, and sold in Washington and North Dakota, making their way to the forum states through a series of resales and relocations.[15]

The Montana and Minnesota Supreme Courts disagreed.[16] Even though the "particular vehicles" injuring the plaintiffs were not designed, manufactured, or first-sold in the forum states, Ford's marketing and advertisements influenced forum residents like the plaintiffs to purchase its vehicles.[17] That, the state high courts concluded, sufficiently connected Ford's forum activities with the plaintiffs' claims.[18]

On March 25, 2021, the U.S. Supreme Court affirmed.

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[7] *See, e.g.*, In re Zantac (Ranitidine) Prods. Liab. Litig., 546 F. Supp. 3d 1192, 1203–04 (S.D. Fla. 2021).

[8] *Ford*, 141 S. Ct. at 1023.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.* at 1022–23.

[13] *Id.*

[14] *Id.* at 1023, 1026.

[15] *Id.* at 1023.

[16] *Id.*

[17] *Id.* at 1023–24.

[18] *Id.*

Analysis and Holding

The Due Process Clause limits a court's authority to exercise jurisdiction over a defendant. For purposes of specific jurisdiction, the Supreme Court has explained that to comport with traditional notions of fair play and substantial justice, 1) the defendant must "purposefully avail[] itself of the privilege of conducting activities" in the forum state, and 2) the plaintiff's claim "must arise out of or relate to the defendant's contacts" with the forum state.[19]

Although the Supreme Court articulated this multi-step analysis for specific jurisdiction long ago, it has only recently defined the contours of the "relatedness" prong. In *Bristol-Myers Squibb*, more than 600 plaintiffs—the vast majority of whom were not California residents—brought product liability claims against the manufacturer of the prescription drug Plavix in California state court.[20] The manufacturer–defendant moved to quash for lack of personal jurisdiction over the nonresidents' claims.[21] The Supreme Court agreed, concluding that those claims were not related to the defendant's forum contacts: "For specific jurisdiction, a defendant's general connections with the forum are not enough . . . . What is needed . . . is a connection between the forum and the specific claims at issue."[22] As such, the Supreme Court held that the mere fact that Plavix is "prescribed, obtained, and ingested" by *other* plaintiffs in California is not enough to create specific jurisdiction over nonresident plaintiffs.[23]

Relying on *Bristol-Myers Squibb*, Ford argued that although it did substantial business in the forum states (e.g., advertising, selling, and servicing cars), none of those activities related to the plaintiffs' claims.[24] The specific cars involved in the car accidents had not been designed, manufactured, or sold in the forum states.[25] The Supreme Court, however, rejected Ford's strict causation requirement: "None of our precedents has suggested that only a strict causal relationship between the defendant's in-state activity and the litigation will do . . . . The first half of [the Court's articulated] standard asks about causation; but the back half, after the 'or,' contemplates that some relationships will support jurisdiction without a causal showing."[26]

Instead, the Court noted that Ford had advertised, sold, and serviced in Montana and Minnesota the same car models that were involved in the accidents.[27] Ford ran extensive advertisement campaigns, "urg[ing] Montanans and Minnesotans to buy its vehicles."[28] The company "encourage[d] a resale market for its products" by having its dealerships buy and sell used Ford vehicles.[29] And the company "foster[ed] an

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[19] *Id.* at 1024–25 (citations omitted).

[20] 137 S. Ct. at 1777–78.

[21] *Id.* at 1778.

[22] *Id.* at 1781.

[23] *Id.* at 1781.

[24] *Ford*, 141 S. Ct. at 1026.

[25] *Id.*

[26] *Id.*

[27] *Id.* at 1028.

[28] *Id.*

[29] *Id.* at 1022, 1028.

ongoing relationship between Ford and its customers" through its maintenance and repair services.[30] The Court therefore hypothesized, despite the lack of any such allegation, that the car owners would not have bought their respective cars had Ford not advertised and provided services for those car models in the forum.[31] The Court then contrasted the facts in *Ford* with those in *Bristol-Myers Squibb*, where nonresident plaintiffs had not purchased or used the product in the forum state and did not suffer any injuries there.[32]

Accordingly, significant to the Court's analysis in *Ford* was the fact that the car accidents occurred in the forum and injured forum residents.[33] As such, there was nothing "unfair" about "requiring Ford to litigate . . . in Minnesota and Montana" when "[*t*]*heir* residents, while riding in vehicles purchased within *their* borders, were killed or injured in accidents on *their* roads."[34]

THE IMPACT

Although the *Ford* Court rejected a "strict causal relationship" interpretation, it made clear that the relatedness requirement "incorporates real limits" and cautioned that its decision should not be interpreted to "mean anything goes."[35] In a concurring opinion, Justice Alito further explained: "To say that the Constitution does not require the kind of proof or causation that Ford would demand . . . is not to say that no causal link of any kind is needed."[36] That, however, has not stopped the plaintiffs' bar from arguing that *Ford* significantly relaxed the standard for specific jurisdiction, including in drug and device cases.[37]

In *Simmons v. Cardinal Health, Inc.*,[38] for example, the plaintiff tested the bounds of *Ford*. There, the plaintiff underwent knee surgery while living in Texas, which required the use of bone cement.[39] After moving to Louisiana, plaintiff underwent a revision surgery, allegedly due to the defectiveness of the bone cement.[40] He sued the German manufacturer of the cement in Louisiana, relying on *Ford* to argue that defendant knew or should have known that its product would reach Louisiana because it was generally available in the United States through a distributor.[41] Unlike *Ford*, however, the defendant–manufacturer had no offices or employees in Louisiana, made

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[30] *Id.* at 1023, 1028.

[31] *Id.* at 1029.

[32] *Id.* at 1030.

[33] *Id.* at 1031.

[34] *Id.* at 1032 (Alito, J., concurring) (emphases in original).

[35] *Id.* at 1026.

[36] *Id.* at 1033 (Alito, J., concurring).

[37] Invoking *Ford*, plaintiffs have tried to push the bounds in other areas of product liability litigation as well. *See, e.g.*, Martins v. Bridgestone Americas Tire Operations, LLC, 266 A.3d 753, 759–61 (R.I. 2022).

[38] 2021 WL 1577843.

[39] *Id.* at *1.

[40] *Id.*

[41] *Id.* at *4.

no direct sales in Louisiana, and provided no support to Louisiana residents.[42] Because the plaintiff "failed to establish any minimum contacts with Louisiana," the court concluded there was no specific jurisdiction.[43]

Similarly in *Kingston v. AngioDynamics, Inc.*,[44] the plaintiff sued the manufacturer of an implantable medical device, alleging that the manufacturing process resulted in a defective product. Although the plaintiff lived and sought medical treatment in Kentucky and the device had been manufactured in New York, she sued in Massachusetts.[45] Relying on *Ford*, she argued that the defendants' research and development and regulatory activities in Massachusetts were sufficient to meet the relatedness prong and create specific jurisdiction.[46] The court disagreed, concluding that the connection between those in-state activities and the eventual (allegedly defective) manufacture of the product in New York and sale in Kentucky was too tenuous.[47]

The debate about the impact of *Ford* is playing out in the context of innovator liability as well, with divergent results. In *Whaley v. Merck & Co.*,[48] for example, a California resident allegedly used the generic version of Singulair. Shortly after starting his prescription, he began experiencing confusion and hallucinations, and was eventually diagnosed with medication-induced bipolar disorder.[49] Although the plaintiff never ingested the brand-name medication, he sued the manufacturers of Singulair under a theory of innovator liability. As in *Ford*, the plaintiff argued that the brand-name defendants' in-state activities—e.g., research, marketing, and sales of Singulair—gave rise to the warning label claims.[50] The court agreed, finding *Ford* "highly instructive" and explained that the defendants "advertised, marketed, and sold the Singulair product in California, which included the allegedly deficient label. These contacts are relevant even when they are not an effort to promote or sell [the generic version]."[51]

The court in *In re Zantac (Ranitidine) Products Liability Litigation*[52] reached a different result. There, the plaintiffs sued the manufacturers and marketers of Zantac under theories of direct and innovator liability. The brand-name manufacturers moved to dismiss the innovator liability claim for lack of personal jurisdiction. As in *Whaley*, the plaintiffs responded that the defendants' in-state sales force, promotion efforts, research, and sales conferred specific personal jurisdiction.[53] After considering *Ford*,

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[42] *Id.*

[43] *Id.*

[44] 2021 WL 3022320, at *2.

[45] *Id.* at *2, 6.

[46] *Id.* at *7.

[47] *Id.* at *9 ("Kingston's argument that certain operations occurred in [Massachusetts], and that those operations led to the ultimate—and allegedly flawed—design . . . , which led to its eventual manufacture in New York, which led to its distribution to and subsequent harm in Kentucky, is too tenuous to state a colorable claim.").

[48] No. 3:21-cv-1985, 2022 WL 1153151 (S.D. Cal. Apr. 12, 2022).

[49] *Id.* at *2.

[50] *Id.* at *5.

[51] *Id.* at *5, 7.

[52] 546 F. Supp. 3d at 1203–04.

[53] *Id.* at 1202.

the court held that none of these activities related to labeling decisions, which is the sole basis to hold defendants liable under innovator liability.[54]

Rather than clarify the "relatedness" requirement, then, the *Ford* decision will likely cause more confusion and jurisdictional fights. Indeed, Justices Alito and Gorsuch authored separate concurrences on this very point: "Where this leaves us is far from clear. For a case to 'relate to' the defendant's forum contacts, the majority says, it is enough if the 'affiliation' or 'relationship' or 'connection' exists between them. But what does this assortment of nouns *mean*? Loosed from any causation standard, we are left to guess."[55] While defendants can take some comfort that due process requires some connection between the litigation and defendants' forum activities—i.e., blatant forum-shopping will not be condoned—lower courts will likely struggle with the exact contours of the *Ford* decision for months and years to come.

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[54] *Id.* at 1214.

[55] *Ford*, 141 S. Ct. at 1034–35 (Gorsuch, J., concurring) (emphasis in original) (citation omitted).

Significant Regulatory, Compliance, and Enforcement Developments, 2021

STEPHANIE PHILBIN & LAUREN FARRUGGIA*

The COVID-19 pandemic continued to dominate the U.S. Food and Drug Administration's (FDA or agency) priorities for 2021, with FDA making some substantial regulatory changes, including some spurred by the proliferation of new SARS-CoV-2 viral mutations. Meanwhile, FDA continued to devote significant regulatory attention to software as a medical device (SaMD), including those devices using artificial intelligence (AI) and machine learning (ML).

COVID-19

Despite the availability of COVID-19 vaccines under Emergency Use Authorization (EUA) and FDA's marketing approval of the Pfizer-BioNTech vaccine in August 2021 and Moderna's vaccine in January 2022 following the agency's review of the biologics license application for each, COVID-19 continued to spread, in large part due to the emergence of SARS-CoV-2 viral mutations.[1] As new variants propagated throughout the year, FDA moved quickly to assess any impact on diagnostic test functionality and performance.

On January 8, 2021, FDA issued a safety communication alerting clinical laboratory staff and health care providers that the agency was actively monitoring the potential impact of viral mutations on authorized COVID-19 molecular tests.[2] This safety alert followed reports of false negative results where mutations occurred in the part of the virus's genome assessed by the affected tests. At the time, FDA identified three authorized molecular tests that could be impacted by SARS-CoV-2 genetic variants, but the agency clarified that any impact did "not appear to be significant."[3] Meanwhile, the agency continued to receive a high volume of new EUA submissions requiring additional resources to ensure adequate review, as Dr. Timothy Stenzel, Director, Office of In Vitro Diagnostics, Center for Devices and Radiological Health, noted

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[1] Press Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine; Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine (Jan. 31, 2022), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[2] Press Release, U.S. Food & Drug Admin., FDA Issues Alert Regarding SARS-CoV-2 Viral Mutation to Health Care Providers and Clinical Laboratory Staff (Jan. 8, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-alert-regarding-sars-cov-2-viral-mutation-health-care-providers-and-clinical-laboratory.

[3] *Id.*

during FDA's January 13, 2021 Virtual Town Hall Series on COVID-19 Test Development and Validation.[4]

Following this safety alert, in February 2021, FDA issued a guidance document, Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests, in further response to emerging variants and the potential impact on test development and performance post-authorization.[5] In this guidance, FDA indicated that during EUA review, it intends to consider the performance of a test across all known viral variants, as well as the developer's plans for post-authorization monitoring for performance against future variants. The agency also revised a number of EUAs for molecular, antigen, and serological tests to establish conditions of authorization in response to the continued emergence of new variants. Notably, FDA recommended, but did not require, that test developers consider disclosing in an EUA request whether the test's labeling should include limiting statements representing the time period and geographic location of which clinical specimens used in the test's evaluation were collected, suggesting further that test developers disclaim that "the clinical performance has not been established in all circulating variants, and that performance may vary depending on the variants, and their prevalence, circulating at the time of patient testing."[6]

In December 2021, FDA made available on its website a page devoted to assessing the impact of viral mutations on COVID-19 tests, including identifying a list of tests for which FDA has identified performance issues with respect to certain variants.[7]

The other major regulatory shift for test developers occurred on November 15, 2021, when FDA issued a revised Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency ("Test Guidance").[8] These revisions were shortly followed by a statement from the U.S. Department of Health and Human Services (HHS) announcing the withdrawal of a policy established in August 2020 that directed FDA not to require premarket review of laboratory developed tests (LDTs).[9]

In the revised Test Guidance, FDA significantly changed its enforcement policy to now require, with limited exceptions, EUAs or traditional marketing authorizations (e.g., a granted De Novo or 510(k) clearance) for COVID-19 LDTs and other diagnostic or serology tests. This ended FDA's policy that previously allowed developers to offer their COVID-19 tests prior to or without an EUA after the product was validated and notification of such validation was provided to FDA. The agency

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[4] Transcript of FDA Virtual Town Hall Series—Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests at 6 (Jan. 13, 2021), https://www.fda.gov/media/145290/download.

[5] U.S. FOOD & DRUG ADMIN., POLICY FOR EVALUATING IMPACT OF VIRAL MUTATIONS ON COVID-19 TESTS—GUIDANCE FOR TEST DEVELOPERS AND FOOD AND DRUG ADMINISTRATION STAFF (Feb. 2021), https://www.fda.gov/media/146171/download.

[6] *Id.* at 8.

[7] *SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests*, U.S. FOOD & DRUG ADMIN. (Dec. 28, 2021), https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests.

[8] U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-2019 TESTS DURING THE PUBLIC HEALTH EMERGENCY—GUIDANCE FOR DEVELOPERS AND FOOD AND DRUG ADMINISTRATION STAFF (Nov. 15, 2021), https://www.fda.gov/media/135659/download.

[9] Press Release, U.S. Dep't of Health & Hum. Servs., Statement by HHS Secretary Xavier Becerra on Withdrawal of HHS Policy on Laboratory-Developed Tests (Nov. 15, 2021), https://www.hhs.gov/about/news/2021/11/15/statement-hhs-secretary-xavier-becerra-withdrawal-hhs-policy-laboratory-developed-tests.html.

also identified its priorities for EUA review of certain types of tests, including at-home and point-of-care diagnostic tests that can be manufactured in high volumes and certain high-volume, high-throughput laboratory-based molecular diagnostic tests (and home collection kits for use with such tests). FDA clarified that COVID-19 LDTs offered prior to issuance of the revised Test Guidance now required submission of an EUA request within sixty days from the issuance of the revised Test Guidance, but generally such products could continue to be offered while FDA reviewed the EUA request. In addition, FDA opted not to recognize any additional states or territories for the regulation of COVID-19 testing as of the date of issuance of the revised Test Guidance. Thus, COVID-19 LDTs could continue to be offered without notification of test validation or submission of an EUA request to FDA where the test is designed, developed, and used within a single, high-complexity Clinical Laboratory Improvement Amendments certified laboratory that has been authorized by a state or territory, previously recognized by FDA, that has chosen to authorize laboratories within that state or territory to develop COVID-19 tests and perform specimen testing.

What will 2022 bring for the regulation of COVID-19 tests? The agency continues to assess the impact of the omicron and omicron BA.2 variants (and any new variants should they emerge) on test performance. Moreover, as public health needs change or more COVID-19 tests are authorized, FDA may reassess its priorities for review of such tests.

In addition, the agency will continue to step up its enforcement actions against those bad actors distributing counterfeit COVID-19 tests. FDA remains focused on pursuing violations for COVID-19-related devices. As was the case in 2020, FDA targeted manufacturers with enforcement action throughout 2021. As of May 1, 2022, FDA published on its website sixty-three Warning Letters issued to medical device manufacturers during 2021, including: 1) seventeen for COVID-19 test developers; 2) sixteen for mask manufacturers; 3) thirteen for thermographic device manufacturers; and 4) thirty-four for devices that were considered "Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)."[10] Stakeholders can continue to expect enforcement activity in this space for the duration of the COVID-19 public health emergency, particularly as FDA's regulatory treatment of COVID-19 tests continues to evolve in response to the stage of the pandemic and the emergence of new viral mutations.

Interestingly, there are some signs of returning to normal within CDRH. On June 7, 2022, the agency announced the withdrawal of its June 2020 guidance establishing that, for device marketing submissions and applications on hold, FDA did not intend to consider a submission or application to be withdrawn for an additional 180 days beyond the relevant response date.[11] This means that, as of July 7, 2022, FDA will generally consider a marketing submission or application to be withdrawn if the submitter or applicant does not provide a complete response to a major deficiency letter or an additional information letter consistent with preexisting guidance.

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[10] *Warning Letters*, U.S. FOOD & DRUG ADMIN. (current as of Apr. 28, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[11] 87 Fed. Reg. 34,691 (June 7, 2022).

SAMD, AI, AND ML

Although FDA's COVID-19 response remained one focus of the agency's time and effort, in 2021 FDA also devoted considerable attention to Software as a Medical Device (SaMD), including artificial intelligence and machine learning functionalities.

In January 2021, FDA released the agency's first Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan ("Action Plan").[12] This Action Plan was a follow-up to FDA's April 2019 proposed AI/ML-based SaMD regulatory framework and discussion paper ("Discussion Paper").[13] The Action Plan emphasized the deep potential for such technology to change patient outcomes and streamline health care delivery, but also recognized the need for continued stakeholder engagement to adequately establish the agency's regulatory framework for AI/ML-based SaMD oversight.

The Action Plan identified several key action items for the agency as it continues to build out a regulatory framework for AI/ML-based SaMD. FDA attempted to progress through these action items throughout 2021, as detailed below:

- Announcement of Intention to Issue a Draft Guidance on Predetermined Change Control Plan: FDA signaled its commitment to refining a regulatory framework that would allow for some post-market SaMD modifications based largely on the establishment and utilization of SaMD Pre-Specifications and an Algorithm Change Protocol set forth in a proposed "Predetermined Change Control Plan." Although FDA in its Action Plan told stakeholders to expect availability of a draft guidance later in 2021 addressing a Predetermined Change Control Plan, the agency has yet to publish it.
- Encourage Harmonization of Good Machine Learning Practice (GMLP) Development: FDA first used the term "GMLP" in its Discussion Paper and clarified that the GMLP framework is meant to be "akin to good software engineering practices or quality system practices."[14] The agency stressed its active participation in worldwide GMLP development efforts, including its membership in the Xavier AI World Consortium Collaborative Community and the Pathology Innovation Collaborative Community. Following the Action Plan's publication, in October 2021, FDA, Health Canada, and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA)

[12] U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ACTION PLAN (Jan. 2021), https://www.fda.gov/media/145022/download.

[13] U.S. FOOD & DRUG ADMIN., PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD)—DISCUSSION PAPER AND REQUEST FOR FEEDBACK (Apr. 2019), https://www.fda.gov/media/122535/download.

[14] *Id.* at 9.

issued a set of ten guiding principles meant to aid the development of GMLP.[15]

- Public Workshop on Algorithm Transparency and Support of Algorithm Evaluation and Improvement: As previewed in the Action Plan, on October 14, 2021, FDA held a public workshop to seek feedback from stakeholders on how device labeling supports transparency to users and ways in which such transparency might enhance the safety and effectiveness of these devices. FDA also sought to gather input on the types of information that would be helpful for a manufacturer to include in the labeling and public facing information of AI/ML-enabled medical devices.[16] Separately, FDA emphasized in the Action Plan the need to carefully consider bias and generalizability in AI/ML-based medical devices and highlighted its support of numerous regulatory science research efforts to develop methods to evaluate and remediate these issues.
- Support of Stakeholders Piloting Real-World Performance (RWP) Process: FDA recognized the importance of real-world data collection and monitoring as a critical element of its proposed regulatory framework for oversight of modifications to AI/ML-based SaMD. FDA announced its intention to advance RWP monitoring pilots with stakeholders on a voluntary basis and seeks to build from these learnings to develop a framework for establishing and validating RWP parameters and metrics.

Building on these efforts, in September 2021, FDA's Digital Health Center of Excellence published a list of AI/ML-enabled medical devices on its website.[17] The identified devices include those cleared via 510(k) premarket notifications, authorized pursuant to De Novo requests, and approved via premarket approval applications. Although FDA cautioned that while not exhaustive or comprehensive, the list is intended to increase transparency and access to information on these devices that span across medical disciplines. FDA intends to update the list (which, as of May 1, 2022, included 343 devices) on a periodic basis. The list will surely grow as AI/ML-enabled medical devices continue to gain popularity and as AI/ML technology advances.

The agency has already taken steps in 2022 to further define its regulatory approach to AI/ML-enabled medical devices. FDA announced a virtual meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee to be held on July 28, 2022.[18] The meeting will address approaches for evaluating the performance of algorithm-based skin lesion analyzer technology and its application in

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[15] U.S. FOOD & DRUG ADMIN., HEALTH CANADA & MEDS. & HEALTHCARE PRODS. REGUL. AGENCY, GOOD MACHINE LEARNING PRACTICE FOR MEDICAL DEVICE DEVELOPMENT: GUIDING PRINCIPLES (Oct. 2021), https://www.fda.gov/media/153486/download.

[16] *Virtual Public Workshop—Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices*, U.S. FOOD & DRUG ADMIN. (Oct. 14, 2021), https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-workshop-transparency-artificial-intelligencemachine-learning-enabled-medical-devices.

[17] *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, U.S. FOOD & DRUG ADMIN. (Sept. 22, 2021), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.

[18] 87 Fed. Reg. 32,172, 32,173 (May 27, 2022).

detecting skin cancers in various patient care settings. Interested stakeholders have until July 11, 2022 to comment on the public docket. The Advisory Committee meeting may provide FDA with additional perspective as the agency continues to assess AI/ML-enabled devices.

2021 Significant Settlements

JUSTINE E. LENEHAN*

I. INTRODUCTION

This chapter summarizes a selection of significant settlements in 2021 between members of the food and drug industry and the U.S. Food and Drug Administration (FDA) alongside the U.S. Department of Justice (DOJ). The enforcement authority of FDA and DOJ includes both civil penalties and criminal prosecution.

Consistent with prior years, a majority of these settlements arise from DOJ's use of the False Claims Act (FCA), which imposes liability on persons and companies who defraud governmental programs and contracts. In 2021, the federal government recovered $5.65 billion in FCA judgements and settlements, roughly $5.07 billion (90%) of which came from health care and life sciences companies.[1] Total recoveries amount to over $70 billion since Congress overhauled the FCA in 1986 in order to encourage whistleblower complaints.[2] Whistleblower, or *qui tam*, actions continued to be a driving force behind DOJ enforcement activity, with 598 whistleblower suits filed in 2021 (as compared to 203 cases filed by the government), which resulted in DOJ recovering over $1.6 billion from these and earlier filed suits and $237 million awarded to relators for their role.[3]

Notably, the amount recovered in 2021 marked the second largest annual total in FCA history, second only to the roughly $6.2 billion recovered in 2014.[4] This annual recovery is more than double DOJ's annual recovery amount in 2020 (a ten-year low), suggesting that DOJ has rebounded from the novel coronavirus (COVID-19) pandemic's impact on DOJ's ability to investigate and litigate fraud against the government.

Also, as noted in last year's edition of Significant Settlements, the federal government committed record amounts of money in emergency relief packages during the COVID-19 pandemic. The availability of these federal funds will undoubtedly be a source of healthcare-related fraudulent activity and result in increased fraud-related investigations and prosecutions by DOJ. In fact, the U.S. Attorney General announced in May 2021 the establishment of the COVID-19 Fraud Enforcement Task Force in an effort to foster partnership across government agencies to enforce against COVID-19-

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1 Fraud Statistics – Overview (DOJ Dec. 2021).

2 *Id.*

3 *Id.*; Press Release, U.S. Dep't of Justice, Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021 (Feb. 1, 2022).

4 *Id.*

related fraud.[5] We have not yet seen any settlements in 2021 resulting from healthcare-related FCA allegations arising out of COVID-19 relief programs; however, DOJ is actively pursuing and has announced charges for such violations.[6] Experts expect that this trend will continue, if not increase, in 2022 and beyond.

While we can expect FCA enforcement related to the COVID-19 pandemic to play a significant role in DOJ activity, DOJ will also continue to prioritize existing efforts more generally. For instance, in 2021, DOJ continued its emphasis on targeting entities that engaged in fraud related to healthcare services provided to patients. This included, for example, fraud involving the payment of kickbacks to referring physicians, whether in cash or in kind, and the provision of medically unnecessary services improperly billed to federal healthcare programs.

This chapter reviews some of the key FCA settlements and other representative settlements and consent decrees between the food and drug industry and the government in 2021.

II. DRUGS

A. Taro Pharmaceuticals USA, Inc., Sandoz Inc., and Apotex Corporation[7]

Taro Pharmaceuticals USA, Inc. ("Taro"), Sandoz Inc. ("Sandoz"), and Apotex Corporation ("Apotex") (collectively, the "Companies") agreed to pay a total of $447.2 million to resolve allegations that the Companies conspired to fix the price of various generic drugs in violation of the FCA and Anti-Kickback Statute. Taro agreed to pay $213.2 million, Sandoz agreed to pay $185 million, and Apotex agreed to pay $49 million. The generic drugs involved addressed a variety of health conditions, including nonsteroidal anti-inflammatory drugs used to treat pain and arthritis, corticosteroids used to treat skin conditions, drugs used to treat high cholesterol and triglyceride levels, among others.

The government alleged that Taro, Sandoz, and Apotex paid and received compensation through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for generic drugs manufactured by the Companies. The Anti-Kickback Statute prohibits companies from receiving or making payments in return for selling or purchasing drugs for which payment may be made by a federal healthcare program.

Each of the Companies also entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that includes internal monitoring and price transparency provisions and requires the Companies to implement compliance measures such as risk assessment programs, executive recoupment provisions, and compliance-related certifications for executives and board members.

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[5] Press Release, U.S. Dep't of Justice, Attorney General Announces Task Force to Combat COVID-19 Fraud (May 17, 2021).

[6] *See, e.g.*, Press Release, U.S. Dep't of Justice, DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19 (May 26, 2021).

[7] Press Release, U.S. Dep't of Justice, Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs (Oct. 1, 2021).

These civil settlements follow the Companies' earlier resolution of criminal charges through deferred prosecution agreements. In addition to the total of $447.2 million in civil settlements, Taro paid a criminal penalty of $205.6 million, Sandoz paid a criminal penalty of $195 million, and Apotex paid a criminal penalty of $24.1 million. Each Company also admitted to conspiring to fix prices on various generic drugs.

B. Kaléo Inc.[8] and Riad "Ray" Zahr, People's Drug Store, and Ray's Drugs[9]

Kaléo Inc. ("Kaléo") agreed to pay $12.7 million to resolve allegations that the company caused the submission of false claims for the drug Evzio, an injectable form of naloxone hydrochloride indicated for use to reverse opioid overdose. One month later, a pharmacist in Michigan, Riad "Ray" Zahr, and two specialty pharmacies formerly owned and operated by Zahr agreed to pay $1 million to resolve allegations that they submitted false claims for Evzio to Medicare.

Insurers often required receipt of prior authorization requests in order to cover Evzio. Kaléo allegedly directed prescribing doctors to send prescriptions to preferred pharmacies that submitted false prior authorization requests for the drug that misrepresented to insurers that the physicians submitted the request (when the pharmacies did so) and/or contained false or misleading information regarding patients' medical histories (for example, false statements that patients had previously tried and failed less costly alternatives to Evzio). The government identified Zahr and his two specialty pharmacies, People's Drug Store and Ray's Drugs, as pharmacies allegedly involved in this scheme.

Additionally, in violation of the Anti-Kickback Statute, the government alleged that 1) Kaléo, Zahr, and the two specialty pharmacies dispensed Evzio without collecting co-payments from government beneficiaries; and 2) Kaléo illegally remunerated prescribing physicians and their office staff to induce and reward the prescription of Evzio.

These settlements with Kaléo, Zahr, and the two specialty pharmacies also resolve claims brought under the *qui tam* provisions by a former employee of Kaléo; the whistleblower will receive roughly $2.5 million of the settlement amount with Kaléo and $200,000 of the settlement amount with Zahr and the specialty pharmacies.

C. Incyte Corporation[10]

Incyte Corporation ("Incyte") agreed to pay $12.6 million to resolve allegations that the company paid kickbacks in violation of the FCA. Specifically, Incyte allegedly used an independent foundation as a conduit to cover copayments of federal beneficiaries taking Incyte's drug Jakafi, a drug approved to treat myleofibrosis. Incyte was the sole donor to this fund, which was opened to assist only myleofibrosis patients.

The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying any remuneration—including payment of patients' copay obligations—to induce federal beneficiaries to purchase the company's drugs. The government alleges

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[8] Press Release, U.S. Dep't of Justice, Kaléo Inc. Agrees to Pay $12.7 Million to Resolve Allegations of False Claims for Anti-Overdose Drug (Nov. 9, 2021).

[9] Press Release, U.S. Dep't of Justice, Pharmacist and Two Pharmacies Agree to Pay $1 Million to Resolve Allegations of False Claims for Anti-Overdose Drug (Dec. 8, 2021).

[10] Press Release, U.S. Dep't of Justice, Incyte Corporation to Pay $12.6 Million to Resolve False Claims Act Allegations for Paying Kickbacks (May 4, 2021).

that, through the fund, Incyte paid the copays of federal beneficiaries taking Jakafi who were ineligible for assistance because they did not have the indicated disease. Consequently, Incyte caused the submission of false claims to Medicare and TRICARE.

This settlement also resolves claims brought under the *qui tam* provisions by a former compliance executive of Incyte; the whistleblower will receive roughly $3.59 million of the settlement amount.

III. MEDICAL DEVICES

A. St. Jude Medical Inc.[11]

St. Jude Medical Inc. ("St. Jude") agreed to pay $27 million to resolve civil allegations that, between November 2014 and October 2016, it knowingly sold defective heart devices to healthcare facilities that then implanted such devices into patients insured by federal healthcare programs.

The government contended that St. Jude failed to provide FDA with material information regarding injuries and deaths resulting from the defective devices that, if communicated at that time, would have led to a product recall. Specifically, St. Jude allegedly withheld information on serious adverse health events in connection with the premature depletion of the battery in certain models of St. Jude's implantable defibrillators used in patients at risk of cardiac arrest due to an irregular heartbeat.

The devices were ultimately subject to a Class I recall in October 2016, although thousands of defective devices had been implanted into patients since November 2014, during which time the government contended that St. Jude knowingly caused the submission of false claims to federal healthcare programs.

The settlement also resolved claims brought under the *qui tam* provisions by a patient who received one of the devices.

B. Alere Inc. and Arriva Medical LLC[12]

Alere Inc. ("Alere") and Alere San Diego Inc. ("Alere San Diego") agreed to pay $38.75 million to resolve civil allegations that the companies violated the FCA by billing, and causing others to bill, the Medicare program for defective rapid point-of-care testing devices.

The government contended that, from 2008 to 2016, the companies knowingly sold defective INRatio blood coagulation monitors used by Medicare beneficiaries. The patients were those individuals taking anticoagulant drugs who used the monitoring device to determine a clinically appropriate and safe dosage for the medications. The Alere companies allegedly knew that the devices' software algorithm contained a material defect that produced inaccurate and unreliable results for certain patients. The companies allegedly concealed the defect for years, following over a dozen deaths and hundreds of injuries associated with this defect. The devices were ultimately removed from the market after a nationwide Class I product recall.

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[11] Press Release, U.S. Dep't of Justice, St. Jude Agrees to Pay $27 Million for Allegedly Selling Defective Heart Devices (July 8, 2021).

[12] Press Release, U.S. Dep't of Justice, Medical Device Companies Alere Inc. and Alere San Diego Inc. Agree to Pay $38.75 Million to Settle False Claims Act Allegations (July 8, 2021); Press Release, U.S. Dep't of Justice, Mail-Order Diabetic Testing Supplier and Parent Company Agree to Pay $160 Million to Resolve Alleged False Claims to Medicare (Aug. 2, 2021).

Alere was also the subject of a second settlement for alleged violations of the FCA, along with its subsidiary, Arriva Medical LLC ("Arriva"). Arriva and Alere agreed to pay $160 million to resolve civil allegations that the companies violated the FCA. Two Arriva founders had previously paid $1 million to resolve allegations that they participated in the kickback scheme.

The government contended that, from April 2010 to the end of 2016, Arriva (with Alere's approval) paid kickbacks to Medicare beneficiaries by providing them with "free" or "no cost" glucometers and by routinely waiving, or failing to make reasonable efforts to collect, their copayments. The settlement also resolves allegations that Arriva and Alere caused the submission of false claims to Medicare by providing a meter to all new patients without regard to their eligibility for one and billing Medicare for the new meters. Lastly, the settlement resolves claims that Arriva submitted false claims to Medicare on behalf of deceased beneficiaries.

This settlement also resolves claims brought under the *qui tam* provisions by a former employee at an Arriva call center who will receive more than $28 million as part of his share of the recovery.

Arriva ceased business operations in 2017.

C. Arthrex Inc.[13]

Arthrex Inc. ("Arthrex") agreed to pay $16 million to resolve civil allegations that the company violated the FCA by paying kickbacks to a Colorado-based orthopedic surgeon, resulting in the submission of false claims to the Medicare program. Specifically, the government contended that Arthrex provided remuneration to the surgeon in the form of royalty payments supposedly for the surgeon's contributions to two Arthrex products when, in fact, the remuneration was intended to induce the surgeon's use of Arthrex products.

Arthrex also entered into a five-year CIA with HHS-OIG that outlined requirements for future compliance. This settlement also resolves claims brought under the *qui tam* provisions; the whistleblower will receive $2.5 million of the False Claims Act settlement.

D. Neurosurgeon Wilson Asfora, M.D., Medical Designs LLC, and Sicage LLC[14]

Neurosurgeon Wilson Asfora, M.D. and two medical device distributors owned by Asfora, Medical Designs LLC and Sicage LLC, agreed to pay a combined total of $4.4 million to resolve civil allegations that the companies made illegal payments to Asfora to induce the use of certain medical devices in violation of the Anti-Kickback Statute and that Asfora submitted claims for medically unnecessary surgeries in violation of the FCA.

Specifically, the government contended that for nearly a decade, Asfora, Medical Designs, and Sicage knowingly and willfully engaged in three kickback schemes: 1) Medical Designs and Sicage allegedly paid Asfora profit distributions in exchange for Asfora's use of the companies' devices in his spine surgeries; 2) Medical Designs resold other manufacturers' spinal devices and split the profits with Asfora when

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[13] Press Release, U.S. Dep't of Justice, Medical Device Company Arthrex to Pay $16 Million to Resolve Kickback Allegations (Nov. 8, 2021).

[14] Press Release, U.S. Dep't of Justice, Neurosurgeon and Two Affiliated Companies Agree to Pay $4.4 Million to Settle Health Care Fraud Allegations (May 3, 2021).

Asfora used those devices in surgeries; and 3) Asfora received kickbacks from medical device manufacturer Medtronic USA Inc. in exchange for using Medtronic's infusion pumps. These kickbacks were allegedly paid in the form of lavish meals and alcohol to Asfora through a restaurant he owned with his wife.

The government also contended that Asfora knowingly submitted false claims to federal health care programs for medically unnecessary procedures using devices in which he had financial interests, despite receiving warnings from physician colleagues that such procedures were medically unnecessary. Other settlements related to the provision of unnecessary medical procedures are discussed in the following section.

Asfora and his two distribution companies are excluded from participation in federal health care programs for a term of six years. This settlement also resolves claims brought under the *qui tam* provisions by two doctors who will receive $800,000 as part of their share of the recovery.

Medical Designs and Sicage also agreed to pay $100,000 in penalties for alleged violations of the Center for Medicare and Medicaid Services' (CMS) Open Payments Program in that they failed to report to CMS Asfora's ownership interests and payments made to Asfora. This program, established by the Affordable Cares Act, requires medical device companies to disclose to CMS physician ownership interests and certain transfers of value to a physician.

IV. HEALTHCARE SERVICES

Settlements related to healthcare services generally concerned one of two categories of alleged activities: 1) the provision of medically unnecessary or medically substandard services resulting in the submission of false claims to federal healthcare programs in violation of the FCA; and/or 2) the payment or receipt of remuneration in violation of the Anti-Kickback Statute, which may also give rise to FCA violations if such activity resulted in the submission of false claims to a federal healthcare program.

A. Medically Unnecessary or Medically Substandard Services

1. SavaSeniorCare LLC[15]

SavaSeniorCare LLC and related entities ("Sava") agreed to pay $11.2 million (plus additional amounts if certain financial contingencies occur) to resolve allegations that Sava caused its skilled nursing facilities (SNFs) to bill Medicare programs for rehabilitation therapy services that were not reasonable, necessary, or performed skillfully and that Sava billed Medicare and Medicaid programs for grossly substandard skilled nursing services.

The government alleged that Sava:

- Knowingly engaged in a systemic effort to increase Medicare billing and pressured its SNFs to meet unrealistic financial goals that resulted in the provision of unreasonable, unnecessary, or unskilled services to Medicare patients and, ultimately, the submission of false claims for such services;

[15] Press Release, U.S. Dep't of Justice, SavaSeniorCare LLC Agrees to Pay $11.2 Million to Resolve False Claims Act Allegations (May 21, 2021).

- Delayed patient discharge from its facilities in order to increase its Medicare payments;
- Knowingly submitted false claims to Medicaid for coinsurance amounts for beneficiaries eligible for both Medicaid and Medicare and for which Sava had also submitted false claims to Medicare;
- Knowingly submitted false claims to Medicare and Medicaid for grossly substandard nursing services (e.g., failing to have sufficient staffing, failing to follow appropriate pressure ulcer protocols and appropriate falls protocols, and failing to appropriately administer medications to patients).

Sava also entered into a five-year chain-wide CIA with the HHS-OIG that requires an independent review organization to annually review patient stays and associated paid claims by Medicare. The CIA also requires an independent monitor to review the quality of resident care. This settlement also resolves four claims brought under the *qui tam* provisions.

2. Interface Rehab[16]

Interface Rehab ("Interface") agreed to pay $2 million to resolve allegations that Interface submitted Medicare claims for medically unreasonable or unnecessary rehabilitation therapy services. This settlement resolves Interface's role in a July 2020 DOJ settlement with Longwood Management Corporation and twenty-seven affiliated SNFs in which those parties agreed to pay $16.7 million to resolve similar allegations.

Specifically, the government alleged that Interface submitted false claims for "Ultra High" levels of therapy at eleven SNFs. The amount of Medicare reimbursement varies depending upon the skilled therapy and nursing needs for qualifying patients; the "Ultra High" level is the highest level of Medicare reimbursement. Interface allegedly pressured therapists to increase the amount of therapy provided to patients and to bill patients at the "Ultra High" level in order to meet Interface's pre-planned Medicare revenue targets.

This settlement also resolves claims brought under the *qui tam* provisions by a former Director of Rehab at Interface; the whistleblower will receive $360,000 of the settlement amount.

3. Ascension Michigan and Related Hospitals[17]

Ascension Michigan and related hospitals, Providence Park Hospital, St. John Hospital and Medical Center, St. John Macomb Oakland Hospital, and Ascension Crittenton Hospital (collectively, "Ascension") agreed to pay $2.8 million to resolve allegations that Ascension submitted false claims to federal healthcare programs for medically unnecessary procedures performed by a gynecologic oncologist.

Specifically, the government alleged that Ascension knew such claims were falsely submitted and improperly kept payment for fees related to unnecessary hysterectomies that the doctor performed, chemotherapy services that the doctor administered or

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[16] Press Release, U.S. Dep't of Justice, Interface Rehab to Pay $2 Million to Resolve False Claims Act Allegations (July 23, 2021).

[17] Press Release, U.S. Dep't of Justice, Ascension Michigan to Pay $2.8 Million to Resolve False Claims Act Allegations (Aug. 5, 2021).

ordered, and evaluation and management services by the doctor that were either not performed or not rendered as represented.

Ascension allegedly had concerns about this doctor's quality of care, based upon patient complaints and higher-than-average rates of pulmonary embolisms and surgical infections and, in fact, hired a third party doctor to conduct a peer review of the doctor's patients. The peer reviewer found that for a majority of the doctor's services, a less aggressive surgery or medical intervention would have been consistent with the standard of care. In 2018, Ascension made a self-disclosure to HHS-OIG related to the professional and facility fees it billed to federal healthcare programs for the doctor's services and ultimately ended its contractual relationship with the doctor.

This settlement also resolves claims brought under the *qui tam* provisions in which the whistleblowers will receive a total of $532,000 of the settlement amount.

B. Payment of Kickbacks

1. Prime Healthcare Services, Dr. Prem Reddy, and Dr. Siva Arunasalam[18]

In a joint resolution with the DOJ and the California Department of Justice, one of the largest hospital systems in the country and two of its doctors agreed to pay $37.5 million to resolve alleged FCA and California False Claims Act violations. Specifically, the settlement involved Prime Healthcare Services ("Prime"), Prime's Founder and Chief Executive Officer Dr. Prem Reddy, and California interventional cardiologist Dr. Siva Arunasalam. Arunasalam agreed to pay $2 million, Reddy agreed to pay $1.775 million, and Prime agreed to pay $33.725 million. Notably, Prime and Reddy previously paid a combined total of $65 million in 2018 related to allegations of false claims and overbilling.

Specifically, the government alleged that:

- Prime paid Arunasalam kickbacks in its purchase of Arunasalam's physician practice and surgery center in that the purchase price exceeded fair market value and was not commercially reasonable. Such payments were made to induce Arunasalam to refer patients to one of Prime's hospitals;
- One of Prime's entities, High Desert Heart Vascular Institute, and Arunasalam used Arunasalam's billing number to bill Medicare and Medi-Cal for services provided by a different doctor whose Medicare and Medi-Cal billing privileges had been revoked;
- Certain Prime hospitals billed Medi-Cal and federal benefit programs for false claims based upon inflated invoices.

Prime and Reddy entered into a five-year CIA with HHS-OIG that requires, among other things, that Prime maintain a compliance program and engage an Independent Review Organization to review arrangements entered into or on behalf of its affiliates. This settlement also resolves claims brought in two lawsuits under the *qui tam* provisions by a former Prime executive and a former employee in the billing office at

[18] Press Release, U.S. Dep't of Justice, Prime Healthcare Services and Two Doctors Agree to Pay $37.5 Million to Settle Allegations of Kickbacks, Billing for a Suspended Doctor, and False Claims for Implantable Medical Hardware (July 19, 2021).

a Prime hospital. The former executive will receive nearly $10 million of the False Claims Act settlement.

2. Akron General Health System[19]

Akron General Health System (AGHS) agreed to pay $21.25 million to resolve allegations of improper relationships with referring physicians which resulted in the submission of false claims to Medicare in violation of the FCA. The Cleveland Clinic Foundation acquired AGHS in 2015 and, upon learning of these practices, voluntarily disclosed its concerns to the government.

The government alleged that AGHS compensated area physician groups substantially in excess of fair market value in exchange for patient referrals in violation of the Anti-Kickback Statute and the Physician Self-Referral Law. The Physician Self-Referral Law (commonly called the Stark Law) prohibits hospitals from submitting claims to Medicare for certain services referred by physicians with whom the hospital has an improper financial arrangement. Further, AGHS then submitted claims to federal healthcare programs for services rendered to these unlawfully referred patients in violation of the FCA.

This settlement also resolves claims brought under the *qui tam* provisions by the former Director of Internal Audit at AGHS.

3. Alliance Family of Companies LLC and Ancor Holdings LLP[20]

Alliance Family of Companies LLC ("Alliance"), a national electroencephalography (EEG) testing company, and Ancor Holdings LLP ("Ancor"), a private investment company and investor of Alliance, agreed to pay a combined total of $15.3 million to resolve allegations of misconduct that resulted in the submission of false claims to federal healthcare programs. Specifically, Alliance agreed to pay $13.5 million to resolve allegations that it caused the submission of false claims resulting from kickbacks to referring physicians and sought payment for work not performed or for which Alliance was entitled to a lesser reimbursement. Ancor agreed to pay $1.8 million to resolve allegations that, through its management agreement with Alliance, Ancor caused false billings as a result of the kickback scheme.

The government alleged that Alliance induced physicians to order its EEG tests by providing kickbacks in the form of free EEG test-interpretation reports, allowing certain physicians who were not specialized in the testing area to submit claims to the government as though they interpreted the results. The government also alleged that Alliance received increased reimbursements as a result of its use of inaccurate billing codes for certain EEG testing and billed for specialized digital analysis it did not perform. Of the $13.5 million payable by Alliance, roughly $13 million is payable to the federal government and $475,000 is payable to state Medicaid programs. However, Alliance must pay additional amounts if certain financial events occur and must forego claims to $390,000 in suspended payments otherwise owed by Medicare. Alliance also entered into a five-year CIA with the HHS-OIG.

The government alleged that Ancor learned of Alliance's kickback scheme during due diligence Ancor performed prior to its investment in Alliance and that Ancor

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[19] Press Release, U.S. Dep't of Justice, Northern Ohio Health System Agrees to Pay Over $21 Million to Resolve False Claims Act Allegations for Improper Payments to Referring Physicians (July 2, 2021).

[20] Press Release, U.S. Dep't of Justice, EEG Testing and Private Investment Companies Pay $15.3 Million to Resolve Kickback and False Billing Allegations (July 21, 2021).

caused the submission of false claims when it allowed such conduct to continue after entering into a management contract with Alliance. Of the $1.8 million payable by Ancor, $1.78 million is payable to the federal government and $64,000 is payable to state Medicaid programs.

This settlement also resolves claims brought in six lawsuits under the *qui tam* provisions.

V. CONCLUSION

These settlements illustrate DOJ's commitment to enforcing the FCA against not only offending corporate entities but also individuals and entities connected to and aware of the activities of offending entities (for instance, investors or successors-in-interest following a change in ownership).

More broadly, the 2021 settlements illustrate FDA's and DOJ's commitment to medical product safety, as well as their continued emphasis on ensuring patient safety by holding accountable those who compromise the medical care given to patients. DOJ also expects its enforcement practices to serve as a deterrent against others who may seek to misuse public funds.

Food and Drug Cases to Watch in 2022

JAMES M. BECK, RENE BEFURT, AUGUST T. HORVATH, WILLIAM JANSSEN & GINGER PIGOTT*

We asked our Top Cases chapter authors for their picks on which current litigations, regulatory actions, and other developments have the potential to change the food and drug landscape in the balance of 2022. Some of the cases described here are appeals or other forms of continuation of important cases discussed in preceding chapters in this volume; others represent new issues that may result in important new rulings and precedents.

BABY FOOD HEAVY METALS SUITS[1]

A February 2021 report released by the Subcommittee on Economic and Consumer Policy of the U.S. House of Representatives Committee on Oversight and Reform reported data from baby food manufacturers on concentrations of arsenic, lead, mercury, and cadmium in baby foods, concluding that seven major manufacturers of these products contained one or more of these metals at dangerous levels. The results were swift, predictable, and expensive for the companies involved, each of which became the subject of multiple suits that have been consolidated into joint proceedings.

The baby food metals cases are still in early stages, and the industry and legal communities will be watching for developments, whether in litigation or settlement, that will inform how companies in other issues deal with similar litigation fallout resulting from government reports.

ENVIRONMENTAL SUSTAINABILITY SUITS[2]

Several food and beverage companies recently have been the targets of suits seeking to hold them liable for the contributions of their plastic packaging to environmental pollution. In 2021, a suit in California against several such companies, which had been removed by the defendants to federal court, was remanded back to state court.[3] The Northern District of California judge ruled that the case, brought under California law, is appropriately litigated in the courts of that state. The court rejected the defendants' contention that the case invoked issues of "federal common law" regarding interstate

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* We extend extra thanks to these contributing authors to other chapters of this volume who also suggested and summarized cases to watch for this chapter.

1 *In re* Nurture Baby Food Litig., No. 1:21-cv-01217 (S.D.N.Y.); *In re* Gerber Prods. Co. Baby Food Litig., lead case No. 2:21-cv-01977 (D.N.J.); Stewart et al. v. Hain Celestial Grp. Inc., No. 2:21-cv-00678 (E.D.N.Y.); *In re* Plum Baby Food Litig., No. 4:21-cv-00913 (N.D. Cal); Tyler Baker et al. v. Walmart Inc., No. 3:21-cv-00182 (E.D. Ark.).

2 Earth Island Inst. v. Crystal Geyser Water Co. et al., No. 20-CIV-01213 (Super. Ct. Cal., San Mateo Cty.); Earth Island Inst. v. The Coca-Cola Co., No. 2021CA001846B (Super. Ct. D.C.).

3 Earth Island Inst. v. Crystal Geyser Water Co. et al., No. 20-CIV-2212-HSG (N.D. Cal.) (Order Granting Motion to Remand, Feb. 23, 2021).

pollution and public nuisance, although it did not go as far as to embrace the plaintiffs' position that federal common law on these topics no longer exists. As these cases wend their way through the courts, they will be observed closely for their implications for efforts to hold companies liable for environmental pollution involving their packaging.

AMARIN PHARMA V. HIKMA PHARM. U.S.[4]

In last year's Top Cases of 2020 volume, we reported on the *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA* ("*GSK*")[5] case holding that a skinny-labeled generic carvedilol drug product induced infringement of the relevant patent covering the carved-out method-of-use. The beginning of 2022 saw a decision in the District of Delaware in which the judge dismissed a similar case, holding that the specific facts and circumstances that led the Federal Circuit to find liability in *GSK* were absent in *Amarin*; in particular, defendant Hikma did not make the same kinds of statements encouraging physicians to use their drug for off-label uses that would infringe the manufacturer's patents. Merely identifying the generic drug as equivalent to the patented product, without more, was insufficient to trigger inducement of infringement liability, the court ruled.

In February 2022, the parties stipulated for the severing of the now-dismissed inducement claims against Hikma from the main infringement claims against other defendants and the entry of final judgment in favor of Hikma, so that the plaintiffs could immediately appeal the Hikma dismissal. The court declined to do so. The court also denied Amarin and Hikma's request for "a telephonic status conference to obtain the Court's guidance as to the preferred method for affording Amarin an opportunity to immediately appeal the Court's dismissal of the claims against Hikma."[6] It appears, then, that an appeal of the dismissal may have to wait until the conclusion of the case, if it is filed at all. Pharmaceutical industry observers will be tracking this case because of its potential impact on the new rule that was thought to be created by the Federal Circuit in *GSK*.

FOOD PRICE-FIXING CASES[7]

The year 2021 saw significant developments in several antitrust price-fixing cases involving the food industry. Dating back to 2019 and before, these cases allege the existence of old-school cartels in several prominent food areas and are the subject of multidistricted federal proceedings.

One set of cases involves broiler chickens, and the plaintiffs include prominent restaurant chains. They allege that the handful of companies that control 90% of this market have engaged in price fixing for a period of many years. On May 27, 2022, the Northern District of Illinois court handling the multidistricted action granted class certification to classes of direct purchasers, indirect purchasers, and end-user consumers. Portions of the case have already been settled out, including a $181 million settlement between end-user consumer plaintiffs and six of the defendants. Another

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4 No. CV 20-1630-RGA-JLH, D.I. 97 (D. Del. Jan. 4, 2022).

5 976 F.3d 1347 (Fed. Cir. 2020).

6 No. CV 20-1630-RGA-JLH (D. Del. Jan. 4, 2022) (Order on Misc. Motion, Apr. 1, 2022).

7 *In re* Broiler Chicken Antitrust Litig., No. 1:16-cv-08637 (N.D. Ill.) (chicken); *In re* Cattle Antitrust Litig., No. 0:19-cv-01222 (D. Minn.) (beef).

group of cases alleges that the four largest meat-packing companies engaged in a buyers' cartel to depress the prices of beef through collusive bidding and other tactics. The District of Minnesota court handling this case denied a motion to dismiss in September 2021.

These cases follow high-profile price-fixing actions against tuna producers that resulted in criminal convictions in 2019 against major tuna cannery executives, followed by private suits that were temporarily derailed in 2021 by a Ninth Circuit Court of Appeals ruling affirming decertification of a direct purchaser class. Re-hearing the appeal en banc, the Ninth Circuit in April 2022 re-certified the class.[8] Defendant StarKist has indicated that it may seek Supreme Court review of the class certification decision, contending that the decision split with other circuits on the question of whether a class can be certified notwithstanding a significant proportion of non-injured parties swept up in the definition of the class.

This wave of cartel litigation in the food sector may impact the way companies interrelate in many other food and non-food sectors, as well as setting new precedents in class certification and antitrust law. High-value settlements and/or verdicts associated these cases may make headlines later in 2022 and onward.

MALLORY V. NORFOLK SOUTHERN RAILWAY CO.[9]

The U.S. Supreme Court again intends to plunge back into the heady law of personal jurisdiction. This is a consent-based personal jurisdiction appeal. The plaintiff is a Virginia citizen employed by the defendant railway company. He alleged that he was injured when exposed to harmful carcinogens while working at the railway company's sites in Virginia and North Carolina. The railway company was incorporated in Virginia and has its principal place of business there. Plaintiff sued the railway company in Pennsylvania (nothing having to do with the lawsuit occurred there). The claimed basis for personal jurisdiction in Pennsylvania was consent. Like many states, Pennsylvania has enacted a statute that requires foreign corporations to register with the Commonwealth in order to do business there. But Pennsylvania's statute adds that such registration suffices to impart *general* personal jurisdiction over the registrant in the courts of Pennsylvania. (*General* or "all-purpose" jurisdiction allows a court to hear any claim against a defendant, regardless of where it arose.) The trial judge in this lawsuit and, later, Pennsylvania's unanimous Supreme Court ruled the legislature's statute unconstitutional. That holding evidently aligns Pennsylvania with every other state and federal court that has considered the question since 2014—except for Georgia. The plaintiff argues "turnabout is fair play" on corporations that have extracted forum consent from consumers for years. The railway company contends that national uniformity (save Georgia) shows that the country's judiciaries well understand the meaning of *Goodyear*, *Daimler*, and *BNSF* where the U.S. Supreme Court clarified that just "doing business" in a state cannot support an exercise of general personal jurisdiction (rather, the defendant must be "essentially at home" there for such sweeping jurisdiction to exist). This appeal will be heard during the Court's October 2022 Term.

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[8] Olean Wholesale Grocery Co-Op v. Bumble Bee Foods LLC, No. 19-56514 (9th Cir.) (Dkt. 186-1, Apr. 8, 2022).

[9] Docket No. 21-1168 (Sup Ct.).

OPIOID LITIGATION[10]

Recent decisions have erected obstacles to efforts by state Attorneys General to hold pharmaceutical companies responsible for America's opioid abuse academic. In November 2021, a California judge ruled that major drug manufacturers are not liable for California's opioid epidemic, rejecting claims of public nuisance, false advertising, and unfair competition. That same month, the Oklahoma Supreme Court overturned a $465 million bench trial verdict against Johnson & Johnson, ruling the state's public nuisance statute does not extend "to the manufacturing, marketing, and selling of prescription opioids." In the Oklahoma case, other defendants Purdue Pharma and Teva Pharmaceuticals previously had settled for $270 million and $85 million respectively, leaving Johnson & Johnson as the sole defendant.

Other opioid cases continue in courts around the country. Other states are free to find that their nuisance and other laws encompass the allegations of their Attorneys General or other opioid plaintiffs, but against the background of the California and Oklahoma decisions, defendant drug manufacturers have new hopes for successful defenses. Further trials in these cases will be watched closely.

ZANTAC MDL APPEALS[11]

In April 2022, three of the plaintiffs in the multidistricted litigation over the alleged presence of carcinogens in Zantac (ranitidine) heartburn medication argued their appeals before the Eleventh Circuit Court of Appeals. They are appealing the December 2020 ruling of a Southern District of Florida judge that brand-name manufacturers have no liability for allegedly inadequate warnings on generic equivalents of their products, sold by other drug manufacturers, as reported by Bill Janssen in last year's Top Cases volume. As Bill wrote, these cases could have wide applicability across the generic drug sector, and numerous industry participants and observers await the outcome of these appeals.

HEALTH FREEDOM DEFENSE FUND, INC. V. BIDEN[12]

The Biden Administration filed a Notice of Appeal April 20, 2022, of the ruling by a Southern District of Florida judge that its mandate that individuals wear masks on public transportation to prevent the spread of COVID-19 is beyond the legal authority of the Centers for Disease Control and Prevention (CDC), finding that Congress never gave CDC power that "extends far beyond it to population-wide preventative measures like near-universal mask requirements that apply even in settings with little nexus to interstate disease spread, like city buses and Ubers." At issue is whether the Public Health Services Act of 1944, authorizing CDC to issue regulations "necessary to prevent the introduction, transmission, or spread of communicable diseases," includes the authority to require the wearing of masks by passengers and employees in aircraft,

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[10] California v. Purdue Pharma LP et al., No. 2014-00725287 (Super. Ct. Cal., Orange Cty. Nov. 1, 2021); Oklahoma v. Johnson & Johnson et al., No.118,747, 2021 OK 54 (Okla. Nov. 9, 2021).

[11] Cartee v. Boehringer Ingelheim Pharms., Inc. et al., No. 21-10305 (11th Cir.); Williams v. Boehringer Ingelheim Pharms., Inc. et al., No. 21-10306 (11th Cir.); Plumbers & Pipefitters Local Union 630 v. GlaxoSmithKline LLC et al., No. 21-10335 (11th Cir.).

[12] No. 8:21-cv-1693-KKM-AEP (M.D. Fla.).

buses, trains, taxis, airports, bus and ferry terminals, and train and subway stations. The case has important implications for the extent of CDC's authority to enforce national public health measures for the prevention of COVID-19, which continues to spread in 2022, and any future disease outbreaks.

LACKS V. THERMO FISHER SCIENTIFIC INC.[13]

Lacks v. Thermo Fisher is an unjust enrichment suit filed in the District of Maryland in October 2021. The case concerns a line of replicated cells obtained from patient Henrietta Lacks during her cancer treatment in 1951 by a Johns Hopkins research physician. Known as "HeLa cells," an abbreviation of Ms. Lacks' name, these tissues were found to be exceptionally resilient and have been distributed freely for research by Johns Hopkins and, according to the university's web site, have "contributed to many medical breakthroughs, from research on the effects of zero gravity in outer space and the development of polio and COVID-19 vaccines, to the study of leukemia, the AIDS virus and cancer worldwide."[14] The suit, by Ms. Lacks' estate, alleges that Thermo Fisher profited unjustly from the tissue samples and genetic information taken without permission from Ms. Lacks, seeking disgorgement of all of the defendant's profits from sales of products developed using the HeLa cell line and for injunctive relief.

As of April 2022, the case was before the court on Thermo Fisher's motion to dismiss, with its high profile attracting amicus briefs from several public-interest organizations, including the National Women's Law Center and the Lawyers' Committee for Civil Rights Under Law. The amici favored the plaintiff in the suit, arguing for a right to recover for the alleged breach of doctor–patient duties "enabled by the historic, systemic disregard of legal principles regarding medical experimentation as to Black, low-income, and other systemically oppressed groups." Whatever the outcome of the motion and subsequent proceedings, the *Lacks* case will be monitored for its implications for the rights of patients in their tissues and genetic materials as used in scientific inquiry.

IN RE ROUNDUP PRODUCTS LIABILITY LITIGATION[15]

The long-running multidistricted litigation over alleged carcinogens in Monsanto's Roundup weed killer hit a bump in May 2021 when California federal judge Vince Chhabria rejected a $2 billion settlement as inadequate to compensate future victims who have not yet contracted or been diagnosed with cancer or who are otherwise not covered in the $9.6 billion settlement already reached with existing cancer patients. Judge Chhabria called the settlement "clearly unreasonable," citing the length of time that it can take to develop and be diagnosed with Hodgkin lymphoma, and concluded that the deal was too favorable for defendant Monsanto. This decision exemplifies a recent trend toward more active judicial review of the fairness of class settlements.

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[13] No. 1:21-cv-02524 (D. Md.).

[14] *The Importance of HeLa Cells*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/henriettalacks/importance-of-hela-cells.html.

[15] No. 3:16-md-02741 (N.D. Cal.).