Top Food and Drug Cases, 2019, & Cases to Watch, 2020

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Introduction

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"May you live in interesting times" is often said to be an ancient curse from China. This is untrue; the expression appears to have originated with British politicians in the 1930s. False designation of origin aside, however, the year 2020 has been interesting in precisely the ill-favored sense meant by the expression. Interesting circumstances forced the postponement of much of the work done by many organizations, including FDLI, and including specifically this volume. Most of the chapter manuscripts for the 2019 volume of FDLI's annual roundup of the most important and interesting legal controversies affecting the food and drug industries had been submitted by March, when so much in U.S. society suddenly changed. After a hiatus of work on this volume and careful consideration, we decided, when FDLI's 2020 Annual Meeting was rescheduled to October, that despite most of a year having passed since the end of 2019, the excellent contributions of our team of knowledgeable and experienced practitioners still deserved publication, at least in electronic form. Updated where necessary, they will be of immediate interest to practitioners and, we hope, like past volumes, will earn a permanent place on food and drug attorneys' bookshelves—even if only their virtual shelves—as a permanent record of cases whose influence will endure.

As in the past, contributors from diverse backgrounds have each nominated and described a chosen case for this book. FDA enforcement actions usually figure prominently in our roundup, and this year, Anne Walsh and Sara Koblitz describe the D.C. District Court's ruling limiting the FDA's freedom to designate a product as either a "drug" or "device" in accordance with its enforcement preferences. James Beck covers an important new preemption case in pharmaceutical product liability, a subject that seems to come up reliably in issues of this volume. Lynn Tyler covers the first case in which the Federal Trade Commission sought judicial relief for an alleged abuse of the citizen petition process as a tactic for delaying generic entry. Dan Logan discusses a landmark Supreme Court ruling that appears to lower the bar for resisting Freedom of Information Act requests by demonstrating that the information sought is confidential. Ralph Hall reports on an important appellate decision on the Trump administration's attempt to require disclosure of wholesale prescription drug prices in television advertisements. Jacqueline Chan describes a food company's challenge to a state law seeking to define the meaning of a traditional meat so as to restrict its use by marketers of plant-based alternatives. Mital Patel discusses the Ninth Circuit's *en banc* review of a First Amendment challenge to a California ordinance mandating large health warnings on outdoor signage advertising sugar-sweetened beverages. On the private class-action side, Bill Janssen covers an important ruling on causation in product liability cases, and I describe the Ninth Circuit's elucidation of the "reasonable

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consumer" standard as it pertains to the likelihood of consumers being misled by beverage labels.

We welcome Justine Johnson to our crew of authors with her summary of significant settlements in 2019, and Lauren Farruggia and Jonathan Havens describe important regulatory and enforcement developments from the past year. In recognition that not much of the year 2020 is left as this volume goes to press, we have curtailed our joint coverage of cases to watch in 2020 for this volume, but we do cover two important appellate cases on which action is expected in what remains of 2020 or in early 2021.

We hope this belated roundup of the most important 2019 decisions in the food and drug area provides you with the same education and enjoyment as our previous volumes, and we look forward, hopefully without excessive optimism, to a return to our traditional format and publication timetable in 2021. Unlike many activities in society, activity in many legal and regulatory arenas was not much reduced in 2020, so we expect to have much more to fill you in on.

Genus Medical Technologies, LLC v. U.S. Food and Drug Administration

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WHY THIS CASE MADE THE LIST

For more than twenty years, the U.S. Food and Drug Administration's ("FDA's" or "the Agency's") position has been that it could regulate a product as either a drug or a medical device as long as the product meets both statutory definitions. The implications of this approach, however, lead to a significantly more onerous regulatory standard for products that, based on FDA's self-granted whim, FDA deems to be a drug rather than a medical device. In *Genus Medical Technologies v. FDA*, the U.S. District Court for the District of Columbia rejected FDA's long-held position and limited FDA's discretion with respect to product classification.

The Court, relying on the plain language of the definitions for "drug" and "device" set forth in the Federal Food, Drug, and Cosmetic Act ("FDCA"), rejected the position that FDA "could classify *any* diagnostic device as a drug because no limiting principle would trammel its authority."[1] The Court mandated FDA to regulate as a device any product that meets the statutory definition in the FDCA.[2] This case is a good example of a federal court limiting the deference it gives to FDA where the plain meaning of the FDCA places strict limits on FDA's administrative decisions.

DISCUSSION

Legal Background

The FDCA, initially enacted in 1938, provides statutory authority for FDA to oversee the safety of food, drugs, medical devices, and cosmetics.[3] Amended many times over the last eighty years, the FDCA eventually established separate regulatory schemes for products regulated by FDA.[4] Under the FDCA, products are classified

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1 Memorandum Opinion, Genus Medical Tech., LLC v. U.S. Food and Drug Admin., No. 19-544, 2019 U.S. Dist. LEXIS 210397, at *13 (D.D.C. Dec. 6, 2019) [hereinafter Memorandum Opinion].

2 *See id.* at *13–14.

3 Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

4 *Compare, e.g.,* 21 U.S.C. subchapters IV to 21 U.S.C. subchapters V and VI.

and regulated based on the statutory definitions governing each type of product that falls under FDA's purview.[5]

As it stands now, the FDCA sets forth two dramatically different regulatory schemes for drugs and devices based on their respective statutory definitions. Though both drugs and devices are "intended for use in the diagnosis of disease or other conditions," in the "cure, mitigation, treatment, or prevention of disease," or "to affect the structure or function of the body of man or other animals," Congress provided a key statutory distinction based on how a particular product achieves its intended purpose.[6] Specifically, a device "does not achieve its primary intended purposes through chemical action within or on the body of man or other animals" and "is not dependent upon being metabolized for the achievement of its primary intended purposes."[7]

Drugs and devices are subject to different regulatory schemes, with the drug pathway being significantly more onerous and expensive. User fees alone for a generic drug are approximately $200,000 or more[8] compared to only around $7,600 for devices.[9] Drugs are also subject to a more rigorous pre-market review process, as well as different post-market compliance requirements. Given these differences, the jurisdictional designation of a product is of great importance.

Factual Background

Genus manufactures a line of affordable barium sulfate oral solution contrast agents, Vanilla SilQ, which patients ingest prior to undergoing radiographic procedures. Barium sulfate has been used safely as a contrast agent for more than fifty years.[10] The product coats the inside of the esophagus, stomach lining, or intestine, and absorbs x-rays, which provides contrast in the resulting images that permits radiologists to better visualize the gastrointestinal tract. Barium sulfate is neither absorbed nor metabolized when used as a contrast agent.[11]

Initially classified as a device in the 1970s, FDA announced in July 1997 in response to several Citizen Petitions that all contrast agents—without specific reference to barium sulfate—would henceforth be regulated as drugs rather than devices, regardless of their physical properties and intended use, for purposes of administrative efficiency and regulatory consistency.[12] For nearly twenty years, between 1997 and 2016, there was no further regulatory activity related to barium sulfate. And in 2016, FDA approved Bracco Diagnostics Inc.'s ("Bracco's") seven versions of barium sulfate as drug products.

In 2017, FDA sent Genus a Warning Letter asserting that because all contrast agents are drugs, its products were unapproved "new drugs" under the FDCA and therefore

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5 *See, e.g.*, 21 U.S.C. § 321(f), (g)(1), (g)(2), (h), (i).

6 *See* 21 U.S.C. § 321(g) (defining "drug"), (h) (defining "device").

7 21 U.S.C. § 321(h).

8 Generic Drug User Fee Rates for Fiscal Year 2019, 83 Fed. Reg. 35649 (July 27, 2018).

9 Medical Device User Fee Rates for Fiscal Year 2019, 83 Fed. Reg. 36598 (July 27, 2018).

10 *See, e.g.*, Barimex, 510(k) Premarket Notification, K760736 (Nov. 9, 1976).

11 Ex. E to Decl. of Ed Powers, Genus Medical Technologies, LLC v. U.S. Food and Drug Administration, No. 19-544, at *4 (D.D.C. May 29, 2019).

12 *See* FDA, Consolidated Response to Pending Citizen Petitions on the Regulation of Ultrasound Contrast Agents, Docket No. 96P-0511, at 53 (July 25, 1997).

subject to the resource-intensive drug approval process and misbranded as currently marketed.[13] Genus responded with its position that barium sulfate met the statutory definition of "device" and therefore must be regulated as such.[14] While FDA agreed that the relevant products met the FDCA definition of "device," FDA posited that it had discretion to regulate them as drugs because they also met the statutory "drug" definition, citing the overlap in the statutory definitions of "drug" and "device."[15] FDA argued that it must regulate contrast agents uniformly, and because all contrast agents meet the definition of "drugs" but not necessarily "devices," FDA would regulate them all as devices in accordance with its response to the 1997 Citizen Petition.[16]

Genus appealed internally within FDA by submitting a Request for Designation, but after receiving the same response, Genus sued FDA in the U.S. District Court for the District of Columbia.[17] Genus alleged that FDA's decision to regulate its Vanilla SilQ barium sulfate products as drugs rather than medical devices violated both the FDCA and Administrative Procedure Act ("APA"). Genus first argued that FDA failed to make a classification decision when it determined that Vanilla SilQ should be regulated as a drug. Genus also argued that FDA's interpretation of the "overlap" in the statutory definitions of "drug" and "device" violates the plain language of the FDCA and therefore was arbitrary and capricious in violation of the APA.

Court Decision

In May 2019, Genus filed a motion for summary judgment seeking a declaration requiring FDA to regulate Genus's Vanilla SilQ products as devices; in July 2019, FDA countered with a cross-motion for summary judgment requesting affirmation of its classification of barium sulfate as a drug.[18] On December 6, 2019, the Honorable James E. Boasberg granted Genus's motion for summary judgment, vacated FDA's classification of Vanilla SilQ as a drug, and remanded the classification back to FDA for further administrative proceedings consistent with the Court's decision.[19]

FDA argued in its motion that the FDCA provides FDA discretion to regulate any product meeting the definition of "device" as a drug, notwithstanding the distinct statutory definitions and regulatory schemes that Congress adopted for each product.[20] The FDCA, in relevant part, defines "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."[21] It defines "device" to have the same intended purpose, but provides a key statutory distinction: a device does not achieve "its primary intended purposes through chemical action within or on the body of man" and "is not dependent upon being

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[13] Memorandum Opinion, *supra* note 1, at *6–7.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] Complaint, Genus Medical Technologies, LLC v. U.S. Food and Drug Administration, No. 19-544 (D.D.C. Feb. 28, 2019).

[18] Motion for Summary Judgment, Genus Medical Technologies, LLC v. U.S. Food and Drug Administration, No. 19-544 (D.D.C. May 30, 2019).

[19] Memorandum Opinion, *supra* note 1, at *20.

[20] Cross-Motion for Summary Judgment, Genus Medical Technologies, LLC v. U.S. Food and Drug Administration, No. 19-544 (D.D.C. July 11, 2019) [hereinafter Cross-Motion for Summary Judgment].

[21] 21 U.S.C. § 321(g)(1).

metabolized for the achievement of its primary intended purposes."[22] But because the two definitions both include articles "intended for use in the diagnosis" of disease, FDA asserted that all articles meeting the definition of a "device" also meet the definition of a "drug."[23] Under this interpretation, FDA boldly declared that it could choose—based on regulatory convenience or any other unenumerated consideration—whether to regulate any particular medical device as a drug.

In granting Genus's motion for summary judgment, the court rejected FDA's attempt to regulate Vanilla SilQ barium sulfate products as a drug, finding that the product plainly meets the definition of a device.[24] Specifically, Judge Boasberg held that FDA's theory of unfettered discretion to regulate devices as drugs contradicts the plain language of the FDCA. Relying on the canons of statutory interpretation, the Court held that FDA's interpretation that the diagnostic product is a drug—even if it plainly falls under the device definition—would render superfluous the device definition in the statute. Indeed, Judge Boasberg explained that the drug-device distinction would be meaningless under FDA's interpretation:

If a product that meets both definitions is nonetheless treated as a drug, then the device-drug distinction would be rendered meaningless. Put otherwise, the FDA could classify *any* diagnostic device as a drug because no limiting principle would trammel its authority. That would turn the statutory scheme on its head.[25]

Employing Step 1 of the framework established by *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, the landmark Supreme Court decision on application of statutory terms by administrative agencies,[26] Judge Boasberg determined that "[i]n the end, the plain text dictates the result here. Congress readily could have afforded the agency discretion to determine which of these pathways a product must take . . . . But it did not do so here."[27]

Judge Boasberg rejected FDA's argument that any overlap in the definitions implicitly grants the Agency discretion to decide whether to regulate a product as a device or a drug. FDA based its argument on the evolution of the drug and device definitions; the FDCA once explicitly excluded devices from the definition of drug but was redrafted to remove that express exclusion. FDA argued that this revision awarded the Agency the discretion it sought, but Genus pointed out that this revision was made only to enable combination drug/device products to be regulated as drugs where appropriate. The Court, once again, agreed with Genus, stating "Congress's intent was not—as the FDA would have the Court believe—to delegate unfettered discretion to the FDA to regulate all devices as drugs."[28] The Court also rejected FDA's reliance on case law (predominantly *Bracco Diagnostics, Inc. v. Shalala*[29]) that implicitly granted FDA the discretion it sought, as those cases arose in different contexts and under

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[22] *Id.* § 321(h)(3).

[23] Cross-Motion for Summary Judgment, *supra* note 20, at 9.

[24] Memorandum Order, *supra* note 1, at *14.

[25] *Id.* at *13.

[26] Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984).

[27] Memorandum Order, *supra* note 1, at *14.

[28] *Id.* at *16; *see also id.* at *20 ("In sum, *Bracco* does not suggest that the FDA can ignore the plain language of the FDCA; it does not have discretion to regulate all contrast agents uniformly, irrespective of their defining features under the statute.").

[29] 963 F. Supp. 20 (D.D.C. 1997).

different permutations of the drug and device definitions.[30] In the end, the Court held that such discretion is not implicitly in the statute nor is the statute ambiguous enough to support such an interpretation.

Thus, the court granted Genus's motion for summary judgment and held that "a product that meets the device definition must be regulated as such."[31]

IMPACT OF THE DECISION

This case expressly limits FDA's regulatory discretion, which in and of itself is significant because courts generally defer to an agency when questions of technical or regulatory procedure arise.

But here, the Court stepped in to curb significant overreach by FDA. Indeed, FDA's assertion was so breathtakingly broad that it would have left the medical device industry in a state of uncertainty, rendering the entire distinction between drugs and devices meaningless. But the distinction between a drug and a device is a critical one, and one with substantive financial and practical implications.

The U.S. Department of Justice filed its Notice of Appeal at the end of January 2020.[32] As of the time this paper was submitted for publication, the United States Court of Appeals for the D.C. Circuit set a briefing schedule through August 6, 2020.

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[30] *Id.* at *18–19.

[31] *Id.* at *14.

[32] Notice of Appeal, Genus Medical Tech., LLC v. U.S. Food and Drug Admin., No. 20-5026 (D.C. Cir. filed Jan. 31, 2020).

Merck Sharp & Dohme Corp. v. Albrecht[1]

JAMES M. BECK[2]

WHY IT MADE THE LIST

Since 2008, parties to pharmaceutical product liability cases have struggled with the "clear evidence" implied preemption standard articulated by the United States Supreme Court in *Wyeth v. Levine*.[3] In cases of allegedly inadequate warnings about FDA-approved prescription drugs, *Levine* rejected the contention that FDA approval, by itself, preempted state-law warning-based claims. Preemption could occur, *Levine* held, if "the FDA would not have approved" the label that the plaintiff claim state law required, so that simultaneous compliance with state and federal law would be "impossible."[4]

Following *Levine*, courts varied in the rigor with which they applied the "would not have approved" standard described by the Supreme Court. However, in those situations where FDA had actually rejected the warning being advocated by the plaintiff, most courts held that such warning claims was preempted.[5] Another area of general agreement was that preemption generally, and the question of what FDA "would have" done in particular, was a question of law for courts, as opposed to juries, to determine.[6]

However, in *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F.3d 268 (3d Cir. 2017), the Third Circuit departed from both of these points of post-*Levine* consensus and imposed a standard for impossibility preemption that was effectively impossible to meet. Preemption in *Fosamax* had been recognized by the lower court because "approximately one month" after the plaintiff's injury, "FDA sent

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[1] ___ U.S. ___, 139 S. Ct. 1668 (U.S. 2019).

[2] James M. Beck is a Senior Life Sciences Policy Analyst at Reed Smith LLP.

[3] 555 U.S. 555 (2009) ("Levine").

[4] *Id.* at 571.

[5] Cerveny v. Aventis, Inc., 855 F.3d 1091, 1101–03 (10th Cir. 2017); Rheinfrank v. Abbott Laboratories, 680 F. Appx. 369, 386 (6th Cir. 2017); Chambers v. Boehringer Ingelheim Pharm., Inc., 2018 WL 849081, at *4–5 (M.D. Ga. Jan. 2, 2018); Amos v. Biogen Idec, Inc., 249 F. Supp.3d 690, 699–700 (W.D.N.Y. 2017); Willis v. Abbott Laboratories, 2017 WL 5988215, at *4 (W.D. Ky. Dec. 1, 2017); Swanson v. Abbott Laboratories, 2017 WL 5903362, at *7–8 (S.D. Ohio Nov. 28, 2017); Christison v. Biogen Idec, Inc., 199 F. Supp.3d 1315, 1347–48 (D. Utah 2016); *In re* Depakote, 87 F. Supp.3d 916, 921–23 (S.D. Ill. 2015); Cleary v. Biogen, Inc., 2017 WL 4126240, at *5–6 (Mass. Super. Sept. 13, 2017); Gentile v. Biogen Idec, Inc., 2016 WL 4128159, at *8 (Mass. Super. July 25, 2016).

[6] Guilbeau v. Pfizer, Inc., 880 F.3d 304, 318 (7th Cir. 2018); *Cerveny*, 855 F.3d at 1096; Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1343 (10th Cir. 2015); *In re* Pharm. Industry Average Wholesale Price Litigation, 582 F.3d 156, 173 (1st Cir. 2009); Lofton v. McNeil Consumer & Specialty Pharm., 672 F.3d 372, 375 (5th Cir. 2012); Risperdal & Invega Product Liability Cases, 2017 WL 4100102, at *7 (Cal. Super. March 16, 2017).

Defendant a letter approving the change to the Adverse Reactions section of the label but denying the change to the Precautions section."[7]

The Third Circuit vacated and remanded, while addressing the "cryptic and open-ended" nature of the "clear evidence" preemption inquiry under *Levine*.[8] The Third Circuit viewed "clear evidence" as an "undefined" "anomaly."[9] To address this anomaly, the Third Circuit first equated *Levine's* reference to "clear evidence" with the heightened "clear and convincing" standard of proof.[10] However, imposition of a more stringent burden of proof was at odds with United States Supreme Court precedent, which rejected heightened implied preemption standards of proof.[11] Second, in a singular result, ignoring prior in-circuit precedent,[12] *Fosamax* held that the "counterfactual" preemption question of whether FDA would have rejected the plaintiff's proposed label change was a question of fact for the jury, not an issue of law for the judge.[13] Under *Fosamax*, had that decision stood, "[a] state-law failure-to-warn claim will only be preempted if a jury concludes it is highly probable that the FDA would not have approved a label change."[14] The likelihood of summary judgment on preemption was even more remote, available only when no "reasonable juror, looking at all the evidence and trying to reconstruct a hypothetical event, could conclude that it is less than highly probable that the FDA would have rejected the change."[15]

The defendant appealed to the United States Supreme Court, and on June 28, 2018, the Supreme Court granted *certiorari*.[16]

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[7] *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., 951 F. Supp.2d 695, 702 (D.N.J. 2013) (citation omitted).

[8] 852 F.3d at 282.

[9] *Id.* at 284.

[10] *Id.* at 285 (noting that to establish impossibility preemption by clear evidence, "[t]he manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, as in most civil cases," but by "clear and convincing evidence").

[11] Geier v. Am. Honda Motor Co., 529 U.S. 861, 870 (2000) ("Neither do we believe that the pre-emption provision, the saving provision, or both together, create some kind of 'special burden' beyond that inherent in ordinary pre-emption principles—which 'special burden' would specially disfavor pre-emption here.").

[12] Two of those prior decisions, *Fosamax* dismissed as "offhand" rulings. 852 F.3d at 288 & n.106 (disregarding rulings in *In re* Federal-Mogul Global Inc., 684 F.3d 355, 364 n.16 (3d Cir. 2012), and Horn v. Thoratec Corp., 376 F.3d 163, 166 (3d Cir. 2004)). However, many more such rulings existed. *See* South Jersey Sanitation Co. v. Applied Underwriters Captive Risk Assurance Co., 840 F.3d 138, 143 (3d Cir. 2016); Roth v. Norfalco LLC, 651 F.3d 367, 374 (3d Cir. 2011); Elassaad v. Independence Air, Inc., 613 F.3d 119, 124 (3d Cir. 2010); Deweese v. Nat'l R.R. Passenger Corp., 590 F.3d 239, 244 n.8 (3d Cir. 2009); Orson, Inc. v. Miramax Film Corp., 189 F.3d 377, 380 (3d Cir. 1999) (en banc); Taj Mahal Travel, Inc. v. Delta Airlines, Inc., 164 F.3d 186, 190 (3d Cir. 1998); Travitz v. Northeast Dep't ILGWU Health & Welfare Fund, 13 F.3d 704, 708 (3d Cir. 1994); Pennsylvania Med. Soc'y v. Marconis, 942 F.2d 842, 846 (3d Cir. 1991); Ayers v. Philadelphia Hous. Auth., 908 F.2d 1184, 1188 (3d Cir. 1990); Pokorny v. Ford Motor Co., 902 F.2d 1116, 1119 (3d Cir. 1990).

[13] 852 F.3d at 297. The rationale for this ruling was that, since the preemption question involved the likelihood of a future event, the decision maker had to weigh conflicting evidence, draw inferences, and assess the motives and thought processes of FDA officials. *Id.* at 289–91.

[14] *Id.* at 293.

[15] *Id.* at 297.

[16] Merck Sharp & Dohme Corp v. Albrecht, 138 S. Ct. 2705 (2018).

DISCUSSION OF THE FACTS, HOLDING, AND RATIONALE

Fosamax is an FDA approved prescription drug made by defendant Merck Sharp & Dohme Corp. ("Merck"). This drug was FDA approved for prevention and treatment of osteoporosis in postmenopausal women.[17] Fosamax is one of a class of drugs, called bisphosphonates, whose chemical properties allow them to retard the resorption of calcium in post-menopausal women's bones, thereby maintaining bone strength and mass. Retarding calcium loss unfortunately has some drawbacks, alleged by plaintiffs, that over the long term can lead to "microcracks" that increase the otherwise very low risk of "atypical" femoral fractures ("AFF").[18] That risk is what the *Fosamax* litigation is about.

This risk of AFF from long-term Fosamax use had also been the subject of FDA review, which gave rise to Merck's preemption defense. The initial labeling for Fosamax, following its 1995 FDA approval, did not mention AFF."[19] In 2008, Merck submitted a safety update addressing AFF and, based on some recent medical articles, suggested there might be association between long-term bisphosphonate use and AFF, which it called "stress fractures."[20]

FDA did not act before Merck filed a new drug application (NDA) supplement, seeking FDA approval to add AFF-related language to the label that did not confirm causation. Substantial dialogue with FDA ensued, with FDA looking toward classwide labeling for all bisphosphonates. Ultimately, in May 2009, FDA formally approved changes to the Adverse Reactions section but rejected the rest of Merck's NDA supplement.[21]

The FDA explained that the defendant's "justification" for the proposed change to the Precautions section was "inadequate" because "[i]dentification of 'stress fractures' may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature." FDA invited Merck to "resubmit" its application and to "fully address all the deficiencies listed."[22]

Defendant instead withdrew its application, which according to the majority meant that the label was unchanged until 2011, when FDA completed its own investigation and mandated language that referenced AFF rather than stress fractures.[23]

As in *Levine*,[24] the majority in *Albrecht* was accused of playing fast and loose with the facts to minimize the basis for preemption.[25] Justices concurring in the result in *Albrecht* mentioned a number of additional facts: (1) at the time the label change was pending, AFF was still considered a form of "stress fracture"; (2) also while the label

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[17] Merck Sharp & Dohme Corp. v. Albrecht, ___ U.S. ___, 139 S. Ct. 1668, 1673, 203 L. Ed. 2d 822 (2019) ("*Albrecht*").

[18] *Id.* at 1673–74. *See* Eve Donnelly, Anas Saleh, Aasis Unnanuntana & Joseph M. Lane, *Atypical Femoral Fractures: Epidemiology, Etiology, and Patient Management*, 6(3) CURRENT OPINION SUPPORT PALLIATIVE CARE 348 (Sept. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556525/.

[19] *Albrecht*, 139 S. Ct. at 1674.

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.* at 1674-75.

[24] 555 U.S. at 613-19.

[25] *Albrecht*, 139 S. Ct. at 1685 (Alito, J, for the Chief Justice and Kavanaugh, J.).

change was pending, FDA took the position that "the data that FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of" AFF; (3) in 2010, an FDA task force again found "no established causal association" between bisphosphonates and AFF; and (4) FDA's amicus brief in *Albrecht* confirmed that "FDA's decision not to require a label change prior to October 2010 reflected the [Agency's] determination that a new warning should not be included in the labeling."[26]

The Supreme Court unanimously reversed the Third Circuit's legal rulings but did not reach the ultimate preemption question. All nine justices agreed that preemption is "a question of law, normally for a judge to decide without a jury."[27] "We here decide that a judge, not a jury, must decide the pre-emption question."[28] Further, "where we have determined that the question is 'for the judge and not the jury,' we have also held that 'courts may have to resolve subsidiary factual disputes' that are part and parcel of the broader legal question."[29] *Albrecht* analogized to patent cases, where courts have long decided any subsidiary factual issues involved in patent construction.[30]

The majority gave several reasons: preemption "involves the use of legal skills"; "judges . . . are better equipped" both "to evaluate the nature and scope of an agency's determination" and "to understand and to interpret agency decisions"; "judges are normally familiar with principles of administrative law"; and "uniformity is . . . a virtue" when "determin[ing]" the "scope and effect" of the nationally applicable decisions of a federal agency.[31]

As a consequence of preemption being a legal question, the second aspect of the Third Circuit's decision—the heightened burden of proof—became a non-issue. When deciding preemption as a legal question, "the judge must simply ask himself or herself whether the relevant federal and state laws irreconcilably conflict."[32] Also of general consequence, *Albrecht* marks the Supreme Court's first recognition of overwarning as a legitimate FDA concern. "Label information is designed to 'prevent overwarning' so that less important information does not 'overshadow' more important information."[33]

Specifically with respect to prescription drugs, *Albrecht* reiterated that the boundaries of implied impossibility preemption remain tied to a manufacturer's ability to use an FDA regulatory process permitting certain label changes without prior FDA approval. "[A]n FDA regulation called the 'changes being effected' or 'CBE'

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[26] *Id.* at 1685–86 (citations and quotation marks omitted).

[27] *Id.* at 1679. Similarly, Justice Alito's concurrence stated, "I agree with the Court's decision on the only question that it actually decides, namely, that whether federal law allowed [defendant] to include in the [drug] label the warning alleged to be required by state law is a question of law to be decided by the courts." *Id.* at 1684.

[28] *Id.* at 1676.

[29] *Id.* at 1680 (quoting Teva Pharm. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 135 S. Ct. 831, 838 (2015)).

[30] *Id.* at 1679–80 (relying on Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996)).

[31] *Id.* at 1679–80 (citations omitted).

[32] *Id.* at 1679 (citations and quotation marks omitted).

[33] *Id.* at 1673 (quoting 73 Fed. Reg. 49603, 49605–06 (FDA Aug. 22, 2008) & 73 Fed. Reg. 2848, 2851 (FDA Jan. 16, 2008)). *See* Ridings v. Maurice, 444 F. Supp. 3d 973, 992 (W.D. Mo. 2020); Sabol v. Bayer HealthCare Pharm., Inc., 439 F. Supp. 3d 131, 147 (S.D.N.Y. Feb. 12, 2020); McGrath v. Bayer HealthCare Pharm., Inc., 393 F. Supp. 3d 161, 169 (E.D.N.Y. 2019); Klein v. Bayer HealthCare Pharm., Inc., 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019) (all discussing overwarning post-*Albrecht*).

regulation permits drug manufacturers to change a label without prior FDA approval if the change . . . 'add[s] or strengthen[s] a . . . warning where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm."[34] The Court also emphasized that only agency actions constituting "law" for Supremacy Clause purposes have preemptive effect.[35] These actions include "notice-and-comment rulemaking," "formally rejecting a warning label," and any "other agency action carrying the force of law."[36] Where "the CBE regulation permits changes . . . a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both."[37]

Although the only issue actually decided by *Albrecht* was that preemption was a question of law,[38] the majority did "elaborate"[39] on the criteria for "clear evidence" of impossibility preemption in cases "like" *Levine*.[40] Concerning the *Levine* formulation that "clear evidence that the FDA would not have approved a change to [the drug's] label," being required for impossibility preemption,[41] the majority opined:

> In a case like [*Levine*], showing that federal law prohibited the drug manufacturer from adding a warning that would satisfy state law requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning.[42]

The "question of [FDA's] disapproval 'method' [was] not now before" the Court in *Albrecht*, so that aspect of preemption was not addressed.[43]

IMPACT

The greatest impact of *Albrecht* will be on preemption itself. The Court's rationale is not limited to any particular form of preemption. Disputes involving compliance with the FDCA in preemption cases will be resolved by judges whether they arise in the context of implied preemption, as in *Albrecht*, or in a determination of express

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[34] *Albrecht*, 139 S. Ct. at 1673 (quoting 21 C.F.R. §314.70(c)(6)(iii)(A)).

[35] *Id.* at 1679.

[36] *Id.* (citing, *inter alia*, 21 U.S.C. §355(o)(4)(A)). This regulatory provision requires that FDA "shall promptly notify" a manufacturer whenever the Agency "becomes aware of new information . . . that the Secretary determines should be included in the labeling of the drug." Thus, "the only agency actions that can determine the answer to the preemption question . . . are agency actions taken pursuant to the FDA's congressionally delegated authority." *Albrecht*, 139 S. Ct. at 1672, 1679.

[37] *Id.* at 1679.

[38] *See* Dolin v. GlaxoSmithKline LLC, 951 F.3d 882, 891 (7th Cir. 2020) ("[I]n *Albrecht*, the principal holding was that the 'clear evidence' standard for the impossibility preemption defense is a question of law for a court to decide.").

[39] *Albrecht*, 139 S. Ct. at 1676.

[40] *Id.* at 1678.

[41] *Levine*, 555 U.S. at 571.

[42] *Albrecht*, 139 S. Ct. at 1678.

[43] *Id.* at 1679.

preemption. This ruling should have significant effect in medical device express preemption cases, where "parallel claims" alleging FDCA violations are the primary means to avoid preemption.[44] Preemption being a legal issue should also reduce both sides' reliance on regulatory experts in preemption cases, since experts are not permitted to opine on questions of law,[45] and one court has already so held.[46]

The determination that preemption is solely a legal issue, including resolution of "contested brute facts,"[47] should also impact how courts address preemption questions. In patent cases, for instance, dispositive motions involving patent construction are decided without a weighted viewing of the facts most favorably to the non-moving party.[48] Also, on appeal, judicial factfinding in patent cases cannot be overturned unless the trial court's result is "clearly erroneous."[49] The same level factual playing field may become the norm in preemption determinations as well. Finally, interlocutory appeal of preemption decisions may become more available, since the purely legal question of preemption is no longer tied to any jury's ultimate resolution of litigation.

The majority's emphasis on formal regulatory actions alone having preemptive effect will circumscribe the universe of possible FDA actions that defendants can assert as a basis for preemption. Informal give and take between manufacturers and the agency are insufficient, so potential defendants will have to utilize more formal avenues if they anticipate future reliance on FDA actions as preemptive.[50] The preemptive effect of FDA guidance documents is questionable under this standard, as are warning letters and other preliminary FDA enforcement activity—none of which

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[44] *See* Delfino v. Medtronic, Inc., 2019 WL 2415049, at *10 (Minn. App. June 10, 2019) (express preemption case; "the issue of whether [something] constituted a federal requirement is a question of law to be decided by a judge"); Conley v. St. Jude Med., LLC, ___ F. Supp. 3d ___, 2020 WL 5087889, at *8 (M.D. Pa. Aug. 28, 2020) (express preemption case; "Preemption is a matter of law.").

[45] *See*, *e.g.*, Burkhart v. Washington Metro. Area Transit Auth., 112 F.3d 1207, 1213 (D.C. Cir. 1997) ("Each courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards.").

[46] *Delfino*, 2019 WL 2415049, at *12 ("determining compliance with a regulation . . . is a question of law"; "expert opinion as to a legal matter is generally inadmissible," so trial court "did not abuse its discretion by prohibiting [plaintiff's expert] from opining on a legal question").

[47] *Id.* at 1680.

[48] Business Objects, S.A. v. Microstrategy, Inc., 393 F.3d 1366, 1371–72 (Fed. Cir. 2005); Searfoss v. Pioneer Consol. Corp., 374 F.3d 1142, 1148 (Fed. Cir. 2004); Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001).

[49] The Court so held in the *Teva v. Sandoz* decision cited in *Albrecht*. *See* 135 S. Ct. at 836–37. *See* Obasi Inv. Ltd. v. Tibet Pharm., Inc., 931 F.3d 179, 188 n.9 (3d Cir. 2019) (applying "clearly erroneous" standard under *Albrecht*).

[50] *Albrecht*'s "language could be understood as indicating that less formal exchanges of correspondence . . . are not enough to provide such 'clear evidence.'" *Dolin*, 951 F.3d at 890. *See In re* Avandia Mktg., Sales & Prods. Liab. Litig., 945 F.3d 749, 760 (3d Cir. 2019) ("informal phone conversations with an FDA official" could not support preemption after *Albrecht*); Crockett v. Luitpold Pharm., Inc., 2020 WL 433367, at *7–8 (E.D. Pa. Jan. 28, 2020) (inconsistent FDA "non-approvable letters" not preemptive).

are, in and of themselves, legally binding.[51] Any form of "formal" FDA activity, however, retains preemptive force.[52]

Finally, every clause of *Albrecht*'s "like" *Levine* "elaboration" on the "clear evidence" standard for implied impossibility preemption will generate legal arguments, as product liability plaintiffs utilize every available avenue to escape preemption. "*Albrecht* is better understood as a clarification of the impossibility standard in [*Levine*] rather than as a repudiation of it."[53] Perhaps most significantly in this regard, unlike *Levine*:

> In *Albrecht*, the Court wrote that the "clear evidence" needed is "evidence . . . that the FDA, in turn, . . . would not approve a change to the drug's label. . . ." That language implies that the manufacturer must have actually requested a change and that the FDA rejected it.[54]

Albrecht's "elaboration" also refers to warning changes advanced by "manufacturers," so whether impossibility preemption can be based on the results of formal FDA proceedings instituted by others—most notably citizen's petitions[55]—will be litigated. Post-*Albrecht* decisions so far continue to treat FDA resolution of citizen petitions as preemptive.[56] *Albrecht*'s statement about FDA being "fully informed" invites plaintiffs to attack the adequacy of submissions to the Agency, something prohibited in *Buckman*,[57] a decision nowhere cited by the majority. After *Albrecht*, some defendants have been required to come forward with evidence that a "fully informed" FDA would reject the language advocated by the plaintiff.[58] Exposing FDA's decision-making process to outside scrutiny is unlikely,[59] so

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[51] FDA guidance documents typically recite that they are not legally binding. *Cf.* Kelsey v Alcon Laboratories, Inc., 2019 WL 1884225, at *6–7, 10–11 (Utah Dist. April 22, 2019) (involving a guidance document expressly incorporated as medical device "special controls"). FDA "regulatory letters do not constitute final agency action." Exela Pharma Sciences, LLC v. Sandoz, Inc., ___ F. Supp. 3d ___, 2020 WL 5535026, at *13 (W.D.N.C. Sept. 15, 2020) (citation and quotation marks omitted). *See, e.g.*, *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943 (D.C. Cir. 2012) ("FDA's warning letters . . . neither mark the consummation of the agency's decisionmaking process nor determine [anyone's] legal rights or obligations.") (footnote omitted).

[52] *Dolin*, 951 F.3d at 891 ("formal[] FDA mandate[] that all [similar drugs] carry a uniform, class-wide warning label" was preemptive); Thomas v. Bracco Diagnostics, Inc., 2020 WL 1016273, at *10 (W.D. La. Feb. 27, 2020) (same).

[53] *Dolin*, 951 F.3d at 888.

[54] *Id.* at 890 (quoting *Albrecht*, 139 S. Ct. at 1972). *See Crockett*, 2020 WL 433367, at *7 ("[I]t is not sufficient for the proponent to contend that if it had submitted a new label—with additional warnings—to the FDA, the FDA *would have* rejected the warning.").

[55] FDA Citizen petitions initiate the sort of "official" administrative proceeding that *Albrecht* required. *See* 21 C.F.R. §10.30.

[56] Cerveny v. Aventis, Inc., 783 F. Appx. 804, 808 n.9 (10th Cir. 2019); State v. Purdue Pharma L.P., 2019 WL 3776653, at *2–3 (N.D. Dist. July 22, 2019).

[57] *See* Buckman Co. v. Plaintiffs Legal Comm., 531 U.S. 341, 351 (2001) (finding preempted "claims [that] would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court").

[58] A.Y. v. Janssen Pharm., Inc., 224 A.3d 1, 16 (Pa. Super. 2019); *In re* Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings, 430 F. Supp. 3d 516, 531 (N.D. Ill. 2019).

[59] United States *ex rel.* Touhy v. Ragen, 340 U.S. 462 (1951).

determinations of whether FDA received full information could be referred to the Agency itself for adjudication.[60] Under *Albrecht*, "the FDA, and only the FDA, can determine what information is "material" to its *own* decision to approve or reject a labelling change."[61]

Finally, to the extent that *Albrecht* makes litigation of *Levine*'s "clear evidence" standard more complicated and expensive, another effect will be to shift the focus of preemption in prescription drug cases to the other requirements of FDA's CBE regulation. Chief among these is the regulation's requirement that a manufacturer possess "newly acquired information" concerning a "clinically significant adverse reaction[]."[62] *Albrecht* did not address any aspects of prescription drug preemption beyond the *Levine* "clear evidence standard," so these other prerequisites to the application of the CBE regulation are unaffected[63] as defining the boundaries of implied impossibility preemption.[64]

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[60] Such an approach has been taken in the *Zofran* MDL, where the defendant filed a citizen petition with FDA to determine if the Agency was "fully informed." Other alternatives are to assert FDA "primary jurisdiction" or to ask FDA—as the Supreme Court did in *Albrecht*—for its views as *amicus curiae*. *See* Williams v. Mentor Worldwide LLC, 2019 WL 4750843, at *6 (N.D. Ohio Sept. 30, 2019) (post-*Albrecht* preemption decision relying on FDA amicus brief). *See* Kisor v. Wilkie, ___ U.S. ___, 139 S. Ct. 2400, 2418 n.6 (2019) (an agency appearing as amicus is "not a party to the litigation," so "there [is] simply no reason to suspect that the interpretation [does] not reflect the agency's fair and considered judgment").

[61] *Avandia*, 945 F.3d at 759 (emphasis in original). *Avandia* rejected preemption where FDA "stated that it had reviewed the data . . . and found that the information presented is inadequate." *Id.* at 758 (citation and quotation marks omitted).

[62] 21 C.F.R. §201.57(c)(6)(i) ("newly acquired information" for purposes of CBE regulation must involve a risk that is "potentially fatal," "serious even if infrequent," or can "be prevented or mitigated through appropriate use of the drug").

[63] Courts have declined to hold that these CBE prerequisites are subsumed within the clear evidence test. Boone v. Boehringer Ingelheim Pharm., Inc., ___ A.3d ___, 2020 WL 2121063, at *13 n.33 (Conn. May 4, 2020) ("The clear evidence standard in [*Albrecht*] applies only when a defendant seeks to prove that compliance with a state law obligation remains impossible notwithstanding its ability to act unilaterally under federal law."). Accord Estep v. Boehringer Ingelheim Pharm., Inc., 2020 WL 5290777, at *4–5 (Conn. Super. Aug. 25, 2020); Adkins v. Boehringer Ingelheim Pharm., Inc., 2020 WL 1890681, at *4 (Conn. Super. Mar. 13, 2020); Pradaxa Cases, 2019 WL 6043513, at *2 n.3 (Cal. Super. Nov. 8, 2019); Roberto v. Boehringer Ingelheim Pharm., Inc., 2019 WL 5068452, *12 n.20 (Conn. Super. Sept. 11, 2019).

[64] Indeed, quite a few courts have gone this route, deciding preemption cases post-*Albrecht* by determining that either lack of "new" evidence or absence of a "clinically significant risk" precluded resort to CBE warning changes, and thus supported dismissal of warning claims as preempted. Gayle v. Pfizer Inc., ___ F. Supp. 3d ___, 2020 WL 1685313, at *5–6 (S.D.N.Y. Apr. 7, 2020); Mahnke v. Bayer Corp., 2020 WL 2048622, at *3–5 (C.D. Cal. Mar. 10, 2020); Ridings v. Maurice, 444 F. Supp. 3d 973, 992–93 (W.D. Mo. 2020); Thomas v. Bracco Diagnostics, Inc., 2020 WL 1016273, at *9–10 (W.D. La. Feb. 27, 2020); Sabol v. Bayer HealthCare Pharm., Inc., 439 F. Supp. 3d 131, 147–48 (S.D.N.Y. Feb. 12, 2020); Drescher v. Bracco Diagnostics Inc., 2020 WL 699878, at *5 (D. Ariz. Jan. 31, 2020); McGrath v. Bayer HealthCare Pharm., Inc., 393 F. Supp. 3d 161, 171 (E.D.N.Y. 2019); Goodell v. Bayer HealthCare Pharm., Inc., 2019 WL 4771136, at *4 (D. Mass. Sept. 30, 2019); Klein v. Bayer Healthcare Pharm., Inc., 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019); *Estep*, 2020 WL 5290777, at *7–12; *Adkins*, 2020 WL 1890681, at *5–7; *Pradaxa Cases*, 2019 WL 6043513, at *3–4 (Cal. Super. Nov. 8, 2019); *Roberto*, 2019 WL 5068452, at *13.

FTC v. Shire ViroPharma: Start with a Bang, Finish with a Whimper

BY LYNN C. TYLER[1]

With considerable publicity, in February, 2017, the Federal Trade Commission ("FTC") filed a complaint against Shire ViroPharma, Inc. ("Shire") in Delaware, alleging that Shire had committed an unfair method of competition in violation of § 13(b) of the FTC Act, 15 U.S.C. § 53(b) ("the Act"). The basis for the allegations was that Shire had abused FDA's citizen petition process and filed other papers in an effort to delay competition for Vancocin, a highly profitable drug for treating a life-threatening gastrointestinal infection. The district court dismissed the complaint, however, because the FTC did not allege Shire was currently violating the Act or was about to violate the Act. The FTC appealed to the Third Circuit, which affirmed.[2]

WHY IT MADE THE LIST

The high prices for pharmaceuticals, and allegedly anti-competitive actions taken by pharmaceutical manufacturers to maintain or even increase those prices, are regularly in the news these days. These actions can include patent "evergreening," "patent thickets," and "pay-for-delay" deals, among others. FDA's citizen petition process has also been criticized and received congressional attention over the years as one source of the potentially anti-competitive actions taken to maintain high drug prices. This case appears to have been the first in which the FTC sought judicial relief for an alleged abuse of the citizen petition process. The question can be complex because it also involves a company's First Amendment right to petition the government.

DISCUSSION

Factual and Procedural Background

Vancocin capsules are an oral antibiotic used to treat *Clostridium-difficile* associated diarrhea, which is a serious, potentially life-threatening gastrointestinal infection. When Vancocin capsules were developed, the New Drug Application (NDA) submitted to FDA did not include *in vivo* clinical endpoint studies because the capsules were an alternative delivery system to Vancocin oral solution, which FDA already knew to be safe and effective. Instead, the NDA included *in vitro* dissolution data (which measures how quickly the capsules dissolve) and *in vivo* pharmacokinetic

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[2] *FTC v. Shire ViroPharma, Inc*., 917 F.3d 147 (3d Cir. 2019).

data (which compares the absorption of the drug in capsule form versus oral solution form).[3]

Shire acquired Vancocin capsules in 2004. From then until 2009, Vancocin capsules accounted for all of Shire's net revenue and in 2011 for fifty-three percent of Shire's net revenue.[4] Vancocin was vulnerable to generic competition, however, because it lacked both patent protection and regulatory exclusivity. One primary barrier to generic entry remained, however. Even though Vancocin capsules had been approved based on *in vitro* dissolution testing and *in vivo* pharmacokinetic studies, initially FDA recommended that generic manufacturers seeking to demonstrate bioequivalence conduct more expensive *in vivo* clinical endpoint studies. In October 2004, however, FDA convened an Advisory Committee meeting to reassess bioequivalence testing for locally-acting gastrointestinal drugs like Vancocin.[5]

Shire soon became concerned that FDA would allow the approval of a generic version of Vancocin based on *in vitro* dissolution testing and *in vivo* pharmacokinetic studies, rather than traditional bioequivalence studies. In November, 2005, Shire hired a consultant who confirmed its fears and recommended filing a citizen's petition supported by clinical data. In February, 2006, FDA advised a generic manufacturer that it could show bioequivalence for Vancocin by *in vitro* dissolution testing. FDA also shared this guidance with other generic manufacturers. In March, 2007, the first generic manufacturer submitted its ANDA for Vancocin and two other generic manufacturers followed suit later that year.[6]

During the relevant time period, FDA would automatically suspend the approval of an Abbreviated New Drug Application (ANDA) if a branded manufacturer filed a citizen's petition.[7] Although FDA was obligated at the time to respond to every citizen's petition within 180 days[8] FDA's response did not have to dispose of the entire petition within that time. FDA's response could deny the petition, approve it in whole or in part, provide a tentative response, or delay a decision by modifying or postponing any suggested action.

Between March, 2006 and April, 2012, Shire submitted forty-three filings to FDA and instituted three federal court proceedings.[9] In its 2017 Complaint, the FTC alleged these filings were designed to delay the approval of generic Vancocin capsules by convincing FDA to require ANDA applicants to conduct *in vivo* clinical endpoint studies. Shire's FDA filings included a citizen's petition and various amendments to it, as well as public comments on other manufacturers' ANDAs.[10]

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[3] *Id*. at 151.

[4] *Id*.

[5] *Id*.

[6] *Id*. at 151-52.

[7] Subsequently, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided that FDA cannot delay ANDA approval due to a citizen petition unless "a delay is necessary to protect the public health." 21 U.S.C. § 355(q)(1)(A)(ii). Under the amendment, FDA may also deny a citizen petition filed "with the primary purpose of delaying" an ANDA approval that "does not on its face raise valid scientific or regulatory issues." *Id.* § 355(q)(1)(E).

[8] The regulation now states FDA "intends to furnish a response" within 150 days. 21 C.F.R. § 10.30(e)(5).

[9] The lawsuits were either dismissed or withdrawn.

[10] 917 F.3d at 152.

In April, 2012, the FDA denied Shire's citizen's petition, stating it "lacked merit" and was "unsupported," and also approved three generic versions of Vancocin. Within a few months, Shire lost seventy percent of its sales of Vancocin. Shire divested itself of Vancocin in 2014. Nonetheless, as noted above it was not until February, 2017 that the FTC filed the suit over Shire's actions, alleging that the filings were anti-competitive and were also shams and thus not protected by the First Amendment.[11]

Legal Analysis

Section 13(b) of the FTC Act[12] authorizes the FTC to seek relief against an unfair method of competition when the defendant "is violating" or "is about to violate" the Act. The Third Circuit began its analysis by considering whether § 13(b) is jurisdictional.[13] Citing *Arbaugh v. Y&H Corp.*,[14] the Third Circuit wrote that the Supreme Court "has instructed us to assume that statutory limitations are nonjurisdictional unless Congress provides otherwise."[15] The court saw no indicia in § 13(b) suggesting that Congress intended to "rank a statutory limitation . . . as jurisdictional."[16] Rather, the FTC's claim arose under a law of the United States and thus fell within the district court's original jurisdiction under 28 U.S.C. § 1331.[17]

Turning to the merits, the Third Circuit affirmed the district court's dismissal of the FTC's complaint. The court first reviewed administrative remedies available to the FTC under § 5 of the FTC Act.[18] The court then noted that § 13(b) was not part of the original FTC Act, but rather was added later to give FDA the ability to quickly enjoin ongoing or imminent illegal conduct. In § 5 administrative proceedings, the FTC must prevail to obtain a cease and desist order.[19] Even if the FTC issues a cease and desist order, it must seek a court's aid to enforce the order.[20] To provide a quicker remedy, Congress amended the FTC Act in 1973 to allow the FTC to obtain a temporary restraining order or preliminary injunction in district court whenever it "has reason to believe" that violations of the FTC Act are occurring or are about to occur.[21] Section 13(b) thus empowers the FTC to address ongoing or impending illegal conduct promptly, rather than wait for an administrative proceeding to conclude.[22]

According to the court, the FTC's position was that it was entitled to pursue immediate relief in a district court under § 13(b), rather than via the administrative remedy set forth in § 5. The court began its analysis with the language of the FTC Act, citing *Murphy v. Millennium Radio Grp. LLC*,[23] for the proposition that when a

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[11] *Id.* at 153.

[12] 15 U.S.C. § 53(b).

[13] 917 F.3d at 153.

[14] 546 U.S. 500, 503 (2006).

[15] 917 F.3d at 153.

[16] *Id*. at 154.

[17] *Id*.

[18] 15 U.S.C. § 45.

[19] *See id.* § 45(b).

[20] *Id.* § 45(l).

[21] *Id.* § 53(b).

[22] 917 F.3d at 155.

[23] 650 F.3d 295, 302 (3d Cir. 2011).

statute's language is clear "the sole function of the courts—at least where the disposition required by the [text] is not absurd—is to enforce [the statute] according to its terms."[24]

Section § 13(b) provides in part:

> Whenever the [FTC] has reason to believe—
>
> (1) that any person, partnership, or corporation *is violating, or is about to violate,* any provision of law enforced by [the FTC,] and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the [FTC] and until such complaint is dismissed by the [FTC] or set aside by the court on review, or until the order of the [FTC] made thereon has become final, would be in the interest of the public—
>
> the [FTC] by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice.[25]

Applying this language to the case, the court wrote:

> Section 13(b) requires that the FTC have reason to believe a wrongdoer "is violating" or "is about to violate" the law. *Id.* § 53(b)(1). We conclude that this language is unambiguous; it prohibits existing or impending conduct. Simply put, Section 13(b) does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant "is" committing or "is about to" commit another violation.[26]

The court added that § 13(b)'s history reinforced the plain language. The section was not added to afford the FTC a remedy against hypothetical conduct, but rather to afford immediate access to the enforcement powers of the courts pending the completion of its own administrative process. "In short, we reject the FTC's contention that Section 13(b)'s 'is violating' or 'is about to violate' language can be satisfied by showing a violation in the distant past and a vague and generalized likelihood of recurrent conduct."[27]

The court considered the allegations in the FTC's complaint and found them insufficient to meet the "is violating" or "is about to violate" standards. Relevant to this issue, the court stated that the complaint:

> alleges generally that Shire "is engaged in the business of, among other things, developing, manufacturing, and marketing branded drug products, including *inter alia*, Cinryze." Compl. ¶ 8. As to the likelihood that Shire will engage in illegal behavior, the FTC alleges, "[a]bsent an injunction, there is a cognizable danger that [Shire] will engage in similar conduct causing future harm to competition and consumers. [Shire] knowingly

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[24] 917 F.3d at 156.

[25] 15 U.S.C. § 53(b)(1)–(2). Emphasis added.

[26] 917 F.3d at 156.

[27] *Id*. at 159.

> carried out its anticompetitive and meritless petitioning campaign to preserve its monopoly profits. It did so conscious of the fact that this conduct would greatly enrich it at the expense of consumers." *Id.* ¶ 150. Without mentioning Cinryze by name, the FTC alleges that Shire "has the incentive and opportunity to continue to engage in similar conduct in the future. At all relevant times, [Shire] marketed and developed drug products for commercial sale in the United States, and it could do so in the future. Consequently, [Shire] has the incentive to obstruct or delay competition to these or other products." *Id.* ¶ 151.[28]

The court found these "vague" allegations "woefully inadequate" to state a claim under § 13(b). More specifically, the court faulted the complaint for failing to allege that Shire had "engaged in sham petitioning in the five-year gap between the 2012 cessation in petitioning and the 2017 lawsuit" and for not including "specific allegations that Shire is 'about to violate' the law by petitioning as to Cinryze, the only other drug mentioned."[29] Accordingly, as noted above, the court affirmed the dismissal of the FTC's complaint.

IMPACT

The FTC did not seek review of the court's decision, either from the panel, the Third Circuit *en banc*, or the Supreme Court. Going forward, it appears that if the FTC wants to challenge alleged abuse of FDA's citizen's petition process, it will have to either pursue its own administrative process first or go to court while the alleged abuse is ongoing or about to occur, not years after it has been completed. Litigation in a district court to enjoin anticipated or ongoing conduct could prove rather difficult because it may require the FTC to show the citizen's petition is a sham before FDA has ruled on the petition. The sham showing would be necessary to overcome the defendant's First Amendment defense. Thus, as a practical matter, *FTC v. Shire ViroPharma* may leave the FTC with only its administrative process to challenge alleged abuses of the citizen's petition process.

Also, the issue may now be less likely to arise in this specific context. As the Court observed, in the FDAAA Congress provided that FDA cannot delay the approval of an ANDA based on a citizen petition unless "a delay is necessary to protect the public health."[30] Under the amendment, FDA may also deny a citizen petition filed "with the primary purpose of delaying" ANDA approval that "does not on its face raise valid scientific or regulatory issues."[31]

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[28] *Id*. at 160.

[29] *Id*.

[30] *Id.* at 152 n.7 (citing 15 U.S.C. § 355(q)(1)(A)(ii)).

[31] *Id.* (citing 15 U.S.C. § 355(q)(1)(E)).

Food Marketing Institute v. Argus Leader Media

T. DANIEL LOGAN*

WHY IT MADE THE LIST

On June 24, 2019, in a dozen pages, the Supreme Court upended forty years of precedent regarding Exemption 4 of the Freedom of Information Act (FOIA) that had been relied on by federal agencies, submitters, and requestors of information.[1] Specifically, the decision sets forth a new standard for determining when commercial or financial information, obtained from a third party, can be considered "confidential" for the purposes of FOIA and withheld from release under that statute. The consequences of the decision have yet to be seen, but it is likely that the bar for demonstrating that commercial and financial information is confidential under FOIA Exemption 4 has been substantially lowered, making it much more difficult for the public to obtain such records and information by way of FOIA. The Food and Drug Administration (FDA) collects and holds significant stores of business and financial information from product applications, inspections, and submissions. It also receives significant numbers of FOIA requests for such information. Thus, the decision has the potential to vastly change the degree to which FDA makes commercial and financial information submitted to it available.

DISCUSSION

FOIA Exemption 4 Prior to Food Marketing Institute

Generally, under the FOIA, agencies must make documents and information available to the public upon request, except where a specific statutory exemption or exclusion applies. Exemption 4 of the FOIA prohibits the release of documents or information containing "commercial or financial information obtained from a person and privileged or confidential."[2] Thus, in response to a request under the FOIA, the federal government is required to withhold certain business and financial information, but only if such information meets the threshold condition of confidentiality. Because the term "confidential" is not defined by the statute, since the passage of FOIA in 1966, courts have developed their own tests for assessing the confidentiality of information provided by industry to the federal government.[3] The initial tests developed by courts were supplanted in 1974 by the standard set by the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) in *National Parks &*

* Kleinfeld, Kaplan & Becker LLP

1 Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356 (2019).

2 5 U.S.C. § 552(b)(4).

3 *See, e.g.*, Sterling Drug, Inc. v. F.T.C., 450 F.2d 698, 701 (D.C. Cir. 1971); Gen. Servs. Admin. v. Benson, 415 F.2d 878, 881 (9th Cir. 1969).

Conservation Ass'n v. Morton.[4] In that case, the Court examined the legislative history of the FOIA statute and determined that commercial or financial information was "confidential" if the disclosure of that information would: (1) impair the government's ability to obtain such information in the future; or (2) cause substantial harm to the competitive position of the person from whom the information was adopted.[5] This test became the dominant approach for confidentiality determinations under Exemption 4 of the FOIA and was eventually adopted broadly.[6]

Subsequently, in *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, the D.C. Circuit reaffirmed the *National Parks* test, but clarified that such test should only be applied where commercial or financial information is "required" to be provided to the government.[7] Under *Critical Mass*, commercial or financial information that is "voluntarily" provided to the government must be withheld from disclosure if such information would "customarily not be released to the public by the person from whom it was obtained." That the D.C. Circuit declined to extend *National Parks* may have presaged the *Food Marketing Institute* decision twenty-seven years later.

Factual and Procedural Background

In February 2011, the Argus Leader (Argus), a newspaper based in Sioux Falls, South Dakota, submitted a request to the U.S. Department of Agriculture (USDA), seeking records related to the Supplemental Nutrition Assistance Program (SNAP), formerly referred to as the "food-stamp" program.[8] Specifically, the request sought retail store SNAP records for 2005 to 2011, including: store identifier, store name, store address, store type, and store-specific yearly redemption amounts or Electronic Benefit Transfer (EBT) sales figures.[9] Although USDA released all other data requested, relevant here, it withheld the redemption data from release under FOIA Exemption 4.[10] Argus disagreed with the USDA's rationale and brought suit in federal court. At trial, USDA presented evidence that retailers do not disclose SNAP redemption data because release of such information would harm the competitive positions of stores to which the SNAP redemption data pertained. Relying on Eighth Circuit case law incorporating the *National Parks* standard, the district court disagreed and ordered the release of the SNAP data, finding that while there was a likelihood of some commercial harm to retail stores, the evidence presented did not show that such harm would be "substantial."[11] After USDA declined to appeal the district court's ruling, Food Marketing Institute (FMI), a trade association representing grocery stores, intervened and filed its own appeal with the U.S. Court of Appeals for the Eighth

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4 498 F.2d 765 (D.C. Cir. 1974).

5 *Id.* at 770.

6 *See* Contract Freighters, Inc. v. Sec. of U.S. Dep't of Transp., 260 F.3d 858, 861 (8th Cir. 2001) (survey of cases).

7 975 F.2d 871, 879–80 (D.C. Cir. 1992) (*en banc*).

8 Argus Leader Media v. U.S. Dep't of Agric., 900 F. Supp. 2d 997, 1000 (D.S.D. 2012).

9 *Id.*

10 Note that USDA initially withheld under both Exemption 3 and 4 of the FOIA. Although the district court affirmed USDA's action, the Court of Appeals for the Eighth Circuit reversed and remanded, finding that Exemption 3 was not applicable. Argus Leader Media v. U.S. Dep't of Agric., 740 F.3d. 1172, 1173 (8th Cir. 2014).

11 Argus Leader Media v. U. S. Dep't of Agric., 224 F. Supp. 3d 827, 833–35 (D.S.D. 2016) (citing Contract Freighters, Inc. v. Sec'y of U.S. Dep't of Transp., 260 F.3d 858, 861 (8th Cir. 2001)).

Circuit, which affirmed the district court's ruling.[12] The Supreme Court granted FMI's petition for certiorari and held oral argument on April 11, 2019.

The Court's Ruling in Food Marketing Institute v. Argus Leader Media

Majority Opinion

The key issue addressed by the Court's decision is "when does information provided to a federal agency qualify as 'confidential?'"[13] Although the Supreme Court previously had considered the meaning of "confidential" in the context of FOIA Exemption 7(D),[14] the Court had not opined on such terms' meaning with regard to FOIA Exemption 4.

Justice Gorsuch, writing for the 6-3 majority, rejected the *National Parks/Critical Mass* framework for determining what information is "confidential" for the purposes of FOIA Exemption 4 as a "relic from 'a bygone era of statutory construction'" [15] that had drawn considerable criticism, even from the D.C. Circuit.[16] Panning the rationale of *National Parks* as supported by a "selective tour of the legislative history," the Court explained that the appropriate starting point for statutory analysis is "careful examination of the ordinary meaning and structure of the law itself."[17] Notably, the Court rejected the argument that Exemption 4 must be construed to mirror a common law term of art, "confidential commercial information," stating that no evidence had been presented that necessitates such a reading.[18]

Instead, noting that the term is not defined by the statute, the Court looked to the "ordinary, contemporary, common meaning" of the term when FOIA was enacted in 1966.[19] Based on examination of contemporaneously published dictionaries, the Court concluded that "confidential" meant "private" or "secret" at the time of FOIA's enactment and the term continues have the same meaning.[20] It further posited that two conditions could be required for information transmitted between parties to be considered confidential. First, "information communicated to another remains confidential whenever it is customarily kept private, or at least closely held, by the person imparting it."[21] Second, "information might be considered confidential only if the party receiving it provides some assurance that it will remain secret."[22] The Court considered whether both conditions must be met for information to be considered "confidential" under FOIA Exemption 4. Explaining that it would be "hard to see how

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12 Argus Leader Media v. United States Dep't of Agric., 889 F.3d 914 (8th Cir. 2018).

13 *Food Mktg. Inst.*, 139 S. Ct. at 2360.

14 *Id.* at 2364 (citing U.S. Dep't of Justice v. Landano, 508 U.S. 165 (1993)); 5 U.S.C. § 552(b)(7)(D).

15 *Id.*

16 *Id.* at 2635 (noting that *Critical Mass* declined to extend the *National Parks* test to commercial or financial information voluntarily provided to the government).

17 *Id.* at 2364.

18 *Id.* at 2365.

19 *Id.* at 2362.

20 *Id.* at 2363.

21 *Id.*

22 *Id.*

information could be deemed confidential if its owner shares it freely,"[23] the Court concluded that at least the first condition must be met and had been met with regards to store-level SNAP data. Finding that the second condition was easily satisfied by USDA's promises to retailers to keep store-level SNAP data private, the Court found it unnecessary to decide whether or not information would lose its confidential character under FOIA Exemption 4 if communicated to the government absent an assurance of privacy.[24]

Ultimately, the Court propounded a new standard to be applied for determinations of confidentiality under FOIA Exemption 4—"where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4."[25]

Minority Dissent

Justice Breyer, writing for the minority, concurred with the majority's two conditions for confidentiality, but argued that a third condition was also necessary: "[r]elease of . . . information must . . . cause genuine harm to the owner's economic or business interests."[26] In the view of the dissent, the term "confidential" pertains to the *nature* of the information, not just the submitter's treatment of such information. Moreover, the dissent argues that the majority decision frustrates FOIA's purpose of "broad disclosure of government records,"[27] because it would, in effect, shield the relationship between the government and private business from public scrutiny by lowering the bar for demonstrating confidentiality of business records.

IMPACT

Because the Court's decision swept away forty years of precedent, businesses, agencies, and courts are left to apply and interpret the new standard for determinations of confidentiality under FOIA Exemption 4. Many questions have been left unanswered. One critical question is whether an assurance of privacy from the government is necessary for information to be considered confidential, and if so, must such assurance be express or may it be implied? What kind of evidence will it require of private entities to demonstrate "confidentiality," particularly with regard to the "assurance of secrecy" prong, if that showing is required? Moreover, how should FDA and regulated entities engage with various statutes and regulations that employ the term "confidential commercial information"?[28] Will the information FDA has historically made proactively available be curtailed? As it works to answer these questions, FDA stands to be a litmus for how agencies will apply (and litigate) the *Food Marketing Institute* decision.

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[23] *Id.*

[24] *Id.*

[25] *Id.* at 2366.

[26] *Id.* at 2367 (Breyer, J. dissenting).

[27] *Id.* at 2368 (citing C.I.A. v. Sims, 471 U.S. 159, 166 (1985)).

[28] *See, e.g.*, 21 U.S.C. § 350(a) (publication of new dietary ingredient submissions); 21 U.S.C. § 360eee-1(g)(1)(E)(i) (relating to drug track-and-trace requirements); 21 U.S.C. § 387k(e) (publication of modified risk tobacco product applications).

Merck, et al. v. United States Department of Health and Human Services

RALPH F. HALL*

WHY IT MADE THE LIST

There are two core reasons why *Merck et al. v U.S. Department of Health and Human Services*[1] ("Merck") is a top case for 2020. First, drug pricing is one of the hot issues of our time. Lawsuits that address (and in this case overturn) efforts to address drug pricing merit our attention.

Second, recent events have increased the focus on administrative law matters. For example, see the announcement from Health and Human Services ("HHS") that certain premarket submissions could not be required for laboratory developed tests ("LDTs") because FDA did not follow certain administrative law requirements in that FDA had not used notice and comment rule making.[2] In addition to the specific effort to address drug pricing, this case also addresses some broader administrative law questions of relevance to FDA.

DISCUSSION

Background

For many years, policy makers have tried to address the perceived high cost of drugs in America.[3] This debate and the concerns over drug pricing goes back over four decades. In fact, The Drug Price Competition and Patent Term Restoration Act of 1984 (generally referred to as the Hatch Waxman Act) was a major effort to reduce drug pricing by increasing generic competition.[4] Over time there have been a plethora of policy proposals coming from many sectors—some of which have resulted in statutes or regulations or have triggered changes within the private sector. These policy suggestions or initiatives include increasing generic drug competition; permitting the government to negotiate drug pricing; limitations on price increases; permitting the importation of drugs from other countries, particularly Canada; limiting patent settlements and licensing; increased antitrust enforcement; and utilizing an

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1 Merck et al. v. U.S. Dep't of Health & Human Servs., 962 F.3d 531 (D.C. Cir. 2020).

2 *Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests,* U.S. DEP'T HEALTH & HUMAN SERVS. (Sept. 1, 2020), https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html.

3 We leave to others the debate as to whether drug prices are "too high," whether drug pricing is morally suspect, and the best policies to address drug pricing.

4 *See generally* 21 U.S.C. §355(j).

international drug price index. For example, in 2013, the Supreme Court weighed in on antitrust aspects of pharmaceutical patent settlements and licensing,[5] and just recently in September 2020, the Trump Administration finalized a rule permitting the importation of certain drugs from Canada.[6]

One policy approach advocated by a number of stakeholders was to mandate that pharmaceutical companies publicly disclose certain drug price information to the consumer/user/final purchaser. While the consumer picking up a prescription at the drug store would know the cost to that person (particularly the co-pay), the consumer would not know the acquisition cost of that drug or of substitutable drugs (generally generics).

It was hoped that by making the acquisition cost/price of drugs publicly available, drug prices would decline because of one or more of three dynamics:

- By having more information, consumers (perhaps within the aid of health care professionals such as doctors and pharmacists) would be able to pick the cheaper of several interchangeable alternatives;
- Publicizing "high" or "unfair" prices could create public pressure or a public backlash, which would compel the manufacturer or distributor to reduce prices; or
- Finally, making acquisitions costs and other price related information publicly available could increasing the negotiating power of government or commercial drug purchasers.

In 2018, the Trump Administration acted to effectuate this policy approach when it started the process to mandate such disclosure by rule.

The Rule Itself

As one part of an overall program to reduce drug prices, HHS issued a rule that mandated the disclosure in television ads of the Wholesale Acquisition Cost (WAC) of many prescription drugs. The final rule was promulgated over the objection of a number of stakeholders, primarily drug companies and related entities. [7]

While the objectors strongly factually questioned whether the mandated disclosures would actually reduce drug prices,[8] the objectors also filed suit against HHS. In this lawsuit, they raised a number of legal issues—including First Amendment claims, lack of statutory authority to promulgate such a rule, and numerous issues with the relevance, accuracy, or value of the information being disclosed.

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[5] FTC v. Actavis, Inc., 570 U.S. 136 (2013).

[6] U.S. DEP'T HEALTH & HUMAN SERVS., IMPORTATION OF PRESCRIPTION DRUGS (2020), https://www.hhs.gov/sites/default/files/importation-final-rule.pdf?utm_medium=email&utm_source=govdelivery.

[7] Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019) (to be codified at 42 C.F.R. pt. 403). The proposed rule was published on October 18, 2018 at 83 Fed. Reg. 52,789. For our purposes, the rule was finalized in essentially the same form as the proposed rule.

[8] The Court did not directly address whether the mandated disclosures would result in lower drug costs but did focus on the differences between the WAC or list price and what consumers actually paid for drugs.

In essence, this rule mandated that direct to consumer (DTC) advertisements for drugs and biologics[9] include in the advertisement the WAC or list price of that drug.[10] The rule modified certain provisions of federal health care programs (primarily Medicare Parts B and D as well as certain Medicaid provisions). While the rule technically only applied to drugs sold under such government payment programs, it was expected that private purchasers would benefit from this information as well.

Obviously, any administrative agency must have statutory authority before it can issue any rule or regulation. In this situation, HHS asserted that it had the statutory authority to issue this rule based on two statutory grants of authority. Specifically, HHS stated:

We proposed to use our authority under sections 1102 [42 U.S.C. §1302] and 1871 [42 U.S.C. §1395hh] of the Social Security Act to require manufacturers to disclose their list prices in DTC television advertisements.[11]

Once the rule was finalized in 2019, litigation immediately followed. The plaintiffs, among other arguments, asserted that the rule violated their First Amendment rights and also was issued without statutory authority.

In July 2019, the District Court stayed the rule, ruled that HHS did not have the statutory authority to issue this rule, and vacated the rule. The District Court did not reach the constitutional question.[12]

The government appealed, and in June 2020, the Court of Appeals affirmed the District Court.

Key Issues

Conceptually, the case raises two key legal issues.

First, the plaintiffs raised fascinating First Amendment issues. The plaintiffs argued that the rule unconstitutionally forced the drug companies to make speech that the companies did not desire to make.[13] Second, the plaintiffs asserted that HHS did not have the statutory authority to issue this rule. More specifically, did HHS have the authority to issue this rule under either §1302 or §1395hh?

Remember, courts generally avoid reaching constitutional questions if there is some other basis, such as a statutory question, that resolves the case. In this case, the assessment of the statutory basis for the rule (or, in this case, the lack thereof) resolved the case and so the constitutional issues were not addressed at either the district court or appellate court level (and will not be further discussed here).[14]

To start, it is "black letter law" that an administrative agency must have statutory authority before it can legally issue any rule or regulation. As the appellate court stated:

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[9] While there are, of course, definitional differences between drugs and biologics, for simplicity purposes, this paper will refer to both simply as drugs.

[10] The final rule includes some exceptions to this disclosure requirement, a standard length of treatment for price purposes, some definitions, and the precise language that was to be used for the disclosure. While interesting, these details are not relevant to the legal issues being discussed herein.

[11] Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. at 20735.

[12] *See* Merck & Co., et al. v. U.S. Dep't Health & Human Servs., 385 F. Supp. 3d 81 (D.D.C. 2019).

[13] The "Forced Speech" doctrine includes foundational cases such as *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985).

[14] Of course, had the district court or appellate court determined that HHS had the statutory authority to issue the rule, the courts may have had to address the constitutional issues.

"[A]n agency . . . has no power to act . . . unless and until Congress confers power upon it."[15]

As set forth in the rule itself, HHS relied on §1302 and §1395hh as its authority to issue this rule. Both provisions, interestingly, deal with the "administration" of certain federal health care beneficiary programs. Neither specifically addresses drug prices or information disclosures.

Section 1302(a), in relevant part, gives the Secretary the power to "make and publish such rules and regulations, not inconsistent with [the Social Security Act], as may be necessary to the efficient administration of the functions with which [the Secretary] is charged."[16]

Section1395hh(a)(1) provides somewhat similar power to HHS. It states: "[The] Secretary shall prescribe such regulations as may be necessary to carry out the administration of the [Medicare] insurance programs."[17]

The key in both statutory provisions is that the power has been delegated by Congress to HHS to create rules and regulations for the "administration" of the responsibilities of the Secretary of HHS. So, the clear question that faced the appellate court is whether mandating the disclosure of WAC information is within this grant of authority to "administer" these federal beneficiary programs.

Obviously, the plaintiffs said "no" and HHS said "yes."

The Court of Appeals agreed with the plaintiffs and held that these general grants of authority to "administer" these programs did not include the power to mandate the disclosure of WAC or list prices. As such, the rule was invalid and the court did not need to reach the constitutional question.

Analysis

To begin, the case involves an agency's interpretation of its authorizing statute and thus triggers a *Chevron* discussion. The Court started by discussing whether the rule in question falls under either *Chevron* Step One (has the legislature directly spoken to the issue) or under *Chevron* Step Two (if the statute is ambiguous, the Court will uphold HHS' construction of the statute if it is a "reasonable interpretation").[18]

The Court found that there was not a reasonable basis for HHS' interpretation of these two provisions. In reaching this result, the Court set forth four reasons why the rule "strays far off the path of administration."[19]

First, neither the WAC nor the list price bears any meaningful relationship to the actual price that either the government or beneficiaries pay for drugs. In fact, the government could not articulate a rational connection between the WAC and prices paid by beneficiaries. The government even stated at oral argument that the WAC is "a price that's rarely paid."[20] The Court further pointed out that no state has adopted the WAC as the applicable price. Rather, actual prices paid are based upon a slew of other factors including co-pay levels, varying discounts, average sales prices, and negotiated prices. As such, the Court could not find a reasonable basis for agreeing

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15 Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986).

16 42 U.S.C. §1302(a).

17 42 U.S.C. §1395hh.

18 Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 468 U.S. 837 (1984).

19 Merck et al. v. U.S. Dep't of Health & Human Servs., 962 F.3d 531, 538 (D.C. Cir. 2020).

20 *Id.* at 539.

with HHS that the "administration" of these health care programs is advanced by this rule.

Second, the Court rejected HHS' argument that the there is a connection between the "administration" of these health programs and this mandated disclosure of the WAC as a means to inform consumer decisions. Because of the at best attenuated relationship between the WAC and what consumers pay, such information will not inform such decisions and may, in fact, further confuse consumers. Again, no connection to the administration of the programs at issue.

Third, the disclosure rule is aimed at all consumers, not just Medicare or Medicaid beneficiaries. This fact further distances this rule from the actual administration of these programs. Its breadth was too wide.

Finally, the breadth and impact of this rule negates the argument that the rule is administrative. The Court reiterated that courts should not lightly assume some congressional delegation of power to make major economic, policy, and political decisions without some explicit statement of congressional intent.[21] In doing so, the Court cited the Supreme Court's statement in *Utility Air Regulatory Grp. v. EPA*: "When an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,' we typically greet its announcement with a measure of skepticism." [22] There is a significant difference between major policy decisions and "administering" a government program.

HHS' expansive reading of what could be include within the "administration" of these programs would, in the Court's view, give HHS almost unbridled power and would be a "staggering" delegation of power.

In the end, the Court viewed "administration" as applying to the "practical management and direction of" the various programs within HHS—not major policy initiatives.[23] This rule strays far from the standard concept of "administration" of a program being the processes by which the program works and not the substantive policies of the program. HHS could not bridge the chasm between what could be legitimately viewed as administrative processes and this highly substantive rule.

IMPACT

This decision has two key impacts and leaves open a serious question for later cases.

First, without a more explicit delegation of authority from Congress, HHS does not have the tool of mandating disclosure of certain price or cost information in direct to consumer ads. Rather, HHS needs to find other tools to address drug pricing or needs to have Congress pass some explicit authorizing statute.

Second, and more broadly, this decision reminds all stakeholders that there are limits to an administrative agency's authority. Among other limitations, the agency must have statutory authority before enacting new rules—particularly those with major social, economic, policy, or political impacts. As FDA issues new programs, rules, or policies, the question must always be asked as to whether such actions are within powers granted by Congress to FDA. Courts will not "rubber stamp" agency assertions of authority.

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[21] *See, e.g.*, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

[22] 134 S. Ct. 2427, 2444 (2014).

[23] *Merck*, 962 F.3d at 537.

Other events such as HHS' recent LDT announcement and the HHS announcement that all new rules require the explicit approval of the Secretary[24] may further build on the requirements for and limits on agency actions.

Finally, the Court did not address the First Amendment issues raised by the plaintiffs as the Court was able to resolve this case without addressing these questions. The complex issues remain open for another day, another case, and potentially another court.

[24] *HHS Statement on Regulatory Process*, U.S. DEP'T HEALTH & HUMAN SERVS., (Sept. 20, 2020), https://www.hhs.gov/about/news/2020/09/20/hhs-statement-on-regulatory-process.html.

Turtle Island Foods SPC d/b/a Tofurky Company v. Soman

JACQUELINE J. CHAN*

WHY IT MADE THE LIST

Plant-based eating has grown significantly, with U.S. plant-based food dollar sales having grown by 11.4% in the past year and 29% over the past two years, and an estimated total plant-based market value of $5 billion.[1] Unsurprisingly, to meet consumer demand, companies are quickly crowding the marketplace, introducing new plant-based food options directly into the mainstream.

Many of these products serve as alternatives to traditional meat or dairy products. To convey the plant-based food product's form, function, and flavor, companies will often refer to the name of the traditional meat or dairy counterpart in their plant-based food product names. Multiple states, however, have enacted or propose to enact laws that prohibit the use of such traditional terms for foods that are not derived from the named meat or dairy product. Such states generally assert that the purpose of such laws is to protect consumers from being misled or confused by false or misleading labeling.

Turtle Island Foods, SPC, doing business as The Tofurky Company v. Nikhil Soman, in his official capacity as Director of the Arkansas Bureau of Standards (E.D. Ark.) is one of the recent lawsuits to challenge such a state law. In this lawsuit, Turtle Island Foods, which does business as The Tofurky Company ("Tofurky"), successfully secured a preliminary injunction of Arkansas's Act 501 on First Amendment constitutional grounds.[2] Although the court's order granting the preliminary injunction focused specifically on Act 501 as it applied to Tofurky, it offers plant-based food companies some guidance on challenging similar laws in other states and, more broadly, on how to label similar food products in a truthful and non-misleading manner. The court's opinion aligns with prior case precedent supporting the following general principle: consumers are unlikely to be misled where traditional meat and dairy terms are appropriately qualified to clearly distinguish the food from its traditional counterparts.[3]

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1 *See* Kate Good, *U.S. Plant-Based Retail Market Worth $5 Billion, Growing at 5X Total Food Sales*, PLANT BASED FOODS ASSOCIATION (PBFA) (Mar. 3, 2020), https://plantbasedfoods.org/plant-based-foods-retail-sales-data-2020/.

2 Turtle Island Foods SPC d/b/a Tofurky Co. v. Soman, No. 4:19-cv-00514, 2019 WL 7546141 (E.D. Ark. Dec. 11, 2019) [hereinafter Preliminary Injunction Order].

3 *See, e.g.*, Ang v. WhiteWave Foods Co. et al., No. 13-cv-1953, 2013 WL 6492353 (N.D. Cal. Dec. 10, 2013); Gitson v. Trader Joe's Co., No. 13-cv-01333, 2015 WL 9121232 (N.D. Cal. Dec. 1, 2015).

As demand for plant-based foods grows and the marketplace becomes more competitive, the stakes for plant-based food companies related to the labeling of their foods likely will similarly rise. This lawsuit, along with Tofurky's lawsuit challenging the constitutionality of a similar Missouri law,[4] will be one for food manufacturers to watch closely this year.

DISCUSSION

Arkansas's Act 501

In March 2019, the Arkansas State Legislature enacted Act 501, titled "An Act to Require Truth in Labeling of Agricultural Products that are Edible by Humans; and for Other Purposes" ("Act 501").[5] The stated purpose of Act 501 is "to protect consumers from being misled or confused by false or misleading labeling of agricultural products that are edible by humans." Among other provisions, Act 501 essentially prohibits foods from being labeled with meat terms where the product is not derived from the named meat.[6] For example, it prohibits representing the food as "beef or a beef product when the agricultural product is not derived from a domesticated bovine."[7] Further, although Act 501 does not specifically refer to dairy or dairy-derived products, certain provisions can be interpreted as prohibiting the use of traditional dairy terms as well for foods that do not include the named dairy product. For example, Act 501 explicitly prohibits "[u]tilizing a term that is the same as or similar to a term that has been used or defined historically in reference to a specific agricultural product."[8] The Act imposes civil penalties for violation of its provisions with each individual violation of Act 501 punishable by a civil penalty of up to $1,000.[9]

Tofurky Sues Arkansas Over Constitutionality of Act 501

Two days before Act 501 was to take effect, plaintiff Tofurky filed a complaint against defendant Nikhil Soman, in his official capacity as the Director of the Arkansas Bureau of Standards ("State"), on July 22, 2019, challenging the constitutionality of Act 501.

Tofurky is a company that develops, produces, markets, and sells plant-based food products, including plant-based meats. Its plant-based meats are made with vegan ingredients, such as soy, tempeh, wheat, and jackfruit. Tofurky's names for these plant-based products include traditional meat-based terms, like "chorizo," "ham roast," and "hot dogs," qualified by terms like "all vegan," "vegetarian," and "plant-based." Tofurky markets and sells its products nationwide, including in Arkansas.

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4 Turtle Island Foods, SPC, doing business as The Tofurky Company, and The Good Food Institute, Inc. v. Mark Richardson, Case No. 18-cv-4173 (W.D. Mo.). This case is discussed further below under "Impact."

5 Ark. Code Ann. § 2-1-301 *et seq.*

6 Act 501 also prohibits "[r]epresenting the agricultural product as rice when the agricultural product is not rice" and "[a]ffixing a label that uses a variation of rice in the name of the agricultural product when the agricultural product is not rice or derived from rice." Ark. Code Ann. § 2-1-305(7) & (11).

7 Ark. Code Ann. § 2-1-305(8).

8 Ark. Code Ann. § 2-1-305(10).

9 Ark. Code Ann. § 2-1-306.

Tofurky specifically challenged the constitutionality of the following six provisions of Act 501 under the First Amendment, the Fourteenth Amendment, and the Dormant Commerce Clause:

> 2-1-305. Prohibited activities. A person shall not misbrand or misrepresent an agricultural product that is edible by humans, including without limitation by:
>
> (2) Selling the agricultural product under the name of another food;
>
> ***
>
> (5) Representing the agricultural product as a food for which a definition and standard of identity has been provided by regulations under § 20-56-219, or by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as it existed on January 1, 2019, unless: (A) The agricultural product conforms to the definition and standard; and (B) The label of the agricultural product bears the name of the food specified in the definition and standard and includes the common names of optional ingredients other than spices, flavoring, and coloring present in the food as regulations require;
>
> (6) Representing the agricultural product as meat or a meat product when the agricultural product is not derived from harvested livestock, poultry, or cervids;
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> ***
>
> (8) Representing the agricultural product as beef or a beef product when the agricultural product is not derived from a domesticated bovine;
>
> (9) Representing the agricultural product as pork or a pork product when the agricultural product is not derived from a domesticated swine;
>
> (10) Utilizing a term that is the same as or similar to a term that has been used or defined historically in reference to a specific agricultural product.

Tofurky contended that these provisions prohibit truthful and non-misleading speech while exposing Tofurky to substantial risk of ruinous civil penalties. It asserted that its labels do not mislead consumers, and, in fact, they emphasize by using commonly understood terms that the products are plant-based alternatives to meat from live animals. According to Tofurky, Act 501 would actually create consumer confusion if companies could not use clear terms that accurately describe the taste, appearance, and texture of their products and, instead, were required to use less descriptive terms like "plant-based protein" or "veggie tube." Tofurky concluded that compliance with Act 501 would put Tofurky at a significant commercial disadvantage where the company must choose (1) to continue to sell its products as packaged at risk of ruinous civil liability; (2) to design and distribute Arkansas-specific packaging; (3)

to change its packaging entirely nationwide; or (4) to refrain from marketing or selling its products in Arkansas.

The Decision

On August 14, 2019, Tofurky moved for a preliminary injunction prohibiting the State from enforcing the challenged provisions of Act 501. Tofurky's challenge of the six provisions of Act 501 focused on violations of the Free Speech Clause of the First Amendment and the Due Process Clause of the Fourteenth Amendment.

On December 11, 2019, the Court granted Tofurky's motion on First Amendment grounds. Because the Court granted the preliminary injunction on First Amendment grounds, it did not reach Tofurky's Fourteenth Amendment arguments. Notably, the Court confined its analysis to an "as applied" challenge brought by Tofurky, examining only whether Act 501 was constitutional as it applied to Tofurky's advertisements.[10] Accordingly, the preliminary injunction applies only to Tofurky and not to other similarly situated companies.

In determining whether a preliminary injunction would be appropriate, the Court considered the following four factors: (1) the threat of irreparable harm to Tofurky; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that Tofurky will succeed on the merits; and (4) the public interest. Because Act 501 was passed through the "democratic process," the Court found that the State was entitled to a higher degree of deference, requiring that Tofurky was "likely to prevail on the merits" (as opposed to having a "fair chance" of success).

LIKELIHOOD OF SUCCESS ON THE MERITS

In evaluating Tofurky's likelihood of success on the merits of its First Amendment claim, the Court applied the four-part commercial speech test as articulated by the U.S. Supreme Court in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). Where commercial speech is neither false nor inherently misleading, factors two through four must be answered affirmatively for the law to be found constitutional:

> (1) Whether the commercial speech at issue concerns lawful activity or is misleading;
>
> (2) Whether the governmental interest is substantial;
>
> (3) Whether the challenged regulation directly advances the government's asserted interest; and
>
> (4) Whether the regulation is not more extensive than necessary to further the government's interest.

This case primarily turns on the first *Central Hudson* factor, namely: does the commercial speech concern unlawful activity or is misleading and thus may be prohibited entirely by the government? The Court explained that "misleading" speech includes speech that is "inherently misleading," meaning speech that "inevitably will

[10] Preliminary Injunction Order, *supra* note 2, at *7–8.

be misleading" to consumers.[11] This may be inferred from reviewing the "particular content or method of the advertising" as well as "experience [that] has proved that in fact such advertising is subject to abuse."[12]

Unsurprisingly, the parties disagreed on this point. Tofurky argued that Act 501 unconstitutionally restricted its commercially protected speech, whereas the State contended that Tofurky's speech was inherently misleading and thus not subject to First Amendment protection. In reviewing each of Tofurky's seven labels as a whole, the Court agreed with Tofurky, finding the speech *not* to be inherently misleading:

> It is true, as the State contends, that these labels use some words traditionally associated with animal-based meat. However, the simple use of a word frequently used in relation to animal-based meats does not make use of that word in a different context inherently misleading. This understanding rings particularly true since the labels also make disclosures to inform consumers as to the plant-based nature of the products contained therein.[13]

The Court determined that any consumer confusion was "dispel[ed]" by the repeated use of terms indicating that the packages contained no animal-based meat. For all products, the Court pointed to the use of terms like "all vegan" or "plant-based," and use of a symbol depicting the letter "V" in a circle on the front of the packaging (i.e., "a common indicator that a food product is vegan or vegetarian"). The Court also discussed each label, for example, highlighting that the "Veggie Burger" label (1) modified the word "burger" with "veggie;" (2) stated "all vegan" in the middle of the label; and (3) featured the words "white quinoa" next to the image of the burger.

The Court also found untenable the State's argument that use of a meat-based term would leave a typical consumer confused because such an argument would work only if a reasonable consumer would disregard the "ample terminology to indicate the vegan or vegetarian nature of the products" appearing on the labels.[14] The Court further commented that there was no contention that any consumer or potential consumer was actually misled or deceived by Tofurky's packaging, labeling, or marketing. As such, the Court found that, when considering the label as a whole, an ordinary consumer was unlikely to be deceived about whether Tofurky's products contained animal-based meat.

Accordingly, the Court concluded that Tofurky was likely to prevail on its arguments that its labeling was not unlawful or inherently misleading and, thus, Tofurky's commercial speech warranted First Amendment protection.

Given Tofurky's likelihood of success, the Court reviewed the State's speech restriction using an "intermediate scrutiny" standard for the remaining *Central Hudson* factors, and found as follows:

- *Is the governmental interest substantial?* Based on Supreme Court and Eighth Circuit precedent recognizing that "combatting deceptive,

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[11] *Id.* at *10.

[12] *Id.*

[13] *Id.* at *11.

[14] *Id.* at *12.

misleading, or false advertising" was a "legitimate and substantial interest," the Court assumed that the State had a substantial interest in protecting consumers from being misled or confused by false or misleading labeling.

- *Does the challenged regulation directly advance the government's asserted interest?* Given that the Court concluded that Tofurky was likely to prevail on its argument that its speech was not false or misleading, the Court determined that Act 501 is unlikely to "directly and materially" advance the State's interest as stated in Act 501.
- *Is the regulation not more extensive than necessary to further the government's interest?* The Court found that Tofurky was likely to prevail on its argument that Act 501 was more extensive than necessary to serve the State's interest. According to the Court, Act 501's "outright ban" of Tofurky's arguably non-misleading commercial speech is unlikely to be a "reasonable fit" and was "far more extensive than necessary." The Court stated that Tofurky was likely to succeed in demonstrating that the State disregarded far less restrictive and precise means for accomplishing the same purpose. The Court pointed to several alternative approaches the State could have taken, which would include the State (1) requiring "prominent disclosures of the vegan nature of plant-based products;" (2) creating a "vegan" symbol for plant-based product labeling and packaging; or (3) requiring a disclaimer that the products do not contain meat.

THREAT OF IRREPARABLE HARM

The Court determined that Tofurky demonstrated a threat of irreparable harm based on two primary reasons. First, relying on Supreme Court precedent, the Court found that the loss of First Amendment freedoms is "unquestionably" irreparable harm. Given that the Court concluded that Tofurky was likely to prevail on its claim that Act 501 violates its First Amendment right, that violation constitutes irreparable injury. Second, Tofurky could be subject to Act 501's civil penalties at any time, and "likely faces ruinous civil liability, enormous operational costs, or a cessation of in-state operations were Act 501 enforced against it." The Court further pointed to the fact that the State had made no assurances that it will not levy retroactive penalties against Tofurky that may have accumulated during the litigation.

BALANCE OF THE EQUITIES

In evaluating equities, the Court considered the balance between the harm to Tofurky and the injury that granting the injunction will inflict on other interested parties. The Court determined that Tofurky would face "substantial detrimental impact" in complying with Act 501 where Tofurky has already invested significant funds into the labeling and packaging of its products. To comply with Act 501, Tofurky likely would be required to: "(1) risk civil penalties by continuing its current marketing and packaging practices; (2) create specialized marketing and packaging practices for Arkansas, including attempting to police spillover from marketing in nearby states; (3) change its marketing and packaging practices nationwide; or (4)

refrain from marketing or selling its products in Arkansas at all."[15] The Court concluded that each option was a potential burden that created a corresponding chilling effect on Tofurky's commercial speech rights. According to the Court, the State offered no "compelling equities of its own" resulting from a denial of a preliminary injunction. As such, the Court found that Tofurky established the balance of equities in its favor.

PUBLIC INTEREST

The Court found that the grant of an injunction was in the public interest because the case revolved around constitutional rights and Tofurky had demonstrated its likelihood of prevailing on the merits. Absent the entry of a preliminary injunction, the risk of State enforcement action existed, which may in turn chill Tofurky's commercial speech and inhibit such speech from reaching Arkansas consumers. Tofurky argued that Arkansas consumers benefitted from the "free flow of truthful and non-misleading commercial information allowing them to identify plant-based options for their favorite meals." Ultimately, the Court concluded that "[t]he status quo [wa]s represented by that speech being available to consumers in the marketplace."

Accordingly, the Court granted Tofurky a preliminary injunction, which is the first—and a major—step in this case. Although much may happen between now and then, a bench trial has been set for February 2021.

IMPACT

Many states have or are proposing laws similar to Act 501 that place restrictions on the naming of foods using traditional meat or dairy terms. Although the aim of these laws may be similar, not all state laws are the same, with differing levels of restrictions and legal nuances. Thus, as one may expect, not all challenges to these state laws will necessarily provide the same end result as in the present case.

For example, earlier in 2019, Tofurky challenged Missouri's law restricting the use of meat terms for food products and moved for a preliminary injunction on similar First Amendment grounds.[16] Missouri's statute prohibits advertising, offering for sale, or selling all or part of a food using "misleading or deceptive practices," which include, in relevant part, "misrepresenting a product as meat that is not derived from harvested production livestock or poultry."[17] Unlike in Arkansas, Missouri took the position that the statute "only prohibits labels that suggest that plant-based or lab-grown meat is conventional meat from an animal carcass."[18] In other words, "[t]he use of the word 'meat' on a plant-based or lab-grown product would only violate the statute if it lacked an appropriate qualifier 'plant-based,' 'veggie,' 'lab-grown,' 'lab-created."[19] Because Tofurky's labels described plant-based meat as "plant-based meat," the court found that Tofurky was not likely to succeed on its First Amendment claim because the

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[15] *Id.* at *15.

[16] Turtle Island Foods, SPC, doing business as The Tofurky Company, and The Good Food Institute, Inc. v. Mark Richardson, Case No. 18-cv-4173 (W.D. Mo.).

[17] *See* Mo. Rev. Stat. § 265.494(7).

[18] *See* Turtle Island Foods, et al. v. Richardson, No. 2:18-cv-0417, 2019 WL 7546586, at *4 (Sept. 30, 2019).

[19] *Id.*

statute did not prohibit its truthful and non-misleading speech. The court determined that the statute prohibited only speech that would be misleading, which is a permissible government restriction, and denied Tofurky's motion for preliminary injunction.[20]

With this patchwork of state laws, companies similarly situated to Tofurky face a business and legal quandary of how to proceed in labeling and marketing their plant-based food products. As Tofurky asserted, it had four options: (1) continue selling its products as is and risk significant civil penalties; (2) create labeling and advertising specific to each state with risk of non-compliant "spillover" from neighboring states; (3) stop selling products in the specific state altogether; or (4) revamp its labeling and advertising nationally. Although this issue is likely to remain murky for the near future, the Court's opinion from the Arkansas *Turtle Island* case provides useful considerations.

Starting narrowly, Arkansas Act 501 continues to be "good law" as *Turtle Island* moves forward and, further, the preliminary injunction order is specific only to Tofurky. However, the same arguments that were successful for Tofurky also may be successful for companies that label and market their products similar to Tofurky. Likewise, although Tofurky focused primarily on the meat-related provisions, Tofurky's constitutional arguments could similarly apply to other products (e.g., plant-based alternatives to dairy products) where three of the challenged Act 501 provisions relate more broadly to "agricultural products" and not just meat-based products.

More broadly, the Arkansas and Missouri *Turtle Island* cases highlight a primary factor for truthful and not misleading labeling of plant-based foods: clear and prominent qualification of traditional meat or dairy terms in a manner that distinguishes the food from its traditional counterpart. Qualifiers should clearly communicate that the food is not made of meat or dairy, such as "plant-based," "vegan," "dairy-free," or "meat-free." Other label statements related to the actual ingredients that substitute for the "meat" or "dairy" or "Vegan" certification symbols may further support non-misleading labeling. As noted above, this approach is further supported by earlier case law related to the naming of plant-based milks with the standardized term, "milk." As explained by the court in *Ang v. WhiteWave Foods Co. et al.*:

> The crux of the claims is that a reasonable consumer might confuse plant-based beverages such as soymilk or almond milk for dairy milk, because of the use of the word "milk." The Court finds such confusion highly improbable because of the use of the words "soy" and "almond." Plaintiffs essentially allege that a reasonable consumer would view the terms "soymilk" and "almond milk," disregard the first words in the names, and assume that the beverages came from cows. The claim stretches the bounds of credulity. Under Plaintiffs' logic, a reasonable consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper.[21]

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[20] Subsequently, plaintiffs Tofurky and The Good Food Institute appealed the court's denial of their motion for preliminary injunction to the United States Court of Appeals for the Eighth Circuit. As of the date of this writing, the interlocutory appeal was still pending.

[21] Ang v. WhiteWave Foods Co. et al., No. 13-cv-1953, 2013 WL 6492353, at *4.

Nevertheless, the *Turtle Island* case is only at a preliminary stage. It is possible, for example, that the state might be able to successfully defend its position with a combination of compelling data (for example, a need to protect in-state meat industry jobs from being lost due to competition from plant-based counterparts) and a reasonable enforcement posture (for example, not enforcing Act 501 if the product is labeled in large letters "This is Not Meat!"). Whether the state will come up with such a defense remains to be seen.

Further, the *Turtle Island* case is likely only the beginning of a series of state law challenges. Beyond state law considerations, food companies should also carefully monitor Federal activity that may impact such food labels. In the past few years, FDA has reinitiated its effort to modernize food standards of identity while concurrently considering stakeholder comments related to the use of dairy terms in the names of plant-based foods. U.S. congressional leaders also have called on FDA to enforce its standards of identity more vigorously and have even proposed legislation to encourage such enforcement, such as the DAIRY PRIDE Act (Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese to Promote Regular Intake of Dairy Everyday Act) and the Real MEAT Act of 2019 (Real Marketing Edible Artificials Truthfully Act of 2019). This will be certainly a space to watch for years to come.

American Beverage Association v. City and County of San Francisco

MITAL PATEL*

WHY IT MADE THE LIST

Health and safety warnings are a regular part of the consumer protection landscape. For example, consumers are accustomed to the iconic and standardized nutrition facts label—a result of The Nutritional Labeling and Education Act of 1990. And though now normalized, consumers were initially shocked when they were greeted with the calorie count for a hamburger at their favorite fast-food joint.

But what happens if a local city government tries to mandate a specific warning label in hopes of combating America's growing obesity and diabetes epidemic? In 2015, San Francisco enacted an ordinance requiring that outdoor signs advertising sugar-sweetened beverages include a warning label, covering twenty percent of the sign, that warned potential consumers of the negative health impact of consuming such a product.[1] Trade organizations, including the American Beverage Association ("ABA") quickly pushed back, alleging a violation of their First Amendment rights.[2] This case is representative of the fine line governments must walk when enacting labeling requirements, no matter how well-intentioned the proposed laws may be.

The ABA convinced a Ninth Circuit panel that the ordinance chills commercial speech by forcing beverage manufacturers to convey a controversial message.[3] In an *en banc* rehearing, the Ninth Circuit confirmed reversal, with no dissents, but only on the ground that the size of the warning was unduly burdensome.[4] So, how can the *en banc* decision of the Ninth Circuit be controversial when every active judge of that court agreed with the outcome?

DISCUSSION OF THE FACTS AND PROCEDURAL HISTORY

In 2015, the City and County of San Francisco unanimously voted to mandate a disclosure on print advertisements for sugar-sweetened beverages (SSBs) stating: "WARNING: Drinking beverages with added sugar(s) contributes to obesity, diabetes,

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1 Am. Bev. Ass'n v. City & Cty. of S.F., 916 F.3d 749, 753 (9th Cir. 2019)

2 Am. Bev. Ass'n v. City & Cty. of S.F., 187 F. Supp. 3d 1123 (N.D. Cal. 2016)

3 Also at issue was whether the San Francisco ordinance imposed an undue burden on beverage manufacturers because non-beverage sugar producers arbitrarily escape the ordinance's purview. The Northern District dismissed this issue because, given the high caloric count of sugar-sweetened beverages, it was a reasonable to fight the war on obesity first with sugar-sweetened beverage warnings and not all sugar products. *Id.* at 1140.

4 916 F.3d at 753.

and tooth decay" in a black box occupying no less than twenty percent of the advertisement.[5] SSBs were defined as "soda and other non-alcoholic beverages that contain one or more added sweeteners and more than twenty-five calories per twelve fluid ounces of beverage."[6] Not surprisingly, the ABA, as well as other trade organizations, quickly filed suit in the Northern District of California seeking injunctive relief to prevent the implementation of the ordinance.[7]

The ABA challenged the San Francisco ordinance on First Amendment grounds, claiming the mandate creates a chilling effect on commercial speech by requiring ABA members to bear an unjustified and undue burden of conveying a controversial message hostile to their own products in order to advertise them.[8] In response, San Francisco attempted to justify its mandate by stating there is a substantial government interest in informing the public about the health risks of sugar.[9]

On May 17, 2016, the District Court denied the preliminary injunction motion on the ground that plaintiffs had not established a likelihood of success on the merits.[10] The District Court, convinced by advertising experts who claimed that tobacco product packaging and labeling should bear a health warning of fifty percent to be effective, rejected ABA's argument.[11] Compared to this precedent, the court found a warning twenty percent the size of the packaging to be permissible.

On appeal, the Ninth Circuit reversed the trial court decision and struck down the San Francisco ordinance.[12] The court held that because the warning was required to take up twenty percent of the space on an advertisement, the black box overwhelms other visual elements in the advertisement, and it requires a conveyance of San Francisco's disputed policy views; the warning was found to be unduly burdensome and chilled protected commercial speech under the First Amendment.[13]

DECISION AND REASONING OF THE *EN BANC* PANEL

The full Ninth Circuit granted *en banc* rehearing.[14] Because the parties agreed that the San Francisco ordinance constituted compelled commercial speech, this left the *en banc* court to determine what level of scrutiny to apply to the warning label. Before the rehearing, the Supreme Court of the United States decided *National Institute of Family and Life Advocates d/b/a NIFLA et al. v. Becerra*,[15] which affirmed *Zauderer*[16] as an exception to the strict scrutiny requirement for some First Amendment

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5 187 F. Supp. 3d at 1130.

6 *Id.*

7 *See generally id.*

8 *Id.* at 1142.

9 *Id.* at 1123.

10 *See id.* at 1146.

11 *See id.* at 1138.

12 Am. Bev. Ass'n v. City & Cty. of S.F., 871 F.3d 884 (9th Cir. 2017).

13 *See id*.

14 Am. Bev. Ass'n v. City & Cty. of S.F., 880 F.3d 1019, 1020 (9th Cir. 2018).

15 Nat'l Inst. of Family & Life Advocates v. Becerra (NIFLA), 138 S. Ct. 2361 (2018).

16 Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985) (holding that a compelled disclosure is required to be purely factual and uncontroversial without being unduly burdensome on the advertiser so as to chill its commercial speech).

challenges. The Supreme Court, however, left open the circumstances in which *Zauderer* would apply or how it would apply.

In early 2019, the *en banc* decision affirmed the Ninth Circuit decision, with all active judges agreeing that the San Francisco ordinance must be preliminarily enjoined as likely violating the First Amendment.[17] The reasoning behind the agreed-upon outcome is where the controversy lies.

The Majority

Though speech regulations are typically strictly scrutinized under the First Amendment, the majority opinion, written by Judge Graber, concluded that the appropriate scrutiny was established by *Zauderer* and *CTIA—The Wireless Ass'n v. City of Berkeley.*[18] The majority determined that these two decisions established that the ordinance would be proper only if San Francisco could show that it is reasonably related to a substantial governmental interest, which it could establish by demonstrating that the compelled speech is (1) purely factual, (2) noncontroversial and (3) not unjustified or unduly burdensome. [19]

The majority opinion was narrow, holding that, given evidence presented that smaller warnings would be effective, the size of the required warnings imposed an unconstitutional burden on beverage manufacturers, explicitly declining to decide whether the warnings were factually accurate and uncontroversial.[20]

Ikuta's Dissent in Reasoning and Concurrence in Result

Judge Ikuta disagreed with the majority that *Zauderer* was the appropriate standard.[21] She regards the *Zauderer* standard as a rational basis test, not intermediate scrutiny. Though she agreed with the majority's holding, Judge Ikuta reasoned that heightened scrutiny was the appropriate standard.[22] Such a high standard would be difficult for the government to make. Judge Ikuta wrote that the ordinance as written was "wildly underinclusive" because it did not apply to all sugar-sweetened beverages or all sugar-sweetened products, and it did not apply to all forms of advertising.[23]

Christen Concurrence, Joined by Thomas

Judges Christen and Thomas agreed that *Zauderer* applies to the ordinance, but they would reverse because San Francisco could not show that the speech it sought to compel was purely factual. Because they found the message to be literally false as to Type 1 diabetes, there was no need to assess whether there is an undue burden and, according to Judges Christen and Thomas, the ordinance fails on this ground alone.[24]

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[17] *See* Am. Bev. Ass'n v. City & Cty. of S.F., 916 F.3d 749 (9th Cir. 2019).

[18] 854 F.3d 1105, 1115 (9th Cir. 2017).

[19] 916 F.3d at 756–57.

[20] *Id.* at 757.

[21] *Id.* at 758.

[22] *Id.*

[23] *Id.* at 762.

[24] *Id.* at 766.

Nguyen Concurrence

Judge Nguyen disagreed with the majority's expansion of *Zauderer's* rational basis review to commercial speech that is not false, deceptive, or misleading. Judge Nguyen stated that the majority reached the right result under the wrong legal standard. According to Judge Nguyen's reasoning, because the ordinance is not designed to curb false and misleading speech, it fails intermediate scrutiny.[25]

IMPACT

For years, state and local jurisdictions have been trying to address public health concerns resulting from excess sugar in the American diet through either similar ordinances or, in some cases, through taxes on sugary products. This case reminds us that when the effort at changing behavior is directed through compelled commercial speech, the record must demonstrate that there is a clear public health issue, and the measure must ensure compliance with First Amendment protections. When the science is unquestionable, such as in the case of cigarettes, such compelled commercial speech has held up. If local governments hope to address growing public health concerns through such compelled commercial speech, they must have sufficient scientific support showing more than just that the product contains ingredients that have the potential to be dangerous if used to an excess. But most importantly, it is unclear whether other circuits will apply the *Zauderer* standard in the same way as the majority, given the split amongst the Ninth Circuit panel of judges.

This case is far from over. In January 2020, San Francisco passed a new ordinance, imposing a similar warning requirement on beverage labels, but modifying the text and reducing the required warning size from twenty percent to ten percent of the sign. Unsurprisingly, the same industry groups promptly sued again. The case is currently before the District Court for the Northern District of California. Time will tell if this new ordinance survives the standard set by the majority in this case.

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[25] *Id.* at 769.

In re: Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II)

WILLIAM M. JANSSEN*

WHY IT MADE THE LIST

Amidst great fanfare, the Kingdom of Sweden launched its mighty warship, the *Vasa*, into Stockholm harbor on August 10, 1628. The ship had taken two years and hundreds of craftsmen to build. It was three-fourths the length of a modern football field, more than 150 feet tall, with sixty-four cannons manned by 300 soldiers operating from two gun decks, one built atop the other. The *Vasa* was elaborately ornamented, befitting its intended status as a powerful flagship of the Swedish navy. It had roughly 700 sculptures and decorations, painted in vibrant reds, blues, and yellows; some sculptures were even gilded in gold leaf. "Camouflage and melting into the background wasn't anything for *Vasa*. Instead, the exact opposite applied: the ship would be impossible to miss." The ship was to be "a gigantic billboard for Sweden and [its King] Gustav II Adolf."[1]

There must have been someone responsible for the cannons, and someone else responsible for the gunports; someone was in charge of the masts and the sails, and someone else in charge of the rudder. Almost certainly there also was someone responsible for the sculpting and decorations, and someone in charge of the painting and gold-leafing. But who was responsible for making sure *Vasa* could sail?

Late in the afternoon, *Vasa* cast off from the shore. Soon, a simple gust of wind caused *Vasa* to tilt hard to its port side, water gushed through its open gun-port doors, and in minutes the ship sank to the seafloor—a 1,300-meter maiden voyage ended stunningly within sight of the very shipyard where it had been built.[2] As it turns out, *Vasa* was too tall and heavy for its small hull below the waterline creating a calamitously unstable center of gravity.[3] In other words, the problem with *Vasa* was that it couldn't sail.

The *Vasa* lesson was not well remembered by the claimants in *In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II)*.[4] There, a multidistrict litigation ("MDL") of centralized products liability lawsuits pending throughout the

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1 *The Sculptures of Vasa*, VASA MUSEET, https://www.vasamuseet.se/en/vasa-history/art (last visited Mar. 29, 2020). *See generally Timeline*, VASA MUSEET, https://www.vasamuseet.se/en/vasa-history/timeline (last visited Mar. 29, 2020). The tale of the *Vasa* and of the museum where the now-raised ship is displayed is wonderfully told by the curators of the Vasa Museum, one of Scandinavia's most visited tourist sites.

2 *See Timeline*, supra note 1.

3 *See The Disaster*, VASA MUSEET, https://www.vasamuseet.se/en/vasa-history/disaster (last visited Mar. 29, 2020).

4 387 F. Supp. 3d 323 (S.D.N.Y. 2019) [hereinafter *IIH MDL Summary Judgment*].

country sought damages for intrauterine device contraceptive users who suffered from a rare health disorder known as idiopathic intracranial hypertension. Unfortunately, their claims had the *Vasa* problem—it just couldn't sail. The MDL claimants could not establish that the intrauterine device at issue had the capacity (general causation) to cause this hypertension disorder. What followed was an exhaustively detailed federal district court opinion granting MDL-wide summary judgment. The eloquently comprehensive opinion is now a template for other courts' treatment of the threshold products liability issue of "general causation," a distinction that warrants its placement among the top food and drug cases of 2019.

DISCUSSION

The Mirena MDLs

Mirena is an intrauterine system ("IUS," also called an "IUD"—intrauterine device) used to prevent pregnancy.[5] The system is comprised of a "T"-shaped polyethylene frame connected to a reservoir (containing a mixture of levonorgestrel and silicone) mounted around a vertical stem looped with a polyethylene removal thread. Levonorgestrel is a synthetic progestin. The placement of the Mirena system in a patient's uterus, along with its gradual release of levonorgestrel, operates to prevent pregnancy.[6] The system's developer, manufacturer, and distributor—various Bayer healthcare companies—claim that the use of Mirena is "over 99% effective" in preventing pregnancy for up to five years.[7] The system was approved by FDA in 2009[8] and is now included on the World Health Organization Model List of Essential Medicines.[9]

Two different multidistrict litigations were initiated against Mirena. The first, MDL No. 2434 (centralized in 2013), contended that the device triggered post-insertion uterine perforation in patients and asserted product claims on behalf of about 1,300 affected plaintiffs.[10] The presiding judge in this first Mirena MDL ruled that plaintiffs' expert witnesses were unreliable under the federal courts' *Daubert* standard for expert

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[5] *See About Mirena—What is Mirena*, BAYER, https://www.mirena-us.com/about-mirena/ (last visited Mar. 7, 2020).

[6] *See* Bayer HealthCare Pharms., Inc., MIRENA PACKAGE INSERT §§ 11.1 & 12.1 (FDA approved June 8, 2017), available at https://labeling.bayerhealthcare.com/html/products/pi/Mirena_PI.pdf (last visited Mar. 7, 2020) (noting mechanism of action is believed to be "thickening the cervical mucus preventing passage of sperm into the uterus, inhibition of sperm capacitation or survival, and alteration of the endometrium").

[7] *See id.* In October 2019, Bayer submitted a Supplemental New Drug Application to extend Mirena's indication for up to six years, based on the results of a phase 3 extension trial. *See Bayer Submits Supplemental New Drug Application to FDA for Intrauterine Device (IUD) Mirena® (levonorgestrel-releasing intrauterine system) 52 mg*, CISION PR NEWSWIRE, https://www.prnewswire.com/news-releases/bayer-submits-supplemental-new-drug-application-to-fda-for-intrauterine-device-iud-mirena-levonorgestrel-releasing-intrauterine-system-52-mg-300942050.html (last visited Mar. 7, 2020).

[8] *See About Mirena—Q&A*, BAYER, https://www.mirena-us.com/q-and-a/ (last visited Mar. 7, 2020).

[9] *See* WORLD HEALTH ORGANIZATION, MODEL LIST OF ESSENTIAL MEDICINES 22.1.3 (21st list 2019) (Intrauterine devices–levonorgestrel-releasing intrauterine device–intrauterine system with reservoir containing 52 mg of levonorgestrel).

[10] *See* In re Mirena IUD Prod. Liab. Litig., 202 F. Supp. 3d 304 (S.D.N.Y. 2016), *aff'd*, 713 F. App'x 11, 13 (2d Cir. 2017). *See generally* In re Mirena IUD Prod. Liab. Litig., 938 F. Supp. 2d 1355 (J.P.M.L. 2013) (granting MDL centralization).

gatekeeping, thereby foreclosing those witnesses from offering competent causation testimony for plaintiffs' claims.[11] Without such evidence, plaintiffs' claims did not survive Bayer's omnibus motion for summary judgment, which the district court granted in 2016.[12] The United States Court of Appeals for the Second Circuit affirmed both the *Daubert* expert exclusion order and the ensuing omnibus summary judgment ruling in late 2017.[13] Certiorari was sought but denied by the U.S. Supreme Court.[14]

The second group of litigations, MDL No. 2767, alleged that Mirena triggered the onset of a different medical condition, idiopathic intracranial hypertension ("IIH," otherwise known as pseudotumor cerebri ("PTC")). IIH is an uncommon disease (about one case per year per 100,000 people) involving an increase in intracranial pressure caused by excessive cerebrospinal fluid in the skull. Symptoms can include headaches, a hearing disorder, and a swelling of the optic nerves; in severe cases, IIH can lead to blindness.[15] IIH is a diagnosis by exclusion, and is reported to occur twenty times more frequently in obese or overweight women of child-bearing age. It is treated behaviorally by encouraging weight loss; in more serious cases, lumbar punctures can drain excess cerebrospinal fluid.[16] More than 900 plaintiffs filed IIH product liability claims against Mirena.[17]

MDL centralization was sought, but at first refused, by the Judicial Panel on Multidistrict Litigation back in 2014.[18] On a second application three years later, the Panel reversed course and granted the centralization plaintiffs requested, over defendants' objections, explaining its change of view:

> While we previously expressed concern that individualized causation issues might predominate in this litigation, the records in the many actions filed since then demonstrate that discovery and pretrial motions concerning the issue of general causation have been, or will be, at the center of all actions—that is, whether the hormonal component in Mirena is capable of causing intracranial hypertension.[19]

The Panel selected Judge Paul A. Engelmayer of the Southern District of New York to preside over the new MDL.

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[11] *See* In re Mirena IUD Prod. Liab. Litig., 169 F. Supp. 3d 396 (S.D.N.Y. 2016) (discussing Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)).

[12] *See* In re Mirena IUD Prod. Liab. Litig., 713 F. App'x 11 (2d Cir. 2017).

[13] *See id.*

[14] Mirena MDL v. Bayer Healthcare Pharm., Inc., __ U.S. __, 138 S. Ct. 1299 (2018).

[15] *See IIH MDL Summary Judgment*, supra note 4, at 327.

[16] *See id.* at 331.

[17] *See id.* at 337 n.2.

[18] *See* In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig., 38 F. Supp. 3d 1380 (J.P.M.L. 2014).

[19] *See* In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II), 249 F. Supp. 3d 1357, 1359 (J.P.M.L. 2017). The Panel added that "[i]ssues concerning general causation, the background science, and Mirena's labeling and regulatory history with respect to the alleged injury will be common to all actions," and, thus, MDL centralization would "eliminate duplicative discovery, prevent inconsistent pretrial rulings on *Daubert* and other issues, and conserve the resources of the parties, their counsel, and the judiciary." *Id.* at 1361.

Court Rulings on the New Mirena MDL

Just as the JPML had anticipated, general causation became the fulcrum issue in the now centralized Mirena IIH lawsuits. Causation, of course, "is a required element in every products liability case."[20] Satisfying that requirement implicates two showings: "General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury."[21]

Plaintiffs nominated seven expert witnesses on general causation; Bayer nominated twelve of its own. In late 2018, after *Daubert* briefing and oral argument, Judge Engelmayer issued an order much like the one issued in the first Mirena MDL. Each of the plaintiffs' seven expert causation witnesses was excluded. The court found that none had reached their conclusions through personal experiments, laboratory work, or new epidemiological assessment; several had based their conclusions on mere case reports or earlier-published epidemiological studies which either had not found IIH causation or had repudiated an earlier IIH causation finding; and several simply proffered "a thesis as to how, biologically, use of Mirena may cause IIH." Accordingly, Judge Engelmayer ruled that each expert's opinions were methodologically unreliable under the *Daubert* standard and, thus, inadmissible.[22]

Tracing the familiar path staked in the first Mirena MDL litigation, Bayer then moved for summary judgment, positing that the court's exclusion of all plaintiff IIH general causation experts left no remaining genuine dispute of material fact. Specifically, Bayer argued that summary judgment was categorically required in a pharmaceutical products case where, as here, the plaintiff lacks expert evidence of general causation, and, alternatively, even if non-expert evidence of general causation could theoretically suffice, the MDL plaintiffs lacked it. The MDL plaintiffs countered by arguing: (1) general causation was not a required element, and proof of specific causation alone could suffice; (2) if general causation was required, various, non-expert forms of evidence could be stitched together in a manner that would allow a factfinder to find general causation; (3) the court had erred in a preliminary order that directed plaintiffs to informally identify corporate admissions by Bayer on which they intended to rely in opposing summary judgment; and (4) summary judgment for Bayer prior to plaintiff-specific discovery was unconstitutional.[23]

The court began its analysis of the parties' competing arguments by dispatching the threshold fight over whether general causation evidence is even needed in pharmaceutical products cases. After noting the plaintiffs' failure to cite convincing authority for this proposition, the court concluded: "plaintiffs' portrait of state law as absolving a products-liability plaintiff from a need to establish general causation—the capacity of the product in question to cause the injury alleged—is simply wrong."[24]

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[20] *IIH MDL Summary Judgment*, *supra* note 4, at 336 (quoting In re Bausch & Lomb Inc. Contact Lens Sol. Prods. Liab. Litig., 693 F. Supp. 2d 515, 520 (D.S.C. 2010)).

[21] *Id.*

[22] *See id.* at 333–34 (summarizing *Daubert* ruling reported at In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II), 341 F. Supp. 3d 213, 233 (S.D.N.Y. 2018)). The court chose not to rule on plaintiffs' pending motions to exclude Bayer's expert general causation witnesses, surmising that those motions might be rendered moot by Bayer's anticipated summary judgment motion. *See id.* at 334.

[23] *See id.* at 335.

[24] *See id.* at 337–39.

To the contrary, wrote the court, "all relevant jurisdictions require some evidence of general causation in products liability cases involving complex products liability (or medical) issues."[25] Judge Engelmayer then explained why this must be so:

> To assure reliable outcomes in a circumstance where the origins of an injury are not obvious or within the scope of a lay juror's everyday experience, and to avoid the risk that juries would equate correlation (the fact that a given plaintiff used a product and developed injuries) with causation, it is imperative that the factfinder be presented evidence that the product was capable of causing the injury of which a plaintiff complains.[26]

Accordingly, to survive Bayer's summary judgment motion, plaintiffs were obligated to produce admissible evidence from which a reasonable jury could find that Mirena was capable of causing IIH.[27]

Bayer invited the court to make short work of the issue. Without expert evidence of general causation (as the plaintiffs were now left in the wake of the court's *Daubert* order), Bayer pitched that summary judgment was inescapable as a matter of law. The court found "much force" to this contention, since it is "well established" that expert causation testimony is necessary where that issue lies outside the knowledge of lay jurors, as it generally does in pharmaceutical and medical device cases.[28] But the court also noted that its controlling appellate authority, the U.S. Court of Appeals for the Second Circuit, had never definitively resolved the question of "expert-less" general causation; so, the court chose the surer course of assuming, for purposes of Bayer's pending summary judgment motion, the possibility that general causation in complicated medical products liability cases could conceivably be shown through non-expert means.[29]

But no such alternative proof existed. First, the court rebuffed plaintiffs' contention that the differential diagnoses of their respective individual doctors could supply all the causation proof the law required. Such doctors' opinions, ruled the court, were formed solely from examining their patients, and thus could not "qualify as a reliable judgment, consistent with *Daubert*, of the capacity of the product in question (here, Mirena) to cause the condition in question (here, IIH)."[30] Quoting an earlier federal *Daubert* ruling, the court noted: "[E]vidence of specific causation is irrelevant without evidence of general causation."[31]

Second, the court brushed aside plaintiffs' suggestion that "snippets" of their excluded expert witnesses' opinions (presumably, short of those witnesses' ultimate, and now excluded, pronouncements of general causation) could be packaged together,

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[25] *Id.* at 337.

[26] *Id.* at 339.

[27] *See id.* at 340. *See also id.* at 336 (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986) ("there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial")).

[28] *See id.* at 341–43.

[29] *See id.* at 343.

[30] *See id.* at 340.

[31] *See id.* (quoting In re Rezulin Prods. Liab. Litig., 441 F. Supp. 2d 567, 578 (S.D.N.Y. 2006)).

presented in that form to the jury, and thereby supply the factfinder with adequate bases for finding general causation. Such a proposal, the court ruled, was "unsustainable": "the propositions here that plaintiffs propose to use as building blocks for a lay finding as to Mirena's capacity to cause IIH are complex, scientific in nature, and highly technical. They patently require expertise to decode and apply."[32] Laying so complicated a "scientific inquiry before a jury in the absence of a reliable expert opinion . . . [and then asking] the jury to reach a conclusion from it as to general causation, is an invitation to speculation, mischief, and error."[33]

Third, the court spurned plaintiffs' argument that Bayer's own general causation expert witnesses could fill the gap because they could tutor the jury on the methodological criteria that a qualified, admissible expert witness would employ in reaching a general causation conclusion. But being schooled on multi-factor epidemiological standards, the court concluded, "is not a mere box-checking exercise. Sophisticated judgments instead must be made about the existence and probative value of each constituent scientific factor and its relations to the others."[34] This is no proper jury function:

Plaintiffs' notion that a jury, taught by Bayer's experts what the [required general causation] criteria are, could then reliably apply them badly misapprehends—indeed, it trivializes—this mode of epidemiological inquiry. If qualified expert epidemiologists can misapply the . . . factors, a lay jury certainly cannot be counted on to individually evaluate and collectively weigh these factors in a suitably scientifically rigorous manner, one that avoids the risk of conflating correlation with causation.[35]

Fourth, the court rejected plaintiffs' position that a certain retrospective case-control study published in 2019 might be placed before the jury in a manner that would allow them to find general causation. Acknowledging that this study did, in fact, find a statistically significant association between Mirena and IIH, the court then observed that the study itself expressly disclaimed any finding of causation because the association it found could be explained by Mirena's use by patients with attributes that already present an enhanced risk of developing IIH (namely, obesity and recent weight gain).[36]

Fifth, the court dismissed the few final arguments posed by the MDL plaintiffs. Contrary to plaintiffs' insistence otherwise, Bayer had never corporately admitted that Mirena caused IIH, nor could FDA-approved labels for other, different levonorgestrel products qualify as general causation proof.[37] And the granting of summary judgment prior to patient-specific discovery did not violate the U.S. Constitution's Seventh Amendment because in the absence of any evidence from which a jury might reliably find general causation, there was no genuine dispute as to material fact and summary judgment was warranted.[38]

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[32] *See id.* at 344. *See also id.* ("At root, plaintiffs seek to exhume excluded testimony of an intrinsically expert nature and to invite a lay jury to derive from it the very proposition that the Court precluded plaintiffs' experts from offering.").

[33] *See id.* at 346.

[34] *See id.* at 348.

[35] *See id.* at 349–50.

[36] *See id.* at 351–53.

[37] *See id.* at 353–57.

[38] *See id.* at 357–58.

IMPACT

The *capacity* of a product to inflict a claimed harm really should not be a controversial prerequisite for product liability victory. Indeed, even in its most pioneering infancy, strict liability theory never doubted the necessity of proving causation.[39] That certainty was borne of a well-settled heritage; a hundred years ago, the eminent Judge Benjamin Cardozo admonished against overlooking this causation truism: "We must be on our guard . . . against confusing the question of negligence with that of the causal connection between the negligence and the injury . . . . 'Proof of negligence in the air, so to speak, will not do.'"[40] Today, notwithstanding variations among states, causation remains a "core" element on which all jurisdictions agree.[41] That element, in turn, is comprised of two showings: is the product capable of causing this particular harm (general causation), and did it inflict that harm on me (specific causation)?[42]

In the world of pharmaceuticals and *Daubert* gatekeeping, however, this first undertaking (general causation) can prove to be a challenging—and often unattainable—climb. As Judge Posner aptly wrote some years back: "Law lags science; it does not lead it."[43] Scientific guesswork, he noted, "even of the inspired sort," has no place in the courts.[44] So, general causation may obligate plaintiffs to produce as evidence something that may well be evading science: proof of a product's toxic capacity. This is not, however, a failing of the justice system. Rather, it is an inescapable attribute of justice. "[T]he classic test for determining cause in 'fact' directs the 'factfinder' to compare what did occur with what would have occurred if hypothetical, contrary-to-fact conditions had existed . . . . An act or omission is not regarded as a cause of an event if the particular event would have occurred without it."[45] Because the bedrock anchor of our compensatory civil law is the responsibility to others, "are-you-responsible-for-what-happened" operates as an irreducible first principle of justice. If it is not possible for you to have been responsible (that is, if general causation is absent), then justice commands your exculpation.

Judge Engelmayer's opinion spans thirty-five pages in the Federal Supplement-Third to explain how he resolved what he called "the gateway issue of general causation" in the Mirena IIH litigations.[46] Its careful, methodical, and scholarly treatment comes with a feature that not all judicial opinions possess: readability. Walking the reader slowly through an easy-to-follow recounting of each step in his

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[39] *See, e.g.*, Greenman v. Yuba Power Prod., Inc., 377 P.2d 897, 900 (Cal. 1963) ("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.") (emphasis added).

[40] *See* Martin v. Herzog, 126 N.E. 814, 816 (N.Y. 1920) (Cardozo, J.).

[41] *See* DAVID G. OWEN, PRODUCTS LIABILITY LAW § 5.3, at 257 (3d ed. 2015).

[42] *See id.* § 11.2, at 721 ("Proof of causation in toxic substance cases always involves, at least implicitly, two separate forms of causal proof: (1) general causation and (2) specific causation. To establish "general causation," a plaintiff must establish that the suspect agent is capable of causing the particular injury or illness suffered by the plaintiff.") (footnotes omitted).

[43] Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) (Posner, J.).

[44] *Id.* ("the courtroom is not the place for scientific guesswork, even of the inspired sort . . . . There may be evidence to back up [an expert's] claim . . . ").

[45] PROSSER AND KEETON ON THE LAW OF TORTS § 41, at 265 (5th ed. 1984).

[46] *IIH MDL Summary Judgment*, *supra* note 4, at 358.

painstaking analysis of complex principles presented in a readily appreciated manner, Judge Engelmayer's opinion now serves as the veritable template for proper general causation decisionmaking.[47]

What will likely make Judge Engelmayer's opinion so influential in the law of general causation is the care with which it was crafted.

Noting that the Mirena IIH plaintiffs had "not adduced any . . . products liability cases disclaiming the need to prove general causation," the court could have reached a preemptive, summary conclusion on the question, but did not; instead, the court chose to parse through a formidable inventory of national case law to reach what, by then, readers would accept as the well-supported conclusion that "all relevant jurisdictions require some evidence of general causation in products liability cases involving complex products liability (or medical) issues."[48] Pages later, Judge Engelmayer was still completing his meticulous explanation why "proof of general causation plays a vital role in complex cases where the capacity of a product to cause a species of injury is not intuitively obvious."[49]

The opinion also contributes to the nation's general causation jurisprudence by its careful and well-explained discussion of the Mirena plaintiffs' reliance on proof of specific causation as a sort of back-filler for their lack of general causation evidence. That back-filling role, Judge Engelmayer explained, is one that specific causation just cannot fill. Plaintiffs proposed to offer the testimony of the myriad of doctors who treated them and then engaged in differential diagnosis to surmise that Mirena caused their respective IIH. "There is of course a proper place for testimony about the causes of an individual plaintiff's symptoms," wrote the court. "That is the essence of the *specific* causation inquiry undertaken if there is competent evidence of general causation."[50] But that "if" matters greatly. At the risk of restating the obvious: unless Mirena can first be reliably shown to be a true candidate for causing a patient's IIH, the product has no business being included in a differential diagnosis assessment at all. Numerous prior court decisions have treated this general-causation-first sequencing as self-evident.[51]

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[47] This is not to disparage his colleague Judge Cathy Seibel's impressive treatment of the general causation issue in the first Mirena MDL, a treatment which Judge Engelmayer credited as informing his IIH decision. *See id.* at 329–30.

[48] *Id.* at 337.

[49] *Id.* at 339.

[50] *Id.* at 340.

[51] *See, e.g.*, In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502, 892 F.3d 624, 643–44 (4th Cir. 2018) ("differential diagnosis is . . . *accomplished by 'determining the possible causes for the patient's symptoms* and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely'") (emphasis added; citations omitted); Kirk v. Schaeffler Grp. USA, Inc., 887 F.3d 376, 392 (8th Cir. 2018) ("A differential etiology *rules in plausible causes and then* systematically rules out less plausible causes until a most plausible cause emerges.") (emphasis added); McManaway v. KBR, Inc., 852 F.3d 444, 454–55 (5th Cir. 2017) ("a differential diagnosis is *only relevant after general causation has been reliably established* 'because a differential diagnosis *presumes* that chemical X can cause condition Y generally, but does not itself so prove'") (emphasis added; citation omitted); Johnson v. Arkema, Inc., 685 F.3d 452, 468–69 (5th Cir. 2012) ("an expert may not rely on a differential diagnosis to circumvent the requirement of general causation;" "before courts can admit an expert's differential diagnosis, which, by its nature, only addresses the issue of specific causation, the expert must first demonstrate that the chemical at issue is actually capable of harming individuals in the general population," rejecting a differential diagnosis "based on the presumption" of general causation); Huerta v. BioScrip Pharmacy Servs., Inc., 429 F. App'x 768, 773 (10th Cir. 2011) ("a differential diagnosis can be admissible if the district court concludes that it

Interestingly, not all courts have shut this sequencing door quite so tightly as Judge Engelmayer and those prior decisions have. Some courts, albeit tepidly, have reserved on the question, refusing to pronounce unequivocally that a physician's patient-specific differential diagnosis could never qualify as *Daubert*-proper general causation evidence.[52] If this reservation is simply based on a "never-say-never" philosophy in opinion-writing, it is a safe judicial approach but not an especially helpful one. To surmise that a differential diagnosis opinion could supply proper general causation proof could be, perhaps, just a shorthand way of acknowledging that the same expert witness could carry both proofs. That is not outside the realm of possibility, to be sure. An expert epidemiologist with a *Daubert*-qualifying history of performing validating general causation science could be summoned to examine a patient and, armed with that expert's own, sound, scientifically-established experience, conduct a differential diagnosis, and then offer an expert opinion that might be accepted as establishing both general and specific causation. But that is not because the differential diagnosis itself carries both proofs; it is because the expert, independent of her differential diagnosis, can separately reach both conclusions. Thus, courts are not necessarily wrong in this "never-say-never" hedge. But it certainly invites the mischief of lower courts misreading this conclusion as justification for allowing general causation to go to the jury on the basis of a physician's testimony that he did a really super, darn good patient exam.[53]

Judge Engelmayer's opinion does not stumble into that misguidance. His opinion sharply focuses the inquiry for readers: pharmaceutical personal injury plaintiffs need *Daubert*-qualifying proof that the product they blame can cause the type of injury that they suffered *and* then *Daubert*-qualifying proof that it did so. As the opinion crisply

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is reliable *and if general causation has been established*") (emphasis added); Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1342 (11th Cir. 2010) (differential diagnosis "involves a process of compiling, or ruling in, a comprehensive list of possible causes that are generally capable of causing the illness or disease at issue, and then systematically and scientifically ruling out specific causes until a final, suspected cause remains"; "It assumes the existence of general causation, and focuses instead on specific causation. The expert must show through reliable evidence that the remaining cause ruled in as actually being capable of causing the condition.").

[52] *See, e.g.*, Sims v. Kia Motors of Am., Inc., 839 F.3d 393, 402 (5th Cir. 2016) (noting that court has never held "that differential diagnosis may never satisfy *Daubert*. Rather we observe that the district court has broad discretion to make the fact-specific inquiry in a given case as to whether such an approach is sufficiently reliable, especially in the absence of evidence 'ruling in' an expert's conclusion."); Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) ("We cannot say that a differential diagnosis *may never* provide a sufficient basis for an opinion as to general causation. There may be instances where, because of the rigor of differential diagnosis performed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance, a differential diagnosis is sufficient to support an expert's opinion in support of both general and specific causation."); C.W. ex rel. Wood v. Textron, Inc., 807 F.3d 827, 838–39 (7th Cir. 2015) ("We disagree with the district court's categorical exclusion of differential etiology as a method to establish general causation . . . . [T]here may be a case where a rigorous differential etiology is sufficient to help prove, if not prove altogether, *both* general *and* specific causation.").

[53] *See* Edward J. Imwinkelried, *The Admissibility and Legal Sufficiency of Testimony About Differential Diagnosis (Etiology): Of Under—and Over—Estimations*, 56 BAYLOR L. REV. 391, 406 (2004) ("Differential etiology analysis is not formal scientific proof. On the general causation issue, an opinion derived from such analysis seems to be at most an educated guess.") (footnotes omitted); *id.* at 414 ("Standing by itself, the differential etiology opinion will almost always be insufficient to establish general causation. Although etiological analysis may identify the factor as the most likely cause in an individual case, without more that analysis raises only a suspicion on the issue of general causation.").

summarizes the point later in its discussion: "Simply put, a jury's role is not to engage in impermissible 'scientific guesswork.'"[54]

Finally, the opinion well serves the general causation jurisprudence in one other way. Judge Engelmayer seems to have come quite close to ruling that an absence of *expert* evidence of general causation necessarily compels the entry of summary judgment in pharmaceutical cases.[55] Perhaps convinced of the wisdom of the "never-say-never" approach here, he stepped back from that leap. What he did next, however, verifies the harmlessness of that choice. For the better part of the next seventeen pages, the opinion carefully weighed the full array of the Mirena plaintiffs' non-expert substitutes for proving general causation. After a searching consideration, each was rejected.[56] Thus, the court's "never-say-never" pause led to an exhaustive assessment that answered the essential question that general causation always poses: was there a reliable factual basis on which a jury could find that Mirena causes IIH, or would jurors be left to guess?

The opinion in *In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. 11)* gives general causation the importance, time, and care it deserves. It is a model for similar analyses by other jurists and thus represents a formidable contribution to the jurisprudence in this area.

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[54] *IIH MDL Summary Judgment*, *supra* note 4, at 344.

[55] *See id.* at 341 ("It is well established that 'expert testimony is required to establish causation' where the issue of causation is 'beyond the knowledge of lay jurors.' Other courts, surveying the law of the 50 states and territories, have concluded that each jurisdiction typically adheres to this principle.").

[56] *See also* In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502, 892 F.3d 624, 647 (4th Cir. 2018) ("There may be cases involving complex issues in which a party admission standing alone can suffice to avoid summary judgment. But we would expect those cases to be rare indeed.").

Becerra v. Dr Pepper/Seven Up, Inc.

AUGUST T. HORVATH*

WHY IT MADE THE LIST

Motions to dismiss cases that are part of the current wave of food and beverage advertising and labeling class action litigation often hinge on whether the plaintiffs have plausibly pled that a reasonable consumer will be deceived by the allegedly implied meaning of some marketing or labeling content that is challenged in the suit. This "reasonable consumer" standard is fairly consistently interpreted across U.S. states and federal districts, and courts can decide whether it has been adequately pled on an early motion to dismiss. When a leading Circuit Court of Appeals issues a decision providing guidance on this standard in this context, it is therefore of great interest to litigants in these cases. The Ninth Circuit Court of Appeals did so on December 30, 2019, in the appeal of a dismissal in *Becerra v. Dr Pepper/Seven Up, Inc.*[1] In that decision, the Ninth Circuit examined the plausibility of the plaintiffs' allegations that the word "Diet" as part of the name of a beverage such as "Diet Dr Pepper" implies not just that the so-labeled soft drink contains less sugar or calories relative to its non-"Diet" counterpart, but promised "that the product would 'assist in weight loss' or at least 'not cause weight gain.'" The Ninth Circuit's decision provided useful guidance on the application of the reasonable-consumer standard generally, as well as a specific, definitive ruling on the viability of "diet" soda cases, one of the major currents in the ongoing food labeling litigation wave.

DISCUSSION

Numerous consumer class action lawsuits have been litigated in various federal districts around the United States in recent years concerning the labeling of foods and beverages, including the construction of these products' names as presented on the front or primary display panel (PDP) of their packaging. These suits often allege that the labeling communicates to consumers something misleading about the presence, absence, absolute amount, or relative amount of one or more ingredients or nutrients, or about the general nutritional quality of the food or beverage. One of the major strains of this litigation has been cases that focus on "diet" and related designations, principally of beverages, but sometimes of food products. Defendants typically seek to dismiss these cases through a motion filed under Federal Rule of Civil Procedure 12(b)(6), in lieu of a pleading in response to the complaint, contending that the complaint does not plausibly allege that a reasonable consumer, acting reasonably

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[1] 935 F.3d 1225 (9th Cir. 2019), appealed from *Becerra v. Dr Pepper/Seven Up Inc.*, No. 17-cv-05921-WHO (N.D. Cal. Aug. 21, 2018).

under the circumstances, would interpret the product's labeling as alleged by the plaintiffs. Even though the suits in question are brought under state consumer protection laws which, by their nature, create something of a patchwork, the case law under these statutes has tended to adopt a consistent expression of this "reasonable consumer" standard. Therefore, the Ninth Circuit's ruling on this standard is cited as persuasive authority in cases across the United States, and potentially has broad influence beyond the California laws that it interprets.

The Reasonable Consumer Standard

Consumer false-advertising lawsuits in the United States generally are filed under state consumer protection or unfair/deceptive acts and practices (UDAP) statutes, there being no federal statute providing a purchaser cause of action for most false-advertising violations. When these suits are lodged against national brands, they commonly are filed in the U.S. District Court in which the plaintiff resides, in anticipation that the defendant likely would seek to remove them to federal court anyway under the Class Action Fairness Act (CAFA).[2] Even when an advertising class action's qualification for federal jurisdiction under CAFA is dubious, plaintiffs' counsel often file the cases in federal court, and defendant food companies, preferring that venue, do not object. Therefore, most of the recent cases, and case law, interpreting these state false-advertising law in the class action context occurs in the federal courts.

California has been the most active jurisdiction in consumer class-action false-advertising lawsuits in recent decades for several reasons, including: (1) the expansive scope and generous private rights of action provided by California's Unfair Competition Law (UCL),[3] False Advertising Law (FAL),[4] and Consumer Legal Remedies Act (CLRA);[5] (2) its perceived consumer-sympathetic judiciary and favorable case law for plaintiffs; and (3) the size of the state's population and economy, which can lead to large estimates of damages even when only a class of California consumers is alleged or certified. Substantively, there is overlap between the required elements of a false-advertising claim under the UCL, FAL, and CLRA, and advertising suits typically are brought under all three, as well as appurtenant common-law causes of action, under a single pled set of facts and allegations.

One common element of a false-advertising case under the UCL, FAL, and CLRA, as well as other laws around the U.S., is that the plaintiffs must initially plead, and later prove, that "members of the public are likely to be deceived" by the challenged advertisements or labels.[6] Analytically, there are two parts to establishing that someone is deceived. First, the person must have been persuaded to believe something to be true. Second, that belief must, in reality, be false. The "reasonable consumer" standard relates to the first of these two parts. Unless the marketing statement challenged has only a single, unambiguous, literal meaning, plaintiffs must plead and prove that it implies something to consumers that plaintiffs can then demonstrate is

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2 28 U.S.C. §§ 1332(d), 1453, 1711-1715.

3 Cal. Bus. & Prof. Code §§ 17200 et seq.

4 Cal. Bus. & Prof. Code §§ 17500 et seq.

5 Cal. Civ. Code §§ 1750 et seq.

6 Williams v. Gerber Prods. Co., 552 F.3d 934, 938 (9th Cir. 2008).

false. Whether members of the public are likely to perceive a particular meaning "must be evaluated from the vantage of a reasonable consumer."[7]

The question of whether reasonable consumers might infer a particular message from an advertisement or label is generally factual in the sense that consumers either do or do not receive the alleged message. At trial, the issue usually is proven through an expert witness who has conducted a consumer survey finding that some percentage of consumers allegedly report inferring the challenged message. But this does not immunize allegations of implied meaning from scrutiny on a motion to dismiss. Even as to matters of fact, the plaintiff must "allege enough facts to state a claim to relief that is plausible on its face."[8] And while factual allegations pled in a complaint generally are taken as true and construed in the light most favorable to the plaintiff for purposes of a motion to dismiss,[9] a plaintiff cannot plead just any baseless, conclusory, unsupported, or implausible set of facts in a complaint and expect to have them credited.[10] Determining whether the facts pled by a plaintiff are plausible is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense."[11]

The definition of a "reasonable" consumer itself has two aspects. It is generally acknowledged that not all consumers are reasonable. In the ultimate proof at trial, establishing "reasonable" consumer reactions through surveys is basically a numbers game. If at least some percentage, generally around 20% to 25%, of consumers are established to have received a particular message, as shown by competent surveys using appropriate controls, then it is assumed, at least presumptively, that among the misled are some reasonable consumers. Courts, however, can and do override, discard, or preclude such survey findings if, on the exercise of their judicial experience and common sense, they find that a challenged message clearly and unambiguously *does not* have the implied meaning alleged by the plaintiffs, in the context in which it is used.[12]

Courts generally have been reluctant to second-guess plaintiffs' allegations of the implied meanings of advertising and marketing claims at the motion-to-dismiss stage. Prior to *Becerra*, the leading case from the Ninth Circuit Court of Appeals was *Williams v. Gerber*,[13] in which the Court overturned a decision dismissing, on implausibility grounds, a suit alleging that packing a juice product with the claim "fruit juice," juxtaposed with images of particular fruits, implied that the juice primarily consisted of the juice of the fruits pictured, rather than the juice of some other, less desirable fruit. *Williams* made it difficult, in the Ninth Circuit, to dismiss a case for the implausibility of its allegations as to the meanings consumers receive from advertising and labeling.

Class-action plaintiffs, however, seemed to respond to *Williams* pushing the envelope of how implausible their claims of implied meaning could be before a court

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[7] *Id.*

[8] Turner v. City & Cty. of San Francisco, 788 F.3d 1206, 1210 (9th Cir. 2015).

[9] Ebner v. Fresh, Inc., 838 F.3d 958, 962 (9th Cir. 2016).

[10] In re Gilead Scis. Sec. Litig., 536 F.3d 1049, 1055 (9th Cir. 2008).

[11] Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009).

[12] *See, e.g.*, Pernod Ricard USA, LLC v. Bacardi U.S.A., 653 F.3d 241 (3d Cir. 2011); Abbott Labs. v. Mead Johnson & Co., 201 F.3d 883 (7th Cir. 2000), *amended*, 209 F.3d 1032 (7th Cir. 2000).

[13] 552 F.3d 934 (9th Cir. 2008).

acknowledged that there are some limits to the generous position articulated in *Williams*. In *Becerra*, they appear to have found such a limit.

THE BECERRA CASE

Background

The defendant in *Becerra* makes several popular beverages, including the soda Dr Pepper and its variant, Diet Dr Pepper. Diet Dr Pepper, marketed since 1962, contains no sugar and has no calories; it is sweetened with the no-calorie sweetener aspartame. Diet Dr Pepper is labeled, like many other diet sodas, to denote these characteristics relative to regular Dr Pepper, which is sweetened with sugar and has about 150 calories per 12-ounce serving. The class representative plaintiff, Shana Becerra, alleged that she believed that the term "Diet" in "Diet Dr Pepper" promised her that the beverage would help her to lose weight or to maintain a healthy weight, as if consuming the product were tantamount to going on a diet, in the sense of adopting a disciplined weight-control plan. She further alleged that not only does Dr Pepper fail to produce the claimed benefit of weight loss or maintenance, but on the contrary, aspartame-sweetened sodas have been shown to contribute to weight gain. As a class representative, she also asserted that she was typical of reasonable California consumers, who allegedly were similarly misled.

It took a total of four complaints to get the ultimate decision by the assigned District Judge in the U.S. District Court for the Northern District of California, the Hon. William H. Orrick. The original and first amended complaints had to be amended further because of technical and procedural defects, so the Second Amended Complaint was the first to be considered on the merits relevant here. In a March 2018 decision, Judge Orrick dismissed the complaint, agreeing with the defendant's contention that "it is not plausible that a reasonable consumer would believe that drinking Diet Dr Pepper would assist in weight loss, beyond the fact that it has no calories."[14] Judge Orrick first recited the law discussed above, and added that in California, where false advertising claims "sound in fraud," pleadings are subject to Federal Rule of Civil Procedure 9(b)'s requirement that they "state with particularity the circumstances constituting fraud or mistake" that are alleged.

Judge Orrick cited two Ninth Circuit cases that had been decided since *Williams v. Gerber* dismissing advertising cases on grounds that the alleged deception was implausible, *Ebner v. Fresh, Inc.*[15] and *Forouzesh v. Starbucks Corp.*[16] In *Ebner*, the Ninth Circuit had affirmed dismissal of an advertising case alleging that a cosmetics company's "lip product was deceptive because the net weight accurately indicated the included product, but the tube design's screw mechanism only allowed 75% of the product to advance up the tube, leaving the remaining 25% inaccessible" because "it was implausible that a rational consumer would make the assumption that there was no further product in the tube once using up the initial 75% when the remainder was plainly visible."[17] In the *Starbucks* case, decided just days before this first *Becerra*

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[14] Becerra v. Dr Pepper/Seven Up, Inc., No. 17-cv-05921-WHO (N.D. Cal. March 30, 2018) (Order Denying Motion to Transfer and Granting Motion to Dismiss).

[15] 838 F.3d 958 (9th Cir. 2016).

[16] No. 16-56355 (9th Cir. March 12, 2018).

[17] *Becerra,* No. 17-cv-05921-WHO (N.D. Cal. March 30, 2018).

decision, the Ninth Circuit affirmed "as a matter of law" that "no reasonable consumer would think (for example) that a 12-ounce 'iced' drink, such as iced coffee or iced tea, contains 12 ounces of coffee or tea and no ice."[18] Further, another Northern District of California judge had recently dismissed a similar case by the same plaintiff against Diet Coke on the same grounds.[19]

After reviewing these precedents, Judge Orrick concluded:

> Diet Dr Pepper is a "diet" product *relative* to regular Dr Pepper, because Diet Dr Pepper contains zero calories. A reasonable consumer knows that this is and always has been true of soft drinks generally—"diet" soft drinks are simply lower calorie or calorie-free versions of their sugar-laden counterparts. A reasonable consumer would have no basis to infer anything more from Diet Dr Pepper's label or advertising than that it is a calorie-free soft drink.[20]

Judge Orrick gave the *Becerra* plaintiffs a chance to amend. In their third amended complaint, it became more clear that the fundamental fault with the plaintiff's implausible deception theory was an out-of-context interpretation of the word "diet" to mean a disciplined weight-loss or weight management program, an interpretation for which the plaintiffs provided dictionary definitions and similar evidence. Their theory turned out to be, or perhaps evolved into, the idea that putting "diet" on a soda can is telling consumers that consuming the product is tantamount to going on a diet, or at least would be part of such a process. Of course, as Judge Orrick point out, the word "diet" does mean a weight loss or weight management program in some contexts—just not when it is printed on a soda can.[21] In that context, a "diet" soda has been understood by reasonable consumers for more than half a century to mean a no- or low-sugar, and/or no- or low-calorie, soft drink, usually relative to the same brand's non-"diet" product. The fact that "diet" can have the meaning ascribed by the plaintiffs in another context did not compel the court to defer judgment on whether such other meaning was plausible in the context in which it was alleged. After all, the word "diet" can have still other meanings—it can mean, for example, the totality of a person's or a community's nutritional intake, as in, "The American diet contains too much fat," or "Jeanine's diet consists almost entirely of caviar and boxed red wine," but such meanings make no sense on a soda can. It was mainly because of this important element, the *context* of the claim, that Judge Orrick again held, "After analyzing each of these new factual allegations, the result does not change. Becerra has not pleaded a plausible claim that reasonable consumers would be deceived by the use of "diet" in the Diet Dr Pepper label."[22]

One of the unsuccessful additions to the *Becerra* complaint deserving of special mention is the inclusion of results of a consumer survey that plaintiffs' counsel had

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[18] *Id.*

[19] Becerra v. Coca-Cola Co., No. C-17-05916-WHA, 2018 WL 1070823, at *3 (N.D. Cal. Feb. 27, 2018).

[20] *Id.*

[21] Becerra v. Dr Pepper/Seven Up, Inc., No. 17-cv-05921-WHO (N.D. Cal. Aug. 21, 2018) (Order Granting Motion to Dismiss).

[22] *Id.*

commissioned, purporting to show that a substantial proportion of consumers view diet sodas as weight-loss products. Introducing such a survey in a pleading would appear, superficially, a potent strategy, given the importance of consumer surveys for deciding questions of advertising interpretation later in the case and assuming that the court must credit the results of the survey for purposes of a motion to dismiss. This latter assumption, however, turns out to be wrong; a court is *not* required to accept the results of a survey at face value when deciding a motion to dismiss. On the contrary, Judge Orrick held that such a survey, when offered in support of allegations that are otherwise implausible, does not carry much weight at all. The plaintiffs did not provide sufficient backup materials for the court to evaluate their survey—"it appears in the complaint without reference to methodology, what questions were asked, or who administered it"—and in the framework of a pleading, it may be difficult or impossible to do so. It certainly is impossible to provide the defendant with the opportunity to critique or rebut the survey in briefing a pleading motion. Further, even if the survey were taken as "true," the wording of its questions was such that it did not lend itself to the interpretation put on the results by the plaintiffs' counsel who had commissioned it.

The Ninth Circuit Decision

Because review of a decision dismissing a case requires reference only to the case pleadings and the parties' arguments, dismissal of a complaint for failure to state a claim is reviewed *de novo*.[23] In considering the deception allegations, the Ninth Circuit assigned the same importance to the context of the challenged claims that Judge Orrick had:

When considering the term in its proper context, no reasonable consumer would assume that Diet Dr Pepper's use of the term "diet" promises weight loss or management. In context, the use of "diet" in a soft drink's brand name is understood as a relative claim about the calorie content of that soft drink compared to the same brand's "regular" (full-caloric) option.[24]

The Circuit Court noted that the plaintiff had been selective and misleading in her selection of dictionary definitions of "diet" in the third amended complaint, quoting definitions in which "diet" was used as a noun and as a verb, but omitting the more on-point definitions from the same dictionaries of diet when used as an adjective—"For example, the Merriam Webster Dictionary defines the adjective 'diet' as 'reduced in or free from calories[—]a diet soft drink.'"[25]

The Ninth Circuit generally agreed with the District Court on the handling of the survey added to the third amended complaint, with perhaps one nuance:

Although we must accept the allegations surrounding the survey as true at this stage of the litigation, a reasonable consumer would still understand 'diet' in this context to be a relative claim about the calorie or sugar content of the product. The survey does not address this understanding or the equally reasonable understanding that consuming low-calorie products will impact one's weight only to the extent that weight loss relies on consuming fewer calories overall."[26]

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[23] *Ebner*, 838 F.3d at 962.

[24] *Becerra*, 945 F.3d at 1229.

[25] *Id.*

[26] *Id.* at 1231.

Judge Orrick did not appear to agree with the qualification at the beginning of this passage. However, the Ninth Circuit's statement that "we must accept the allegations surrounding the survey as true at this stage of the litigation" differs less from Judge Orrick's conclusion and carries less value for plaintiffs than might appear, given the rest of the Ninth Circuit's analysis. The Ninth Circuit seems to have held that while it must accept as true the allegations that the survey existed, that respondents answered the questions as alleged in the complaint, and possibly even that the survey was scientifically credible, the court clearly is *not* required to accept the plaintiff's interpretation of the survey results as support for the other complaint allegations. Thus, the Ninth Circuit held, "the survey does not shift the prevailing reasonable understanding of what reasonable consumers understand the word 'diet' to mean or make plausible the allegation that reasonable consumers are misled by the term 'diet.'"[27]

IMPLICATIONS, IMPACT, AND RELATED CASES

Becerra comes after a recent, consistent decision by the Second Circuit Court of Appeals in *Excevarria v. Dr Pepper Snapple Group, Inc.*,[28] in which, as in *Becerra*, the plaintiffs alleged that the word "diet" in the name of Diet Dr Pepper "is misleading because it conveys certain promises about the beverage's usefulness in assisting with weight loss or healthy weight management, when in fact (plaintiffs allege, based on a number of studies) the aspartame in Diet Dr Pepper likely causes weight gain." The Second Circuit upheld dismissal of the case, but in a way that was less satisfying and useful for plaintiffs seeking to dismiss such cases. Firstly, the Second Circuit's decision was a Summary Order that does not have precedential effect and may only be cited as persuasive authority. More importantly, the Second Circuit declined to decide whether "a reasonable consumer would understand the word 'diet' to convey promises about weight loss or management," instead focusing on whether there was a plausible basis for the plaintiffs' allegations that aspartame in sodas causes weight gain, which it concluded—based on reviews of the plaintiffs' cited studies by District Courts within the Circuit—there was not.[29] Besides being non-precedential, then, these decisions were confined to cases involving aspartame-based diet soft drinks, and did not squarely address the reasonable consumer's interpretation.

Other courts followed the *Becerra* holding with respect to other, substantially identical, attacks on "diet" soda labeling, even without waiting for the Ninth Circuit to affirm Judge Orrick. In *Geffner v. The Coca-Cola Company*,[30] the Second Circuit Court of Appeals affirmed such a dismissal, addressing the issue that they had declined to decide in *Excevarria*. Citing the two Orrick decisions but writing before the *Becerra* appeal was decided, the Second Circuit held that:

> [c]onsistent with the rulings of every court that has addressed this issue, we hold that when included in a soft drink title, the adjective "diet" (1)

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[27] *Id.*

[28] No. 18-1492 (2d Cir. Apr. 17, 2018) (Summary Order).

[29] *Id.* The Second Circuit had held similarly, again in Summary Order format, earlier in 2019 in *Manuel v. Pepsi-Cola Co.*, No. 19-1748 (2d Cir. March 15, 2019) (Summary Order).

[30] 928 F.3d 198 (2d Cir. 2019).

> refers specifically to caloric content rather than a generic promise of weight-loss, and (2) carries a primarily relative (in relation to the non-diet soft drink equivalent), rather than an absolute, meaning.[31]

This decision established the meaning of a "diet" soda as a matter of law in the Second Circuit, leaving no apparent room for plaintiffs to introduce survey or other evidence purporting to show that it has any other meaning.

The *Becerra* and *Geffner* appellate decisions have put an end to cases challenging the designation of a "diet" soda as a weight loss or weight maintenance claim in the two most active circuits for food labeling litigation, and it is difficult to foresee such cases gaining traction in other circuits. Taken together, the various District Court and Circuit Court of Appeals decisions about diet soda provide a case study in how courts achieve consensus that a widespread false-advertising theory is devoid of merit. The first necessary step is for a District Court judge to brave the general appellate disapproval of dismissing this type of claim by writing a reasoned opinion, applying common sense to the allegations of deception and giving the "reasonable consumer" some credit for having cognitive ability and an understanding of context. This creates space for other District Court judges to agree, and if a plaintiff is inclined to appeal, the appellate courts—again, citing each other, as well as the trial courts—can, possibly in stages starting with the easier aspects of the decision, solidify the consensus. It may take a few years, but an implausible theory that has cost the food industry substantial resources, and that potentially might have cost much more, can, in this way, be consigned to the legal scrap heap.

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[31] *Id.*

2019 Significant Settlements

BY: JUSTINE E. JOHNSON*

INTRODUCTION

This chapter summarizes a selection of significant settlements in 2019 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 2019, the federal government recovered $3.05 billion in FCA judgments and settlements, $2.6 billion of which came from health care and life sciences companies.[1] The 2019 recovery increased five percent from the ten-year low of $2.9 billion in 2018 and total recoveries amount to $62 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 633 whistleblower suits filed in 2019 (as compared to 146 cases filed by the government), which resulted in DOJ recovering $2.1 billion from these and earlier filed suits and $244 million awarded to relators for their role.[3]

Reflecting DOJ's focus on drug companies' role in the prescription opioid crisis, two of the largest recoveries involved opioid manufacturers, Insys Therapeutics and Reckitt Benckiser Group plc, both detailed in this chapter. Consistent with DOJ's memorandum issued in September 2015 commonly referred to as the "Yates Memorandum," DOJ also continued its commitment under the FCA to deter and remedy fraud by corporations and individuals alike. The settlement reached with Diabetic Care Rx LLC and a private equity firm, Riordan, Lewis & Haden Inc., involved settlement by two executives in an amount totaling over $300,000. Further, many of the resolutions involved multi-year Corporate Integrity Agreements ("CIAs"), which require individual accountability for corporate decision-making going forward.

Certain DOJ policy developments in 2019 also help to reveal what DOJ may prioritize in lawsuits and investigations going forward. In April 2019, DOJ issued

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1 Fraud Statistics – Overview (DOJ Dec. 2019).

2 *Id.*

3 *Id.*; *Press Release, Justice Department Recovers Over $3 Billion from False Claims Act Cases in Fiscal Year 2019*, DOJ (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

updated guidance that, while binding only on the Criminal Division, is intended to assist prosecutors across the department in their evaluation of corporate compliance programs.[4] The Criminal Division evaluates each corporate compliance program in the context of the individual investigation; however, the guidance encourages prosecutors to consider a set of factors including: (i) whether the program was well designed (e.g., the company appropriately identified, assessed, and defined its risk profile and designed a program to address this risk, had an appropriate reporting structure and investigation process, etc.); (ii) whether the program was implemented effectively; and (iii) whether the program actually works in practice. DOJ expects that successful compliance programs will be designed to identify the type of misconduct most at risk of occurring in the company's line of business, and the success of a program may directly impact a prosecutor's decision to "charge only the corporation's employees and agents or to mitigate charges or sanctions against the corporation."[5] Further, in an effort to encourage companies to voluntarily disclose misconduct, DOJ issued guidance in May 2019 that sheds light on DOJ's position of awarding credit to defendants who cooperate in an FCA investigation by identifying the type of activities eligible for credit.[6]

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 2019.

DRUGS

Reckitt Benckiser Group plc[7]

Reckitt Benckiser Group plc ("RBG") agreed to pay $1.4 billion to resolve potential criminal and civil liability related to a federal investigation into the sales and marketing of Suboxone, an opioid addiction treatment drug, by Indivior Inc. ("Indivior"), a wholly-owned subsidiary of RBG until December 2014 (then known as Reckitt Benckiser Pharmaceuticals Inc.). This resolution included: (i) $647 million in forfeiture of proceeds; (ii) $700 million in civil settlements with the federal government and the states; and (iii) $50 million in an administrative resolution with the Federal Trade Commission ("FTC"), and constitutes the largest recovery by the U.S. in a case regarding an opioid drug.

The government alleged that Indivior (and from 2010 to 2014, RBG either directly or through its subsidiaries) engaged in an illicit nationwide scheme to increase

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[4] DOJ CRIMINAL DIVISION, EVALUATION OF CORPORATE COMPLIANCE (June 2020), https://www.justice.gov/criminal-fraud/page/file/937501/download.

[5] DOJ, JUSTICE MANUAL—9-28.800 CORPORATE COMPLIANCE PROGRAMS (July 2019), https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations#9-28.800.

[6] *Press Release, Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual*, DOJ (May 7, 2019), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual; DOJ, JUSTICE MANUAL—4-4.112 GUIDELINES FOR TAKING DISCLOSURE, COOPERATION, AND REMEDIATION INTO ACCOUNT IN FALSE CLAIMS ACT MATTERS (May 2019), https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112.

[7] *Press Release, Justice Department Obtains $1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History*, DOJ (July 11, 2019), https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case.

prescriptions of Suboxone by promoting the film version of the product with unsubstantiated, false and misleading claims that it was less-divertible, less-abusable, and less susceptible to unintended pediatric exposure than other buprenorphine drugs. The government further alleged that Indivior discontinued the tablet form of Suboxone with the intent to delay the entry of generic tablet forms of the drug to the market (and not due to alleged concerns of pediatric exposure).

RBG executed a non-prosecution agreement that required the forfeiture of $647 million in proceeds received from Indivior and prohibits RBG from manufacturing, marketing, or selling Schedule I, II, or III controlled substances in the U.S. for three years. With respect to the civil investigation, RBG agreed to pay $500 million to the federal government and up to $200 million to state governments to resolve claims that Indivior's marketing of the product caused the submission of false claims to government health care programs. This settlement resolves six lawsuits filed under the whistleblower provision of the FCA. Lastly, RBG entered into a consent decree with FTC and agreed to pay the commission $50 million to resolve claims that the company engaged in unfair methods of competition in violation of the Federal Trade Commission Act.

Insys Therapeutics[8]

Insys Therapeutics ("Insys") agreed to pay $225 million to resolve criminal and civil liability related to kickbacks and other unlawful marketing practices allegedly perpetrated by Insys in connection with its marketing of Subsys, a sublingual fentanyl spray. This resolution included: (i) $195 million in civil remedies; and (ii) $30 million in criminal restitution ($2 million monetary fine and $28 million forfeiture of proceeds). Additionally, an operating subsidiary pled guilty to five counts of mail fraud, and Insys entered into a five-year deferred prosecution agreement with DOJ and an "unprecedented" five-year CIA and Conditional Exclusion Release with the Office of Inspector General ("OIG"). Insys filed for Chapter 11 bankruptcy five days after announcement of the settlement, the proceedings of which remain ongoing;[9] however, it is expected that DOJ will recover at least a portion of the agreed settlement amounts.

The civil settlement resolves five lawsuits filed under the whistleblower provision of the FCA. The government and whistleblowers alleged that Insys induced prescribing of Subsys through kickbacks to physicians and nurse practitioners, which took the form of payments for "sham speaker program speeches," employment of the friends and family of prescribers, and "lavish meals and entertainment."[10]

OIG required that Insys agree to a detailed statement of facts detailing its criminal conduct and acknowledge that such conduct provides a basis for the company's exclusion from federal health care programs. However, OIG chose not to pursue its permissive exclusion authority at this time citing Insys' cooperation in the prosecution of company executives and agreement to enhanced CIA requirements (such as enhanced material breach provisions), subject to Insys' fulfillment of its obligations

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[8] *Press Release, Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations*, DOJ (June 5, 2019), https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal [hereinafter *Press Release, Insys Therapeutics*].

[9] *See* United States v. Insys Therapeutics Inc. et al., No. 1:19-cr-10191 (D.C. Mass.).

[10] *Press Release, Insys Therapeutics*, *supra* note 8.

under the CIA. DOJ noted that OIG's Conditional Exclusion Release in which it reserved its exclusionary authority is counter to its normal practice in FCA settlements.

Avanir Pharmaceuticals[11]

Avanir Pharmaceuticals ("Avanir") agreed to pay more than $108 million in criminal penalties and civil damages related to the false and misleading marketing of its product, Nuedexta, and the payment of kickbacks to a physician to induce prescribing the product. Avanir also agreed to cooperate in the indictment against four individuals, three former employees and one of the product's top prescribers, related to the kickback scheme.

This resolution includes $95 million in civil remedies, which resolved FCA allegations of kickbacks and false and misleading marketing of the product to providers in long term care facilities for unapproved uses of the drug (specifically, for behaviors associated with dementia). The government alleged that Avanir remunerated physicians and other healthcare professionals in the form of money, honoraria, travel, and food in exchange for issuing prescriptions for the drug or participating in speaker programs. Further, the government alleged that the company took advantage of the Centers for Medicare and Medicaid Service's efforts to reduce the use of anti-psychotics on dementia patients in long-term care facilities by, among other things, promoting misinformation about typical behaviors of patients suffering from pseudobulbar affect that, in fact, are commonly observed in dementia patients. The civil settlement resolves two lawsuits filed under the whistleblower provision of the FCA.

Avanir also entered into a CIA with the Department of Health and Human Services OIG that requires Avanir, among other things, to implement additional controls related to physician interactions and conduct internal and external monitoring of promotional activities. The CIA also requires that compliance-related certifications be obtained from Avanir's Board of Directors and key executives, increasing individual accountability.

Avanir also entered into a three-year deferred prosecution agreement to resolve allegations that the company violated the Anti-Kickback Statute by paying a physician and offering him other financial incentives to increase the number of prescriptions he issued to beneficiaries of federal healthcare programs, as well as inducing him to recommend that other physicians do the same. Under this agreement, Avanir must pay a monetary penalty of $7.8 million and forfeit proceeds in the amount of $5.1 million. In identifying the facts and circumstances that prompted a deferred prosecution agreement, the agreement explicitly identified Avanir's ongoing cooperation with the investigation, the extensive remedial measures taken by the company (including terminating or permitting the resignation of multiple employees), and its enhanced compliance program in response to the allegations. Further, a conviction would likely have prompted the OIG of the Department of Health and Human Services to impose a mandatory exclusion of the company from all federal health care programs, resulting in potentially substantial negative consequences to consumers.

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[11] *Press Release, Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations*, DOJ (Sept. 26, 2019), https://www.justice.gov/opa/pr/pharmaceutical-company-targeting-elderly-victims-admits-paying-kickbacks-resolves-related.

Diabetic Care Rx LLC (doing business as Patient Care America) and Riordan, Lewis & Haden Inc.[12]

Compounding pharmacy Diabetic Care Rx LLC, doing business as Patient Care America ("PCA"), two PCA executives, and private equity firm Riordan, Lewis & Haden Inc. ("RLH") agreed to pay a combined amount of $21.36 million to resolve allegations of involvement in a kickback scheme to generate referrals of prescriptions, reimbursed through a federal health care program for military members and their families, in violation of the FCA. The government alleged that the defendants made kickback payments to outside "marketers" who targeted military members and their families and solicited medically unnecessary prescriptions for expensive compounded pain and scar creams and vitamins. This resolution included: (i) payment by PCA and RLH in the amount of $21.05 million; and (ii) payment by two executives in amounts at least $300,000 and $12,788, respectively.

Notably, this is the first time DOJ named a private equity firm alongside one of its portfolio companies in a lawsuit under the FCA. RLH managed PCA on behalf of its investors and the government emphasized the connection between PCA's kickbacks and RLH's liability. The private equity firm allegedly knew of and agreed to pay the outside marketers to generate the prescriptions and financed the kickback payments to these individuals. The government also noted RLH's participation in high-level management of PCA (with two RLH partners on PCA's Board of Directors), as well as PCA's daily operations (with PCA's CEO agreeing to seek RLH's approval on all key company decisions).[13]

The settlement resolves a lawsuit filed under the whistleblower provision of the FCA by two former employees of PCA.

PharMedium Services, LLC[14]

Compounding pharmacy PharMedium Services LLC ("PharMedium") and two of its executives agreed to be bound by a consent decree of permanent injunction to settle allegations that PharMedium distributed adulterated, misbranded, and unapproved new drugs in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). PharMedium operated four registered outsourcing facilities in Tennessee, Mississippi, Texas, and New Jersey and manufactured and distributed drugs intended to be sterile, such as oxycontin and morphine sulfate.

The government's complaint alleged that the drugs were prepared, packed, or held under insanitary conditions in which they may have been contaminated with filth or rendered injurious to health and that the company failed to comply with current good

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[12] *Press Release, Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations*, DOJ (Sept. 18, 2019), https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million.

[13] *See* First Amended Complaint in Intervention, United States ex rel. Medrano and Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care America, et al., No. 15-CV-62617 (S.D. Fla. Oct. 1, 2019).

[14] *Press Release, District Court Orders Illinois Compounding Company and Two Executives to Comply with Drug Safety Standards*, DOJ (May 22, 2019), https://www.justice.gov/opa/pr/district-court-orders-illinois-compounding-company-and-two-executives-comply-drug-safety; *Press Release, Federal Judge Enters Consent Decree Against Compounder PharMedium Services for Violations at Multiple Facilities*, FDA (May 22, 2019), https://www.fda.gov/news-events/press-announcements/federal-judge-enters-consent-decree-against-compounder-pharmedium-services-violations-multiple.

manufacturing practices. Further, the complaint alleged that PharMedium failed to comply with all requirements for drugs compounded in a registered outsourcing facility and did not properly label their products with adequate directions for use. This enforcement action came after multiple inspections of PharMedium's corporate headquarters and outsourcing facilities between 2013 and 2018 that resulted in an FDA warning letter citing insanitary conditions and other violations of the FDCA. PharMedium had previously received a warning letter from FDA in 2007 for similar violations.

PharMedium voluntarily ceased operations at its Tennessee facility after inspection by FDA. In order to reopen the Tennessee facility, PharMedium must complete certain corrective actions and receive authorization from FDA. PharMedium has also ceased operations at its Mississippi facility and must, among other things, hire an independent expert to review the company's operations at its Texas and New Jersey facilities to ensure compliance with the FDCA. The two PharMedium executives identified in the complaint and the consent decree are the individuals responsible for establishing and maintaining current and future compliance with the law.

MEDICAL DEVICES

ACell Inc.[15]

ACell Inc. ("ACell") agreed to pay $15 million to resolve criminal and civil liability arising from claims related to its MicroMatrix device, a powder wound dressing product. This resolution included: (i) a $3 million fine pursuant to a plea agreement for failure to report to FDA its recall of MicroMatrix devices in violation of the FDCA; and (ii) a $12 million civil settlement over five years to resolve allegations that the company caused false claims to be submitted to federal health care programs for MicroMatrix in violation of the FCA.

ACell pled guilty to one misdemeanor count for its failure to report to FDA its recall of the MicroMatrix devices from the market over safety concerns. After learning that over 30,000 MicroMatrix devices were contaminated with endotoxin levels that posed health risks to patients, ACell discretely removed the product from inventories, hospitals, and other healthcare centers. ACell admitted that it did not report the removal of the devices to FDA; it concealed the reason for removal from doctors, hospitals, and the company's salesforce; and it did not notify doctors who had already used devices from the contaminated lots.

Under the civil settlement, the government alleged that ACell engaged in false and misleading marketing of MicroMatrix by directing its sales representatives to inform physicians that non-topical and internal use of the device was safe and effective (contrary to its indication for the treatment of topical wounds). The government further alleged that ACell provided coding recommendations to healthcare providers that improperly inflated Medicare reimbursement, notwithstanding that two consultants separately advised the company that such coding was incorrect. Lastly, the government alleged that ACell improperly induced prescribers to order MicroMatrix

[15] *Press Release, Medical Device Maker ACell Inc. Pleads Guilty and Will Pay $15 Million to Resolve Criminal Charges and Civil False Claims Allegations*, DOJ (Jun 11, 2019), https://www.justice.gov/opa/pr/medical-device-maker-acell-inc-pleads-guilty-and-will-pay-15-million-resolve-criminal-charges.

products through various payment and entertainment benefits. This settlement resolves one lawsuit filed under the whistleblower provisions of the FCA.

ACell also entered into a five-year CIA with the Department of Health and Human Service's OIG requiring, among other things, that the company implement a risk assessment and internal review process designed to identify ongoing compliance risks. Further, the CIA requires sign-off certifications from the company's Board of Directors and certain executives, as well as increased training, auditing, and monitoring to address the types of activities at issue.

DIETARY SUPPLEMENTS

ABH Nature's Products, Inc.[16]

Three dietary supplement companies under common ownership, ABH Nature's Products, Inc., ABH Pharma, Inc., and StockNutra.com, Inc., as well as their owner (collectively "ABH") agreed to a consent decree of permanent injunction to settle allegations that ABH manufactured, prepared, labeled, packed, held, and distributed dietary supplements in violation of current good manufacturing practices.

The government's complaint alleged that FDA had observed "several critical deviations" from current good manufacturing practices in its inspection of ABH's manufacturing facilities. Specific practices included failure to confirm that the dietary supplements met the product's specifications for identity, purity, strength, and composition; failure to implement a product system that ensured the quality of the product; failure to detail necessary information in production records; and failure to properly investigate a consumer complaint. Further, the complaint alleged that ABH violated the FDCA by marketing the product to be used in the treatment of certain medical conditions such as cancer, heart disease, HIV, and AIDS, causing the product to be misbranded and an unapproved new drug.

The injunction obligates ABH to destroy all dietary supplements that are in its possession, custody, or control within fifteen days. Further, ABH must implement several consumer safety measures before resuming the manufacture and distribution of its products, including hiring an independent expert to inspect the facility and certify that all deficiencies have been corrected. ABH must also engage a labeling expert to review product labeling and certify that all claims on its dietary supplements comply with the FDCA. Pursuant to the consent decree, on January 21, 2020, ABH issued a recall of *all* of its dietary supplement products manufactured and sold between January 2013 and November 2019.[17]

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[16] *Press Release, Federal District Court Orders New York Company to Stop Distributing Adulterated and Misbranded Dietary Supplements*, DOJ (Dec. 26, 2019), https://www.justice.gov/opa/pr/district-court-orders-long-island-company-stop-distributing-adulterated-and-misbranded.

[17] *Company Announcement, ABH NATURE'S PRODUCTS, INC., ABH PHARMA, INC., and STOCKNUTRA.COM, INC. Issues Nationwide Recall of All Lots of Dietary Supplement Products*, FDA (Jan. 21, 2020), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abh-natures-products-inc-abh-pharma-inc-and-stocknutracom-inc-issues-nationwide-recall-all-lots.

CONVENTIONAL FOOD

Golden Gate Soy Products Inc.[18]

Food company Golden Gate Soy Products Inc. ("Golden Gate") and two owners/executives agreed to a consent decree of permanent injunction to settle allegations that Golden Gate manufactured and distributed ready-to-eat tofu and other soy-based products in a facility with chronic insanitary conditions in violation of the FDCA. The government's complaint alleged that the company's facility contained *Listeria monocytogens* ("*L. mono*") for a prolonged period and that the facility failed to have adequate measures in place to reduce the consequent risk of health hazards.

The complaint cited three prior FDA inspections of the Golden Gate facility (2017, 2018, and 2019) that each uncovered violations of FDA food safety regulations. Among other things, the inspections found the presence of *L. mono* in Golden Gate's food preparation area and that food was held in insanitary conditions for distribution. FDA advised Golden Gate of its violations, to which the company responded with promised corrective actions; however, FDA found in a follow up inspection that none of Golden Gate's remedial measures were adequate.

The consent decree prohibits Golden Gate from receiving, preparing, processing, packing, holding, labeling, or distributing food at its facility or any other facility until it complies with specific remedial measures and receives a written determination from FDA that Golden Gate's manufacturing practices comply with the FDCA. Among other things, Golden Gate must hire a qualified independent expert to develop an effective sanitation control program.

Topway Enterprises (doing business as Kazy's Gourmet)[19]

Food company Topway Enterprises, doing business as Kazy's Gourmet ("Topway"), and three principals of the business agreed to a consent decree of permanent injunction to settle allegations that Topway sold ready-to-eat fish and fishery products in a facility with serious insanitary conditions in violation of the FDCA. The government's complaint alleged, among other things, that the company failed to adequately control the growth of *L. mono* at its facility.

This enforcement action came after several FDA inspections identified the presence of egregious sanitation deficiencies, including poor employee sanitation and production practices and significant facility deficiencies (e.g., cracked and uncleanable floors, uncleaned utensils, fish particles on walls, etc.). In July 2019, FDA suspended Topway's food facility registration, prohibiting the company from selling or distributing food from the facility,[20] and advised restaurants and retailers in two states

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[18] *Press Release, District Court Orders California Firm to Stop Manufacturing and Distributing Adulterated Food*, DOJ (Nov. 25, 2019), https://www.justice.gov/opa/pr/district-court-orders-california-firm-stop-manufacturing-and-distributing-adulterated-food; *Press Release, California-Based Food Manufacturer Agrees to Stop Production After Repeated Food Safety Violations*, FDA (Nov. 26, 2019), https://www.fda.gov/news-events/press-announcements/california-based-food-manufacturer-agrees-stop-production-after-repeated-food-safety-violations.

[19] *Press Release, District Court Orders Texas Company to Stop Selling Adulterated Food*, DOJ (Aug. 30, 2019), https://www.justice.gov/opa/pr/district-court-orders-texas-company-stop-selling-adulterated-food.

[20] *Press Release, FDA Suspends Facility Registration of Texas-Based Seafood Producer After Significant, Repeated Food Safety Violations*, FDA (July 22, 2019), https://www.fda.gov/news-

to stop selling or serving Topway seafood products.[21] This was the sixth instance in which FDA exercised its authority to suspend a food facility registration since receiving such authority under the FDA Food Safety Modernization Act.

The consent decree requires Topway to comply with specific remedial measures and incorporates safeguards to ensure that future processing at Topway's facility complies with FDCA requirements.

CONCLUSION

The 2019 settlements illustrate FDA's and DOJ's commitment to food and drug safety, particularly as this relates to the prescription opioid crisis, sterile compounding violations, and dietary supplement fraud. The recoveries also illustrate DOJ's efforts to enforce the FCA against individuals through joint and several liability with offending corporations.

The recovery figures are generally consistent with recent years, with a slight increase from the ten-year low observed in 2018. While it does not appear that the 2016 change in presidential administration affected FCA enforcement goals and activity, it remains to be seen whether the upcoming 2020 election will have this same result. Such a trend would likely manifest slowly, if at all, as lawsuits are pursued by long-time DOJ FCA attorneys and often take several years to resolve.

What will undoubtedly remain, however, is the strong interest of relators in initiating FCA lawsuits. Although the number of *qui tam* actions initiated in 2019 dropped since an all-time high of 757 lawsuits initiated in 2013, whistleblowers will likely continue to make up a majority of newly initiated FCA actions.

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events/press-announcements/fda-suspends-facility-registration-texas-based-seafood-producer-after-significant-repeated-food.

[21] *Alerts, Advisories & Safety Information, FDA Advises Restaurants and Retailers in Texas and Louisiana to Stop Selling or Serving Topway Enterprises Inc. Doing Business as Kazy's Gourmet Seafood Products due to Possible Listeria Contamination*, FDA (July 18, 2019), https://www.fda.gov/food/alerts-advisories-safety-information/fda-advises-restaurants-and-retailers-texas-and-louisiana-stop-selling-or-serving-topway-enterprises.

Significant Regulatory, Policy, and Enforcement Developments: 2019

LAUREN FARRUGGIA AND JONATHAN HAVENS*

A new decade is upon us, as are substantial federal and state policy, regulatory, and enforcement developments for the tobacco, hemp-derived products, and food and beverage industries. Such developments include:

- President Trump signed H.R. 1865 into law late last year, which bans the sale of tobacco products to anyone under the age of 21;
- The Trump Administration (the Administration) finalized its partial ban on flavored e-cigarette products, while the U.S. Food and Drug Administration (FDA or the Agency) issued its enforcement policy on unauthorized flavored e-cigarettes that appeal to children;
- FDA issued its Final Rule outlining new graphic warnings for tobacco products;
- The U.S. Department of Agriculture (USDA) approved the first set of state and tribal plans for domestic production of hemp under the U.S. Domestic Hemp Production Program;
- FDA issued Warning Letters to fifteen companies for illegally selling products containing cannabidiol (CBD), and published a revised Consumer Update, in which the Agency detailed specific safety concerns and questions about CBD products; and
- FDA issued final Nutrition Facts label (NFL) rule guidance, just days before the NLR went into effect for companies with annual sales over $10 million.

MINIMUM AGE FOR TOBACCO SALES INCREASED TO 21

On December 20, 2019, President Trump signed H.R. 1865 into law, changing the "Minimum Age of Sale of Tobacco Products" within Section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) from 18 to 21 years of age.[1]This new requirement applies to the sale of cigarettes, cigars, and e-cigarettes, alike. Nineteen states and over 500 localities had previously adopted 21 as the minimum tobacco

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[1] Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94, (2019).

purchase age, but in light of recent concerns surrounding youth access to, among other things, e-cigarette products, national uniformity is a significant public health win.

This change went into effect immediately: FDA published a note on its website the same day President Trump signed the legislation into law, explaining that "[i]t is now illegal for a retailer to sell any tobacco product—including cigarettes, cigars and e-cigarettes—to anyone under 21."[2] The Health and Human Services (HHS) Secretary is tasked with publishing a final rule in the Federal Register within 180 days of enactment to update associated regulations with the new minimum age requirement.[3] At the time this article was published, HHS had not yet issued this regulation.

PARTIAL BAN OF FLAVORED E-CIGARETTES ANNOUNCED; FDA ISSUES ENFORCEMENT POLICY

After first announcing its intention to ban most flavored e-cigarette products in September 2019, in an effort to curb youth access to e-cigarettes (and, seemingly in response to vaping-related deaths and injuries), the Administration finally moved forward with a "partial" flavor ban on January 2, 2020.[4] FDA had previously prepared one version of the ban in early November 2019 for President Trump's review (which would have required candy, fruit, mint, and possibly menthol flavors to be removed from the market within thirty days, and which would have outlined an enforcement policy addressing such products that lack premarket authorization), but, because of supposed political concerns raised by the vaping community, the Administration declined to move forward.[5] The vaping community's "#wevapewevote" social media campaign, along with analyses of the number of vapers in swing states that was posted on Twitter and elsewhere, seems to have been quite effective in convincing the Administration to reconsider its approach to the partial flavor ban.

FDA's final version of the partial ban includes an enforcement policy on "unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint."[6] Tobacco and menthol flavored e-cigarettes are excluded from the policy, as are e-liquids used in open tank systems available at vape shops, which FDA concluded will "balance the public health concerns related to youth use of ENDS

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[2] *Selling Tobacco Products in Retail Stores*, U.S. FOOD & DRUG ADMIN. (Dec. 20, 2019), https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores.

[3] *See supra*, note 1, § 603(b)(1).

[4] *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Sept. 11, 2019), https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html.

[5] *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, U.S. FOOD & DRUG ADMIN. (Sept. 11, 2019), https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[6] *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint*, U.S. FOOD & DRUG ADMIN. (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children; U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION: GUIDANCE FOR INDUSTRY (April 2020) [hereinafter ENFORCEMENT GUIDANCE], https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market

products with considerations regarding addicted adult cigarette smokers who may try to use ENDS products to transition away from combustible tobacco products."[7] Companies that have not ceased "manufacture, distribution and sale of" these identified, unauthorized products within thirty days of publication of the partial ban would be subject to FDA enforcement action.[8]

By way of background, on July 28, 2017, FDA announced a comprehensive plan to overhaul the Agency's tobacco regulatory efforts.[9] Under this plan, the deadline for marketing applications for non-combusted products such as electronic nicotine delivery systems (ENDS) or e-cigarettes was August 8, 2022;[10] however, the U.S. District Court for the District of Maryland moved this deadline up significantly, to May 12, 2020.[11] But, as long as an e-cigarette product was on the market as of August 8, 2016 (i.e., the effective date of FDA's Deeming Rule, which subjected tobacco products to the FD&C Act's regulatory controls), the manufacturer could continue to market its product until the May 2020 marketing application deadline (and during FDA's review of its application).[12]

Despite this deadline, however, FDA has indicated that it would begin to prioritize enforcement of the following products starting on February 6, 2020:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or likely to promote use of ENDS by minors.[13]

A few key takeaways and observations:

- It appears that FDA, and state and local inspectors contracted by the Agency, started retail enforcement sweeps beginning on February 6, 2020.[14] Retailers should have planned to stop selling all flavored (except tobacco- and menthol-flavored) cartridge-based products.

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7 ENFORCEMENT GUIDANCE, *supra* note 6, at 5.

8 *See supra*, note 6.

9 *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death*, U.S. FOOD & DRUG ADMIN. (July 27, 2017), https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

10 U.S. Food & Drug Admin., FDA's Comprehensive Plan for Tobacco and Nicotine Regulation (July 31, 2019), https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation.

11 ENFORCEMENT GUIDANCE, *supra* note 6, at 5.

12 *Id.* at 5–6.

13 *Id.* at 3.

14 *See, e.g.*, *Warning Letter to City Vapes Premium eJuice Inc.*, U.S. FOOD & ADMIN. (Feb. 28, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/city-vapes-premium-ejuice-inc-604021-02282020.

The exact definition of "cartridge-based" is not yet clear. Also unclear is which ENDS products are currently undergoing premarket review at FDA. This information is important, as a flavored product may remain on the market as long as a premarket tobacco product application (PMTA) is pending before FDA.

- The partial ban seems to be a win for JUUL, the maker of popular pod-based vaping products. The San Francisco-based company decided to remove many of its popular flavors mid-last year in response to pressure from regulators and public health advocates.[15] The partial ban should serve to re-even the playing field for JUUL.
- Not only is the ban merely partial, as tobacco- and menthol-flavored products are carved out from it, but it is not necessarily permanent. If and when FDA approves a flavored ENDS product PMTA, that product could come back on the market. With that said, it is not clear if a flavored, cartridge-based product could ever meet the rigorous "public health" standard by which FDA is required to review tobacco products.
- While the partial, and possibly temporary ban has been viewed as a win for the vaping industry, it is important to recognize that *all* vaping products—cartridge-based, open tank, and otherwise—will eventually need to undergo PMTA review. Again, for products on the market as of August 8, 2016, the PMTA submission deadline is May 12, 2020. The PMTA process is not for the faint of heart. As noted by the U.S. Small Business Administration in the Deeming Rule, FDA estimated that PMTA costs would be between $28,566 and $2,595,224 per ENDS delivery unit, with an average cost of $466,563 and between $12,112 and $398,324 per e-liquid used in such devices, with an average cost of $131,643.[16] These projections may be grossly underestimated, and the real costs may indeed be substantially higher. As suggested by the estimates above, a separate PMTA is needed for each delivery unit model, as well as for each and every flavor SKU. SBA further noted that over ninety percent of tobacco manufacturers and tobacco retailers are small businesses, meaning that these costs will be particularly significant for the vast majority of industry.[17] And, finally, although some vape shops might not realize it, if they mix e-liquid flavors, FDA considers them to be manufacturers. Unless they cease flavor mixing—something that vape shops have used to attract customers and achieve profitability—they, too, will need to submit PMTAs.

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[15] Allison Aubrey, *Juul Suspends Sales of Flavored Vapes And Signs Settlement To Stop Marketing To Youth*, NPR (Oct. 17, 2019), https://www.npr.org/sections/health-shots/2019/10/17/771098368/juul-suspends-sales-of-flavored-vapes-and-signs-settlement-to-stop-marketing-to-.

[16] *FDA Seeks Comments on Premarket Tobacco Product Applications Proposed Rule*, U.S. SMALL BUS. ADMIN., OFFICE OF ADVOCACY (Oct. 1, 2019), https://advocacy.sba.gov/2019/10/01/fda-seeks-comments-on-proposed-pmta-and-recordkeeping-requirements/.

[17] *Id.*

FDA ISSUES FINAL RULE ON NEW GRAPHIC WARNINGS FOR TOBACCO PRODUCTS

On August 15, 2019, FDA published a court-ordered proposed rule that would mandate graphic health warnings for cigarette packaging and advertisements to "promote greater public understanding of the negative health consequences of smoking."[18]

FDA's proposed warnings are graphic and feature thirteen "photo-realistic" images of "some of the lesser-known, but serious health risks of cigarette smoking," including secondary harm to children, fatal lung disease in non-smokers, head and neck cancer, reduction of blood flow (which can lead to erectile dysfunction or require digit or limb amputation), and type 2 diabetes. On March 18, 2020, FDA published its final rule and an accompanying Guidance document outlining the submission process for required cigarette rotational packaging plans, which must provide for "the random and equal display and distribution of the required warnings on cigarette packaging and quarterly rotation of the required warnings in cigarette advertising."[19] Although the final rule only finalized eleven of the original thirteen proposed warnings, the final rule still require the images to occupy the top fifty percent of both the front and rear panels of cigarette packages and at least twenty percent of the area at the top of cigarette advertisements.[20] Companies have fifteen months (or by June 18, 2021) to comply with these requirements.[21]

This proposal represents FDA's latest effort in cigarette packaging reform since Congress required the Agency to take action after it passed the 2009 Family Smoking Prevention and Tobacco Control Act (the Act). In June 2011, FDA first issued a final rule requiring graphic warnings for cigarette packaging and advertisements;[22] however, this rule was quickly challenged by the tobacco industry under First Amendment grounds and was overturned by the U.S. Court of Appeals for the District of Columbia (D.C. Circuit) in *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012). Applying the intermediate scrutiny standard articulated in *Central Hudson Gas & Elec. Co. v. Public Serv. Comm. of N.Y.*, 447 U.S. 557 (1980), the D.C. Circuit determined that FDA did not put forth substantial evidence that its graphic warnings would "directly" reduce smoking by a "material degree," so FDA could not compel tobacco companies to use its graphic warnings on cigarette labeling.

But, in October 2016, several public health and medical groups filed a lawsuit against FDA again, arguing that the Agency unlawfully delayed issuing a final rule

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[18] *Cigarette Health Warnings*, U.S. FOOD & DRUG ADMIN. (Aug. 15, 2019), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warnings.

[19] *FDA Requires New Health Warnings for Cigarette Packages and Advertisements*, U.S. FOOD & DRUG ADMIN. (Mar. 17, 2020), https://www.fda.gov/news-events/press-announcements/fda-requires-new-health-warnings-cigarette-packages-and-advertisements; 85 Fed. Reg. 15,638, 15,710 (Mar. 18, 2020).; U.S. FOOD & DRUG ADMIN., SUBMISSION OF PLANS FOR CIGARETTE PACKAGES AND CIGARETTE ADVERTISEMENTS: GUIDANCE FOR INDUSTRY 4 (Mar. 2020) [hereinafter CIGARETTE PACKAGE GUIDANCE], https://www.fda.gov/media/133839/download.

[20] CIGARETTE PACKAGE GUIDANCE, *supra* note 19, at 6.

[21] 85 Fed. Reg. at 15,638.

[22] 76 Fed. Reg. 36,628, 36,777 (June 22, 2011).

requiring warnings for cigarette packaging and advertisements in violation of the Act.[23] In March 2019, Judge Indira Talwani of the U.S. District Court for the District of Massachusetts ordered FDA to publish a proposed rule by August 2019 and a final rule by March 2020.[24] Seemingly in anticipation of a subsequent industry challenge to the latest set of warnings, FDA has made a concerted effort to support its final rule through a "comprehensive, science-based research and development process," citing over 200 studies in the proposed and final rules. Even still, proving that the proposed graphic warnings will be effective in reducing smoking will not be easy, and time will tell whether another challenge is in the works as firms work to comply with the packaging plan requirements.

USDA APPROVES HEMP PLANS FOR FIRST SET OF STATES AND INDIAN TRIBES

In late October 2019, USDA issued its long-awaited hemp production interim final rule, which provided states and Indian tribes with the opportunity to submit plans concerning the monitoring and regulation of hemp production for USDA's approval.[25] On December 27, 2019, USDA approved the first set of plans submitted by Louisiana, New Jersey, and Ohio, and the Flandreau Santee Sioux, Santa Rosa Cahuilla, and La Jolla Band of Luiseno tribes.[26] USDA approved these plans in the middle of its public comment period on the interim final rule, which was extended until January 29, 2020.[27]

USDA approval is significant, as hemp growers must be licensed or authorized under an applicable state, tribe, or USDA production program in order to produce hemp. At least seventeen additional states and twenty Indian tribes have submitted, or are in the process of drafting, a hemp plan for USDA's review.[28] USDA appears to be making plan approval decisions on a rolling basis now that the docket has closed for public comment.

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[23] *See supra*, note 13.

[24] Mem. and Order Granting Injunctive Relief, *Am. Acad. Of Pediatrics et al. v. FDA*, No. 16-11985 (D. Mass. 2019).

[25] 84 Fed. Reg. 58,522, 58,564 (Oct. 31, 2019).

[26] *USDA Approves First State and Tribal Hemp Production Plans*, U.S. DEP'T OF AGRIC. (Dec. 27, 2019), https://www.ams.usda.gov/content/usda-approves-first-state-and-tribal-hemp-production-plans.

[27] *USDA Extends U.S. Domestic Hemp Production Program Interim Final Rule Comment Period to January 29*, U.S. DEP'T OF AGRIC. (Dec. 17, 2019), https://www.ams.usda.gov/content/usda-extends-us-domestic-hemp-production-program-interim-final-rule-comment-period-january.

[28] *Status of State and Tribal Hemp Production Plans for USDA Approval*, U.S. DEP'T OF AGRIC. (last visited Mar. 19, 2020), https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review.

FDA ISSUES NEW ROUND OF CBD WARNING LETTERS, REVISES CONSUMER UPDATE

On November 25, 2019, FDA announced[29] that it had issued Warning Letters to fifteen companies for illegally selling products containing CBD.[30] Simultaneous with this round of CBD-related enforcement, the Agency also published a revised Consumer Update, in which it detailed specific safety concerns and questions about CBD products.[31] Although FDA raised these concerns and questions before (e.g., at its May 31, 2019 CBD hearing and in a previous version of the Consumer Update), the Agency was a bit more specific in these most recent communications.

The November 2019 Warning Letters maintain the themes evident in earlier enforcement sweeps from 2015, 2016, 2017, and 2018, but also include new language representing FDA's determination that CBD is not presently recognized as generally recognized as safe (GRAS) in human or animal food.

In the most recent Warning Letters, FDA cited problematic labeling and claims observed on retailers' websites, in social media posts, and in customer testimonials. While the Agency certainly continued to target aggressive therapeutic claims aimed at vulnerable populations (such as children or the chronically ill) as it has in the past, notably, the Agency also addressed less aggressive claims, including use to manage "aches and pain," "minor pain that comes with exercise," skin irritation, inflammation, promoting a "calming effect," and improving mood. In spite of this new scrutiny, however, we have not yet seen standalone enforcement action for these traditionally lower-risk claims; each target made aggressive therapeutic claims, as well.

FDA took issue with many retailers' CBD dietary supplement labeling, noting that, simply because a product may be otherwise properly labeled as a dietary supplement, once it contains CBD, the product is no longer a permissible supplement. Among the myriad reasons why CBD firms may decide to label their ingestible products as supplements is that they are required to do so by state law (e.g., New York). Just as in the less aggressive claims context, discussed above, simply labeling a CBD product as a supplement is not currently grounds for receiving a Warning Letter, although FDA has made clear that CBD products are excluded from the dietary supplement definition under Section 201(ff)(3)(B) of the FD&C Act.[32] There would have to at least be an aggressive claim before FDA would issue a Warning Letter for a product being labeled as a supplement. The Agency also cited many retailers for use of health claims in the

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[29] *FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns*, U.S. FOOD & DRUG ADMIN. (Nov. 25, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details.

[30] *Warning Letters and Test Results for Cannabidiol-Related Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products (last visited Sept. 24, 2020).

[31] *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis (last visited Sept. 24, 2020).

[32] *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, U.S. FOOD & DRUG ADMIN. (current as of August 3, 2020), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

pet product context, rendering such products unapproved new animal drugs under the FD&C Act.

Ultimately, it is clear that the Agency is trying to curb the recent explosion of CBD products. These Warning Letters emphasize that no health claims, no matter how seemingly innocuous, are permissible. CBD ingestibles marketed without health claims are likely lower risk, but because of FDA's concern about marketing to vulnerable user populations, companies choosing to market in this space should be exceedingly careful, as the Agency could police such sales more aggressively in the future.

Although the Agency's cannabis and cannabis-derived products Consumer Update is not new—FDA issued it for the first time in July 2019—this version contains some enhancements to FDA's previously articulated positions. Based on what the Agency has characterized as a "lack of scientific information supporting the safety of CBD in food," FDA indicated definitively in this version, for the first time, that it cannot conclude that CBD is GRAS among qualified experts for its use in human or animal food. By way of background, any substance that is intentionally added to food is a food additive that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

Moreover, the Agency again detailed the potential risks associated with using CBD products, including: liver injury, affecting the metabolism of other drugs, and sedation or drowsiness caused by use with alcohol or other depressants. FDA also reiterated potential side effects that CBD could cause, including: changes in alertness, gastrointestinal distress, and changes in mood. Finally, the Agency again noted that there are several unknowns related to CBD, including: what happens if you take CBD daily for sustained periods of time, what is the effect of CBD on the developing brain, what are the effects of CBD on the developing fetus or breastfed newborn, how does CBD interact with herbs and botanicals, and does CBD cause male reproductive toxicity in humans. Again, while FDA had previously teed up potential risks, side effects, and unknowns related to CBD, the Agency has further specified these points in the most recent iteration of the Consumer Update.

Historically, the Agency has focused its CBD enforcement on marketers making aggressive therapeutic claims (e.g., for treatment of Alzheimer's disease, psychiatric disorders, and diabetes). In a potential foreshadowing of expanded enforcement, the Agency indicated in its update that, in addition to continuing to pursue such products, it will also monitor the marketplace for any product that poses a risk to public health, including those with dangerous contaminants (e.g., pesticides, heavy metals, delta-9 tetrahydrocannabinol (THC)) and those marketed to vulnerable populations (e.g., the elderly, children, adolescents, pregnant, and lactating women).

FDA's revised Consumer Update does not discuss use of, or risks associated with, topical CBD products, use of which has been expressly permitted by FDA in the past (absent therapeutic claims). Accordingly, topical products without claims continue to be permissible, although it is worth monitoring this area closely. The Agency's focus instead remains on CBD added to human foods and supplements, and animal foods and feeds, which still remain, in the Agency's view, illegal to market under the FD&C Act.

While it cannot be denied that the Agency was more specific in its safety assessments and questions in its Consumer Update and Warning Letters than it had

been previously, FDA's latest concerns in the CBD context are nothing new. The Agency continues to remain focused on aggressive therapeutic claims, but has now suggested that it will monitor products for general therapeutic claims, as well, particularly when directed at vulnerable populations.

CANNABIS AND CBD POSTSCRIPT

Although the following developments occurred in 2020, we would be remiss if we did not discuss them in this piece.

More recently:

- On March 5, 2020, FDA issued a report to Congress, as required by the Further Consolidated Appropriations Act, related to the Agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in FDA-regulated products (the Report).[33] In short, the Report represents anywhere from a "non-event" to potentially good news for the CBD industry. Informing the sense that the Report is a "non-event" is that many of the points FDA raised in the Report (e.g., lack of sufficient CBD research, potential concerns regarding cumulative exposure, and the inability to market CBD ingestibles (despite the very limited amount of enforcement, absent aggressive disease claims)) are ones the Agency has addressed previously. As far as the Report being potentially good news for industry, the Agency stated in the Report that it is "actively considering potential pathways for certain CBD products to be marketed as dietary supplements . . . [including] actively evaluating potential rulemaking to allow CBD in dietary supplements."[34] Depending on the parameters of such prospective regulations, a CBD supplement rulemaking could provide more certainty to industry and could allay fears of enforcement action being taken simply because a product is offered in a supplement format. However, evaluating a potential rulemaking is not the same as drafting a rule. Thus, the sense that FDA will for certain issue a CBD rulemaking this year (or ever) may be misguided.
- On July 8, 2020, FDA's report to Congress, "Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated," was made public.[35] The Agency's July 8 report to Congress focuses almost entirely on its

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[33] U.S. Food & Drug Admin., Report to U.S. House Committee on Appropriations and U.S. Senate Committee on Appropriations—Cannabidiol (CBD)—Report in Response to Further Consolidated Appropriations Act, 2020, https://www.scribd.com/document/450303002/FDA-CBD-report#download (last visited Sept. 24, 2020).

[34] *Id.* at 2, 9.

[35] U.S. Food & Drug Admin., Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations—Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated, https://hempindustrydaily.com/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf.

CBD product sampling efforts.[36] It provides little in terms of policy or overall conclusions regarding the extent to which currently-marketed CBD products are mislabeled or adulterated, which was supposed to be the purpose of the report, per Congress's direction in the Further Consolidated Appropriations Act. For the first time in the report, though, FDA details its testing efforts prior to the passage of the 2018 Farm Bill. Also detailed in the Report, in 2019, FDA identified thirty-four CBD products for the testing of certain characteristics, including cannabinoid content and certain elements, by reviewing consumer and industry complaints submitted to the Agency and by conducting online surveillance. Products identified for testing included products marketed with "disease claims" and products intended for vulnerable populations, and were marketed as tinctures/oils, capsules/powders, edibles, beverages, and products marketed for pets. Of the twenty-one products that specified how much CBD was present per serving, seven (thirty-three percent) contained CBD within twenty percent of the amount indicated. Of the ten products that did not indicate the amount of CBD included in the product, six contained CBD and four did not. In addition, fifteen of the thirty-one products (forty-eight percent) contained THC. FDA further indicated in the July 8 report that it plans to conduct long-term sampling and has developed a sampling methodology to create a representative, random sample of the current CBD product marketplace. The Agency will favor products with a higher market share.

- On July 22, 2020, FDA announced the availability of its draft guidance for industry, "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research."[37] The Draft Guidance outlines several key thoughts regarding research and development of cannabis and cannabis-derived drug products. Importantly, the document provides a new method for drug sponsors, investigators, and applicants (developers) to calculate the percent of delta-9 tetrahydrocannabinol (THC) present in botanical raw materials, extracts, and finished products, which is relevant to assess the controlled substance status of the tested material. The 2018 Farm Bill legalized the production of hemp, which is defined as cannabis and derivatives or extracts of cannabis with no more than 0.3 percent THC by dry weight. Any cannabis or cannabis derivative with more than 0.3 percent THC is considered a Schedule I controlled substance ("marihuana") under the Controlled Substances Act (CSA) and subject to the Drug Enforcement Administration's (DEA) authority.

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[36] For more information on FDA's Sampling Study, *see* Lauren Farruggia and Jonathan Havens, *FDA Sends CBD Enforcement Policy to OMB, Issues Cannabis Clinical Research Draft Guidance, and Submits CBD Testing Report to Congress*, SAUL EWING ARNSTEIN & LEHR LLP CLIENT ALERT (July 24, 2020), https://www.saul.com/node/68341.

[37] U.S. FOOD & DRUG ADMIN., CANNABIS AND CANNABIS-DERIVED COMPOUNDS: QUALITY CONSIDERATIONS FOR CLINICAL RESEARCH GUIDANCE FOR INDUSTRY: DRAFT GUIDANCE FOR INDUSTRY (July 2020), https://www.fda.gov/media/140319/download.

In the Draft Guidance, FDA recommends that developers base the calculation of THC percentage "on the composition of the formulation with the amount of water removed, including any water that may be contained in excipients." This new method of testing, while targeted at drug development, could provide insight into how the Agency may calculate the THC content of consumer CBD products in the future, although that remains to be seen. Testing is crucial early in the development process, according to the Agency, so that developers may "gain insight into the potential control status of their product" from the start. FDA recommends that sponsors and developers consult with DEA regarding the control status of their cannabis materials or products that are under development, should such materials exceed 0.3 percent THC. The Draft Guidance also addresses source material for cannabis drug products, explaining that, while any cannabis meeting the definition of "hemp" under the 2018 Farm Bill is legal, currently, only cannabis above 0.3 percent THC sourced from the National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP) is permitted for clinical research (i.e., even cannabis grown in compliance with the laws and regulations of a state medical cannabis program would not be permitted to support development of a drug product for which FDA approval is sought). While the Agency's statements regarding the importance of research and development of cannabis-derived therapeutics are encouraging, until DEA expands sourcing availability for "marihuana" research, there will be little progress in domestic research and development. DEA is reportedly in the process of allowing additional growers and bulk manufacturers to register with DEA to produce and distribute cannabis for research purposes, but this process has been extremely protracted.

- Finally, and also on July 22, 2020, FDA sent to the White House Office of Management and Budget (OMB) a draft guidance, "Cannabidiol Enforcement Policy."[38] Because the draft guidance is not yet publicly available, we can only speculate about its contents. However, it seems that clarity could finally be coming to the CBD space, presuming OMB clears the guidance and FDA issues it thereafter. It is hard to believe that the Agency will back off completely from its "ingestibles are not permitted" stance. Perhaps the enforcement policy will be claims-focused (e.g., outlining further what would constitute impermissible disease claims). This seems somewhat unlikely, as industry already has a good sense of what FDA will tolerate and what it will not as all enforcement action against CBD products, to date, has centered on very aggressive disease claims. However, if the Agency outlines the same in a formal enforcement discretion policy, it could give more certainty to marketers offering ingestible products bearing anything other than

[38] *See* OMB, OIRA, "Cannabidiol Enforcement Policy; Draft Guidance for Industry; Availability," received July 22, 2020, https://www.reginfo.gov/public/jsp/EO/eoDashboard.myjsp.

disease claims. Less likely is that FDA will lay out specific serving size limits (e.g., unless and until the Agency issues a CBD ingestibles rule, any supplement with 50 mg CBD per serving or less will be subject to enforcement discretion). This also seems unlikely, given the data gaps FDA perceives to exist and thus the lack of support for establishing consumption limits. While some stakeholders think that 50 mg CBD or less per serving might be an appropriate limit, we do not believe the Agency will be that proscriptive in an area that it seems to still be wading its way through. On the product standards front, it is possible that FDA could start to hold ingestible CBD marketers to the Agency's dietary supplement regulations (e.g., good manufacturing practice (GMP) requirements). This is certainly what the supplement industry/trade associations have been pushing for, as it would raise the bar for the industry, push out unsavory firms who are producing unsafe products, and allow marketers to say that they comply with FDA requirements (which would hopefully smooth out the true patchwork of state requirements), among other benefits. However, it is not clear that FDA is prepared to go that far. OMB review time is difficult to predict, in that some guidance documents get reviewed quickly (e.g., less than two months in the case of FDA's cannabis clinical research guidance), whereas others take several months or longer. Generally, we might expect to see a decision from OMB on the enforcement policy somewhere between October and January 2021 (or longer).

NEW NUTRITION FACTS LABEL REQUIREMENT GOES INTO EFFECT FOR LARGEST FIRMS, FDA ISSUES RELATED GUIDANCE DAYS BEFORE DEADLINE

On May 27, 2016, FDA published final rules on the new Nutrition Facts Label (NFL) for packaged foods.[39] Despite rollout delays, the Agency finally seemed poised to move forward with the NFL rules as of late March 2018. However, it was not until December 30, 2019, just two days before the NFL rules were set to go live for firms with annual sales over $10 million, that FDA issued its final NFL guidance aimed at conventional food and dietary supplement manufacturers.[40] Manufacturers with less than $10 million in annual food sales have an additional year to comply.[41] The guidance addresses a number of topics, including: (1) the definition of a single-serving container; (2) reference amounts customarily consumed (RACCs), which are used by companies to determine serving sizes; (3) dual-column labeling, including formatting

[39] 81 Fed. Reg. 33,741, 33,999 (May 27, 2016).

[40] U.S. FOOD & DRUG ADMIN, FOOD LABELING: SERVING SIZES OF FOODS THAT CAN REASONABLY BE CONSUMED AT ONE EATING OCCASION, REFERENCE AMOUNTS CUSTOMARILY CONSUMED, SERVING SIZE-RELATED ISSUES, DUAL-COLUMN LABELING, AND MISCELLANEOUS TOPICS: GUIDANCE FOR INDUSTRY (Dec. 2019) [hereinafter FOOD LABELING GUIDANCE], https://www.fda.gov/media/133699/download.

[41] *Industry Resources on the Changes to the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. (current as of September 18, 2020), https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label.

issues for products that have limited space for nutrition labeling; and (4) a variety of other issues, such as requirements relating to the labeling of chewing gum and to multi-unit retail food packages.

Per the guidance, a single-serving container is a product that is packaged and sold individually (i.e., that bears an NFL and contains less than 200 percent of the applicable RACC for that product).[42] The entire content of a single-serving container must be labeled as one serving.[43] The Agency provides as an example of a single-serving container a 20-oz bottle of soda.[44] The RACC for carbonated beverages is 12 oz (360 mL); a 20-oz bottle of soda contains approximately 167 percent of the RACC and meets the definition of a single-serving container.[45]

By contrast, products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable RACC (e.g., a 75-gram bag of chips that is 250 percent of the RACC of 30 grams for chips) must provide an additional column within the NFL that lists the quantitative amounts and percent daily values (DVs) for the entire package, as well as a column listing the quantitative amounts and percent DVs for a serving that is less than the entire package (i.e., the serving size derived from the RACC), unless an exception applies.[46] The first column must list nutrition information based on the serving size for the product, and the second column must list the nutrition information based on the entire contents of the package.[47]

The dual-column labeling requirements also apply to products in discrete units.[48] If a discrete unit weighs at least 200 percent and up to and including 300 percent of the applicable RACC, the serving size will be the amount that approximates the RACC, and the product label must provide dual-column labeling for the discrete unit, unless an exemption applies.[49] The first column would list the nutrition information based on the serving size, while the second column would list the nutrition information for the individual unit.[50]

With regard to dual-column labeling exemptions for small packages, an exemption is available for products that have: (1) a total surface area available to bear labeling of less than 12 square inches; or (2) a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Some other notable exemptions from the requirement include: (1) raw fruits, vegetables, and seafood for which nutrition labeling is provided voluntarily on the product or in advertising, or as is required when claims are made about the product; (2) products that require further preparation (e.g., pancake mix) and for which an additional column of nutrition information for the "as prepared" form of the food is voluntarily provided; (3) products

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42 FOOD LABELING GUIDANCE, *supra* note 40, at 6.

43 *Id.*

44 *Id.*

45 *Id.*

46 *Id.* at 12.

47 *Id.*

48 *Id.*

49 *Id.*

50 *Id.*

that are commonly consumed in combination with another food (e.g., cereal and milk) and for which an additional column of nutrition information for the combination is voluntarily provided; (4) products for which an additional column of nutrition information for two or more groups for which Reference Daily Intakes (RDIs) are established (e.g., both infants and children less than four years of age) and provided; (5) popcorn products for which an additional column of information per 1 cup popped popcorn is provided; and (6) varied-weight products.[51]

In explaining the reasoning behind the NFL rules, and the guidance, Claudine Kavanaugh, Ph.D., MPH, RD, Director of the Office of Nutrition and Food Labeling in FDA's Center for Food Safety and Applied Nutrition, noted that:

The new Nutrition Facts label has updated serving sizes for many foods. We know that Americans are eating differently, and the amount of calories and nutrients on the label is required to reflect what people actually eat and drink—not a recommendation of what to eat or drink. The new label, including this dual column layout, will drive consumers' attention to the calories and Percent Daily Value of nutrients that they are actually consuming.[52]

Despite the Agency's issuance of draft guidance in November 2018, the timing of the final guidance—so close to the NFL rules' compliance date—could lead to some stress, to say the least. Fortunately, however, FDA announced that it does not plan to take enforcement action until July 1, 2020, focusing in the meantime on working to educate manufacturers that are not in compliance.[53]

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[51] *Id.* at 13.

[52] *FDA Issues Final Guidance on Serving Sizes, Dual-Column Labeling*, U.S. FOOD & DRUG ADMIN. (Dec. 30, 2019), https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-guidance-serving-sizes-dual-column-labeling.

[53] *Id.*

Cases to Watch

WILLIAM E. JANSSEN, LYNN C. TYLER*

The year 2020 has turned out to be a year to remember, even if unwillingly. Usually published in April, this volume's publication was delayed to early October 2020 to coincide with FDLI's delayed Annual Meeting. That didn't leave much of 2020 to watch for cases. Accordingly, we cover fewer cases to watch than in a typical year, and the next expected action on some of the cases we cover may well occur in 2021. Even so, we polled our Top Cases chapter authors for their prognostications on which litigations currently in process have the potential to change the food and drug landscape, and they did a great job in coming up with cases to watch.

FORD MOTOR CO. V. BANDEMER

Ford Motor Co. v. Montana Eighth Judicial District Court[1]

These two consolidated cases—one from Minnesota and one from Montana—explore a constitutional personal jurisdiction question the U.S. Supreme Court raised in 1984 and then avoided ever since. They involve two car crashes, one in each State, and the lawsuits that ensued. Both lawsuits proposed to exercise "specific" personal jurisdiction over the cars' manufacturer (Ford Motor Company) in the States where the crashes occurred. The claimants reason that Ford "deliberately cultivated a market" for its products in Minnesota and Montana (which it did), and that local State residents were injured in-State by Ford products (which they were). But Ford argues that those facts are not enough to confer "specific" personal jurisdiction. Instead, quoting a flurry of Supreme Court personal jurisdiction opinions over the years, Ford posits that "specific" personal jurisdiction can exist only when a defendant's behavior of purposefully availing itself of the privilege of doing business in a State is what actually causes the claimed injury in that State. Then, and only then, insists Ford, can "specific" personal jurisdiction be possible. (Under that test, "specific" personal jurisdiction would fail here: the two cars that crashed were sold by Ford to their original owners in States other than Minnesota and Montana, and had been later re-sold to others.) In 1984, the Supreme Court handed down *Helicopteros Nacionales de Columbia, S.A. v. Hall*,[2] where it explained that "specific jurisdiction" will exist when the lawsuit's cause of action "arise[s] out of or relate[s] to" a foreign entity's activities in that forum State. The Court then went on to decide that case on other grounds. But the majority opinion dropped a cagey footnote (No. 10) to expressly "assert no 'view'" on whether a distinction exists between the phrase "arises-out-of" and the phrase "relates-to," or

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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] No. 19-369 (U.S.), on appeal from Bandemer v. Ford Motor Co., 931 N.W.2d 744 (Minn. July 31, 2019).

[2] 466 U.S. 408, 414 (1984).

the "validity or consequences of such a distinction," or even whether "relates-to" could, alone, be enough to establish "specific" personal jurisdiction. It seems that question, left hauntingly unanswered for thirty-six years, will finally be tackled this Court Term. The ramifications for product liability litigation of all types—including drug and device disputes—are significant far-reaching. Oral argument before the U.S. Supreme Court in this case has been scheduled for October 7, 2020.

Polansky v. Executive Health Resources, Inc.[3]

The plaintiff/relator, Jesse Polansky, M.D. ("Relator"), brought a False Claims Act (FCA) qui tam action in the Eastern District of Pennsylvania on behalf of the United States. Relator alleged that Executive Health Resources, Inc. ("EHR") caused its hospital clients to fraudulently bill Medicare and Medicaid by falsely designating patient admissions as inpatient when they should have been designated as outpatient. The claims at issue included reimbursement claims certified by EHR from January 1, 2009 to October 1, 2013. During that period, the definition of an inpatient admission was set forth in Centers for Medicare & Medicaid Services (CMS) guidance, specifically § 210 of the 1989 edition of the Medicare Hospital Manual.

Relator's theory was that the claims were "legally false" under the FCA because the hospitals had (allegedly) falsely certified that they had complied with a statute or regulation which was a condition for Government payment. Applying *Azar v. Allina Health Services*[4] and the D.C. Circuit's definition of "substantive legal standard" in *Allina Health Servs. v. Price*,[5] the district court decided that the 24-hour policy in the 1989 Manual and its predecessors was a "substantive legal standard" within the scope of Section 1395hh(a)(2) of the Medicare Act. Thus, it could only be adopted by a notice-and-comment rulemaking. Relator's theory failed as a matter of law because it was undisputed that the 24-hour policy did not go through the notice-and-comment process. Given that the policy was not properly adopted, it was not a condition for Government payment with which the hospitals could have falsely certified compliance. In other words, FCA liability could not be predicated on agency guidance.

An appeal was taken to the Third Circuit and briefing was completed August 27, 2020. As of the date of this publication, oral argument has not been scheduled.

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[3] No. 19-3810 (3d Cir.), on appeal from 422 F. Supp. 3d 916 (E.D. Pa. Nov. 5, 2019).

[4] 139 S. Ct. 1804 (2019).

[5] 863 F.3d 937, 943 (D.C. Cir. 2017).