Top Food and Drug Cases, 2020, & Cases to Watch, 2021

Edited by August T. Horvath

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Top Food and Drug Cases, 2020 & Cases to Watch, 2021

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Introduction

AUGUST T. HORVATH*

As a general matter, "looking back at 2020" is a singularly unpleasant prospect for the vast majority of us. It is also a preoccupation that, many of us are increasingly suspecting with dread, we may not be entirely able to jettison for the foreseeable future, if not for the rest of our lives. Certainly from the viewpoint of mid-2021, that star-crossed year is very much still with us, upending everything from the Food and Drug Law Institute's usual practice of publishing this volume in hard copy and distributing it at a face-to-face Annual Meeting to much broader aspects of our personal and professional lives. For those working in and around the pharmaceutical and health care industries, obviously, the impact of the global medical crisis of COVID-19 was even more profound. Efforts that, without too much exaggeration, could be called "heroic" were made in these communities and ultimately will have saved countless lives. The health, medical, and pharmaceutical industries have never been more important, nor the focus of more attention. The American legal and regulatory apparatus did its part to facilitate the response to the pandemic, including, where necessary, by stepping out of the way.

And yet, life goes on, after a fashion. In this year's review of the most significant food and drug law cases and regulatory matters from 2020, COVID-19 does not play a major role. For the most part, the cases we cover here were controversies that began in previous years, and only in 2020 reached the point of a court decision or other outcome. As in prior years, the cases and developments covered by our estimable team of contributors range broadly across different aspects of food and drug law, and we even include some developments not strictly from food and drug law that we expect to have an impact on our areas of focus. We hope that FDLI's members continue to find our volume informative, interesting, and worth archiving for future reference. Be sure to keep an eye on our Cases to Watch at the end of the book, as well, and see how we do on predicting the impact of what appear to our contributors to be the most important cases currently in progress.

As the wellspring of food and drug law, the FDA and related federal enforcement is always a subject of our chapters. This year, James Beck addresses the agency's response to the COVID crisis through its invocation of the Public Readiness and Emergency Preparedness (PREP) Act, and the consequences for private litigation. Contributors Niall MacMenamin, Rene Befurt, and Genna Liu cover a D.C. Circuit decision that new FDA health warnings required on cigar products violated the Tobacco Control Act and the Administrative Procedure Act. Lynn Tyler describes the latest developments in a closely watched federal criminal prosecution for alleged off-label medical device promotion. Dan Logan and Jackie Chan report on a Supreme Court case that was argued in 2020 but decided shortly before we went to press in

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April 2021, limiting the Federal Trade Commission's authority to seek restitution in actions under Section 13(b) of the FTC Act, with far-reaching implications for the powers of federal enforcement agencies, such as FDA, that have similarly worded enforcement authority.

We never neglect private litigation in these pages, and in this year's volume, we cover important developments across the food and drug spectrum. Ralph Hall describes a key Ninth Circuit ruling on the parameters under which medical device product liability litigation can be preempted by FDA's regulatory activities, with potential implications for drugs and biologics. Ginger Pigott and Michael Goodman cover a series of recent cases that have shaped the development of failure-to-warn claims in the prescription drug and device arena during 2020. Mital Patel and Jennifer Yoo discuss a recent spate of consumer class actions challenging flavor designators on a variety of food products such as ice cream and non-dairy milk beverages. Sara Koblitz explains an important Federal Circuit decision in the "skinny label" or "carveout" provisions of Hatch-Waxman in the context of pharmaceutical patent litigation. Bill Janssen discusses a key development in innovator liability theory in pharmaceutical product liability cases.

Our annual volume is never complete without our three roundup chapters. Lauren Farruggia and Jonathan Havens return to describe important regulatory and enforcement developments from the past year, and Justine Lenehan covers significant settlements between federal enforcement agencies and their targets over the course of 2020. And the chorus of authors weighs in, as noted above, on in-progress cases that we think are worth watching for the balance of 2021. As always, there is more than a little to interest any active practitioner in the food, drug, and related spaces in these pages.

We hope this summary of important 2020 decisions in the food and drug area provides you with the same education and enjoyment as our previous volumes. Last year, we wrote in this introduction that we looked forward "hopefully without excessive optimism, to a return to our traditional format and publication timetable in 2020." Our optimism *was* slightly excessive, but we achieved the timetable part, and are happy to be back on schedule for both this volume and the FDLI Annual Meeting at which it will be released. We wish our audience the best for the next year, and look forward to our summary of next year's top cases.

AMG Capital Management, LLC v. Federal Trade Commission

T. DANIEL LOGAN & JAQUELINE J. CHAN*

WHY IT MADE THE LIST

On first glance, a case about the Federal Trade Commission's (FTC's) remedies against payday lending may not appear relevant to food and drug law and its practitioners. However, in effect, many agencies pull enforcement approaches from the same toolbox; a ruling that shrinks the toolbox for one agency may do so for all others. Both the FTC and the Food and Drug Administration (FDA) have relied on analogous statutory authority to seek injunctions as a means of obtaining a wider array of equitable remedies, including disgorgement.

DISCUSSION

Background

Section 13(b)[1] of the Federal Trade Commission Act (FTC Act) permits the FTC to file a suit seeking a temporary restraining order or a preliminary or permanent injunction when it has reason to believe that a person or entity is violating or about to violate any law under its purview. Although the statutory text only mentions injunctions, until recently, the prevailing interpretation among courts had been that Section 13(b) permits deployment of the full suite of the court's remedies in equity. Such interpretation rests on the Supreme Court decisions in *Porter v. Warner Holding Co.*[2] and *Mitchell v. Robert DeMario Jewelry, Inc.*,[3] the former of which held, in the context of the Emergency Price Control Act, that because the statute at issue authorized injunctive relief, it triggered the court's equity jurisdiction, which in turn, enables "all the inherent equitable powers of the District Court . . . ." Accordingly, a court sitting in equity may "go beyond the matters immediately underlying its equitable jurisdiction and decide whatever other issues and give whatever other relief may be necessary under the circumstances."[4]

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1 15 U.S.C. § 53(b).

2 328 U.S. 395, 398 (1946).

3 361 U.S. 288 (1960).

4 361 U.S. at 291.

FTC, FDA, and other agencies have relied on the *Porter* and *Mitchell* decisions and subsequent case law to obtain equitable restitution from defendants.[5] For instance, in *United States v. Rx Depot, Inc.*, FDA sought and obtained a preliminary injunction to prevent defendants from facilitating the sale of Canadian prescription drugs to U.S. customers. The parties then agreed to a consent decree of permanent injunction.[6] Subsequently, FDA petitioned for disgorgement of defendant's profits under 21 U.S.C. § 332(a), which states that "district courts . . . shall have jurisdiction . . . to restrain violations of [21 U.S.C. § 331] . . . ." The district court determined that the disgorgement was not available under the Federal Food, Drug, and Cosmetic Act (FFDCA).[7] On appeal, the Tenth Circuit reversed, stating that 21 U.S.C. § 332(a) "invokes the equity jurisdiction using the same statutory language the Supreme Court construed in *Mitchell* to authorize all equitable remedies."[8] It concluded that disgorgement was available under the FFDCA unless the statute contains a "clear legislative command or necessary and inescapable inference prohibiting disgorgement" or "disgorgement is inconsistent with the purposes of the [F]FDCA."[9] A similar interpretation has also been adopted by the Third Circuit.[10]

F.T.C. v. AMG Capital Management (9th Circuit)

In the case at issue, the FTC initially filed a complaint against a collection of businesses owned by Scott Tucker, alleging that the defendants had violated Section 5 of the FTC Act[11] for deceptive conduct relating to the terms of payday loans, including hidden fees and misleading terms.[12] In 2016, the district court, relying on Section 13(b), permanently enjoined Mr. Tucker from engaging in loan-related activities and ordered a restitution of $1.27 billion, to be paid to the FTC.[13] Defendants appealed to the Ninth Circuit, arguing that, among other things, the district court acted beyond the authority of Section 13(b) by effectively imposing a monetary penalty rather than an equitable form of relief necessary to effectuate the injunction.[14]

On appeal in 2018, the three-judge panel upheld the district court's order, concluding that Tucker's argument was compelling but ultimately foreclosed by repeated holdings that Section 13 permits district courts to grant "any ancillary relief necessary to accomplish justice, including restitution."[15]

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[5] *See, e.g.*, F.T.C. v. Com. Planet, Inc., 815 F.3d 593, 599 (9th Cir. 2016) (FTC); United States v. Rx Depot, Inc., 438 F.3d 1052 (10th Cir. 2006) (FDA).

[6] 438 F.3d at 1054.

[7] *Id.*

[8] *Id.* at 1058 (citing *Mitchell*, 361 U.S. at 291–92).

[9] *Id.*

[10] *See* United States v. Lane Labs-USA Inc., 427 F.3d 219 (3d Cir. 2005).

[11] 15 U.S.C. § 45(a)(1).

[12] *See* Press Release, Fed. Trade Comm'n, FTC Charges Payday Lending Scheme with Piling Inflated Fees on Borrowers and Making Unlawful Threats when Collecting (April 2, 2012), https://www.ftc.gov/news-events/press-releases/2012/04/ftc-charges-payday-lending-scheme-piling-inflated-fees-borrowers.

[13] F.T.C. v. AMG Services, Inc., et al., 2016 WL 5791416 at *14, Case No. 2:12-cv-00536 (D. Nev. Sept. 30, 2016).

[14] F.T.C. v. AMG Capital Management, LLC, 910 F.3d 417, 426 (9th Cir. 2018) (hereinafter *AMG Capital Management*).

[15] *Id.* (quoting F.T.C. v. Com. Planet, Inc., 815 F.3d 593, 598 (9th Cir. 2016)).

In an interesting turn, Judge O'Scannlain, the majority opinion's author, also elected to write a separate concurrence. In that concurrence, he forcefully concludes that the text and structure of Section 13 do not support the "strained" interpretation that empowers courts to award "equitable monetary relief."[16] First, Judge O'Scannlain argues that, based on the plain meaning of the term and as used in Section 13(b), the term "injunction" means just that and "cannot reasonably be interpreted to authorize *other* forms of equitable relief."[17] Second, the concurrence points out that while Section 13(b) "empowers the [FTC] to stop *imminent* or *ongoing* violations, an entirely different provision . . . allows the [FTC] to collect monetary judgements for past misconduct."[18] The concurrence points to Section 19 of the FTC Act, which separately permits the FTC to seek "such relief as the court finds necessary to redress injury to consumers," including "the refund of money or return of property, [and] the payment of damages."[19] Judge O'Scannlain argues that by relying on Section 13(b) to obtain monetary relief, the FTC has effectively sidestepped the procedural hurdles Congress put in place to obtain relief pursuant to Section 19, which requires the FTC to either "promulgate rules that define unlawful practices ex ante, or first to prosecute a wrongdoer in an administrative adjudication that culminates in a cease and desist order."[20] Finally, the concurrence argues that restitution under Section 13(b) is not a form of equitable relief.[21] In Judge O'Scannlain's view, because restitution under Section 13(b) has not been limited to the recovery of identifiable assets in the defendant's possession, it is "indistinguishable from a request to obtain a judgment imposing a merely personal liability upon the defendant to pay a sum of money" and instead "bears the hallmarks of a penalty," a remedy at law, rather than equity.[22] Joined by another member of the three judge panel, the concurrence urged for rehearing *en banc* in order to overturn the prior precedent permitting the FTC to seek disgorgement. Ultimately, *en banc* review was denied and the district court's disgorgement order was upheld.

Whether intending to do so or not, Judge O'Scannlain's strident concurrence provoked a circuit split that led to the Supreme Court considering and ultimately reversing the majority opinion.

F.T.C. v. Credit Bureau Center (7th Circuit)

In 2019, following Judge O'Scannlain's concurrence in *F.T.C. v. AMG Capital Management*, a Seventh Circuit panel overruled thirty-year-old precedent, holding that the plain language of Section 13(b) "does not authorize restitutionary relief."[23] The

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[16] *Id.* at 429 (O'Scannlain, J., concurring).

[17] *Id.* at 430 (O'Scannlain, J., concurring) (emphasis in original).

[18] *Id.* at 431 (O'Scannlain, J., concurring) (emphasis in original).

[19] *Id.* (O'Scannlain, J., concurring) (citing 15 U.S.C. § 57b(b)).

[20] *Id.* at 432 (O'Scannlain, J., concurring).

[21] *Id.* at 433–34 (O'Scannlain, J., concurring) (citing Kokesh v. S.E.C., 137 S. Ct. 1635, 198 L. Ed. 2d 86 (2017)).

[22] *Id.* at 434–35 (O'Scannlain, J., concurring) (quoting Great-W. Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204, 212–13 (2002) (internal quotation marks omitted)).

[23] F.T.C. v. Credit Bureau Ctr., LLC, 937 F.3d 764, 767 (7th Cir. 2019), *cert. granted*, 141 S. Ct. 194, 207 L. Ed. 2d 1118 (2020), *vacated*, 141 S. Ct. 810 (2020), *and cert. denied*, 141 S. Ct. 195, 207 L. Ed. 2d 1118 (2020) (overruling F.T.C. v. Amy Travel Serv., Inc., 875 F.2d 564, 570 (7th Cir. 1989)).

majority decision explained "the prevailing interpretation of [S]ection 13(b) developed in the shadow of . . . decisions that took a capacious view of implied remedies."[24] However, in the intervening years, the Supreme Court has adopted a more restrained approach to statutory interpretation and has instructed courts to "consider whether an implied equitable remedy is compatible with a statute's express remedial scheme."[25] In addition to the plain language rationale put forth by the Ninth Circuit concurrence, the opinion also notes that two other provisions within the FTC Act expressly authorize equitable remedies, Sections 5(l) and 19(b), whereas Section 13(b) does not.[26] After denial of *en banc* review by the Seventh Circuit, the Supreme Court initially granted certiorari and consolidated the case with *AMG Capital Management*,[27] but ultimately vacated the order granting certiorari and un-consolidated the cases,[28] opting to hear arguments in the Ninth Circuit case alone.

F.T.C. v. AMG Capital Management (Supreme Court)

In April 2021, following oral arguments[29] earlier in the year, the Supreme Court issued a unanimous decision holding that Section 13(b) of the FTC Act does not authorize monetary relief.[30] The opinion, authored by Justice Breyer, hews closely to the arguments made by Judge O'Scannlain's concurrence. Justice Breyer's opinion concludes that the text and structure of Section 13(b), as well as the structure of the FTC Act itself, make clear that Congress intended for the term "permanent injunction" to have a limited meaning that "does not extend to a grant of monetary relief."[31] Rather, reading the statute to permit the FTC to dispense with the "historically important" administrative proceedings required by Sections 5 and 19 of the FTC Act to obtain monetary relief "would allow a small statutory tail to wag a very large dog."[32] The decision notes that, in addition to the administrative process, Sections 5 and 19 of the FTC Act impose conditions and limitations on when a court may award monetary relief; therefore, it is highly unlikely that Congress would have enacted a provision implicitly permitting the FTC to obtain monetary relief *sans* such constraints.[33] Ultimately, Justice Breyer determines that interpreting Section 13(b) as authorizing injunctive but not monetary relief "produces a coherent enforcement scheme."[34] Addressing the FTC's arguments that the precedent set by *Porter* and *Mitchell* should

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[24] *Id.* at 776 (citing Porter v. Warner Holding Co, 328 U.S. 395, 398 (1946); Mitchell v. Robert DeMario Jewelry, Inc., 361 U.S. 288 (1960)).

[25] *Id.* at 767 (citing Meghrig v. KFC W., Inc., 516 U.S. 479, 486 (1996)).

[26] *Id.* at 783 (citing 15 U.S.C. §§ 45(l), 57b(b)).

[27] F.T.C. v. Credit Bureau Ctr., LLC, 141 S. Ct. 194, 207 L. Ed. 2d 1118, *vacated*, 141 S. Ct. 810 (2020).

[28] *F.T.C. v. Credit Bureau Ctr.*, LLC, 141 S. Ct. 810 (2020).

[29] Transcript of Oral Argument at 26–28, 34–36, AMG Capital Management, LLC v. F.T.C., 141 S. Ct. 194, 207 L. Ed. 2d 1118 (2020) (No. 19-508), *available at* https://www.supremecourt.gov/oral_arguments/argument_transcripts/2020/19-508_3f14.pdf.

[30] AMG Capital Management, LLC v. F.T.C., No. 19-508, 593 U.S. __, 141 S. Ct. 1341, slip op. at 1 (2021), *available at* https://www.supremecourt.gov/opinions/20pdf/19-508_l6gn.pdf.

[31] *Id.* at 7.

[32] *Id.* at 8.

[33] *Id.* at 9–10.

[34] *Id.* at 10.

apply, Justice Breyer notes that "the scope of equitable relief that a provision authorizes remains a question of interpretation for each case."[35] He further explains that *Porter* and *Mitchell* involved different statutes and neither decision "purport[ed] to set forth a universal rule of interpretation."[36]

Aside from the textual and precedential arguments, it seems apparent that policy concerns may have animated the outcome. For one, the Court appears to be concerned that in practice, the FTC is circumventing the administrative process with greater frequency, noting that the FTC brings more cases in court (forty-nine complaints filed and eighty-one permanent injunctions obtained in fiscal year 2019) than via the administrative process (twenty-one new administrative complaints and twenty-one final orders in the same period).[37] Moreover, the Court suggests that the FTC is aware of the limits of Section 13(b), as it has recently requested Congress revise that provision to expressly authorize restitution and disgorgement.[38]

IMPACT OF THE DECISION

The Supreme Court's decision in *AMG Capital Management* clarifies that a statute's injunction authority does not, without more, permit a district court to root around in the toolbox of equity. While the decision will have an immediate impact on the manner by which FTC seeks monetary remedies, it grants other similarly situated agencies a minor reprieve. By taking the position that the scope of equitable remedies available under statute is a case-by-case determination, agencies seeking monetary relief under similar statutes will not necessarily be forced to look elsewhere but will have to be fairly cautious unless those statutory authorities explicitly provide for such relief. While the FTC has express authorities under which it can request monetary penalties,[39] the FFDCA, outside of 21 U.S.C. § 332, does not contain provisions that expressly permit FDA to obtain equitable remedies, such as disgorgement. FDA has sought and obtained equitable remedies to great effect,[40] but it is likely that it would be unable to do so under a more restrictive view of 21 U.S.C. § 332. The decision here may not hobble FDA's enforcement efforts, but it could certainly make it more difficult for the agency to put forward more "creative" approaches to obtaining funds from violators of the FFDCA.

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35 *Id.* at 11 (citing Mertens v. Hewitt Associates, 508 U.S. 248, 257 (1993) (internal quotation marks omitted)).

36 *Id.* at 11.

37 *Id.* at 6 (citing FED. TRADE COMM'N, FISCAL YEAR 2021 CONGRESSIONAL BUDGET JUSTIFICATION 5 (Feb. 10, 2020), https://www.ftc.gov/system/files/documents/reports/fy-2021-congressional-budget-justification/fy_2021_cbj_final.pdf).

38 *Id.* at 14 (citing *Hearing before the Senate Committee on Commerce, Science, and Transportation on Oversight of the Federal Trade Commission*, 116th Cong., 2d Sess., 3–5 (2020) (prepared Statement of the FTC)).

39 21 U.S.C. §§ 45(l), 57b(b).

40 *See, e.g.*, United States v. Universal Mgmt. Servs., Corp., 191 F.3d 750, 754 (6th Cir. 1999) (upholding district court's injunction order mandating restitution by way of full refunds for 800,000 devices sold for $88.30 each).

Department of Health and Human Services PREP Act Declaration and Amendments[1]

JAMES M. BECK[2]

WHY IT MADE THE LIST

In 2020, the U.S. Food and Drug Administration's (FDA's) regulatory landscape, like the rest of the world, was dominated by the COVID-19 pandemic caused by the SARS-CoV-2 virus. In the COVID-19 era, no decision by a court—at least not yet—has been as important in its impact on COVID-related litigation as the Declaration issued on March 20, 2020 by former Secretary of the U.S. Department of Health and Human Services (HHS) Alex Azar pursuant to the Public Readiness and Emergency Preparedness (PREP) Act,[3] and subsequently amended three times in 2020. This declaration, as amended, has effectively immunized much of the nation's response to the COVID pandemic from civil litigation under state law.

The PREP Act, enacted in 2005,[4] authorized the secretary of HHS to create immunity from liability for persons responding to public health emergencies, preempting state-law remedies and replacing them with a federal compensation program.[5] The PREP Act was amended in 2013 to expand the scope of available immunity to products receiving FDA emergency use approval in pandemic situations.[6] Its preemption clause invalidates any state and local law that "is different from, or is in conflict with, any requirement applicable under [the PREP Act]."[7]

Once HHS has issued a PREP Act declaration concerning a pandemic "countermeasure," immunity applies to any "covered person" with respect to all "claims for loss" caused by, arising out of, relating to, or resulting from the "administration" or the "use" of a "covered countermeasure" if a declaration has been issued with respect to that countermeasure.[8] Thus, the HHS definitions of "covered persons" and "covered countermeasures" is key.

The HHS declarations were the first time that the PREP Act's immunity provisions had been interpreted by the department since that statute had been enacted in 2005.

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1 85 Fed. Reg. 15198 (HHS March 20, 2020), *as amended*, 85 Fed. Reg. 21012 (April 15, 2020); 85 Fed. Reg. 35100 (June 8, 2020); 85 Fed. Reg. 52136 (Aug. 24, 2020); 85 Fed. Reg. 79190 (Dec. 9, 2020); 86 Fed. Reg. 7872 (Feb. 2, 2021); and 86 Fed. Reg. 9516 (Feb. 22, 2021). *See* HHS OGC, Advisory Opinion 21-01 (Jan. 8, 2021).

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

3 42 U.S.C. § 247d-6d *et. seq.*

4 Public Law 109-148, Div. C, §2.

5 *See* 42 U.S.C. § 247d-6d–63.

6 *See* Pandemic & All-Hazards Preparedness Reauthorization Act, Public Law 113-5, amending 42 U.S.C. § 300hh-1.

7 42 U.S.C. § 247d-6d(b)(8).

8 42 U.S.C. § 247d-6d(a)(1).

Given the scope of the pandemic and the importance of the immunity issues addressed by these declarations, they are more worthy of inclusion in the top twenty than most judicial decisions.

DISCUSSION OF THE FACTS, DECISIONS, AND RATIONALE

In mid-March, 2020, as the COVID-19 pandemic was shutting down the United States and much of the world, HHS announced in the Federal Register[9] that it was conferring COVID-19-related tort immunity pursuant to the PREP Act and the Pandemic and All-Hazards Preparedness Reauthorization Act.[10] Accompanying the immunity grant was a "Countermeasures Injury Compensation Program (CICP)," as authorized by the PREP Act.[11] The scope of tort immunity extended to "any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures."[12] The immunity extended not only to the manufacture and use of drugs and medical devices directly employed to combat COVID-19, but further to "products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic."[13]

The only exception to the PREP Act immunity program is for "willful misconduct," as defined in the PREP Act.[14] In cases of willful misconduct, the PREP Act authorizes "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by" such actions.[15] Federal claims for willful misconduct can "be filed and maintained only in the United States District Court for the District of Columbia."[16]

Under the preemption provisions of the PREP Act, the immunity HHS conferred prevails not only over state law, but also supersedes potential liability imposed by other federal laws.

> [A] covered person shall be immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure.[17]

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[9] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (HHS March 17, 2020).

[10] 21 U.S.C. §§ 564A-B.

[11] 85 Fed. Reg. at 15201.

[12] *Id.* at 15198.

[13] *Id.*

[14] *Id.* The PREP Act defines "willful misconduct" as "an act or omission" that is "intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; **and** in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." 42 U.S.C. § 247d-6d(c)(1)(A) (emphasis in original). Congress intended this "standard for liability [to be] more stringent than a standard of negligence in any form or recklessness." *Id.* at § 247d-6d(c)(1)(B).

[15] 42 U.S.C. § 247d-6d(d)(1).

[16] *Id.* §247d-6d(e)(1). The burden of proof is clear and convincing evidence. *Id.* 42 U.S.C. § 247d-6d(c).

[17] 85 Fed. Reg. at 15199.

Several groups of "covered persons" were entitled to claim immunity under HHS' first declaration. These include "manufacturers," "distributors," "program planners," and "qualified persons." HHS defined "manufacturer" as:

> [A] contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.[18]

HHS defined "distributor" as:

> [A] person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: manufacturers; re-packers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.[19]

HHS defined a "program planner" as:

> [A] state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure . . . . [A] private sector employer or community group or other "person" can be a program planner when it carries out the described activities.[20]

HHS defined a "qualified person" as:

> [A] licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures . . . ; or a person within a category of persons identified as qualified in the Secretary's Declaration.[21]

Thus, the scope of the immunity created by HHS' declaration broadly extends to anyone engaged in manufacturing, distributing, planning for the use of, or actually using a "covered countermeasure."

Those "covered countermeasures"—what PREP Act immunity actually applies to—consist of "qualified pandemic or epidemic product[s]," "security

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[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *See id.* at 15201–02 (listing as "qualified persons" all persons "authorized" "to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures" under several circumstances, including as provided in an FDA Emergency Use Authorization).

countermeasure[s]," and "a drug, biological product or device authorized for emergency use."[22] HHS likewise defined each of these "countermeasures":

> A "qualified pandemic or epidemic product means a drug or device . . . or a biological product [chiefly vaccines] . . . , that is manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause.[23]

The primary example of preempted claims is "liability claims alleging negligence by a manufacturer in creating a vaccine."[24]

A "security countermeasure" for a pandemic under the PREP Act is:

> [A] drug or device . . . or a biological product . . . that [t]he Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological . . . agent identified as a material threat . . . , or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and is determined . . . to be a necessary countermeasure to protect public health.[25]

All "countermeasures" must be FDA "approved or cleared," "investigational" under the FDCA, or else "licensed" or "authorized for emergency use."[26] These include "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19" and "any device used in the administration of any such product, and all components and constituent materials of any such product."[27]

The scope of immunity extends to preclude claims brought by anyone in a "population" "who should be vaccinated or take a drug or other countermeasure" or "who uses or who is administered a Covered Countermeasure."[28] In addition, PREP Act "liability immunity is afforded" to "manufacturers and distributors" whether or not a "countermeasure is used by or administered to this population."[29] Similarly, immunity extends to "program planners and qualified persons when [a] countermeasure" is used by anyone in the "population."[30] The PREP Act declaration also recognized a causation element, requiring that the "provision of the

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[22] *Id.* at 15199.

[23] *Id.* at 15199. In addition, this definition encompasses products designed to prevent, cure, or mitigate the adverse effects of other "qualified" products, as well as other products intended to "enhance" the effect of another "qualified" product. *Id.*

[24] *Id.* at 15200.

[25] *Id.* at 15199 (numbering removed).

[26] *Id.*

[27] *Id.* at 15202.

[28] *Id.* at 15200, 15202.

[29] *Id.* at 15200.

[30] *Id.*

countermeasures" or other "activities and decisions" must "directly relate to the countermeasure activities"[31]

Off-label use is also immunized, as to "manufacturers and distributors without regard to whether the countermeasure is used by or administered to [the intended] population," and also if used by others (off-label use), as long as the others "reasonably could have believed the recipient was in this population."[32] "Further, "liability immunity is afforded . . . to manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in [any particular] geographic areas."[33] The duration of this COVID-related PREP Act immunity "extends . . . through October 1, 2024"—over four and a half years—and possibly longer for products "obtained for the Strategic National Stockpile."[34] Immunity may extend even to claims brought by persons who are ineligible for the Act's compensation program.[35]

The import of the original declaration was that the immunity was broad enough so that public and private health professionals would be able to direct and control COVID-related countermeasures immunized from judicial second-guessing. However, almost at once the courts began intruding, drawing a distinction between the alleged "failure" of "program administrators"—mostly nursing homes—to employ COVID countermeasures and the alleged negligent employment of such countermeasures. The first category, claims of nonfeasance, were being allowed to proceed notwithstanding the broad terms of PREP Act immunity.

> [T]he complaints do not allege that Plaintiffs' injuries arose from . . . administration to them of vaccines or medicines (or for that matter protective gear)—activities that the PREP Act promotes by affording immunity. . . . Plaintiffs are claiming (*inter alia*) that the Defendants committed negligence in that, among other things, they *failed* to take countermeasures, some of them allegedly federally required.[36]

Nor were defendants facing such nonfeasance claims allowed to remove actions to federal court under the PREP Act's broad immunization against "all claims for loss caused by, arising out of, relating to, or resulting from" the administration or use of

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[31] *Id.* at 15200.

[32] *Id.*

[33] *Id.* at 15201, 15202.

[34] *Id.* at 15201, 15202.

[35] *Id.* at 15201 ("requirements for compensation . . . may not align with the requirements for liability immunity"); *id.* at 15202 ("immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population").

[36] Estate of Maglioli v. Andover Subacute Rehabilitation Center I, 478 F. Supp.3d 518, 532 (D.N.J. 2020) (emphasis in original). *See* Lutz v. Big Blue Healthcare, Inc., 480 F. Supp.3d 1207, 1216–17 (D. Kan. 2020); Brown v. Big Blue Healthcare, Inc., 480 F. Supp.3d 1196, 1206–07 (D. Kan. 2020); Eaton v. Big Blue Healthcare, Inc., 480 F. Supp.3d 1184, 1195 (D. Kan. 2020); Gunter v. CCRC OPCO-Freedom Square, LLC, 2020 WL 8461513, at *4 (M.D. Fla. Oct. 29, 2020); Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC, 2020 WL 6140474, at *7–8 (W.D. Pa. Oct. 16, 2020); Estate of Jones v. St. Jude Operating Co., LLC, 2020 WL 8361924, at *9 (D. Or. Oct. 14, 2020); Martin v. Serrano Post Acute LLC, 2020 WL 5422949, at *2 (C.D. Cal. Sept. 10, 2020); Jackson v. Big Blue Healthcare, Inc., 2020 WL 4815099, at *6 (D. Kan. Aug. 19, 2020).

covered countermeasures.[37] Instead, federal district courts were remanding PREP Act immunity litigation to state court, on the rationale that, by allowing anything to survive immunity, Congress could not have intended to create federal jurisdiction under the "complete preemption" doctrine.

> Defendants have raised the PREP Act as an affirmative defense here, claiming that the Act provides the sole civil remedy for those circumstances implicating covered countermeasures such that Plaintiff's sole remedy is to seek compensation from the Covered Countermeasures Process Fund by making requests for benefits under the Countermeasures Injury Compensation Fund (CICP). It is clear, however, that the presence of a federal defense does not make the case removable, even if the defense is preemption and even if the validity of the preemption defense is the only issue to be resolved in the case. . . . Thus, the Act is confined to addressing claims related to the administration of certain countermeasures and does not seek to completely preempt the type of state law negligence claims asserted here.[38]

The increasing use of nonfeasance allegations to preclude federal adjudication of COVID-related litigation under the terms of the HHS declaration of PREP Act immunity prompted HHS to file an amended declaration on December 9, 2020.[39] That amendment sought to extend PREP Act immunity to certain purely private sector activities related to the administration, and in some cases the non-administration, of COVID counter measures. It increased the scope of immunity for "substantial federal legal and policy interests . . . [that require] a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world."[40] In particular, PREP Act immunity was declared to reach "situations where not administering a covered countermeasure to a particular individual"[41]—the principle reason courts had been remanding COVID litigation to state court. Other extensions of PREP Act immunity were to "provide liability protections for, among other things, additional private-distribution channels"[42] as well as "an additional category of Qualified Persons . . . [namely] healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice."[43]

To address the "unprecedented global pandemic," HHS intended this extension of litigation-related immunity to provide an avenue for "a uniform interpretation of the

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[37] 42 U.S.C. § 247d-6d(a)(1).

[38] *Gunter*, 2020 WL 8461513 at *3 (citation and quotation marks omitted). *See* Parker v. St. Jude Operating Co., LLC, 2020 WL 8362407, at *5–6 (D. Or. Dec. 28, 2020); Saldana v. Glenhaven Healthcare LLC, 2020 WL 6713995, at *2 (C.D. Cal. Oct. 14, 2020); *Martin*, 2020 WL 5422949, at *2.

[39] Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190 (HHS Dec. 9, 2020).

[40] *Id.* at 79191.

[41] *Id.*

[42] *Id.*

[43] *Id.* at 79192 (this extension immunized treatments for COVID-19 provided by means of telemedicine).

PREP Act" through recognition of "an exclusive Federal cause of action."[44] It did so by express reliance on Supreme Court precedent that permitted federal jurisdiction where an overriding federal interest existed:

> COVID-19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mf'g*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities . . . and . . . in having a uniform interpretation of the PREP Act.[45]

In making this determination, HHS relied on congressionally "delegated . . . authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations."[46]

In the Fourth Amended Declaration, HHS created an additional "pathway" for immunity by removing a prerequisite in the Declaration's other Limitations on Distribution that had previously required "covered persons" using anti-COVID "Covered Countermeasures" to have an agreement with the federal government. It recognized a "third distribution channel" allowing a covered manufacturer, distributor, administrator or user of "covered countermeasures" to qualify for immunity even though "there is no federal agreement or authorization" covering those activities.[47] Thus, an entity, manufacturer, distributor, program planner, or qualified person that satisfies the other requirements of the PREP Act and prior HHS declarations is immunized even if there is no federal agreement to cover those activities and those activities are not part of the authorized activity of an Authority Having Jurisdiction.[48] Thus, the Fourth Amendment broadened PREP Act immunity to reach entities, such as nursing homes or manufacturing plants, acting in a purely private capacity, as long as they "manufacture, test, develop, distribute, administer, or use" Covered Countermeasures.

With respect to the judicial distinction between the administration and non-administration of Covered Countermeasures, the Fourth Amendment extended to include non-administration situations where supplies of such countermeasures are "limited."[49] "[N]ot administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to . . . the administration to . . . an individual.'"[50] As an "example," HHS cited a scarcity situation where a

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[44] *Id.* at 79174.

[45] *Id.* at 78197. *Grable* found federal subject matter jurisdiction over ostensibly state-law claims that "necessarily raise[]" "important" federal issues for which a federal forum was needed to "vindicate [federal] administrative action." *Grable*, 514 U.S. at 314–15. Such situations are "rare," *id.* at 315, but a once-in-a-century pandemic could well qualify.

[46] 85 Fed. Reg. at 78198 & n.25 (citing 42 U.S.C. § 247d-6d(b)(7), providing that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection").

[47] 85 Fed. Reg. at 79194.

[48] *Id.*

[49] *Id.* at 79197.

[50] *Id.* (quoting 42 U.S.C. § 247d-6d).

"person in the vulnerable population was able to receive [a countermeasure] only because it was not administered to the person in the less-vulnerable population."[51] Thus, HHS recognized that "[p]rioritization or purposeful allocation of a Covered Countermeasure . . . can fall within the PREP Act and this Declaration's liability protections."[52]

Nor was PREP Act immunity confined to COVID-19 itself. The Fourth Amended Declaration extends immunity to "other diseases, health conditions, or threats that may have been caused by COVID-19, . . . including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases."[53]

Finally, in response to additional inquiries about preemption, immunity, and allegations of nonfeasance, the HHS Office of General Counsel (OGC) followed up with an Advisory Opinion on the scope of PREP Act preemption on January 8, 2020.[54] HHS AO 21-01 addressed "whether the PREP Act applies where a covered person declined to use a covered countermeasure when it arguably ought to have been used."[55]

This advisory opinion concluded that the PREP Act supported federal jurisdiction as a "complete preemption statute."[56]

> The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.[57]

Recognizing that federal district courts had "labored hard attempting to ordain whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime," AO 21-01 addressed this issue once again.[58] It recognized a continuum of nonfeasance ranging from a "failed in toto to provide any" COVID countermeasures, at one extreme, to challenges to the quantity, timing, and training related to such countermeasures on the other.[59]

The OGC's advisory opinion concluded that only instances of complete nonfeasance, i.e., where a "defendant's culpability is the result of its failure to make any decisions whatsoever, thereby abandoning its duty to act as a program planner or other covered person," would avoid complete preemption under the PREP Act.[60]

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[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *See* ADVISORY OPINION 21-01 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT SCOPE OF PREEMPTION PROVISION, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Jan. 8, 2021), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf.

[55] *Id.* at 1.

[56] *Id.* at 2.

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] *Id.* at 4.

Lesser degrees of culpability than total inaction did not amount to the sort of "willful misconduct" that was actionable under the PREP Act.[61]

The OGC criticized the judiciary's fixation with a "black and white" distinction between use and nonuse of covered countermeasures.[62] While reiterating the allocation of scarce countermeasures example from the Fourth Amended Declaration, AO 21-01 pointed out that:

> There can potentially be other situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure. In contrast, the failure to purchase any PPE, if not the outcome of some form of decision-making process may not be sufficient to trigger the PREP Act.[63]

The immunity from suit that the PREP Act's preemption provisions enforced was broad—extending "to anything "'relating to' the administration of a covered countermeasure."[64]

AO 21-01 found support for this more nuanced distinction between nonuse by allocation and complete nonfeasance in the text of the PREP Act. "Program planners"—persons responsible for "administration, dispensing, distribution, provision, or use" of covered countermeasures—are protected by PREP Act Immunity.[65]

> A program planner is someone who is involved in providing or allocating covered countermeasures. Program planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them. Therefore, decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act.[66]

Only a "failure to make any decisions whatsoever," which effectively "abandon[s]" a defendant's role that otherwise creates immunity, puts that defendant outside of the PREP Act's protection.[67] Since complete preemption is not defeated by the "well-pleaded complaint rule," nonfeasance allegations should be tested by jurisdictional discovery to prevent plaintiffs from pleading arround the PREP Act.[68]

The HHS OGC further concluded that the scope of PREP Act immunity and preemption was the sort of overriding federal issue that conferred federal question jurisdiction under the *Grable* doctrine:

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[61] *Id.* at 3, 5.

[62] *Id.* at 3.

[63] *Id.*

[64] *Id.*

[65] *Id.* at 4 (quoting 42 U.S.C. § 247d-6d(i)(6)).

[66] *Id.*

[67] *Id.*

[68] *Id.*

> Here, ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court. . . . [T]he [HHS] secretarial determination provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.[69]

The Advisory Opinion reiterated that PREP Act determinations are not reviewable "by mandamus or otherwise" by any court.[70] However, AO 21-01 recites that it "is not a final agency action or a final order" and "does not have the force or effect of law."[71]

IMPACT

While undoubtedly broad, the full impact of PREP Act immunity on COVID-19-related litigation remains to be seen. After the December and January HHS pronouncements, less activist judges have decided to take HHS at its word and to cease second-guessing decisions to employ (or not) COVID countermeasures.

> [T]he Court agrees with this administrative agency interpretation of the PREP Act. . . . That the Advisory Opinions are not binding law or formal rules issued via notice and comment does not render them irrelevant. In that most recent guidance [HHS] affirmed that the PREP Act is a complete preemption statute and clarified the scope of the Act relative to the ongoing pandemic.[72]

That is not, however, the majority view. The unfortunate politicization of the national response to the COVID pandemic continues to haunt the interpretation of PREP Act immunity. First, there remains the possibility that the new administration that took office on January 20, 2021 will rescind or otherwise roll back the scope of immunity authorized by its predecessor's declarations.[73] Second, even in the face of administrative continuity the administration does not so act, most courts continue their inclination to reach the same result through creeping judicial nullification. These courts have either ignored or disagreed with HHS's declarations and advisory opinion and continue to remand COVID-related litigation over the allocation and/or nonuse of COVID countermeasures to state court.[74] The HHS discussion of allocation of

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[69] *Id.* at 5.

[70] *Id.* (quoting 42 U.S.C. § 247d-6d(b)(7)).

[71] *Id.*

[72] Garcia v. Welltower OpCo Grp. LLC, 2021 WL 492581, at *6–7 (C.D. Cal. Feb. 10, 2021).

[73] To date, the new administration has continued, rather than repudiated, prior PREP Act declarations. *See* Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 9516 (Feb. 22, 2021); Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 7872 (Feb. 2, 2021).

[74] *See* Mitchell v. Advanced HCS, LLC, 2021 WL 1247884, at *4–5 (N.D. Tex. April 5, 2021); Schuster v. Percheron Healthcare, Inc., ___ F. Supp.3d ___, 2021 WL 1222149, at *3–4 (N.D. Tex. April 1, 2021); Estate of Cowan v. LP Columbia KY, LLC, No. 1:20-CV-00118-GNS, 2021 WL 1225965, at *5 (W.D. Ky. March 31, 2021); Stone v. Long Beach Healthcare Center, LLC, 2021 WL 1163572, at *6 (C.D.

countermeasures as an example of inaction claims has been converted to a strictly limited exception, which of course is never pleaded.

> [While] an "inaction claim" is not necessarily beyond the scope of the PREP Act, such claims only fall under the scope of the PREP Act where: (1) there are limited covered countermeasures; and (2) there was a failure to administer a covered countermeasure to one individual because it was administered to another individual.[75]

Since all competent counsel bringing such claims know, by now, to couch them in terms of inaction, the intent of the PREP Act declarations to restrict COVID-related litigation to federal courts applying something approximating uniform federal standards can thus be thwarted.

Thus, it is far from certain that HHS' efforts to confine litigation over covered COVID countermeasures and PREP Act immunity to federal courts will ultimately be successful, despite its concerted regulatory efforts. Several of the decisions cited herein are now pending on appeal, so the only thing that can be stated with certainty about PREP Act immunity is that the legal landscape will continue to evolve.

Cal. March 26, 2021); Lopez v. Life Care Centers of America, Inc., 2021 WL 1121034, at *14 (D.N.M. March 24, 2021); Estate of McCalebb v. AG Lynwood, LLC, 2021 WL 911951, at *5–6 (C.D. Cal. March 1, 2021); Estate of Jones v. St. Jude Operating Co., LLC, 2021 WL 900672, at *6–7 (Mag. D. Or. Feb. 16, 2021), *adopted*, 2021 WL 886217 (D. Or. March 8, 2021); Dupervil v. Alliance Health Operations, LCC, 2021 WL 355137, at *10 (E.D.N.Y. Feb. 2, 2021); Grohmann v. HCP Prairie Village KS OPCO LLC, ___ F. Supp.3d ___, 2021 WL 308550, at *9 (D. Kan. Jan. 29, 2021); Anson v. HCP Prairie Village KS OPCO LLC, 2021 WL 308156, at *10 (D. Kan. Jan. 29, 2021); Estate of Smith v. Bristol at Tampa Rehabilitation & Nursing Center, LLC, 2021 WL 100376, at *2 (M.D. Fla. Jan. 12, 2021).

[75] Lyons v. Cucumber Holdings, LLC, 2021 WL 364640, at *4 (C.D. Cal. Feb. 3, 2021). *See* Robertson v. Big Blue Healthcare, Inc., 2021 WL 764566, at *8–9 (D. Kan. Feb. 26, 2021) ("no allegations . . . that Plaintiff . . . suffered any loss caused by the prioritization or purposeful allocation of a countermeasure") (citation and quotation marks omitted); *Grohmann*, 2021 WL 308550, at *9 (inaction must be "paired closely" to HHS example).

Cigar Association of America et al. v. United States Food and Drug Administration et al.

NIALL H. MACMENAMIN, RENE BEFURT & GENNA LIU*

WHY IT MADE THE LIST

Do larger, more prominent health warnings deter people from smoking cigars? That is the question the D.C. Circuit Court of Appeals asked in *Cigar Association of America et al. v. United States Food and Drug Administration et al.*,[1] and one that, according to the court of appeals, the Food and Drug Administration (FDA) failed to answer. The court of appeals reversed the District Court for the District of Columbia's decision[2] and ruled that the FDA's new health warning requirements on cigar products violated the Tobacco Control Act (TCA) and the Administrative Procedure Act (APA).[3] Among other concerns, the court of appeals concluded that the agency failed to consider how the proposed warnings would likely affect the number of cigar smokers.

The court of appeals opinion demonstrated the importance of using *targeted* evidence to evaluate the impact of health warning requirements on consumers' behaviors. The court noted that FDA's evidence was insufficient to show that the warning labels would have an impact on current and prospective cigar smokers. Or, in the words of the court's opinion, FDA "failed to bridge the gap between effective communication and fewer smokers."[4] In light of the court of appeals' perception that evidence in this matter was lacking (despite the agency's contrary belief), one can raise this question: What form of evidence could be used to evaluate the impact of the new warning labels on cigar smoker adoption and cessation rates?

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1 964 F.3d 56 (D.C. Cir. 2020).

2 315 F. Supp. 3d 143 (D.D.C. 2018).

3 While this article focuses on cigars, the court decisions also covered pipe tobacco.

4 964 F.3d at 60.

DISCUSSION

Background: Establishment of the Deeming Rule

In May 2016, FDA promulgated the "Deeming Rule," a regulation that deemed all tobacco products, including cigars and pipe tobacco, subject to control of the Federal Food, Drug, and Cosmetic Act (FDCA).[5] Passed under the authority of the TCA, the Deeming Rule submits newly deemed tobacco products to the same regulations previously imposed on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Specifically, newly deemed tobacco products must adhere to more demanding size mandates for health warning displays on tobacco product packages and advertisements. The displays are meant to inform prospective and current smokers that the tobacco product in question—in this matter, cigars—causes various diseases, creates pregnancy risks, is addictive, and is not a safe alternative to cigarettes.[6]

Prior to FDA's introduction of the Deeming Rule, the seven largest U.S. cigar companies, which comprise 95% of the U.S. cigar market, were required to rotate the display of five health warning statements "clearly and conspicuously" in their advertising and packaging.[7] Under the Deeming Rule, for individually sold products, cigar producers would have to display warnings that take up at least 30% of two principal display panels on cigar packages, and needed to be placed near the cash register on a sign that is 8.5 by 11 inches in size and "clear, legible, and conspicuous" in appearance.[8] Furthermore, warnings on advertisements were required to comprise at least 20% of the advertisement area.[9] Overall, the Deeming Rule required that health warnings cover between 390 and 475% *more* of a package's surface area compared to the prior requirements established by the FTC.[10]

Challenging the Deeming Rule: Ruling and Reasoning of the District Court

In July 2016, shortly after the introduction of the Deeming Rule, the Cigar Association of America and other cigar associations filed suit in the district court, challenging, among other things, the requirement to alter the size and format of the health warnings as applied to cigar packaging and advertisements. They asserted that the Deeming Rule violated the TCA and APA, and that FDA had failed to provide concrete findings required by the TCA to justify the additional health warning

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[5] Final Rule Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016).

[6] 21 C.F.R. § 1143.3(a)(1).

[7] This requirement was established as part of a settlement reached between Swisher International, Inc., Altadis U.S.A., Inc., General Cigar Holdings, Inc., John Middleton, Inc., Lane Limited, Inc., and Swedish Match North America, Inc. and the Federal Trade Commission (FTC) in 2000. *See* 315 F. Supp. 3d at 151–52; Press Release, Fed. Trade Comm'n, Nationwide Labeling Rules for Cigar Packaging and Ads Take Effect Today (February 13, 2001), https://www.ftc.gov/news-events/press-releases/2001/02/nationwide-labeling-rules-cigar-packaging-and-ads-take-effect.

[8] 21 C.F.R. § 1143.5(a)–(b). In addition, the Deeming Rule added requirements such as a new warning statement about nicotine addiction.

[9] Ibid.

[10] 315 F. Supp. 3d. at 155.

requirements. Plaintiffs also alleged that FDA failed to explain plausibly why the existing FTC requirements were inadequate.[11]

The district court upheld the Deeming Rule's health warning requirements in July 2018, stating that FDA had presented adequate evidence connecting the rule to the cessation and prevention of cigar use. Specifically, the district court concluded that FDA had demonstrated the importance and efficacy of the proposed warnings by showing that health warning statements help consumers understand the health consequences of tobacco use. The district court pointed to research showing that larger lettering on product packaging more effectively communicates warnings to consumers, for example, by improving noticeability and recall.[12]

The cigar associations appealed the district court's rulings, and the Court of Appeals for the D.C. Circuit issued its opinion in July 2020.

Ruling and Reasoning of the Court of Appeals

The court of appeals reversed the district court's decision and ruled that FDA failed to consider how the imposed warnings would likely affect the number of cigar smokers, therefore violating the TCA and APA.[13]

In rendering its decision, the court of appeals relied on the wording of FDCA section 906(d)(1), which stipulates that FDA may impose warnings if they are determined to be "appropriate for the protection of the public health" with respect to the risks and benefits for the "population as a whole, including users and nonusers of the tobacco product." FDA's finding must also consider the impact of any regulation on the likelihood of cessation ("likelihood that existing users of tobacco products will stop using such products") and the likelihood of adoption ("likelihood that those who do not use tobacco products will start using such products"). The court of appeals acknowledged that the additional health warning requirements are expensive to implement and affect the speech interests of manufacturers. Consequently, the court pointed out, it was essential for FDA to show that the warnings required by the Deeming Rule would actually have an effect on consumption of cigars.[14]

In evaluating the evidence put forth by FDA, the court of appeals concluded that as applied to cigars, the Deeming Rule did not consider the impact of health warnings on cigar adoption and cessation rates. In the text of the Deeming Rule, FDA cited literature that showed tobacco smokers are "more likely to recall warnings that are in a larger size" or "appear on the front/major surfaces" of the product packaging, and that the likelihood that a consumer would notice and pay attention to the warning depends on the warning's size and position.[15] Although FDA contended that health warnings would more effectively convey the health risks of tobacco products, it did not consider the increased or decreased likelihood that consumers would *act* on the information conveyed in the warnings by deciding not to smoke.[16] Even if effective communication and changes in smoking behavior are generally related, the FDA, the D.C. Circuit said, is not relieved of its duty to provide evidence of such connection for

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[11] *Id.* at 159.

[12] *Id.* at 160–61.

[13] 964 F.3d at 59.

[14] *Id.* at 62.

[15] 81 Fed. Reg. at 28,989.

[16] 964 F.3d at 62–63.

the specific product at-issue (cigars).[17] Additionally, the requirement that FDA's evidence focus on cigar users as opposed to all smokers is necessary because they are different consumers. For example, one expert report submitted to the district court found that cigar users have different demographics and usage behaviors than cigarette users, and one study cited by FDA in support of the Deeming Rule showed that cigar smokers might be *less* responsive to graphic health warnings than cigarette users.[18]

IMPACT

The court of appeals decision raises the bar for FDA's regulatory oversight. Under the decision, consistent with requirements set forth by the TCA, FDA must consider how proposed health warnings will likely impact the number of smokers. In particular, FDA must consider the effect of the proposed warning on the likelihood that existing users of tobacco will stop using the product, and the likelihood that those who do not use tobacco products will start using such products. In essence, FDA needs to present concrete evidence to bridge the gap between an updated warning label and its impact on consumer behavior.

The impact of product labelling on consumer perception and decision making has been a topic of academic and commercial research for decades.[19] Labels are powerful elements of branding and advertising strategies, as they help consumers identify products and gather information about their features, quality, positioning, and numerous other characteristics.[20] If one seeks to understand the impact of a warning label—or any label change, for that matter—on consumers' perceptions and behaviors, empirical research can be a suitable place to look for an answer.

Empirical research can be conducted in various ways, including collecting scanner data (detailed data on sales of consumer products that are created when bar codes are scanned at the point of sale in retail locations) from retailers, and asking consumers directly for their input about a topic of interest. Among the tools that researchers use to develop evidence on marketing decisions such as changes to a label, survey research methods are particularly appropriate for evaluating consumer responses to new labelling options. Surveys are commonly used in regulatory and litigation contexts for this purpose and can inform stakeholders when conducted to accepted standards.[21]

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[17] *Id.*

[18] 81 Fed. Reg. at 28,989; Elliott & Shanahan Research, "Literature Review: Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008," prepared for Australian Government Department of Health and Ageing, 2009.

[19] For example, Borin, Cerf, and Krishnan studied the impact of environmental information on consumer perception and purchase likelihood, and Loureiro, Gracia, and Nayga Jr. (2006) studied the value consumers place on nutritional labeling. *See* Norm Borin, Douglas C. Cerf & Ram Krishnan, *Consumer Effects of Environmental Impact in Product Labeling*, 28 J. CONSUMER MARKETING 76, 76–86 (2011); Maria L. Loureiro, Azucena Gracia & Rodolfo M. Nayga, Jr., *Do Consumers Value Nutritional Labels?*, 33 EUROPEAN REV. AGRIC. ECON. 249, 249–68 (2006).

[20] KEVIN LANE KELLER, STRATEGIC BRAND MANAGEMENT 36 (Pearson, 4th ed., 2013).

[21] For example, FDA put forth a draft guidance on survey methodologies for risk evaluation and mitigation strategies, including using a survey design that meets survey objectives, justifying the statistical analysis plan, constructing a survey instrument that tests for reliability and validity, minimizing factors that might contribute to bias, and developing strategies that minimize the burden on respondents and maximize participation. U.S. FOOD & DRUG ADMIN., SURVEY METHODOLOGIES TO ASSESS REMS GOALS THAT RELATE TO KNOWLEDGE (Feb. 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/survey-methodologies-assess-rems-goals-relate-knowledge.

FDA has frequently used surveys to test the effects of product claims and labeling on consumer perception and purchase decisions.[22] However, in the *Cigar Association* matter, FDA remarked that "reliable evidence on the impacts of warnings label . . . on users of cigars . . . does not . . . exist." A survey, however, may have provided FDA with suitable evidence to assess the impact of health warnings on cigar smokers' smoking behavior and prospective smokers' intent to adopt cigar smoking.[23]

The benefits of survey research for the *Cigar Association* matter include:

- A direct sample of the populations of interest: The court of appeals decision identifies two distinct and mutually exclusive populations of interest: existing cigar users and prospective cigar users. A survey sampling plan can directly target these two populations, a benefit already known to FDA. For example, FDA has frequently analyzed national surveys that collect information on different categories of users and prospective users of tobacco products, assessing their usage behaviors, attitudes, and beliefs.[24] In the same vein, FDA could survey a category of cigar users and prospective cigar users to evaluate the impact of the proposed health warnings.
- An estimate of the effect of a warning label on consumer purchase decisions: Surveys can be conducted as an experiment to assess the causal impact of a variable of interest on usage and purchase behavior. In simple terms, an experimental design involves the random assignment of respondents to test and control groups. The only difference between the two groups is the variable of interest: in this case, the size—and possibly the contents—of the warning statement displayed on cigar packaging.[25] A survey researcher can construct separate images of the product with the existing label and the product with a label with a different size and/or statement. With this test and control design, the researcher can directly compare the effects of the proposed health warning label with the current label. For example, researchers could test for a difference in the likelihood of usage between the test and control group. A statistically significant result would suggest that the tested health warning label is likely to impact smoking behaviors.

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[22] For example, FDA used experimental designs to test the effects of nutrient content claims and vitamin-fortified snack foods on consumers' health perceptions, purchase decisions, and information research. *Consumer Research on Labeling, Nutrition, Diet, and Health*, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2018), https://www.fda.gov/food/cfsan-consumer-behavior-research/consumer-research-labeling-nutrition-diet-and-health.

[23] 964 F.3d at 63.

[24] For example, FDA publishes results from the National Youth Tobacco Survey, which is administered by the Centers for Disease Control and Prevention. *National Youth Tobacco Survey (NYTS)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 21, 2020), https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm.

[25] The researcher could test multiple treatment groups for additional formulations of the warning statement.

The *Cigar Association* case is still ongoing in both the court of appeals and the district court, as the parties are still resolving other issues involving grandfathering dates and premarket review. The challenge to the Deeming Rule's health warnings was remanded to the district court, which then vacated the warning requirements and remanded them back to FDA.[26] It is unclear at this point whether or when FDA might initiate new rulemaking proceedings for cigar health warning labels.

[26] Final Judgment and Order at 3 (September 11, 2020).

Morris v. Biomet, Inc., Ebert v. C.R. Bard, Inc., and Zitney v. Wyeth LLC

GINGER PIGOTT & MICHAEL GOODMAN*

WHY THEY MADE THE LIST

These cases[1] made the list together because of their shared impact on the evolution of failure to warn claims during 2020 in the prescription drug and device arena. Two of these add to the growing body of law expanding the type of prescribing physician testimony that breaks the proximate causal chain in a failure to warn context and the third rejects an expansion of the legal duty owed by manufacturers to those prescribing physicians in terms of how warnings are conveyed—no duty to send "dear doctor" letters about label changes. In short, the adequacy of a warning becomes moot in a failure to warn claim where the physician does not recall having reviewed it and/or does not routinely rely on such things. And, under normal circumstances, a manufacturer need not go beyond including the labeling of its product in the usual way.

FRAMEWORK FOR DISCUSSION— FAILURE TO WARN AND THE LEARNED INTERMEDIARY

Failure to warn claims in a prescription product context are almost universally dictated by the learned intermediary doctrine. Adequacy of product labeling is most often judged by reference to the impact on the prescriber as opposed to the patient. While it is true that many failure to warn claims are simply barred by the application of other dispositive legal defenses (primarily preemption), when prescription product cases do get to the point of evaluation, the key is often the testimony of the prescribing physician.

The Restatement (Second) of Torts expresses the basic requirements for a plaintiff to plead and prove a failure to warn claim. A plaintiff must allege and establish (1) the manufacturer either knew, or should have known, of dangers inherent in the use of the product, yet adequate warnings were not given; and (2) if adequate warnings had been provided, the harm would have been avoided.[2] Thus, the first point of dispute is almost always whether the product is "properly prepared, and accompanied by proper

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1 Morris v. Biomet, Inc., —F.Supp.3d—, 2020 WL 5849482 (D. Md. Sept. 30, 2020); Ebert v. C.R. Bard, Inc., 459 F. Supp. 3d 637, 641 (E.D. Pa. 2020); Zitney v. Wyeth LLC, 2020 PA Super 278, 243 A.3d 241, 243 (2020).

2 Restatement (Second) of Torts § 402A cmt. j.

directions and warnings."[3] As noted, in the prescription product context, the manufacturer must make adequate warnings available to the patient's doctor—not to the patient—since physicians are in a better position to understand the risks and also initiate the decision for the patient to use the prescription product.[4] In this context, the physician is the *learned intermediary*.[5]

The second part is the causation element, asking whether different warnings would have resulted in a different outcome. Proximate cause is essential for the survival of failure to warn claims. If the learned intermediary does not read the label, plaintiff cannot show proximate cause and the warning claim fails.[6] For example, a claim was brought by a patient's widow alleging that her husband's prescription antidepressants did not adequately warn his physician of the associated side-effects. But she failed to show that the alleged inadequate warnings proximately caused her husband's death when his physician admitted that he had not read the label.[7] So ended the failure to warn claim regardless of the contents of the warning.

It has also been established that even an allegedly inadequate label does not proximately cause injury if a treating physician has independent knowledge of the risk (from his/her own practice, medical journals, etc.). What was less established was how a court might treat testimony from a treating doctor that was more equivocal about reading the labeling—the "does not recall" versus "never reviewed." This less defined treating physician testimony informs the decisions in two of the three selected cases. The third case discusses the question of how warnings are disseminated and what is required when an undisputedly adequate warning is placed in the box accompanying the product as opposed to disseminated otherwise.

DISCUSSION

Failure to "Recall" Reviewing the Labeling—Ebert v. C.R. Bard, Inc. *and* Morris v. Biomet, Inc.

Ebert v. C.R. Bard Inc. and *Morris v. Biomet, Inc*. examine to what end the learned intermediary must read the prescription product labeling for proximate cause to survive. In *Ebert v. C.R. Bard Inc.,* plaintiff Melissa Ebert (Ms. Ebert) was implanted with Bard's G2 inferior vena cava (IVC) filter that she alleged failed several years later.[8] In her action against Bard, Ms. Ebert brought a failure to warn claim alleging that while Bard cautioned that a filter fracture is a known complication, it did not provide her physician comparative failure rates between the G2 IVC filter and other Bard filters and other non-Bard filters.[9]

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3 Restatement (Second) of Torts § 402A cmt. k.

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

5 *See id.*

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

7 *Id.* at 661.

8 Ebert v. C.R. Bard, Inc., 459 F. Supp. 3d 637, 642 (E.D. Pa. 2020).

9 *Id.* at 646.

Ms. Ebert's physician testified that while he would not have used the G2 IVC filter had he known that the filter carried a significant risk of fracturing, he independently knew that IVC filters could fracture, and, even more notably, he admitted never reading the full G2 IVC's instructions for use (IFU) and could not remember reading any of the IFU before Ms. Ebert's surgery.[10] Additionally, the physician could not testify that he relied on the IFU in deciding whether to use the G2 IVC filter over another filter.[11] Accordingly, the court dismissed the failure to warn claim, reasoning that since the physician did not rely on the IFU, it would have made no difference to the physician's decision to implant the G2 IVC filter in Ms. Ebert.[12]

While *Ebert* was more akin to other cases where the physician admitted to not reading the prescription product's labeling altogether, the court in *Morris v. Biomet, Inc.* dismissed the plaintiff's failure to warn claim as a matter of law, despite there being a scintilla of evidence that remained potentially supporting the existence of proximate cause.[13] In *Morris*, plaintiff Charlotte Morris (Ms. Morris) was diagnosed with a pseudotumor allegedly from Biomet's metal-on-metal hip joint replacement.[14] Ms. Morris' failure to warn claim alleged that Biomet's metal-on-metal hip joint replacement failed to adequately warn her of the *severity and prevalence of the risks* of metal hips and the secondary consequences of long-term exposure to toxic metals in the blood.[15]

Ms. Morris' physician testified that he was already aware that that metal-on-metal devices could cause pseudotumors related to metal-metal hypersensitivity.[16] The physician further testified that he made his own decisions based on peer-reviewed literature.[17] But he also testified that, though he could not recall whether he read the IFU prior to Ms. Morris' surgery, it was his standard practice to familiarize himself with the indications received from the manufacturer.[18] For the sake of ruling on summary judgment, the court seemed to assume that Ms. Morris' physician read the IFU.[19] Yet it still dismissed the failure to warn claim reasoning that "the evidence overwhelmingly shows that [the physician (i.e., the learned intermediary)] placed little weight on Biomet's warnings, indicating the different warnings would not have altered his decision-making."

In both *Ebert* and *Morris,* plaintiffs alleged that the IFUs needed more than merely the risks associated with their respective devices. But their inadequate warnings allegations were almost totally disregarded when it came to light that the respective learned intermediaries *placed little to no weight on the prescription products' labeling.*

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[10] *Id.* at 647.

[11] *Id.* at 648.

[12] *Id.*

[13] Morris v. Biomet, Inc., No. GJH-18-2440, 2020 WL 5849482, at *8, 10 (D. Md. Sept. 30, 2020) (A scintilla of proof that the physician may have read the label is not enough to defeat a motion for summary judgment, but in any event, the physician strongly favored his own research and knowledge over the label information anyway.).

[14] *Id.* at *3.

[15] *Id.* at *10.

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

It follows—from these cases—that neither plaintiff could show their injuries were proximately caused by the alleged inadequate warnings.[20]

Failure to Send Warnings by "Dear Doctor" Letter—Zitney v. Wyeth LLC

Zitney v. Wyeth LLC dismissed arguments that reasonable care in warning prescribing physicians must go beyond a drug's labeling and requires sending a "dear healthcare provider" (aka "dear doctor") letter.[21] In the end, the court in Pennsylvania put a ceiling on the manufacturer's standard of care.[22] The court found the manufacturer's satisfaction of its responsibility to warn of dangers in the FDA-reviewed label and labeling was enough.[23]

Years earlier, the U.S. Supreme Court in *Pliva, Inc. v. Mensing* (*Mensing*) held that generic manufacturers owe a "duty of sameness" under federal law requiring their labels to be the same as the reference listed drug (RLD) the generic drug follows, and therefore any state law claim imposing a duty on generic drug manufacturers to deviate from the RLD label is preempted.[24] A prior Pennsylvania Superior Court decision addressing preemption seemed to leave the door open with respect to similar—but not the same—duties of generic drug manufacturers in the *In re Reglan/Metoclopramide Litigation* decision.[25] *Zitney* managed to avoid any discussion of preemption, which is atypical in a failure to warn case relating to the duties of a generic drug manufacturer.[26] In doing so, the outcome in *Zitney* simplifies the analysis, particularly with prior Pennsylvania authority diverging on the question of what warning activity might be subject to preemption in the wake of *Mensing*.[27]

The plaintiff in *Zitney*, Janine Zitney, was diagnosed with tardive dyskinesia and brought claims against manufacturers of metoclopramide, the generic versions of Reglan, alleging the manufacturers knew but failed to warn her physician that tardive

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[20] The court in *Ebert* provided a footnote that even if her physician had read the IFU, no legal authority supported Ms. Ebert's allegation that Bard's duty to warn extended to providing comparative failure rates. But in *Morris*, the court was not prepared to review whether Biomet had a duty to warn of the magnitude of the risks associated with its metal-on-metal hip joint replacement. Nonetheless, the plaintiffs' inadequate warnings were papered over.

[21] Zitney v. Wyeth LLC, 2020 PA Super 278, 243 A.3d 241, 244 (2020).

[22] *Id.* at 246.

[23] *Id.*

[24] In *Mensing*, the plaintiffs brought failure to warn claims against generic drug manufacturers alleging, in part, that they had a duty to ensure that the plaintiffs' physicians were aware of the dangers associated with the prescription generic drugs by sending out "Dear Doctor" letters. PLIVA, Inc. v. Mensing, 564 U.S. 604, 615, 131 S. Ct. 2567, 2576, 180 L. Ed. 2d 580 (2011). However, federal law mandates that the generic drugs' labeling must mirror the branded drug's label, and the plaintiffs' proposed "Dear Doctor" letters would be considered labeling that the brand did not have. *Id.* at 624. Thus, if the manufacturers acted in accordance with the duty proposed by the plaintiffs, they would be violating the Federal Food, Drug & Cosmetic Act. *Id.* Thus, the U.S. Supreme Court dismissed the plaintiffs' failure to warn claims on the basis of implied preemption. *Id.*

[25] In re Reglan/Metoclopramide Litig., 2013 PA Super 214, 81 A.3d 80, 95 (2013) (finding that there is not a state law claim for plaintiffs' failure-to-communicate theory alleging the defendants' failure to unilaterally update their generic drug labeling, and accordingly, the claim could not be preempted by federal law).

[26] *Zitney*, 243 A.3d at 244.

[27] *Id.* at 246.

dyskinesia was a side effect of using the drug long-term.[28] But for purposes of the specific issue at hand, Mrs. Zitney did not allege that the IFU was inadequate.[29] Instead, her theory was that the manufacturers should have directly conveyed the required safety information to Mrs. Zitney's physician—as her learned intermediary[30]—in an additional "Dear Health Care Provider" letter reiterating the warnings found in the IFU.[31]

The *Zitney* court recognized that there is a reasonable limit to how manufacturers must inform the learned intermediary.[32] That limit coincides with years of FDA rules and enforcement. There was no reason for the court to impose additional requirements to labels that have already been reviewed and approved/cleared by the FDA.[33] As such, the court dismissed Mrs. Zitney's failure to warn claim.[34]

The importance of *Zitney* is in its approach to the issue of duty and warnings. Whereas the Supreme Court's decision in *Mensing* is farther-reaching in terms of its ability to bind other courts, it is directed fundamentally at generic drug manufacturers as it relied on impossibility preemption to dismiss warning claims.[35] The court in *Zitney*, however, did not consider or distinguish between prescription generic and branded drugs. [36] Instead, the court set the ceiling for the manufacturer's duty to notify as no higher than "provid[ing] content-appropriate warning labels in their [prescription product] packaging."[37]

IMPACT AND CONCLUSION

Though there are differences among them, the *Morris*, *Ebert*, and *Zitney* cases intersect in their approach to a learned intermediary's understanding of the risks from the labels at the time of the surgery. There is a general presumption that proximate cause cannot be shown if the physician never reviewed the prescription product's label. And *Ebert* and *Morris* likely expanded that presumption to account for the absence of weight the physician placed on the label compared to his or her own knowledge of the risks. In an effort to mitigate the risk that a plaintiff's physician neglected to read the warnings, the plaintiff in *Zitney* sought to bolster her failure to warn claims by asserting a manufacturer's duty to provide additional communication that ensured the physicians were alerted to and understood the risks. Yet *Zitney* rebuffed this view, setting the ceiling no higher than what is already required under the Federal Food, Drug and Cosmetic Act. Though *Zitney* needs to be tested against a failure to warn claim involving a prescription branded product, the fact that the subject of the suit was a generic drug did not seem to play a role in the court's reasoning. The

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28 *Id.* at 244.

29 *Id.* at 246.

30 Simon v. Wyeth Pharm., Inc., 2009 PA Super 263, ¶ 31, 989 A.2d 356, 368.

31 *Zitney*, 243 A.3d at 244.

32 *Id.* at 246.

33 *Id.*

34 *Id.*

35 *PLIVA, Inc.,* 564 U.S. at 615.

36 *Zitney*, 243 A.3d at 246.

37 *Id.*

fact that *Zitney* was not a preemption decision provides a fresh take on the issue where the adequacy of the label is not challenged. All three are thus important cases in the ongoing evolution of warning claims.

In re Bard IVC Filters Product Liability Litigation

RALPH F. HALL*

WHY IT MADE THE LIST

Product liability cases are a fact of life with FDA-regulated drugs, devices, and biologics. The product liability system is often called upon to determine whether an individual who has suffered some adverse event, at least allegedly caused by the product, is entitled to compensation from the manufacturer. These cases immediately involve the intersection of the FDA regulatory oversight system and the product liability claims. A constant issue in such litigation is whether the Supremacy Clause[1] preempts such private claims because of the actions and decisions of the Food and Drug Administration (FDA).

Drug and device preemption cases came to the forefront beginning in the 1990s and accelerating in the first part of the 2000s with a series of Supreme Court cases such as *Lohr*,[2] *Riegel*,[3] *Wyeth*,[4] *Mensing*,[5] and others. Over time, the jurisprudence in this area has continued to evolve as new facts patterns come before courts and judicial analyses continue to evolve.

In re Bard IVC Filters Product Liability Litigation ("*Bard*")[6] is one of the latest cases to explore the parameters of preemption. While *Bard* involves a medical device and so is under a somewhat different legal structure than drugs or biologics, the lessons of *Bard* apply beyond device litigation.

Bard analyzes the parameters of express preemption, the role of guidance documents as FDA "requirements," the possible need to include comparative information in product labeling, and procedural requirements for preserving a preemption argument for appeal; all topics of importance to all FDA practitioners—not just litigators.

DISCUSSION

Factual and Case Background

Bard involves an intervascular filter (IVF), a device that is used to reduce the risk of pulmonary embolisms in patients with blood clots (or potential for blood clots) in

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1 U.S. Const. Art. VI, cl 2

2 Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

3 Riegel v. Medtronic, Inc. 552 U.S. 312 (2008).

4 Wyeth v. Levine, 555 U.S. 555 (2009).

5 PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011).

6 Booker v. C.R. Bard, Inc., et al., 969 F.3d 1067 (9th Cir. 2020).

their legs. Such clots can break free and travel to the lungs causing serious (potentially fatal) pulmonary embolisms. Some patients cannot take medications (generally "blood thinners") or such medications are not effective in reducing these risks.

IVFs can be used to treat these patients. An IVF is placed in the inferior vena cava and traps or filters any such blood clots before those clots can get to the heart and then be pumped into the lungs. The filter is anchored into the walls of the blood vessels and are permanent.[7]

In this particular case, Ms. Booker's physician implanted a Bard Model G2 IVF in Ms. Booker in 2007. Several years later, the filter fractured, and part of the filter perforated her inferior vena cava. Two surgeries were performed to remove the broken filter. While some parts of the IVF were successfully removed, at least one part remains permanently embedded in Ms. Booker's inferior vena cava.

Over time, thousands of such events are alleged to have occurred and thousands of lawsuits were filed. These cases were combined into one multidistrict litigation (MDL) for certain pretrial purposes. Ms. Booker filed suit against Bard and, as a Georgia resident, asserted design defect and failure to warn claims under Georgia law. One of her claims was that Bard had an obligation to inform the patient (generally via the physician under the learned intermediary doctrine) not only of the risks of the Bard product but also how those risks compare to the risks of competing products.[8]

Bard filed an omnibus motion for summary judgment in the MDL proceedings. In this motion, Bard argued that many of the claims of the various plaintiffs in the MDL litigation were preempted. The District Court disagreed and denied the motion. Ms. Booker's case was subsequently selected for trial.

At trial, the defendant prevailed on various design claims and on a strict liability failure to warn claim. However, Ms. Booker prevailed on her negligent failure to warn claim and was awarded $1.6 million in compensatory damages and an additional $2 million in punitive damages.[9] Bard appealed.

The Ninth Circuit affirmed the district court on all issues.

Regulatory History of IVF Devices

Medical devices[10] are divided into three, generally risk-based, classes.[11] Class I devices are low risk and usually require no premarket submission.[12] Class II, or moderate risk devices, must demonstrate a reasonable assurance of safety and efficacy under the requirements and processes set forth in 21 U.S.C. § 360c(a) and related provisions. These requirements include, but are not limited to, the satisfaction of "special controls" and a determination of substantial equivalence to a predicate

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[7] A more detailed description of the use of IVFs can be found at *In Re Bard IVC Filters Product Liability Litigation, Booker v. C.R. Bard, Inc., et al.*, 969 F.3d 1067, 1070–71 (9th Cir. 2020) (*Bard*).

[8] *Id.* at 1072.

[9] The trial court decision is found at 2018 WL 3037161 (D. Ariz. June 18, 2018).

[10] IVFs are medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. § 321(h).

[11] 21 U.S.C. § 360c(a).

[12] Note that certain Class I devices require premarket submissions under the regulatory structure established for Class II devices, and certain Class II devices must go through the Class III/PMA process. These devices are not relevant for this discussion.

device.[13] Often, these devices are referred to as "510(k)"[14] devices even though these devices are subject to multiple regulatory requirements in addition to the 510(k) substantial equivalence determination. Class III devices are required to go through the "PMA" process as outlined in 21 U.S.C. § 360e.

Initially, IVFs were regulated as Class III devices. In 2000, FDA reclassified these devices as Class II devices and adopted three "special controls": one dealing with biocompatibility of materials[15]; the second dealing with sterility[16]; and the third relating to IVF submissions including certain "labeling, biocompatibility testing, mechanical testing, sterilization procedures and labeling and clinical data controls."[17] The Bard IVF at issue in this case (the so-called "G2" model) received FDA clearance in 2005. It was this product that was implanted in Ms. Booker.

Comparative Labeling

The relevant claim for our purposes is plaintiff's negligent failure to warn claim.[18] The plaintiff asserted that Bard's labeling was inadequate because the labeling (including the Instructions for Use) did not disclose comparative risks of the Bard IVF compared to other products. The crux of the plaintiff's argument is that Bard had a duty under Georgia law to inform the user (or physician in this case) of the risks of the Bard product compared to the risks of competitive products. This comparative information, the plaintiff asserts, would have influenced the decision of the physician as to which product to use.

Two legal issues arise from this argument, one directly addressed by the appellate court and the other not.

First, Bard argued that Georgia law did not recognize a duty by the manufacturer to compare or disclose the risks of the manufacturer's product compared to the risks of competitive products. This is a state law question and, at this stage, does not implicate federal law. The district court found, and the appellate court affirmed, that the adequacy of the warning is a matter for the jury.

Note that in reaching this decision, the court had to find that Georgia law imposes a duty to warn of comparative risks. This is a legal question. If such a duty exists, the adequacy of the actual warning is then a question for the jury.

The Ninth Circuit held that under Georgia law, a manufacturer has a duty to warn of known risks. That duty can extend to a duty to warn the user (or learned intermediary) of comparative risks. Several other federal courts have found such a duty under Georgia law.[19] The court also found no Georgia authority rejecting such a duty. As such, the appellate court utilized what it predicated or believed a Georgia court

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[13] The substantial equivalence requirement arises under 21 U.S.C. §360(k) (generally referred to as §510(k) of the Food Drug and Cosmetic Act). The substantial equivalence requirement is one of the possible "administrative controls" imposed on Class II devices under 21 U.S.C. §360c(a).

[14] 21 U.S.C. § 360(k).

[15] 21 C.F.R. § 870.3375(b)(1).

[16] 21 C.F.R. § 870.3375(b)(2)(i).

[17] 21 C.F.R. § 870.3375(b)(2)ii.

[18] The defendant prevailed on various other design and warning claims. As such, these other claims are not part of the appeal.

[19] Watkins v. Ford Motor Co., 190 F.3d 1213 (11th Cir. 1999); *In re Mentor Corp/Obtape Transobturator Sling Prods. Liab. Litig*., 711 F. Supp. 2d 1348 (M.D. Ga. 2010).

would conclude. Once a duty to warn of comparative risks is legally recognized, the adequacy of that warning became a fact question for the jury. The court found that there was sufficient evidence to support the jury award.[20]

The second question is whether FDA law permits such a comparative warning absent an FDA-approved label with those comparative claims. In this case, the FDA-cleared label did not include comparative claims, and, to the extent apparent from the public record, Bard never requested such comparative information be added to the labeling[21] or Instructions for Use. This question of FDA law clearly overlaps the preemption issue. If FDA does not permit such comparative information in the labeling, then a state court decision mandating the inclusion of such information would seem to directly conflict with FDA requirements.

The challenge, not explicitly discussed in the appellate court decision, is whether Bard could have added some comparative warning without FDA approval. Generally, FDA is reluctant to permit comparative claims in the absence of head-to-head clinical trials designed to establish the accuracy of such comparative claims.[22] If FDA requirements had prevented Bard from including this comparative information, then permitting a jury to find the warning inadequate could seem to set up an express preemption and a conflict preemption argument.

Preemption

Bard asserted that Ms. Booker's claims (and the claims of other plaintiffs in the MDL) were preempted due to the express preemption provisions found at 21 U.S.C. § 360k.[23] Section 360k preempts any state or local requirement (including jury verdicts) that establishes or continues a requirement relating to safety or effectiveness of a device that is "different from, or in addition to," any FDA requirement. It does not appear that Bard argued conflict preemption or implied preemption.

There is a major difference between preemption for a Class III medical device and preemption for a Class II medical device. Generally there is preemption for a Class III device, except if the plaintiff can assert a "parallel claim."[24] Conversely, there is generally quite limited preemption for Class II devices. This difference originated in the Supreme Court decision in *Lohr* when the Supreme Court determined that there

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[20] *Bard*, 969 F.3d at 1076–77.

[21] Labeling is a broad term and includes the label and any other material that "accompanies the product. 21 U.S.C. § 321(m). For our purposes, we will use labeling and Instructions for Use interchangeably.

[22] See, for example, a 2018 FDA guidance entitled: Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers Guidance for Industry. The example at page 21 gives some FDA thinking on the issue of comparative claims (available at https://www.fda.gov/media/133619/download).

[23] Note that while there is an express preemption provision applicable to devices, there is no parallel express preemption provision for drugs and biologics. As such, drug preemption cases generally involve implied or conflict preemption, not express preemption. *See* Wyeth v. Levine, 555 U.S. 555 (2009).

[24] *See* Riegel v. Medtronic, Inc. 552 U.S. 312 (2008). The question of what is a "parallel claim" is a complex and oft-litigated issue but is beyond the scope of this chapter. *Lohr* was based on the 510(k) system as it existed prior to the 1990 Safe Medical Device Amendments (SMDA). The SMDA made major changes and additions to the Class II regulatory oversight system, including requiring an assessment of safety and effectiveness. See, for example, 21 U.S.C. §360c. Despite these statutory changes and commentary such as Ralph H. Hall & Michelle Mercer, *Rethinking* Lohr*: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?*, 13 Minn. J.L. Sci. & Tech. 737, 747–50 (2012), *Lohr* remains the general rule for preemption of Class II medical devices.

was only limited preemption for Class II devices because the then-existing "510(k)" regulatory system did not provide "specific requirements" relating to safety or effectiveness of the device that is needed for express preemption under 360k.[25]

In its preemption analysis in this Class II case, the court primarily relied upon *Lohr*, the "plain language" or "plain wording" of §360k, and FDA's regulations interpreting §360k in 21 C.F.R. § 808.[26, 27] In particular, the appellate court focused on the language in §808(d) that "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . " (emphasis added).

At a high level, the express preemption provision in §360k requires several elements. First, the requirement at issue must relate to safety or effectiveness of the device. That element of §360k is obvious in this case. The entire case revolves around the plaintiff's claim that the Bard IVF device was not safe (i.e., was defective due to an inadequate warning) and the defendant's assertion that the device was safe and that plaintiff's claims to the contrary were preempted.

The second element is that there must be some specific FDA "requirement" that is applicable to the device in question. Under *Lohr* and §808, these requirements must be specific to the device.[28] The validity of the interpretation set forth in §808 is open to some debate. The "specificity" requirement seems consistent with the plain wording of §360k that state law requirements that are "different" from an FDA requirement are preempted.[29] Logically, there must be some requirement in place before something can be different.

However, the court also ruled that for preemption to apply there must both be a specific requirement and that that specific requirement must apply to the device in question. (In a later section, we discuss whether guidance documents are "requirements" given that guidance documents are not legally binding.)

It is unclear how the specificity requirement in §808 and *Lohr* and utilized by the court in *Bard* is consistent with the language of §360k that preempts state requirements that are "in addition to" FDA requirements.[30] A state law requirement is "additive"

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[25] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

[26] The Court did not apply any "presumption against preemption" as has been argued in other cases. Given that the device in question is a Class II device, the Court focused on *Lohr* rather than the Class III preemption case of *Riegel*.

[27] The Court gave substantial weight to FDA's interpretation of the Federal Food, Drug, and Cosmetic Act. *Bard*, 969 F.3d at 1072. The Ninth Circuit seems to have given little or no weight to the statement by the Supreme Court in *Riegel* that §808 was not of value. Specifically, the Supreme Court stated that FDA's interpretation "can add nothing to our [preemption] analysis but confusion." *Riegel*, 555 U.S. at 329. The appellate court also did not seem to consider the varying interpretations FDA has taken in preemption litigation. In other contexts, differing government interpretations of a statute has resulted in courts giving little or no weight to the agency's views.

[28] *Bard*, 969 F.3d at 1074.

[29] Remember that the Court asserts that its primary focus is on the "plain wording" of §360k.

[30] FDA is charged with making complex benefit risk decisions. See, for example, 21 U.S.C. §515e(d)(2). If a state adds new requirements over and above what FDA has deemed appropriate or necessary, that balance can be upset. In addition, if different states can impose additional separate and potentially inconsistent requirements, no manufacturer would be able to see its devices across all fifty states. The preemption provision is intended to thus both preserve FDA's benefit/risk decisions and also to enable the multistate distribution of devices.

only if it involves a requirement not already found in FDA requirements. The "addition to" requirement makes it clear that FDA requirements intended to be both the floor and the ceiling. The need for a "ceiling" on requirements is needed to preserve FDA's role in making benefit/risk decisions and to ensure national uniformity in device design and labeling. By requiring that there be a specific requirement in place before there can be preemption, the court seems to be eliminating the "ceiling" aspect of preemption. If a plaintiff can think of a new requirement, the plaintiff can well argue that there is not an existing specific requirement as mandated by §808(d).

Given the court's view that a "specific" requirement is needed for preemption, the court focused on this question of whether there are specific FDA requirements applicable to the IVF in question.

The first possible "specific requirement" is the FDA clearance of the Bard G2 IVF itself. This argument failed. Again, under *Lohr*, the actual "approval" (technically a "clearance") is not deemed to impose any device-specific requirements. Generally, general requirements do not have preemptive authority under *Lohr*.

Bard argued that the three special controls set forth in 21 C.F.R. § 870.3375 are the specific requirements needed to trigger preemption as required by §808(d) and *Lohr*. The court disagreed. In reaching its decision, the court reviewed each special control and assessed whether that special control is applicable not only to the device in question but also to the issues at hand.

The court rejected the first two special controls (a biocompatibility requirement and a sterility requirement) because, in the court's view, these were not sufficiently specific to this device. As the court said, "[n]either [special control] contains anything specific to intravascular filters, let alone to the particular intravascular filter at issue here."[31] The court viewed these special controls as akin to the "general" requirements for devices found to be insufficient for preemption in *Lohr*. What this apparently means is that, at least in the Ninth Circuit, requirements that apply to more than one device type do not meet the requirement for being "specific" to the device. In order to trigger preemption, it seems that FDA would need to revise these biocompatibility and sterility documents into a series of essentially identical documents that name a series of different devices. The value of this is, of course, open to question.

It is interesting that the court focused on whether these two requirements were "specific to" the IVF rather than asking whether these two special controls were relevant to the issues at hand. Neither special control relates to warnings or labeling. Given the focus in §808(d) and in *Lohr* on the requirement being different, the inapplicability of these two special controls to the case at hand would seem to be an easier pathway for the court.

The third special control[32] does apply explicitly to IVFs. However, the court found that even though this special control specifically applies to IVFs, this special control still failed to meet the preemption test for two reasons. First, this so-called labeling special control was not specific to the Model G2 IVF at issue in this case. Rather, the special control applied to all IVF filters, not just to the Model G2. In reading §808(d), the court determined that the requirement had to be specific (i.e., not a "general requirement") and that the requirement had to apply to the "particular device." In this

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[31] *Bard*, 969 F.3d at 1074.

[32] This special control relates to a number of submission requirements including labeling requirements. *See* 21 C.F.R. § 870.3375(b)(2)ii.

case, the court held that while the specificity element of §808(d) might be satisfied, the applicability of the special control to a "particular device" was not satisfied. The court stated: "[W]e conclude that it [the labeling special control] does not have preemptive effect . . . . [T]he guidance does not impose 'specific requirements applicable to a *particular* device,' . . . such as Bard's G2 filter. Instead, it applies generally to every member of the class of intravascular filters."[33]

If the court is correct, it seems that the only special controls that may have preemptive effect are special controls that apply to a specific model of a device. Special controls that apply to all devices within one product category or one "procode" would not seem to have preemptive effect.[34]

The second reason given by the court for not giving preemptive effect to the "labeling" special control is that "the requirements that the intravascular filter guidance imposes are not relevant to Booker's failure-to-warn claim. State requirements cannot be meaningfully described as 'different from, or in addition to the specific [FDA] requirements if the two requirements are not relevant to each other."[35] This argument seems eminently logical if one is focusing on the "different from" prong of §360k. The logic seems strained if one focuses instead on the "in addition to" prong of §360k. Almost definitely, a state law duty or obligation that is "in addition to" an FDA requirement is a duty or obligation not included in the FDA requirements.

In parsing through the court's decision, it seems that the court has created four categories of requirements for preemption purposes:

- Truly general requirements or obligations such as the 510(k) clearance process. The court does not give these preemptive effect.
- Requirements that apply to a product category such as IVF filters. The court did not give these preemptive effect.
- Requirements that apply to the specific device at issue (not the type of device, but that specific model) but which are not relevant to the issue at hand (thus raising the "different from" issue described above). These are not preemptive under *Bard*.
- Requirements that apply to the specific device at issue and which are directly relevant to the issue in the case. These may well be preemptive.

The view that only guidances or other requirement that apply to one model (and it seems only one model) dramatically limits any preemption arguments for Class II devices. Very few special controls are model-specific. Even special controls created as part of the clearance of a specific device under the de novo process are intended to apply to all similar products. The Class II system relies on special controls that apply to a product category or procode.

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[33] *Bard*, 969 F.3d at 1074.

[34] FDA has established specific product categories as set forth in 21 C.F.R. §§860–898. This is required by statute. *See* 21 U.S.C. § 360c(c)–(f).

[35] *Bard*, 969 F.3d at 1074–75.

Are Guidance Documents Requirements?

We next turn to the question of what is a "requirement." Ms. Booker argued that the special controls for IVFs are not "requirements" under §360k. The plaintiff argued that these "special controls" are actually guidance documents and therefore are not legally binding. This argument is based upon FDA's own description of the role and effect of guidance documents. Specially, FDA states:

> (d) *Are you or FDA required to follow a guidance document?* (1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.
>
> (2) You may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations.
>
> (3) Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.[36]

Guidance documents routinely state at the beginning of the guidance that guidance documents are not legally binding.

Bard argued in response that FDA treats guidance documents as if they are legally binding.

This question gets more complex because, in this case, the actual regulation governing IVFs specifically incorporates guidance documents. The key regulation (21 C.F.R. § 870.3375) specifically lists guidance documents as special controls.

> Sec. 870.3375 Cardiovascular intravascular filter.
>
> (a) *Identification.* A cardiovascular intravascular filter is an implant that is placed in the inferior vena cava for the purpose of preventing pulmonary thromboemboli (blood clots generated in the lower limbs and broken loose into the blood stream) from flowing into the right side of the heart and the pulmonary circulation.
>
> (b) *Classification.* Class II. The special controls for this device are:
>
> (1) "Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'" and
>
> (2) FDA's:
>
> (i) "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)" and

[36] 21 C.F.R. § 10.115(d) (emphasis added).

(ii) "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions."[37]

So, does the incorporation of a guidance in a product classification regulation make the guidance binding? If so, must FDA follow the Administrative Procedures Act if it modifies or amends the guidance, or can it still use the more abbreviated "Good Guidance Practices" procedures?[38]

The court determined that it did not have to decide any of these questions because the court concluded that the "special controls" set forth above were not specific to the IVF in question.[39]

While the court, unfortunately, did not add clarity to this question, the question remains. For purposes such as preemption, regulatory compliance, labeling, etc., should guidance documents be treated as binding? Does FDA, in fact, treat guidances as mandatory? If a manufacturer violates a guidance, does that create the evidence of negligence or defect for a product liability case? Would allegations of defect based on the failure of the manufacturer to follow a guidance create a "parallel claim" as set forth by Justice Scalia in *Riegel*? While guidances may not be de jure binding, are they de facto binding?

Hopefully, another case will clarify these and related questions.

Miscellaneous Issues

For the sake of completeness, *Bard* raises two other, non-FDA specific, issues which should be mentioned.

First, there was a procedure question as to whether the defendant preserved the preemption defense for appeal. Bard did file a motion for summary judgement on preemption in the pretrial MDL proceedings. Bard did not, however, raise preemption in a post-trial motion. Summary judgement orders ordinarily do not quality as "final orders" or "final decisions" ripe for appellate review.[40]

The appellate court, however, followed a line of Ninth Circuit cases holding that an appeal from the denial of a summary judgment motion is appealable if the summary judgement motion involved "purely legal" issues even if there had not been some post trial motion.[41]

Second, Bard also challenged the punitive damages award. The appellate court upheld this award as the evidence was adequate to support the jury decision. Bard's argument that it could not be found to have acted with "a conscious disregard for the safety of others" (the Georgia standard for awarding punitive damages[42]) because the product was FDA cleared was not successful. Remember that the plaintiff argued (and the jury agreed) that additional and comparative risks should have been disclosed.

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[37] 21 C.F.R. § 870.3375 (emphasis added).

[38] 21 C.F.R. § 10.115(d).

[39] *Bard*, 969 F.3d at 1074.

[40] 28 U.S.C. § 1291 sets forth the requirement that there be a final decision before an appeal is proper. *See also*, Ortiz v. Jordan, 562 U.S. 180 (2011).

[41] Banuelos v. Construction Laborers' Trust Fund for S. Cal., 382 F.3d 897 (9th Cir. 2004); Frank C. Pollara Grp., LLC v Ocean View Inv. Holding, LLC, 784 F. 3d 177 (3d Cir. 2015).

[42] Zeigler v. CloWhite Co., 507 S.E.2d 182 (1998).

IMPACT

Several conclusions are apparent from *Bard.*

First, despite many statutory changes made after the time period relevant to the *Lohr* analysis (including a statutory requirement of a reasonable assurance of safety and effectiveness), preemption is a difficult path for defendants in any Class II medical device case. *Lohr* carries great weight. Perhaps the best preemption argument for a defendant is to identify a specific requirement that would be inconsistent with a jury finding of liability. In essence, conflict preemption may be the best argument for defendants rather than express preemption.[43]

Second, the *Bard* decision substantially narrows the types of special controls that will be deemed to be "requirements" for preemption purposes. The group of special controls that are applicable for preemption purposes may be so narrow as to be almost never applicable. This line of argument is consistent with the general reluctance of courts to find preemption for Class II devices. *Lohr* is a tough hurdle for defendants arguing preemption. *Bard* reinforces this challenge by permitting only a very narrow set of special controls to trigger preemption.

Finally, while the court had the opportunity to opine on whether guidance documents are binding, the court declined to reach that question. Sooner or later, a court will need to face this issue.

[43] The differences between these two may be nuanced. The ability to identify a specific FDA requirement that is contrary to the jury finding is one way to consider conflict preemption.

In re Zantac (Ranitidine) Products Liability Litigation

WILLIAM M. JANSSEN*

WHY IT MADE THE LIST

Robert Arthur was an acclaimed mystery writer when he was publishing during the 1930s, 1940s, and 1950s.[1] Among his more famous short stories was *The Glass Bridge*, published in 1957. It recounted the tale of a down-on-his-luck author who had grown old, ill, and forgotten. One day, a visitor came to blackmail him (we never learn why). She is seen trudging through two feet of snow up his front steps and entering his home, but is never seen leaving. The police, suspecting foul play, search the house and surrounding yard. But they come up empty, baffled that the deep, heavy snow encircling the home remained entirely undisturbed . . . except for that single set of footprints leading up to the front door. When questioned, the author (who could not have done any heavy lifting, given his heart condition) taunts the police, cackling that perhaps he killed the blackmailer and then whisked her away over some glass bridge, leaving no trace. The later, springtime discovery of the blackmailer's body at the bottom of a pond down a valley deepens the mystery. Besides the body, the only clue is a white bedsheet from the author's home, seen billowing in a tree nearby. The mystery re-kindles interest in the author and his book sales rebound. Until, that is, the mystery is finally solved—it is discovered that the author had drugged the blackmailer into unconsciousness, wrapped her in one of his spare bedsheets, sprayed the bundle with water until, in the freezing cold, it turned sled-like, which he then nudged over the edge of his back terrace. The frozen bundle slid swiftly down the steep hillside, leaving behind no indentation in the hardened snow, until it came to rest, a good distance later, down near the pond where, with the spring thaw, it sank. The author's taunt, as it turns out, had previewed for the police precisely what he had done—he had used the frozen bedsheet to actually build a "glass bridge" to evade the law (albeit just momentarily).[2]

Like Robert Arthur's "glass bridge," the theory of "innovator liability" attempts the seemingly impossible: to hold a manufacturer liable for injuries caused by a product made, distributed, and sold by an entirely different company. More specifically, innovator liability proposes to demand compensation from the manufacturer of a branded pharmaceutical for injuries alleged to have been inflicted by a competitor—a generic manufacturer. As the last day of the pandemic year of 2020 was drawing to its close, the U.S. District Court for the Southern District of Florida issued its ruling in *In*

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1 *See* BIOGRAPHY—ROBERT ARTHUR, JR., http://www.elizabetharthur.org/bio/rarthur.html (last visited Mar. 22, 2021).

2 Robert Arthur, Jr., *The Glass Bridge*, in ALFRED HITCHCOCK'S MYSTERY MAGAZINE (July 1957).

re Zantac (Ranitidine) Products Liability Litigation.[3] This lengthy decision by the Honorable Robin L. Rosenberg examined innovator liability in a sweeping, multidistrict litigation (MDL) that sought damages under the laws of all fifty states, Puerto Rico, and the District of Columbia. The *In re Zantac* opinion ranks as one of the top food and drug cases of 2020 for three reasons.

First, it performed *Erie* prediction analyses to assess whether the following thirty-five jurisdictions would recognize the theory under either substantive products liability doctrine or general negligence principles: Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Wisconsin, and Wyoming.[4] The opinion predicted that the highest tribunal in each of those thirty-five jurisdictions, if presented with the question, would reject innovator liability both as a matter of products liability and under freeform negligence principles.

Second, these predictions concerned an anomaly in the federal pharmaceutical laws that, a decade ago, the U.S. Supreme Court had characterized as the "unfortunate hand" dealt generic medicine plaintiffs.[5] Unlike their counterparts injured by a branded pharmaceutical, conventional tort theory denies generic-consuming injured claimants the right to sue for most design or warning defects. Because *In re Zantac* may prove the impetus for a congressional rebalancing of the branded/generic pharmaceutical regulatory scheme, it could have far-reaching significance.

Third, the opinion also tested whether personal jurisdiction over defendants could exist for the MDL claimants in the only two states that allow innovator liability claims—California and Massachusetts—if those claims arose elsewhere. The opinion predicted that an exercise of personal jurisdiction in such circumstances would be improper.

DISCUSSION

Zantac (ranitidine) was a "blockbuster" medicine, reportedly one of the first pharmaceuticals to reach $1 billion in annual U.S. sales. When it was approved by FDA in the early 1980s to treat heartburn and other gastric disorders, Zantac had already been in use in thirty-one other countries. By the late 1980s, it had become the best-selling drug in the world. In 1997, the patent held by brand manufacturer Glaxo expired and generic competitors entered the ranitidine market. Approval to sell without a prescription (over-the-counter or OTC) was granted in 2004.[6] As late as 2018,

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[3] __ F. Supp. 3d __, 2020 WL 7866660 (S.D. Fla. Dec. 31, 2020), *appeals pending*, Nos. 21-10305, 21-10307, & 21-10335 (11th Cir.).

[4] For those keeping score, the remaining seventeen American jurisdictions were not addressed in the *In re Zantac* opinion for different reasons: defendants had conceded that two states (California and Massachusetts) had already recognized innovator liability; plaintiffs had conceded that four states (Alabama, Florida, Iowa, and West Virginia) had already rejected innovator liability; and plaintiffs had advised the court that they were not pursuing claims in eleven states (Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, New Jersey, Ohio, Tennessee, Texas, and Washington). *See id.* at *4 n.5.

[5] PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011).

[6] *See generally In re Zantac*, 2020 WL 7866660, at *1; *Timeline: Popular Heartburn Medicine Zantac Pulled Off Store Shelves*, REUTERS—HEALTHCARE & PHARMA (Oct. 21, 2019),

Zantac-brand and generic ranitidine still ranked forty-first on the list of drugs most used in the United States, with prescriptions estimated as approaching 19 million that year.[7] In 2019, it continued to appear in the WHO Model List of Essential Medicines.[8]

Although the medicine had been approved and on U.S. pharmacy shelves for more than thirty-five years,[9] new studies revealed that under certain circumstances, Zantac/ranitidine could break down and form N-nitrosodimethylamine (NDMA), a contaminant identified as a probable human carcinogen.[10] FDA first cautioned the public about this discovery, and later, following additional study, requested the voluntary removal of all Zantac/ranitidine products from the market.[11]

Litigation swelled. In February 2020, with fifteen civil actions pending in nine federal districts (six of which were putative class actions) and an additional 126 related actions pending in twenty-one districts, the Judicial Panel on Multidistrict Litigation directed MDL treatment for the mounting inventory of Zantac/ranitidine personal injury lawsuits.[12] Plaintiffs' counsel proposed ten possible federal districts for transfer, ultimately "coalesc[ing]" on the Southern District of Florida; defendants' counsel proposed either New York or New Jersey as the transferee district.[13] The Panel settled on the plaintiffs' recommendation and ordered the transfers to the Southern District of

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https://www.reuters.com/article/us-health-fda-heartburn-timeline/timeline-popular-heartburn-medicine-zantac-pulled-off-store-shelves-idUSKBN1X014E (last visited Mar. 21, 2021).

[7] *See Ranitidine—Drug Usage Statistics, United States, 2008–2018*, CLINCALC.COM, https://clincalc.com/DrugStats/Drugs/Ranitidine (last visited Mar. 21, 2021).

[8] *See* WORLD HEALTH ORGANIZATION, MODEL LIST OF ESSENTIAL MEDICINES at § 17.1 (2019).

[9] *See* U.S. Food & Drug Admin., *Why Didn't FDA Catch This Impurity When The Product Was Initially Approved?*, QUESTIONS AND ANSWERS: NDMA IMPURITIES IN RANITIDINE (COMMONLY KNOWN AS ZANTAC) (Apr. 1, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-ranitidine-commonly-known-zantac (last visited Mar. 21, 2021) ("Drug manufacturers and FDA continually gain new knowledge about drugs, which is why FDA constantly evaluates quality and safety information over time. As testing methods have become more sophisticated and sensitive, FDA and industry can identify and mitigate previously-unknown risks to patients.").

[10] *See* U.S Food & Drug Admin., *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market: FDA Advises Consumers, Patients, and Health Care Professionals After New FDA Studies Show Risk to Public Health*, FDA NEWS RELEASE (Apr. 1, 2020) (available at https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market) (last visited Mar. 21, 2021).

[11] *See id. See also* Lior Z. Braunstein, Elizabeth B. Kantor, Kelli O'Connell, Amber Jessop Hudspeth, Qian Wu, Nicola Zenzola & David Y. Light, *Analysis of Ranitidine-Associated N-Nitrosodimethylamine Production Under Simulated Physiologic Conditions*, JAMA NETWORK OPEN, Jan. 29, 2021, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2775727 (last visited Mar. 21, 2021) ("[U]nder simulated gastric conditions, NDMA yield from a standard tablet of ranitidine was seen to increase with both increasing nitrite and decreasing pH to levels up to 3 orders of magnitude beyond established limits. . . . Although additional studies are ongoing, these data support recent regulatory actions to limit ranitidine availability.").

[12] In re Zantac (Ranitidine) Prods. Liab. Litig., 437 F. Supp. 3d 1368 (J.P.M.L. 2020) (forming MDL No. 2924).

[13] *Id.* at 1369.

Florida.[14] Soon, hundreds of civil actions arrived to Judge Rosenberg's chambers; thousands of other unfiled claimants "registered" their intended claims.[15]

The brand manufacturer defendants filed motions to dismiss on two grounds. First, they challenged whether the innovator liability claims of generic consumers could survive a Rule 12(b)(6) motion to dismiss because, they argued, no such claims are legally cognizable outside of California or Massachusetts. Second, they challenged whether California-based and Massachusetts-based claims could survive a Rule 12(b)(2) personal jurisdiction challenge if those claims had not arisen out of defendants' contacts with either of those states. Judge Rosenberg granted the motions in defendants' favor on both grounds.

First Challenge: Rule 12(b)(6)—Failure to State a Claim

The highest courts of the thirty-five *In re Zantac* jurisdictions had not yet answered the question plaintiffs posed—can a manufacturer of a brand pharmaceutical be liable to a consumer injured by the generic version of that product (i.e., a version the defendant brand manufacturer did not make, distribute, or sell)? Plaintiffs contended that brand manufacturers should, on negligence principles. Their innovator liability theory reasoned that the brand manufacturers made misrepresentations regarding the safety of their brand drug, that brand drug in turn created a foreseeable market for generic copies, the existence of generic-ingesting consumers was thus necessarily foreseeable, and those consumers' post-ingestion injuries were therefore foreseeable consequences of the brand manufacturer misrepresentations. Accordingly, theorized plaintiffs, the brand manufacturers owed, and breached, a foreseeable duty of care to generic consumers, for which those manufacturers could be liable in tort.[16]

Judge Rosenberg's first task was to calibrate her *Erie* prediction inquiry. As a federal judge presiding over a bundle of diversity-based lawsuits, the redoubtable *Erie Railroad Co. v. Tompkins*[17] obligated her to apply state law. Thus, where the highest court of that state has spoken on a contested point of law, a federal judge is bound to apply their precedent.[18] Where, however, there is no on-point high court pronouncement or applicable state statute, the federal court's chore remains just the same—to apply state law; only this time, the federal judge must discern the content of that law from other sources.[19] Though not reflexively binding, decisions of intermediate state courts on the disputed question should be followed "in the absence

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[14] *Id.* at 1369–70 (noting the "large number" of Zantac actions already pending in S.D. Fla., that district's relative convenience and accessibility "with the resources and the capacity to efficiently handle what could be a large litigation," and also that centralization before Judge Rosenberg "allows us to assign this litigation to an able jurist who has not yet had the opportunity to preside over an MDL" whom, "[w]e are confident . . . will steer this litigation on an efficient and prudent course").

[15] *See In re Zantac*, 2020 WL 7866660, at *2.

[16] *See id.* at *3.

[17] 304 U.S. 64, 78 (1938) ("Except in matters governed by the Federal Constitution or by Acts of Congress, the law to be applied in any case is the law of the State.").

[18] *See* Comm'r v. Bosch's Est., 387 U.S. 456, 465 (1967) ("state law as announced by the highest court of the State is to be followed [because, when] the underlying substantive rule involved is based on state law[,] . . . the State's highest court is the best authority on its own law").

[19] *See* Fidelity Union Tr. Co. v. Field, 311 U.S. 169, 177 (1940) ("but it is still the duty of the federal courts, where the state law supplies the rule of decision, to ascertain and apply that law even though it has not been expounded by the highest court of the State") (footnote omitted).

of more convincing evidence of what the state law is."[20] The approach to *Erie* predictions taken by the United States Court of Appeals for the Eleventh Circuit (the controlling circuit precedent for the Southern District of Florida) added two final wrinkles to this journey. First, federal judges are counseled that states are "generally presume[d]" likely to "adopt the majority view on a legal issue in the absence of indications to the contrary."[21] And, second, when invited to adopt a cause of action the state has not itself yet accepted, federal judges are advised by "considerations of comity and federalism" to "proceed gingerly."[22]

Armed now with this *Erie* methodology, Judge Rosenberg turned to her task. She began by citing the Eleventh Circuit's conclusion that "the overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."[23] This "mountain of authority" would therefore require an impressively convincing basis for predicting that any state would rule otherwise. And Judge Rosenberg found none, after examining the law in the thirty-five jurisdictions.

First, to the extent plaintiffs' Zantac/ranitidine claims were (or had to be) construed as products liability actions, Judge Rosenberg found no room for innovator liability; each of the thirty-five jurisdictions imposed what she labeled as the "product identification" requirement—"for a plaintiff's claim to survive [as a products liability action], the plaintiff must allege that she was injured by the defendant's product."[24] This necessarily ended the inquiry. Generic consumers could neither allege nor prove that they were injured by the brand manufacturer's product because the medicine they ingested was made by someone else.

Second, likely anticipating this dead-end, plaintiffs had insisted their claims were *not* products liability actions at all but instead sounded under general, freeform negligence principles. This, too, proved unsuccessful. Judge Rosenberg determined that some of the thirty-five jurisdictions would allow no such general negligence distinction; in those states, all negligence-grounded claims concerning a product injury are construed as products liability actions—all subject to the same, dooming "product identification" requirement. In those other jurisdictions that would or might recognize a general, freeform negligence distinction, Judge Rosenberg predicted they would all reject a negligence-based innovator liability theory, given the formidable national majority hostile to that theory and "the absence of any strong evidence that these jurisdictions would join the minority view."[25] Jurisdiction by jurisdiction, Judge Rosenberg surveyed each state's foreseeability requirement for its negligence tort and then found that the absence of a relationship between the claimants and the brand

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[20] *See id.* at 177–78. *See also* King v. Order of United Commercial Travelers, 333 U.S. 153, 160–61 (1948); West v. American Tel. & Tel. Co., 311 U.S. 223, 237 (1940).

[21] *See* Bobo v. Tennessee Valley Auth., 855 F.3d 1294, 1304–07 (11th Cir. 2017) (noting approach, but finding convincing "indications" that the Alabama Supreme Court would follow a minority view on a duty question).

[22] Guarino v. Wyeth, LLC, 719 F.3d 1245, 1251 (11th Cir. 2013). *See also* Douglas Asphalt Co. v. QORE, Inc., 657 F.3d 1146, 1154 (11th Cir. 2011) ("It is not the function of federal courts to expand state tort doctrine in novel directions absent state authority suggesting the propriety of doing so.").

[23] *Guarino*, 719 F.3d at 1252–53.

[24] *See In re Zantac*, 2020 WL 7866660, at *7. *See also id.* Appendix A at *12–*39.

[25] *See id.* at *8. *See also id.* Appendix A at *12–*39.

manufacturers, the policy considerations that weighed heavily against innovator liability, and the fact that the generic consumers' injuries were the foreseeable result of laws over which the brand manufacturers had no control, all counseled against recognizing this novel liability theory.[26] Thus ended the generic MDL plaintiffs' putative claims against brand manufacturer defendants . . . in all states but California and Massachusetts.

Second Challenge:
Rule 12(b)(2)—Lack of Personal Jurisdiction

The highest courts in California and Massachusetts had imported innovator liability theory into their common law in 2017 and 2018, respectively.[27] Because the brand manufacturers all had affiliating business contacts with those states, the generic consumer plaintiffs next posited that all their claims could be litigated there, regardless of where those plaintiffs resided, bought and ingested their medicine, or suffered injury. Defendants resisted this contention as mired in a misunderstanding of constitutional personal jurisdiction law. Judge Rosenberg agreed.

The constitutionalization of personal jurisdiction was recognized in 1878 in *Pennoyer v. Neff.* Back then, constitutional fitness for *in personam* civil actions hinged on either of two attributes: the defendant's service in-state with process or the defendant's voluntary appearance.[28] By the second decade of the 21st Century, that begrudging constitutional reach had been relaxed significantly, though a meaningful constitutional restraint still remained. Today, in addition to in-state service and voluntary appearance, defendants can also be sued civilly in any forum where they are "essentially at home" (i.e., general jurisdiction) or where their purposeful acts give rise to or relate to the cause in suit (i.e., specific jurisdiction).[29]

Since Judge Rosenberg was not confronted in *In re Zantac* by any in-state service or consent-based personal jurisdiction claim, her focus rested solely with general and specific jurisdiction. The U.S. Supreme Court had ruled that general (or "all-purpose") personal jurisdiction over a corporate defendant ordinarily exists only where that defendant is incorporated or maintains its principal place of business.[30] Plaintiffs conceded as much, leading Judge Rosenberg to rule that the brand defendants were amenable to general jurisdiction only in their respective states of incorporation and

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[26] *See id.* Appendix A at *12–*39.

[27] *See* T.H. v. Novartis Pharm. Corp., 407 P.3d 18 (Cal. 2017); Rafferty v. Merck & Co., 92 N.E.3d 1205 (2018).

[28] *See* Pennoyer v. Neff, 95 U.S. 714, 733 (1878) (holding that the validity of a state's judgments "may be directly questioned, and their enforcement in the State resisted, on the ground that proceedings in a court of justice to determine the personal rights and obligations of parties over whom that court has no jurisdiction do not constitute due process of law").

[29] *See* Ford Motor Co. v. Montana Eighth Jud. Dist. Ct., 141 S. Ct. 1017, 1024–25 (2021) (discussing differing standards for general ("all-purpose") jurisdiction and specific ("conduct-linked") jurisdiction); Daimler AG v. Bauman, 571 U.S. 117, 121–34 (2014) (same).

[30] *See* Goodyear Dunlop Tires Ops., S.A. v. Brown, 564 U.S. 915, 919 (2011). *See also Daimler*, 571 U.S. at 139 n.20 ("A corporation that operates in many places can scarcely be deemed at home in all of them."). *Cf.* BNSF Ry. Co. v. Tyrrell, 137 S. Ct. 1549, 1558–59 (2017) (acknowledging the possibility of an "exceptional case" where general jurisdiction might exist elsewhere, yet holding that hammering more than 2,000 miles of permanent railroad track into the Montana earth and engaging more than 2,000 employees in Montana would not qualify).

principal place of business (which, for most of those defendants, were not California or Massachusetts).[31] So, Judge Rosenberg moved on.

Specific (or "conduct-linked") jurisdiction exists where a defendant, who has purposefully availed itself of the privilege of conducting activities in a certain forum, is being sued in that same forum on a cause of action that arises from or relates to its activities there.[32] The fact that a defendant has engaged in other significant, ongoing activities in a particular forum—even activities related to the very same product that injured different litigants elsewhere—is not alone enough to confer specific personal jurisdiction; the claims of each putative plaintiff must have arisen from or related to the defendant's in-forum activities.[33] If they do not, specific jurisdiction is foreclosed.

Here, too, Judge Rosenberg was guided by Circuit precedent. In the Eleventh Circuit, the Court of Appeals had ruled, "a tort 'arise[s] out of or relate[s] to' the defendant's activity in a state only if the activity is a 'but-for' cause of the tort."[34] Because the burden of establishing a court's personal jurisdiction lies with the party invoking it, the plaintiffs had the obligation to set out the "specific, non-conclusory facts" necessary to support personal jurisdiction. This, ruled Judge Rosenberg, they had failed to do. First, plaintiffs had not adequately alleged that the brand defendants' in-forum activities in any state were the "but-for" cause of their ingestion of generic ranitidine and resulting injuries. Second, plaintiffs had also not adequately alleged that the defendants should have foreseen that their in-forum, brand-related activities in those states could expose them to liability for the injuries suffered by consumers of the generic medicine.[35] For this reason, personal jurisdiction over any claims by any generic consumers outside of the brand defendants' home states was improper.[36]

IMPACT

When the West Virginia Supreme Court refused the invitation to import innovator liability into its common law a few years ago (one of the FDLI *Top Cases* of 2018),[37] the national trend-line on the vitality of this theory was still forming. As time has passed, the theory's reception by America's courts has chilled decidedly. If the Eleventh Circuit Court of Appeals affirms Judge Rosenberg's *Erie* survey of the country's jurisdictions, and if her predictions are later borne out as high court after high court finally passes on the question, the result will be a textbook example of a

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[31] *See In re Zantac*, 2020 WL 7866660, at *10–*12.

[32] *See Ford Motor Co.*, 141 S. Ct. at 1024–25; Bristol-Myers Squibb Co. v. Superior Ct., 137 S. Ct. 1773, 1780 (2017).

[33] *See id.* at 1781 (in pharmaceutical case brought by injured Californians, rejecting the exercise of specific jurisdiction in California over similar claims asserted by similarly situated plaintiffs but who were injured outside California: "What is needed—and what is missing here—is a connection between the forum and the specific claims at issue.").

[34] Waite v. All Acquisition Corp., 901 F.3d 1307, 1314 (11th Cir. 2018) (citation omitted).

[35] *See In re Zantac*, 2020 WL 7866660, at *10–*11.

[36] For the same reason that their personal jurisdiction averments failed to meet constitutional prerequisites, plaintiffs' attempt to invoke "legislative jurisdiction" (the borrowing by the brand defendants' home states of the innovator liability theory adopted by California and Massachusetts) also failed. *See id.* at *11–*12.

[37] *See* McNair v. Johnson & Johnson, 818 S.E.2d 852 (W. Va. 2018) (discussed in *McNair v. Johnson & Johnson*, TOP FOOD AND DRUG CASES, 2018, & CASES TO WATCH, 2019, at 14 (August T. Horvath, ed., 2019)).

nation divided: two U.S. states allowing an unconventional compensation theory that nearly the rest of the country will have rejected. And because this divide is anchored in state law, a unifying resolution from the U.S. Supreme Court is improbable.

Why is a solution to generic product injuries so exasperatingly elusive?

Most state law failure-to-warn claims asserted against generic manufacturers are preempted because those manufacturers lack discretion on what that warning can say.[38] Likewise, most state law design defect claims against generic manufacturers are preempted because those manufacturers lack discretion to change the composition of the product.[39] Thus, absent a mistakenly printed warning label or a bad-batch manufacturing error, consumers claiming injury from generic medicines are ordinarily afforded no product liability recourse at all—while a similarly injured consumer who purchased the brand medication (the one the generic replicates) possesses state law compensation options. This asymmetrical justice is all the more curious when one considers that script-filling pharmacists may (and, under some regulatory regimes, *must*) fill their customers' prescriptions by substituting the generic version of a medicine for the brand version their doctors ordered.[40]

Not to worry, consumers have long been reassured, this conundrum will cause them trouble rarely, if ever. Brand manufacturers ordinarily enjoy years of patent-protected exclusivity (i.e., no generic competitors) in selling their medicines, and FDA reports that "genuinely new information about drugs in long use (as generic drugs typically are) appears infrequently."[41] So, the risk of a long-undiscovered pharmaceutical defect posing a surprising new risk to some generic consumer is unlikely.

But Zantac was just such an "in-long-use" medicine. And FDA requested its removal from the market because of a new risk discovered more than thirty years after the drug was first approved. Ergo, latently unearthed risks to generic consumers may be unlikely, but they are certainly not unprecedented. Innovator liability proposed an unusual, common law solution to this vexing asymmetry. Yet, for sound analytical and policy reasons, that solution proved to be (in the view of most courts) as intractably unjust as the problem it endeavored to solve. After all, the arrival of generic competition is not, as a rule, a welcome development to brand manufacturers. To the obvious contrary, generics hollow out the market with comparatively inexpensive substitutes to replace the original branded product—precisely as the Hatch-Waxman Act intended. So, absent a patentable enhancement to the branded product, the arrival of generic competition signals the collapse of the branded product's market. To this end-of-product-life tale, innovator liability proposed to add a startling epilogue—uncontainable liability for harm caused to some other company's customers by a product the brand manufacturer has not made, distributed, sold, or profited from. And that liability could go on for years (or forever).

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[38] *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011) ("Federal law . . . demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same.").

[39] *See* Mutual Pharm. Co. v. Bartlett, 570 U.S. 472, 483–84 (2013) ("[T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based. Consequently, . . . 'Mutual cannot legally make sulindac in another composition.'").

[40] *See PLIVA, Inc.*, 564 U.S. at 625.

[41] *See id.* at 625 n.9.

When Justice Traynor first introduced strict products liability into California common law, he explained why that evolution in the law was just: "Implicit in [a product's] presence on the market . . . was a representation that it would safely do the jobs for which it was built."[42] In many ways, this was the birth of modern products liability doctrine, one liberated from the technicalities of written promises, warranties, and commercial sales. Today, Traynor's equation seems to many the very epitome of fairness: if one offers something for sale to another, that seller—having profited from the sale it induced—owes an obligation to ensure what it sold is safe for what it was sold to do. It is hard to imagine a tort theorist, even one from Traynor's halcyon days of legal inventiveness, surmising that product liability could, in any form, ever be de-linked from the injury-causing product. Yet that is precisely what innovator liability proposes. It offers a "glass bridge" of sorts, built to leap over and past settled and sound principles of products liability law. And that is precisely why it has so often failed.

The path to a remedy for injured generic consumers was narrowed further by the U.S. Supreme Court's recent sharpening of the boundaries between general and specific personal jurisdiction. Earlier, injured generic consumers might well have been prepared to decamp to California or Massachusetts to litigate an innovator liability claim, but recent personal jurisdiction case law now often foreclose that option. If a patient sees her doctor in State X, is prescribed a medicine in State X, has that prescription filled with a generic medicine in State X, ingests that medicine in State X, and suffers a resulting injury in State X, then that patient cannot litigate an innovator liability claim in a different state (say, California or Massachusetts) unless the brand manufacturer is incorporated or headquartered there or designed or manufactured the product there (something fewer and fewer brand manufacturers are now likely to do).

Judge Rosenberg's decision was handed down three months before the U.S. Supreme Court released its long anticipated ruling in late March 2021 in *Ford Motor Co. v. Montana Eighth Judicial District Court*.[43] That opinion will force a revisiting of the Eleventh Circuit "but-for" precedent on which she relied, but likely not in a way that impacts the outcome in *In re Zantac*. In *Ford Motor Co.*, the Supreme Court gave content, for the first time, to the second half of the "arises from or relates to" test, ruling that specific personal jurisdiction does not always depend on proof of a causal link between a defendant's in-forum activities and an injured plaintiff's cause of action. Instead, specific personal jurisdiction may also exist in a forum where a plaintiff resides and suffers personal injury (even if the defendant's product was not sold to the injured plaintiff there, manufactured there, or designed there)—if the defendant has purposefully availed itself of the privilege of marketing, selling, and servicing the very same product in that forum.[44] But the Court seemed quite insistent in its new *Ford Motor Co.* decision on keeping tightly shut a forum's doors to those claimants injured and residing elsewhere, and that result portends the same unfavorable outcome for the *In re Zantac* plaintiffs.[45]

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[42] *See* Greenman v. Yuba Power Prod., Inc., 377 P.2d 897, 901 (Cal. 1963).

[43] 141 S. Ct. 1017 (Mar. 25, 2021).

[44] *See id.* at 1026–32.

[45] *See id.* at 1027 n.3 (rejecting view that state courts should have jurisdiction over a national company on any claim, regardless of relatedness: "On that view, for example, a California court could hear a claim against Ford brought by an Ohio plaintiff based on an accident occurring in Ohio involving a car purchased in Ohio. . . . 'Case-linked' jurisdiction would then become not case-linked at all.") (citation omitted).

While the predictive holdings in *In re Zantac* may be both principled and sound, they leave the troubling generic customer asymmetry dilemma unresolved. Given the current formulation of the Hatch-Waxman regime, a common law fix may well be beyond the reach of the judiciary—at least not without ushering in all manner of unintended unhappy consequences. On that score, Justice Thomas offered a fitting, closing thought when he wrote that it is not the judiciary's task—

> to decide whether the statutory scheme established by Congress is unusual or even bizarre . . . . Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results . . . . As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.[46]

Perhaps *In re Zantac* will trigger just such a fresh look.

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[46] *See PLIVA, Inc.*, 564 U.S. at 625–26 (cleaned up).

GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.

SARA W. KOBLITZ*

WHY THIS CASE MADE THE LIST

Congress drafted the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") in an effort to remove barriers to generic drug market entry—and to do so without discouraging pharmaceutical innovation.[1] To that end, the statutory scheme implemented by the Hatch-Waxman Amendments includes a complex patent listing and certification process—informally called "the patent dance"—that seeks to both acknowledge and protect patent rights and also to encourage challenges to those patents to expedite generic approval and market entry. As part of that balance, Congress included in the Hatch-Waxman Amendments a mechanism by which a generic sponsor may omit—or "carveout"—patent-protected methods of use from generic labeling.[2] Widely used, the provision results in a "skinny label" or "carveout" and allows the generic sponsor to avoid infringement of the relevant method-of-use patent.

In October 2020, in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*,[3] the Federal Circuit put this statutory carveout in jeopardy, effectively writing it out of the statute, by holding that a skinny-labeled generic carvedilol drug product induced infringement of the relevant patent covering the carved-out method-of-use.[4] In a controversial 2-1 decision, the court explained that a generic sponsor can be liable for induced infringement even if neither the product labeling nor the product marketing includes direct reference to the carved-out patent-protected method-of-use. Read broadly, the court's decision leaves *every* carveout vulnerable to induced infringement claims and thereby threatens to nullify the carveout. This single patent case—without even acknowledging the potential ramifications to the FDA regulatory scheme—threatens to upset the long-established balance between intellectual property rights and generic drug access that Congress set forth in the Hatch-Waxman Amendments.

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1 Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, 98 Stat. 1585 (1984).

2 21 U.S.C. § 355(j)(2)(A)(viii).

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

4 *Id.*

DISCUSSION

Legal Background

The Federal Food, Drug, and Cosmetic Act (FDCA), initially enacted in 1938, provides statutory authority for FDA to oversee the safety of food, drugs, medical devices, and cosmetics.[5] Pursuant to 1962 amendments, the FDCA requires FDA to review and approve all new drugs for safety and efficacy prior to introduction into interstate commerce.[6] To that end, FDA requires New Drug Applications (NDAs) to include, among other things, data from adequate and well-controlled human clinical trials that are sufficient to establish that the proposed drug is safe and effective for its intended use.[7] Until 1984, this requirement applied to both innovator (or "brand") drugs and generic drugs, which generally made it cost-prohibitive for generic drugs to obtain FDA approval to come to market.[8]

In order to remove barriers to entry and facilitate patient access to affordable medicines, Congress implemented the Hatch-Waxman Amendments in 1984 and modified the FDCA.[9] The Hatch-Waxman Amendments introduced an abbreviated pathway to market for generic drugs permitting FDA to rely on its determination of safety and effectiveness for an approved product—called the Reference Listed Drug (RLD)—for approval of a drug product with the same active ingredient, route of administration, and strength or concentration.[10] Such an application, called an Abbreviated New Drug Application (ANDA), need not include full clinical trials, but it must demonstrate that the proposed generic drug is the same as and bioequivalent to its RLD.[11] The generic drug product labeling also must be identical to that of the approved RLD, other than certain permissible differences, including the "omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the [FDCA]."[12]

In enacting the ANDA pathway to generic approval, Congress recognized that it needed to maintain incentives to encourage further innovation. Thus, NDAs containing full clinical trials became eligible for five or three year periods of exclusivity during which FDA could not receive or approve ANDAs (respectively) and set up a patent listing and certification procedure so that generic sponsors are aware of—and cannot simply ignore—patents covering the RLD.[13] That patent listing process requires NDA holders to submit to FDA a list of all patents that claim the drug or the method of using

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

6 *See* 21 U.S.C. § 355.

7 *Id.*

8 *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 612 (2011).

9 Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (citing, *inter alia*, H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647).

10 21 U.S.C. § 355(j)(2)(A).

11 *Id.*

12 21 C.F.R. § 314.94(a)(8)(iv).

13 *See* 21 U.S.C. §§ 355(b)(1)(A)(viii), (j)(7)(A)(i); Purepac Pharmaceutical Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004) ("In order to determine what patents cover existing brand-name drugs and hence whether any paragraph IV certifications or section viii statements are needed, applicants look in the 'Orange Book . . . .'").

that drug.[14] In turn, FDA publishes the drug and its patents in its list of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").[15] Patents eligible for listing in the Orange Book are limited to drug substance (active ingredient), drug product (formulation and composition), method-of-use, and product-by-process patents.[16] When a method-of-use patent is listed, the sponsor must include a narrative description, called a "use code," that describes "the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product . . . ."[17]

To ensure recognition of those listed patents, each ANDA must include one of four certifications with respect to each patent listed in the Orange Book for the RLD: a Paragraph I certification affirming that no patent information was filed for the RLD; a Paragraph II certification affirming that the listed patent has already expired; a Paragraph III certification affirming that the proposed generic drug will not be marketed prior to the relevant patent's expiration date; or a Paragraph IV certification affirming that the relevant patent is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug.[18] A Paragraph IV certification also requires the ANDA sponsor to provide notice to the RLD holder within forty-five days so that the RLD holder has the opportunity to bring patent litigation prior to the approval of the ANDA, which effectively stays approval of that ANDA for thirty-months as the patent litigation is resolved.[19]

The Hatch-Waxman Amendments also provide an alternative to the patent certification; instead of a patent certification, an ANDA might include a "section viii statement" informing FDA that the proposed ANDA does not seek approval for the use covered by a listed method-of-use patent (and only a method-of-use patent).[20] In that situation, the ANDA applicant "carves-out" from its product labeling the language that the NDA sponsor lists in the "use code" for that patent. Because FDA's role in administering patents is "ministerial," FDA relies on the use code to assess the parameters of the patent claim that must be omitted from the "skinny-labeled" generic labeling to avoid infringement.[21] Though FDA regulations require a generic to have the same labeling as its RLD, the regulations specifically provide for differences arising from carved-out, patent-protected methods of use.[22]

FDA permits carveouts only when the method-of-use information—typically indications, concomitant uses, or patient populations—can be omitted from product labeling without affecting the safety or efficacy of the product for the remaining

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[14] 21 U.S.C. §§ 355(b)(1)(A)(viii), (j)(7)(A)(i).

[15] 21 U.S.C. § 355(j)(7)(A)(i).

[16] 21 C.F.R. § 314.53(b); Applications for FDA Approval to Market a New Drug, 67 Fed. Reg. 65,448, 65,452 (Oct. 24, 2002).

[17] 21 C.F.R. § 314.53(f)(1)(i)(B).

[18] 21 U.S.C. § 355(j)(2)(A)(vii).

[19] 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).

[20] 21 U.S.C. § 355(j)(2)(A)(viii); 21 CFR § 314.94(a)(8)(iv).

[21] Listing of Patent Information in the Orange Book, 85 Fed. Reg. 33,169, 33,170 (June 1, 2020); *see* 21 C.F.R. § 314.53(f)(1)(i)(B).

[22] *See* 21 C.F.R. § 314.94(a)(8)(iv).

indications.[23] FDA often allows such carveouts, as they allow immediate ANDA approval rather than tentative approval until all patents expire or patent litigation is complete (as is required with the submission of a Paragraph III or Paragraph IV certification).[24] Further, RLD sponsors receive no notice of the submission of an ANDA with a section viii statement and thereby no opportunity to bring patent litigation prior to ANDA approval and stay such approval for thirty months to litigate the relevant patent. Because section viii statements often accelerate the approval process, carveouts, when possible, are an attractive option for generic sponsors.

Unsurprisingly, RLD sponsors tend to dislike labeling carveouts (and reliance on section viii statements), as they allow generic competitors to access the market without addressing listed patents. It is not uncommon for RLD sponsors to petition FDA to preclude such carveouts on the grounds that a labeling omission would affect the safety and efficacy of the product for the remaining indications in the labeling.[25] Typically, FDA rejects these petitions and, barring any deficiency in the ANDA, will approve an ANDA with a section viii statement before the expiration of the relevant method-of-use patent.[26]

Once an ANDA is approved, FDA lists it in the Orange Book alongside its RLD.[27] Such listing assists state health agencies, prescribers, and pharmacists to facilitate drug product selection pursuant to state generic drug substitution laws.[28] FDA identifies multi-source drug products that are expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling—therapeutically equivalent and therefore substitutable products—by assigning and listing therapeutic equivalence codes in the Orange Book.[29] FDA assigns ANDAs that are therapeutically equivalent an "A" rating, while products that have not been shown to be therapeutically equivalent are assigned "B" ratings.[30] Each "A" and "B" rated product is assigned a second letter reflecting the dosage form and the basis of FDA's therapeutic equivalence determination.[31] AB-rated products are those that meet necessary bioequivalence requirements for substitution.[32] Therapeutic equivalence codes are based solely on the composition of the drug. Thus, a skinny-labeled generic could be "A" rated against the RLD—and therefore substitutable—even if it is not approved for all of the same indications.

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[23] 21 C.F.R. § 314.127(a)(7); Citizen Petition from Hogan & Hartson, FDA Docket No. 2003P-0518 (Sept. 20, 2004).

[24] Purepac Pharmaceutical Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004).

[25] *See, e.g.*, Citizen Petition from Fish & Richardson, P.C., Docket No. FDA-2016-P-0383 (Jan. 29, 2016) (requesting that FDA preclude carveouts of a protected use from Nucynta ER); Citizen Petition from Millennium Pharmaceuticals, Inc., Docket No. FDA-2017-P-3672 (June 8, 2017) (same from Velcade).

[26] *See, e.g.*, FDA Letter Decision, Docket No. FDA-2016-P-0383 (Apr. 29, 2016) (rejecting a request to preclude carveouts of a protected use from Nucynta ER); FDA Letter Decision, Docket No. FDA-2017-P-3672 (Nov. 6, 2017) (same from Velcade).

[27] 21 U.S.C. § 355(j)(7)(A).

[28] Orange Book Preface (41st ed. 2021).

[29] *See* Orange Book Preface § 1.6.

[30] *See id.* at § 1.7

[31] *Id.*

[32] *Id.*

Factual Background

In 1995, FDA approved GSK's Coreg (carvedilol), 6.25, 12.5, and 25 mg tablets, under NDA 20297 for the treatment of hypertension. FDA subsequently approved Coreg for the treatment of congestive heart failure (CHF) and left ventricular dysfunction following a myocardial infarction, and GSK added these indications to its labeling.[33] After approval of each indication, GSK listed a number of patents in the Orange Book, eventually listing a method-of-use patent, U.S. Patent No. 5,760,069 (the "'069 patent") with the use code U-233, "decreasing mortality caused by congestive heart failure."[34] The '069 patent, however, contained errors; by 2008, GSK corrected these errors, the patent reissued as the RE40000 (the "'000") patent, and GSK listed the reissued in the Orange Book with the same use code.[35]

As GSK amended its Coreg NDA, Teva submitted ANDA 76373 in March 2002 seeking approval to market a generic carvedilol with Coreg as its RLD.[36] Teva initially submitted a Paragraph IV certification for the '069 patent (now '000), but in March 2007 withdrew the Paragraph IV certification and instead submitted a section viii statement to carve out all labeling information related to the CHF indication.[37] Teva received FDA approval in September 2007 and launched a skinny-labeled generic carvedilol with no reference to the CHF indication.[38] At all times, Teva's carvedilol product was listed in the Orange Book with an AB-rating.[39]

Court Decision

GSK sued Teva in the District Court of Delaware in July 2014 for patent infringement, alleging Inducement of Infringement and Contributory Infringement under Title 35 of the U.S. Code.[40] Relevant here, the patent infringement statute provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer."[41] Active inducement requires a demonstration that the party's actions caused the infringement.[42] Courts have found such causation through affirmative intent that the product be used to infringe, as well as mere knowledge that labeling may lead to infringement.[43]

After a trial in 2017—in which GSK presented evidence that Teva's promotional materials referred to Teva's generic carvedilol as "AB-rated generic equivalents" and

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[33] Coreg (carvedilol), Approval Letter, NDA 20297/S-007 (Oct. 1, 2001); Coreg (carvedilol), Approval Letter, NDA 20297/S-009 (Mar. 27, 2003).

[34] GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F. Supp. 3d 582, 586 (D. Del. 2018).

[35] *Id.* at 586–87.

[36] *Id.* at 587.

[37] *Id.*

[38] *Id.*; Not relevant here, Teva added CHF information back into its label at FDA's direction in 2011 even though the '000 patent did not expire until June 2015.

[39] *Carvedilol*, *in* ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 3 - 71 (U.S. Dept. of Health & Human Servs., 28th ed. 2008).

[40] Complaint for Patent Infringement, *GSK v. Teva*, Docket No. 1:14-cv-00878 (D. Del., Jul. 3, 2014).

[41] 21 U.S.C. § 271(b).

[42] GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F. Supp. 3d 582, 586 (D. Del. 2018).

[43] GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347, 1352–53, 1355 (Fed. Cir. 2020).

as generic versions of Coreg—a jury found Teva liable for induced infringement.[44] Teva moved for a Judgment as Matter of Law of no inducement or lost profits, which the court granted in March 2018 stating that "substantial evidence does not support the jury's findings on inducement in either the skinny or full label period."[45] Because Teva's carvedilol labeling did not instruct doctors to prescribe its product for CHF and marketing materials stated only that the product had an "AB rating" to Coreg, the court found that GSK failed to show causation.[46] Further, Teva showed alternative factors—i.e., factors other than the labeling or AB rating—caused physicians to prescribe carvedilol.[47] Without causation, the court held, a finding of inducement cannot stand. Therefore, the court granted Teva's Motion for Judgment as a Matter of Law and overturned the jury verdict.[48]

GSK appealed, and as a patent case, it went to the Federal Circuit. The Federal Circuit reviewed the Judgement as a Matter of Law *de novo*, evaluating whether "'the record is critically deficient of the minimum quantum of evidence' to sustain the verdict."[49] To that end, the Federal Circuit assessed whether the jury's findings were supported by substantial evidence and whether the jury's verdict can be supported by its findings. In no uncertain terms, the Federal Circuit held that while the district court applied the correct standard, the "criteria of induced infringement are met" based on the "ample record evidence of promotional materials, press releases, product catalogs, the FDA labels, and testimony of witnesses from both sides."[50] The majority took this position even though the evidence presented consisted of materials in which Teva had noted that its product was a "generic equivalent of Coreg" and "AB rated" without any reference to specific indications.[51] Notably, the court implied that the labeling alone may have been enough, as "[p]recedent has recognized that the content of the product label is evidence of inducement to infringe."[52] Given that the court found substantial evidence to support the jury's verdict of inducement to infringe the '000 patent, the Federal Circuit overturned the Judgment as a Matter of Law, reinstated the $235 million damages award, and remanded the matter to back to the district court. The court explained that its decision was not based on policy but purely on applicable patent law.[53]

Federal Circuit Chief Judge Prost vehemently dissented. Focusing on the "critical balance" of patent rights with public access to innovation, she noted that the majority decision "undermines this balance," particularly since Congress specifically provided for the skinny label pathway to market.[54] The dissent explained that the crux of the case is "whether Teva induced infringement of GSK's reissue patent, RE40,000, by

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[44] *GSK v. Teva*, 313 F.Supp.3d.

[45] *Id.* at 590.

[46] *Id.* at 590–91.

[47] *Id.*

[48] *Id.* at 599.

[49] GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347, 1351 (Fed. Cir. 2020).

[50] *Id.* at 1355.

[51] *Id.*

[52] *Id.*

[53] *Id.* at 1356.

[54] *Id.* at 1357–58.

marketing its generic carvedilol for unpatented uses through a 'skinny label.' The clear answer: Teva did not."[55]

The dissent criticized the Federal Circuit's holding because it "nullifies Congress's statutory provision for skinny labels," slowing the introduction of low-cost generics.[56] In the dissent's view, Teva "did everything right—proceeding precisely as Congress contemplated."[57] Indeed, Teva followed all statutory and regulatory requirements: Teva never expressly marketed for the carved-out indication, and properly omitted the indication from its labeling until the method of use patent expired.[58] Teva "*never* stated that it was approved, or could be used, to treat CHF."[59] With no legally sufficient evidence to support inducement or to support that doctors prescribed generic carvedilol based on any action taken by Teva, the dissent would uphold the judgement as a matter of law.[60] To do otherwise, the dissent writes, "undermines Congress's design for efficient generic drug approval."[61]

IMPACT OF THE DECISION

As Chief Judge Prost's dissent explains, the Federal Circuit's decision could mean the end of the carveout. While GSK would argue that the decision here should be read more narrowly—applicable only to Teva's specific labeling, which GSK has since asserted did not fully carveout CHF, rather than to ***all*** skinny-labeled generics[62]—the language the Federal Circuit uses implies that merely referencing FDA's assigned therapeutic equivalence code is enough to induce infringement. Indeed, Teva followed the applicable FDA regulations and made no representations specific to CHF but was nevertheless liable for infringement. Consequently, the decision discourages the use of the carveout—a tool that Congress expressly provided to encourage timely generic approval without violating patent rights—in *any* situation. Further, any sponsor of skinny-labeled drugs currently on the market is vulnerable to similar litigation, potentially opening the flood gates for induced infringement litigation.

The Federal Circuit tried to side-step "policy" arguments, but its decision effectively determined that patent rights supersede Congress's statutorily-enacted process for avoiding method-of-use patents, as set forth in the FDCA. It is clear that the FDA regulatory scheme received little consideration from the majority here. The majority even mischaracterizes the dissent's concerns about the abrogation of the Hatch-Waxman Amendment's intent—to "speed the introduction of low cost generics to the market"—as a policy debate "about whether GSK made enough money from carvedilol in past years . . . ."[63] Suggesting that Congress should revisit the patent

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55 *Id.* at 1357.

56 *Id.* at 1358.

57 *Id.* at 1361.

58 *Id.*

59 *Id.* at 1362.

60 *Id.* at 1365.

61 *Id.* at 1374.

62 *See* GSK's Response Brief to Petition for Rehearing *En Banc*, *GSK v. Teva*, Docket No. 18-1976 (Fed. Cir., Jan. 29, 2021).

63 *GSK v. Teva*, 976 F.3d at 1356; *id.* at 1373 (citing Caraco Pharm. Labs., Ltd. v. Novo Nordisk, 566 U.S. 399, 405 (2012)).

profit issue with legislation, the majority overlooks the fact that Congress did just that by enacting the carveout in the first place.[64] Framing the issue here as a debate about windfall profits rather than access to medicine seems to intentionally obfuscate the balance between patent rights and market access that the Hatch-Waxman Amendments expressly addressed. It is illustrative of—and in fact heightens—the tension between innovation and affordability, which is pervasive in the drug industry. Effectively, the majority opinion's complete disregard of the FDCA implications here suggests that the court made a clear choice to protect innovation over accessibility. With a single court decision, the Federal Circuit signaled the supremacy of the patent by undermining the balance that Congress sought to achieve in adopting the Hatch-Waxman Amendments. If this decision holds, at least on the grounds set forth in the October 2020 Federal Circuit decision, Teva may be correct that "the carve-out statute is a dead letter."[65]

At the time this paper was submitted for publication, the Federal Circuit vacated its October 2020 decision, but a decision on the rehearing by the same panel is forthcoming. Teva petitioned the Federal Circuit for a rehearing en banc, and the court granted a panel rehearing composed of the same judges as the October 2020 panel. In that rehearing briefing, Teva pleaded for the court to recognize the enormity of its initial decision, while GSK explained that that decision "merely reaffirmed that section viii is not a get-out-of-jail-free card for generics who do not fully carve out the patented use from their labels."[66] A Federal Circuit decision on the rehearing is forthcoming.

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[64] *Id.*

[65] Petition for Rehearing *En Banc* at 1, *GSK v. Teva*, Docket No. 18-1976 (Fed. Cir., Dec. 2, 2020).

[66] GSK's Response Brief to Petition for Rehearing *En Banc* at 13, No. 18-1976 (Fed. Cir., Jan. 29, 2021).

U.S. v. Facteau: District Court Finally Upholds Misdemeanor Convictions for Off-Label Promotion

LYNN C. TYLER*

After a three-year delay, last September the District Court in *U.S. v. Facteau* denied the defendants' motion for acquittal or new trial, upholding misdemeanor convictions for distributing adulterated and misbranded medical devices based on off-label promotion.[1] The court attributed the delay to the "challenging" issues presented, including the fact "there is no statute that specifically prohibits off-label marketing and yet the Government continues to prosecute the conduct by patching together the misbranding and adulteration regulations, thereby criminalizing conduct that it is not entirely clear Congress intended to criminalize." In its order, the court rejected the defendants' first amendment defense, which will be the focus of this article.

WHY IT MADE THE LIST

After a string of losses dating back over fifteen years, *Facteau* is the first time the government has overcome a First Amendment defense to score a (partial) victory in an off-label promotion case. Although the defendants were acquitted on related felony charges, they were sentenced to time served and to fines of $1,000,000 and $500,000, respectively, on the misdemeanor convictions. As of press time, both defendants have appealed, so the question is whether the government will be able to preserve its win.

DISCUSSION

William Facteau was the CEO, and Patrick Fabian was the VP of Sales, of a medical device company named Acclarent. In the order denying the motion for acquittal, the district court stated the evidence at trial supported the following facts. Beginning in or about 2005, Facteau, Fabian, and others at Acclarent caused Acclarent to develop and design a device known as the Stratus to release the steroid Kenalog-40 in the nasal passages over ten to fourteen days. The Stratus did not elute saline for any significant period of time.

Facteau, Fabian, and others understood that FDA would likely require significantly more testing and clinical data to permit the interstate distribution of the Stratus as a steroid delivery device than it would require for a device that did nothing more than maintain a space in the sinuses and release saline. Facteau, Fabian, and others therefore pursued a strategy to obtain marketing authorization more quickly by concealing from FDA that they intended the Stratus to be used as a steroid delivery device and by

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[1] Case No. 1:15-cr-10076-ADB (D. Mass.).

falsely claiming that the Stratus was a sinus spacer for use with saline that was substantially equivalent to an existing legally marketed spacer.

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

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

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

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

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

The government's case against Facteau and Fabian had to overcome the adverse results in several prior cases where FDA's (or other) restrictions on promotion collided with the First Amendment. Some of the older cases on this issue include *Washington Legal Foundation v. Henney*, *Thompson v. W. States Med.Ctr.*, and *Sorrell v. IMS Health, Inc.* More recently, in *U.S. v. Caronia*, the Second Circuit relied on the First Amendment to reverse a criminal conviction for the off-label promotion of a prescription drug. Following *Sorrell*, the court first held that FDA's ban on off-label promotion is subject to heightened scrutiny: "The government's construction of the FDCA's misbranding provisions to prohibit and criminalize the promotion of off-label drug use by pharmaceutical manufacturers is content- and speaker-based, and, therefore, subject to heightened scrutiny." The court then found that construing the FDCA's misbranding provisions to preclude off-label promotion would violate the First Amendment. To avoid this constitutional difficulty, the court summarized its decision as follows:

> We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA approved prescription drugs . . . . We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.

Accordingly, the court reversed Caronia's conviction.

Taking advantage of *Caronia*, Amarin Pharmaceuticals filed a declaratory judgment action and sought a preliminary injunction against FDA to preclude any enforcement action arising out of proposed truthful and non-misleading, but off-label, promotion of a drug, Vascepa®. Citing Amarin's First Amendment rights, the court issued a preliminary injunction authorizing Amarin to make several specific statements or disclosures to doctors and to disseminate thirteen scientific publications concerning Vascepa®. FDA did not dispute the truth of the statements and/or they were supported by clinical trials FDA had approved. In ruling for Amarin, the court relied heavily on *Caronia*. FDA argued for a narrow interpretation of *Caronia*, limited to its facts, but the court rejected its arguments and concluded "[w]here the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*, *cannot* be the act upon which an action for misbranding is based."

The final case before *Facteau* involving these issues was *U.S. v. Vascular Solutions, Inc.* (VSI). VSI initially marketed its product, a laser used in vein ablation procedures, under a 510(k) clearance with an intended use for the treatment of varicose veins near the surface of the leg. In June 2007, VSI filed a premarket notification seeking to add an indication for perforator vein treatment to its existing clearance. Perforator veins are closer to bones. In response, FDA requested data showing Vari-Lase's safety and efficacy in perforator vein procedures. VSI conducted a clinical trial in late 2007 but did not submit the trial data. In March 2008, FDA informed VSI that the agency considered the application to be withdrawn.

By October 2007, however, VSI had already launched the "Short Kit," which was intended for "short vein" treatments. The government alleged that the undefined term "short vein" was intended to include perforator veins. In October 2009, VSI told its board that it would not submit a 510(k) due to the lack of clinical data supporting its perforator vein use. Nevertheless, VSI's marketing of the Short Kit continued until 2014.

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

In light of this background, we return to the *Facteau* case. The following excerpt from the *Facteau* court's jury instructions reflect that it followed *Caronia* by ruling

that the FDCA does not make off-label promotion a crime, but also followed *VSI* and other cases by ruling that the defendants' speech could be used as evidence of a crime:

> *The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime. Rather*, the FDCA crimes charged are conspiring to introduce, and causing the introduction of, devices into interstate commerce that were adulterated or misbranded. Although you may not convict a Defendant of a crime based solely on truthful, non-misleading statements regarding off-label use, even truthful statements about an off-label use can be considered as evidence. To put it another way, to convict, there must be a criminal act. *Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.*[2]

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

The defendants filed a motion for acquittal or new trial on multiple grounds, including the First Amendment. The gist of the First Amendment argument was that the jury rejected the government's claim that the defendants had engaged in false or misleading speech and thus the First Amendment precluded any conviction. As noted above, however, the district court rejected this argument. Quoting *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993), the district court stated "[t]he First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent." The court concluded: "Here, the use of speech to actively market and promote the device for off-label use, as Defendants did, was evidence of their intent that the device be used for a purpose that the FDA had not approved and was not itself the crime. The Court therefore finds that Defendants' First Amendment rights were not violated by the conviction." The defendants have appealed. Thus, it remains to be seen whether FDA will retain its partial victory.

IMPACT

For now at least, despite the acquittals on the felony charges, *Facteau* represents a significant victory for the government. As in *VSI*, it is another vindication of the government's theory that it can use speech as evidence of criminal conduct. At a minimum, the defendants have likely spent millions in legal fees and have been convicted and sentenced to pay substantial fines, in addition to the time served in

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

prison. These results should have a deterrent effect on others employed in FDA-regulated industries. On the whole then, the First Amendment still appears to be better deployed as a shield after a company's employee(s) have gone astray (despite thorough training), rather than as a sword with which to slash a trail of off-label promotion.

The Scoop on the "Vanilla" Class Action Jurisprudence

MITAL PATEL & JENNIFER YOO*

WHY THESE CASES ARE NOT TOO VANILLA FOR THIS LIST

Class action litigation within the food and beverage industry continues to grow at a steady rate, with an emphasis on allegations involving the advertising and labeling on food products. Through the years, we have seen a litany of litigation against specific types of products within a given period of time. In recent history, butter ingredient claims, products claiming to have less sugar or calories, and chocolate products have been the subject of such class action litigation trends.

The most recent trend since February 2019 has transitioned to a focus on a wide range of *vanilla* products. At the time, chocolate confectioners were facing a number of class action cases arising from their use of "white chocolate" on labels. The vanilla cases first appeared to be a variation on this theme. However, the vanilla cases quickly took on an astonishing life of their own. There have been more than 100 class action lawsuits filed against retailers and food brands related to food products labeled "vanilla"—representing about a quarter of overall food litigation filings in 2019 and 2020. The products at issue in these cases include ice cream, herbal teas, yogurt, soymilk, almond milk, espresso drinks, protein drinks, and many others. The most notable cases allege that "vanilla" on a product label is a deceptive statement because there are other flavorings in the products besides vanilla extract that simulate vanilla.

Until 2020, there had been very little case law to predict how these cases would fare. Throughout the past year, New York courts have shaped the majority of the precedent that governs what Judge P. Kevin Castel aptly, if somewhat tongue-in-cheek, referenced in one opinion as "the vanilla jurisprudence." As of March 2021, New York district courts have dismissed, as a matter of law, nine cases involving allegations that the word "vanilla" on various food product labels falsely communicates to a reasonable consumer that the flavor of the respective food product at issue is derived solely from real vanilla. In each of these cases, the courts found it irrelevant whether the product complied with the Food and Drug Administration's (FDA) labeling regulations implementing the Federal Food, Drug, and Cosmetic Act (FDCA), finding "no extrinsic evidence that the perceptions of ordinary consumers align with these various labeling standards."[1]

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[1] Wynn v. Topco, No. 19-cv-11104 (RA), 2021 U.S. Dist. LEXIS 9714 (S.D.N.Y. Jan 19, 2021).

DECISIONS

Though the majority of these cases have been decided in New York over the last year, California courts have also issued some important rulings for companies defending these types of lawsuits. Based on this body of case law, the "reasonable consumer" defense continues to serve as an important standard to meet in this area of litigation.

The trend of "vanilla" litigation began in February 2019 in the Eastern District of New York when a lawsuit was filed against A&W root beer and cream sodas. In that case, the plaintiff alleged that the products' "made with aged vanilla" label was false and misleading because the soda actually contains a chemical flavor that mimics the taste of vanilla.

The claims in the lawsuits themselves have evolved quite a bit since that initial case and have expanded to include mostly products that are labeled as "vanilla," not just "made with" vanilla. At their start, the cases involved plaintiffs alleging that the products' ingredient lists did not identify vanilla extract despite a representation that the products' flavor was "vanilla." These initial cases largely targeted vanilla-flavored dairy or alternative dairy products, including ice cream, almond milk, soy milk, and creamer. The cases then expanded to include granolas, flavored teas, yogurts, and cake mixes.

The plaintiffs commonly allege vanilla is a "high risk" product for "food fraud" and refer to vanillin, which can be naturally sourced from the vanilla or other plants, or can be synthetically manufactured. According to the allegations, non-vanilla bean vanillin should be disclosed as an "artificial flavor" pursuant to FDA regulations. Plaintiffs initially relied heavily on citations to chapter 21 of the Code of Federal Regulations implementing the FDCA to make their claims, alleging because the labels did not comply with federal regulations, they were, in turn, deceptive. When it became clear the courts were not convinced by these arguments, the suits then evolved to further rely on chromatography analyses, consumer surveys, and allegations that because the products do not contain *enough* vanilla, they do not taste of vanilla. Each strategy has been dismissed by various courts.

As further discussed below, the courts seem to agree that "vanilla" standing alone, as a flavor designator or descriptor of some other food product, does not convey to the reasonable consumer that the sole source of the vanilla flavor is the vanilla bean. Courts have found that consumers use a flavor name like vanilla to differentiate between other flavors, such as plain, chocolate, and strawberry, while shopping. As Judge Marrero of the Southern District of New York explained, "a reasonable consumer would associate the representation of 'Vanilla'—with no additional language modifiers—to refer to a flavor and not to vanilla beans or vanilla extract as an ingredient."[2]

In *Steele v. Wegmans,* the first case to have kicked off New York's cultivation of vanilla jurisprudence, Wegmans made the argument that private plaintiffs cannot enforce federal food law, and that violations of food regulations do not necessarily amount to deceptive practices. Wegmans also laid the foundation that these types of allegations about vanilla do not meet the reasonable consumer standard. Judge Louis Stanton of the Southern District of New York dismissed plaintiffs' case, discrediting

[2] Cosgrove v. Blue Diamond Growers, 2020 U.S. Dist. LEXIS 229294, at *7 (S.D.N.Y. Dec. 7, 2020).

the mass spectrometry analysis relied on by plaintiffs and acknowledging that there are various natural substances which have a vanilla flavor and those interested in the actual ingredients can read the list, which mentions neither vanilla beans nor extracts.[3]

Following Judge Stanton's guidance, multiple courts followed suit, dismissing similar cases applying the same reasonable consumer standards. Most recently, the court in *Dashnau v. Unilever Mfg. (US), Inc*., dismissed another similar case, this time involving a chocolate-coated vanilla ice cream bar.[4] In this case, the one distinguishing factor was that the label contained the words "vanilla *bean* ice cream." However, even with this additional qualifying word, the court determined that such was not a claim akin to the "made with" ingredient claims in cases plaintiffs cited, but instead, this fell in line with the bevy of precedent already before the Southern District of New York.

Prior to *Dashnau*, the court in *Cosgrove v. Or. Chai, Inc.*[5] dismissed the case and found the "vanilla" labeling on a chai tea latte vanilla mix that included representations that it contained natural flavors did not lead to consumers to believe that the company used vanilla beans as a primary or exclusive ingredient for vanilla flavoring. The courts in *Parham v. Aldi Inc.*,[6] *Cosgrove v. Blue Diamond Growers*,[7] and *Wynn v. Topco Assocs., LLC*,[8] found the same in cases with similar allegations, this time involving defendants' vanilla almond milk products. Similar analyses have been applied to lawsuits involving vanilla soymilk, espresso, and protein drinks.[9]

Despite vanilla jurisprudence mostly being built in New York, three courts in California have also started applying similar analyses set forth by the New York courts. In March 2021, a court in the Northern District of California dismissed the complaint in *Harris v. McDonald's Corp.*,[10] wherein the plaintiff complained that McDonald's use of the term "vanilla" on its menu boards and kiosks led customers to believe the vanilla ice cream products to be flavored exclusively with vanilla beans. The court concluded the claims were insufficiently pled and that plaintiffs cannot pass this threshold by asserting their own beliefs as a means to nudge their claim across the line from conceivable to plausible. Previously, in *Zaback v. Kellogg Sales*,[11] the plaintiff claimed he relied on the use of the word "V'nilla" in the product's name, the front of the product's label displaying "naturally flavored" immediately below the words "V'nilla Almond," and the back of the label depicting a vignette of a vanilla plant with only the word "Vanilla" below the vignette, and alleged that despite such representations, the product's vanilla flavoring was not derived exclusively from

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3 472 F. Supp. 3d 47 (S.D.N.Y. 2020).

4 No. 19-CV-10102 (KMK), 2021 U.S. Dist. LEXIS 58194 (S.D.N.Y. Mar. 26, 2021).

5 No. 19-cv-10686 (KPF), 2021 U.S. Dist. LEXIS 32229 (S.D.N.Y. Feb. 22, 2021).

6 No. 1:19-cv-08975 (PGG) (SDA), 2021 U.S. Dist. LEXIS 28892 (S.D.N.Y. Feb. 15, 2021).

7 2020 U.S. Dist. LEXIS 229294 (S.D.N.Y. Dec. 7, 2020).

8 No. 19-cv-11104 (RA), 2021 U.S. Dist. LEXIS 9714 (S.D.N.Y. Jan 19, 2021).

9 Budhani v. Monster Energy Co., No. 20-cv-1409 (LJL), 2021 U.S. Dist. LEXIS 54551 (S.D.N.Y. Mar. 12, 2021) (vanilla coffee energy drink); Barreto v. Westbrae Natural, Inc., No. 1:19-cv-09677 (PKC), 2021 U.S. Dist. LEXIS 3436 (S.D.N.Y. Jan. 7, 2021) (vanilla soymilk); Twohig v. Shop-Rite Supermarkets, Inc., 2021 U.S. Dist. LEXIS 26489 (S.D.N.Y. Feb. 11, 2021) (vanilla soymilk); Pichardo v. Only What You Need, Inc., No. 20-cv-493 (VEC), 2020 U.S. Dist. LEXIS 199791 (S.D.N.Y October 27, 2020) (dismissing case substantially identical to this one, alleging misleading "vanilla" flavor designator on a protein vanilla-flavored drink).

10 No. 3:20-cv-06533 (RS) (N.D. Cal. Mar. 24, 2021).

11 No. 3:19-cv-02327 (S.D. Cal.).

vanilla beans. The court dismissed these claims, explaining that the plaintiff's speculation was insufficient to "nudge [his] claims . . . across the line from conceivable to plausible," and without further specification as to the facts of what plaintiff was alleging, the court did not see any viable claims. In *Clark v. Westbrae Natural, Inc.*,[12] the court, citing to New York precedent in dismissing plaintiff's complaint, gave plaintiff another chance to revise his claims in part because "pictures that suggest the vanilla flavor is derived exclusively from the vanilla bean" could render a label misleading.[13] Though the *Clark* court gave the picture some weight, at least one court ignored a flower vignette, concluding that the label would not mislead the reasonable consumer.[14]

This area of food litigation is still evolving. New cases against vanilla products have been filed throughout 2021. And amidst some dismissals from the courts, a wave of voluntary dismissals has closed many cases before the courts can issue a decision. Nevertheless, there are many pending cases that are sure to continue to shape vanilla jurisprudence.

IMPLICATIONS AND IMPACT

Consumer mislabeling class actions are no novelty in the California food industry, thanks to the state's trio of consumer protection laws. Plaintiffs have their choice between California's Consumer Legal Remedies Act,[15] False Advertising Law,[16] and Unfair Competition Law[17] when alleging that consumers are misled by advertising on a product's label. The growing body of "vanilla jurisprudence" in New York since the first A&W *Sharpe* case is an indicator that food and beverage class action litigation is stretching beyond the confines of the California courts. Vanilla class action suits have since been filed in other courts including Pennsylvania, Massachusetts, and New Jersey. Even when the vanilla cases melt away, the gates may have been opened to these jurisdictions that were not typical hot beds for food and beverage class action litigation.

While vanilla cases dominated food litigation in 2020, there may be an end in sight as the issued opinions suggest increased impatience on the topic. The aforementioned nine dismissals thus far represent a relatively small number of the filed cases. Over half of these cases have been voluntarily dismissed, which may or may not indicate a settlement between the defendants and the plaintiffs' counsel pursuing the claims. The wave of voluntary dismissals suggests that perhaps an end may be in sight—at least in the New York courts. Though many of the cases have been voluntarily dismissed, some are still making their way through the courts and others are still being filed. No case, however, has reached class certification on a contested motion, suggesting that the case law in this area is likely to evolve if cases continue to move forward. The

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[12] 2020 U.S. Dist. LEXIS 224966 (N.D. Cal. Dec. 1, 2020).

[13] Clark v. Westbrae Nat., Inc., No. 20-cv-03221-JSC, 2020 U.S. Dist. LEXIS 224966, at *8 (N.D. Cal. Dec. 1, 2020).

[14] Pichardo v. Only What You Need, Inc., No. 20-CV-493 (VEC), 2020 U.S. Dist. LEXIS 199791, at *14 (S.D.N.Y. Oct. 27, 2020).

[15] Cal. Civ. Code §§ 1750, et seq.

[16] Cal. Bus. & Prof. Code §§ 17500, et seq.

[17] Cal. Bus. & Prof. Code §§ 17200, et seq.

coming year will reveal how courts in other jurisdictions besides New York and California will wrestle with motions to dismiss on these claims and perhaps even motions for class certification.

The lesson from these cases and others is that flavor and ingredient-related representations continue to face considerable scrutiny. If businesses are updating labels or branding this year, it's worth the time to review flavor descriptions and consider the arguments that plaintiffs are asserting to help understand and assess risk.

Even food and beverage manufacturers that are in compliance with FDA regulations can and have been targets of these lawsuits. The food and beverage industry should be aware that plaintiffs have commonly alleged a photograph of a food on packaging that is not the real source of a product's flavor is misleading to consumers. Some manufacturers have tried to avoid lawsuits by including a disclaimer for "natural" or "artificially flavored" products on their packaging. It remains to be seen whether additional court dismissals will put an end to these "flavor of the year" lawsuits or if a new jurisdiction will soon become the new hotbed for class action food litigation.

2020 Significant Settlements

JUSTINE E. LENEHAN*

INTRODUCTION

This chapter summarizes a selection of significant settlements in 2020 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 2020, the federal government recovered $2.2 billion in FCA judgements and settlements, nearly $1.9 billion (86%) of which came from health care and life sciences companies.[1] Total recoveries amount to roughly $64 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 672 whistleblower suits filed in 2020 (as compared to 250 cases filed by the government) resulting in DOJ recovering nearly $1.7 billion from these and earlier filed suits and $309 million awarded to relators for their role.[3]

Notably, however, the 2020 recovery marked a ten-year low, decreasing 27% from the $3.08 billion recovered in 2019. This marked reduction in FCA recoveries in 2020 arguably reflects the impact of the novel coronavirus (COVID-19) pandemic that unavoidably slowed the pace of litigation nationwide and likely does *not* signal a decrease in DOJ's efforts to investigate and litigate alleged fraud against the government. In fact, the number of new matters initiated in 2020 increased over 17% from 2019.[4]

Further, the two stimulus bills enacted during the pandemic,[5] both of which commit the federal government to spend or make available trillions of dollars, have the potential to be a catalyst for increased FCA enforcement for months and years to come. Historically, an increase in fraud-related investigations and prosecutions follows

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1 U.S. DEP'T OF JUSTICE, FRAUD STATISTICS—OVERVIEW (Dec. 2020), https://www.justice.gov/opa/press-release/file/1354316/download.

2 *Id.*

3 *Id.*; Press Release, U.S. Dep't of Justice, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

4 U.S. DEP'T OF JUSTICE, *supra* note 1.

5 Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), Pub. L. No. 116-136 (2020); American Rescue Plan Act of 2021, Pub. L. No. 117-2 (2021).

implementation of federal programs directed at crisis relief. For example, following the 2008 financial crisis, Congress enacted The Emergency Economic Stabilization Act of 2008,[6] which established financial relief programs (such as the Troubled Asset Relief Program, commonly known as TARP) and established new mechanisms for oversight of the programs, very similar to the oversight mechanisms incorporated within the recent legislation passed in response to the COVID-19 pandemic. To date, more than $11 billion has been recovered as a result of TARP-related fraud enforcement.[7] It is likely that similar heightened attention to fraud investigation and prosecution will result here. Even prior to enactment of the CARES Act, then-Attorney General William Barr directed every U.S. Attorney's Office to prioritize the investigation and prosecution of all criminal conduct related to the COVID-19 pandemic, and then-Deputy Attorney General Jeffrey Rosen directed each U.S. Attorney to appoint a Coronavirus Fraud Coordinator for their federal judicial district.[8] We have already seen activity by DOJ and United States Attorneys' Offices prosecuting entities and individuals for fraudulent receipt of federal funds and activity related to products that impermissibly purport to treat, diagnose, and/or prevent COVID-19.[9]

While we can expect FCA enforcement related to the COVID-19 pandemic to play a significant role in DOJ activity, DOJ will also continue to prioritize existing efforts related to opioid abuse, protection of elderly patients and seniors, electronic health records, telehealth schemes, and cybersecurity.[10]

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 2020.

DRUGS

Novartis Pharmaceuticals Corporation

Novartis Pharmaceuticals Corporation (Novartis) agreed to pay more than $642 million in two separate settlements[11] relating to (1) the company's alleged illegal use

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6 Pub. L. No. 110-343 (2008).

7 Letter from the Special Inspector General, Office of the Special Inspector General for the Troubled Asset Relief Program, SIGTARP's Quarterly Report (October 1, 2020–December 31, 2020), https://www.sigtarp.gov/sites/sigtarp/files/2021-01/SIGTARP_First_Quarter_Letter_2021.pdf.

8 Memorandum from the Attorney General, Office of Att'y Gen., U.S. Dep't of Justice, COVID-19 – Department of Justice Priorities (March 16, 2020), https://www.justice.gov/archives/ag/page/file/1258676/download; Press Release, U.S. Dep't of Justice, Attorney General William P. Barr Urges American Public to Report COVID-19 Fraud (March 20, 2020), https://www.justice.gov/opa/pr/attorney-general-william-p-barr-urges-american-public-report-covid-19-fraud.

9 *See, e.g.*, Press Release, U.S. Dep't of Justice, Justice Department Takes Action Against COVID-19 Fraud (March 26, 2021), https://www.justice.gov/opa/pr/justice-department-takes-action-against-covid-19-fraud.

10 *See* U.S. Dep't of Justice, Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference (Feb. 17, 2021), https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar.

11 Press Release, U.S. Dep't of Justice, Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians (July 1, 2020), https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians. Similar to a component of the DOJ's settlement with Novartis, numerous other settlements in 2020 resolved alleged FCA violations

of three foundations as conduits to cover copayments of Medicare patients taking two of Novartis's drugs (Gilenya, for treatment of relapsing forms of multiple sclerosis, and Afinitor, a treatment for progressive neuroendocrine tumors and a second-line treatment for advanced renal cell carcinoma (RCC)); and (2) the company's alleged kickback payments to doctors.

The government alleged that, on numerous instances, Novartis gave money to co-pay foundations under the guise of charitable payments when, in fact, Novartis directed these funds through the foundations to patients taking the company's drugs. In effect, Novartis's payments to these foundations operated as kickback schemes. For instance, upon learning that it would be the only donor to an RCC copay assistance fund operated by a charitable donation, Novartis allegedly informed the foundation that it would be willing to donate only if the eligibility definition was narrowed to ensure that a greater amount of the copay assistance would support patients taking Afinitor. Novartis agreed to pay $51.25 million to resolve these allegations.

Further, to resolve FCA claims that Novartis paid kickbacks to doctors to induce prescription of the company's drugs Lotrel, Valtuma, Starlix, Tekturna, Tekturna HCT, Tekamlo, Diovan, Diovan HCT, Exforge, and Exforge HCT, the company agreed to: (1) pay over $591 million in settlements; (2) forfeit $38.4 million in proceeds; and (3) adhere to strict limitations on any future speaker programs. Novartis also agreed to pay an additional $48 million to resolve state Medicaid claims. The government alleged that Novartis hosted thousands of speaker programs and related events purported to provide educational content when, in reality, such events operated only as a means to bribe doctors.

Novartis also entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires Novartis to, among other things: (1) significantly reduce the number of paid speaker programs and the amounts spent on such programs; (2) hold such programs only in a virtual format and only under limited circumstances; (3) implement measures in order to promote independent from any patient assistance programs; and (4) cooperate in monitoring of its operations.

Gilead Sciences, Inc.

Gilead Sciences, Inc. (Gilead) agreed to pay $97 million to resolve allegations that the company illegally used a non-profit foundation as a conduit to cover copayments of Medicare patients taking Gilead's drug, Letairis, for pulmonary arterial hypertension.[12] Similar to Novartis's alleged activities described above, Gilead

related to pharmaceutical companies impermissibly making kickback payments, disguised as charitable contributions, to cover patients' copayments. *See e.g.*, Press Release, U.S. Dep't of Justice, Patient Services Inc. Agrees to Pay $3 Million for Allegedly Serving as a Conduit for Pharmaceutical companies to Illegally Pay Patient Copayments (Jan. 21, 2020), https://www.justice.gov/opa/pr/patient-services-inc-agrees-pay-3-million-allegedly-serving-conduit-pharmaceutical-companies; Press Release, U.S. Dep't of Justice, Biogen Agrees To Pay $22 Million To Resolve Alleged False Claims Act Liability For Paying Kickbacks (Dec. 17, 2020), https://www.justice.gov/opa/pr/biogen-agrees-pay-22-million-resolve-alleged-false-claims-act-liability-paying-kickbacks; Press Release, U.S. Dep't of Justice, United States Files False Claims Act Complaint Against Drug Maker Teva Pharmaceuticals Alleging Illegal Kickbacks (Aug. 18, 2020), https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-drug-maker-teva-pharmaceuticals.

[12] Press Release, U.S. Dep't of Justice, Gilead Agrees to Pay $97 Million to Resolve Alleged False Claims Act Liability for Paying Kickbacks (September 23, 2020), https://www.justice.gov/usao-ma/pr/gilead-agrees-pay-97-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

claimed to make charitable donations to a foundation but, according to the government, covered copays only for its own drug. Specifically, Gilead utilized data received from the foundation that detailed the amount the foundation spent on Letairis; Gilead used this data to determine its contributions to the foundation and set at an amount sufficient only to cover the copays of its own patients.

Indivior Solutions

As reported in last year's edition of *Top Food and Drug Cases* and announced by DOJ in July 2019, Reckitt Benckiser Group plc, former parent company to Indivior Solutions (Indivior), agreed to pay $1.4 billion as part of a settlement related to its sales and marketing of Suboxone, an opioid addiction treatment drug.[13] Following that resolution, Indivior and its parent companies have now agreed to pay nearly $600 million to resolve criminal and civil liability associated with its marketing of Suboxone. Specifically, Indivior or its parent companies must pay: (1) $289 million in criminal fines, forfeiture, and restitution; (2) $300 million in civil payments to the federal government and participating states; and (3) $10 million for allegations that it violated the Federal Trade Commission Act. The total recovery related to sale and marketing of Suboxone now reaches more than $2 billion—DOJ's largest recovery involving an opioid.

Indivior pleaded guilty to a one-count felony charge and admitted to making false statements to the Massachusetts Medicaid program (MassHealth) to promote Suboxone Film. Specifically, Indivior sent false data to MassHealth indicating that Suboxone Film had the lowest rate of accidental pediatric exposure. The former CEO of Indivior's parent company (Indivior plc), Shaun Thaxter, also pleaded guilty to a one-count misdemeanor charge related to these activities. This resolution of the criminal investigation totals $289 million and includes a criminal fine, forfeiture, and restitution. The plea agreement further requires that: (1) Indivior disband its Suboxone sales force and not reinstate it; (2) Indivior's CEO personally certify on an annual basis that during the prior year (a) Indivior was in compliance with the Federal Food, Drug, and Cosmetic Act and did not commit healthcare fraud or (b) list all non-compliant activity and the steps taken to remedy this activity; and (3) Indivior refrain from using data obtained from surveys from healthcare providers for marketing, sales, and promotional purposes, among other things.

Indivior's parent companies have agreed to pay $300 million to resolve claims that the marketing of Suboxone caused submission of false claims to government healthcare programs. This includes roughly $209.3 million to the federal government and $90.7 million to participating states. Specifically, the government alleged that Indivior companies knowingly (1) promoted Suboxone to physicians who wrote prescriptions for illegitimate medical purposes and were often diverted, among other things; (2) promoted Suboxone to physicians and state Medicaid agencies using false and misleading claims that the product was less susceptible to diversion, abuse, and accidental pediatric exposure as compared to competitive products; and (3) submitted a petition to FDA claiming that the Suboxone Tablet was discontinued due to safety concerns in an effort to delay the entry of generic competition.

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[13] Press Release, U.S. Dep't of Justice, Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay $600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution (July 24, 2020), https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.

Indivior also entered into a five-year CIA with the HHS-OIG subjecting the company to accountability and auditing requirements. For instance, top executives and the Board of Directors must certify compliance with an annual risk assessment to be undertaken by Indivior, and an independent reviewer must conduct multi-faced audits.

Lastly, under a separate agreement with the Federal Trade Commission, Indivior has agreed, among other things, to pay $10 million to resolve allegations that it violated the Federal Trade Commission Act by impeding competition from generic equivalents of Suboxone.

MEDICAL DEVICES

Pentax Medical Company

Pentax Medical Company (Pentax) agreed to pay $43 million to resolve criminal charges arising out of the company's shipment of four types of endoscope products without FDA-cleared instructions for use and due to the company's failure to file timely adverse event reports.[14] Specifically, Pentax must pay a $40 million criminal fine and forfeit $3 million. Pentax also entered into a three-year deferred prosecution agreement pursuant to which the company must comply with certain reform and enhanced compliance requirements.

Pentax admitted that it deliberately chose *not* to use revised FDA-cleared instructions related to cleaning of its medical products for fear that doing so would negatively impact sales. Further, Pentax admitted that, on two separate occasions, it failed to file timely adverse event reports after learning that numerous patients had been infected with serious bacteria following treatment with endoscopes that had been used on other infected patients.

As part of the deferred prosecution agreement, Pentax must conduct audits of its current instructions for use and adverse event report reporting procedures to ensure compliance with FDA requirements. Further, Pentax must enhance its compliance training and maintain an effective compliance program; certifications to this effect must be made annually by Pentax's president, as well as the president of Pentax's parent company and its board of directors.

ResMed Corp.

ResMed Corp. (ResMed) agreed to pay more than $37.5 million to resolve civil allegations that the company violated the FCA by paying kickbacks to durable medical equipment suppliers, sleep labs, and other health care providers in order to induce patient referrals.[15] This settlement resolves five *qui tam* lawsuits in which the whistleblowers will collectively receive $6.2 million of the settlement.

ResMed's activities included provision of: free patient outreach services that enabled suppliers to order resupplies for sleep apnea patients, free and below-cost

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[14] Press Release, U.S. Dep't of Justice, Pentax Medical Company Agrees to Pay $43 Million to Resolve Criminal Investigation Concerning Misbranded Endoscopes (April 7, 2020), https://www.justice.gov/opa/pr/pentax-medical-company-agrees-pay-43-million-resolve-criminal-investigation-concerning.

[15] Press Release, U.S. Dep't of Justice, Resmed Corp. to Pay the United States $37.5 Million for Allegedly Causing False Claims Related to the Sale of Equipment for Sleep Apnea and Other Sleep-Related Disorders (January 15, 2020), https://www.justice.gov/opa/pr/resmed-corp-pay-united-states-375-million-allegedly-causing-false-claims-related-sale.

sleep apnea masks and machines to sleep labs, fully guaranteed interest-free loans in connection with the purchase of ResMed equipment, and non-sleep specialist physicians free home sleep testing devices.

ResMed also entered into a CIA with the HHS-OIG requiring that ResMed implement additional controls regarding its product pricing and sales and that the company monitor its arrangements with referral sources.

Practice Fusion, Inc.

Practice Fusion Inc. (Practice Fusion) agreed to pay $145 million to resolve criminal and civil liability arising out of the company's electronic health records (EHR) software.[16] Notably, this marks the first criminal action against an EHR vendor. Medical professionals rely upon patient data and unbiased medical information contained in EHR software to properly advise patients. However, the government alleged that Practice Fusion received kickbacks from pharmaceutical manufacturers in exchange for implementing clinical decision support (CDS) alerts in its software that were designed to increase prescription of their products.

With respect to its criminal liability, Practice Fusion admitted to soliciting and receiving kickbacks from various pharmaceutical manufacturers in exchange for use of its EHR software to influence physician prescribing of opioid drug products. Specifically, Practice Fusion allowed companies to influence the development, implementation, and design of CDS alerts, including when a prescriber may receive an alert and what the alert would say. Practice Fusion also entered into a deferred prosecution agreement with the U.S. Attorney's Office for the District of Vermont pursuant to which the company must invest heavily in compliance overhauls and commit to stringent oversight and transparency, pay a criminal fine of $25.3 million dollars, and forfeit proceeds of nearly $1 million.

Practice Fusion agreed to pay $118.6 million to the federal government and to states in order to resolve civil allegations that it accepted kickbacks and knowingly caused users of the EHR software (healthcare providers) to submit false claims for federal incentive payments by misrepresenting the capabilities and certifications of its EHR software.

HEALTHCARE SERVICES

Oklahoma Center for Orthopaedic and Multi-Specialty Surgery

The Oklahoma Center for Orthopaedic and Multi-Specialty Surgery (OCOM), its part-owner and management company, USP OKC, Inc. and USP OKC Manager, Inc. (collectively, USP), an Oklahoma City-based physician group, Southwest Orthopaedic Specialists, PLLC (SOS), and two SOS physicians agreed to pay $72.3 million to resolve allegations in connection with improper relationships between OCOM and SOS, resulting in the submission of false claims in violations of the FCA and Oklahoma Medicaid False Claims Act.[17] Specifically, USP agreed to pay $60.86

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[16] Press Release, U.S. Dep't of Justice, Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations (January 27, 2020), https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0.

[17] Press Release, U.S. Dep't of Justice, Oklahoma City Hospital, Management Company, And Physician Group to Pay $72.3 Million To Settle Federal And State False Claims Act Allegations Arising

million to the United States, $5 million to the State of Oklahoma, and $206,000 to the State of Texas. SOS and two of its physicians agreed to pay $5.7 million to the United States and over $495,000 to the State of Oklahoma.

The government alleged that, for over a decade, OCOM and USP gave improper remuneration to SOS and certain physicians in exchange for patient referrals. This remuneration took the form of: free or below-fair market value office space, employees, and supplies; above-market compensation for services provided by SOS; equity buyback provisions and payments to certain physicians in excess of fair market value; and preferential investment opportunities for the provision of anesthesia services at OCOM. As a result of this activity, claims were submitted to the Medicare, Medicaid, and TRICARE programs for illegally referred patients. The government further alleged that USP impermissibly provided preferential investment opportunities to physicians at four surgery facilities in Texas.

OCOM and SOS also each entered into five-year CIAs with the HHS-OIG. Under these agreements, OCOM and SOS will maintain compliance programs and hire an independent reviewer to assess arrangements that their respective entities enter into. Further, key executives must make compliance-related certifications in order to increase individual accountability.

Universal Health Services

Universal Health Services, Inc., UHS of Delaware, Inc. (together, UHS), and a UHS facility, Turning Point Care Center, LLC (Turning Point), agreed to pay a combined total of $122 million to resolve alleged FCA violations for (1) billing for medically unnecessary inpatient behavioral health services; (2) failing to provide adequate and appropriate services; and (3) paying illegal inducements to federal healthcare beneficiaries.[18]

Specifically, UHS agreed to pay to the United States and to participating states a total of $117 million; the federal government will receive roughly $88 million of these funds, with roughly $29 million being returned to individual states. The government alleged that, for over a decade, UHS facilities admitted patients who were not eligible for inpatient or residential treatment and failed to properly discharge admitted patients who no longer needed inpatient care. Further, UHS facilities billed for services not rendered; billed for improper and excessive lengths of stay; failed to provide adequate staffing, training and/or supervision of staff; and improperly used physical and chemical restraints and seclusion. UHS also allegedly failed to provide care consistent with federal and state regulations, such as failing to update individual assessments and treatment plans, failing to provide adequate discharge planning, and failing to provide required therapy services.

On behalf of its inpatient acute and residential behavior health facilities, UHS entered into a five-year CIA with the HHS-OIG pursuant to which an independent monitor selected by OIG will assess and report back on UHS' Behavior Health

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From Improper Payments To Referring Physicians (July 8, 2020), https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal.

[18] Press Release, U.S. Dep't of Justice, Universal Health Services, Inc. and Related Entities To Pay $122 Million To Settle False Claims Act Allegations Relating To Medically Unnecessary Inpatient Behavioral Health Services And Illegal Kickbacks (July 10, 2020), https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act.

Division's patient care protections. An independent reviewer must also assess UHS' inpatient behavior health claims to federal health care programs on an annual basis.

Separately, Turning Point agreed to pay the United States and the State of Georgia $5 million in connection with allegations that, for over a decade, it provided free or discounted transportation services to induce Medicare and Medicaid beneficiaries to seek treatment at its facilities.

This settlement resolves nineteen *qui tam* lawsuits in which the whistleblowers will collectively receive almost $17 million of the settlements. The alleged conduct by UHS and Turning Point was viewed as especially predatory in that it affected vulnerable populations—those seeking care for additional and other behavioral health needs.

CONVENTIONAL FOOD

Blue Bell Creameries L.P.

Ice cream manufacturer Blue Bell Creameries L.P. (Blue Bell) agreed to pay $19.35 million to resolve criminal and civil liability arising from claims that the company shipped contaminated products linked to a 2015 listeriosis outbreak.[19] Blue Bell's former president was also charged in connection with covering up the incident.

On more than one instance, state officials notified Blue Bell that certain of its ice cream products were contaminated with *Listeria monocytogenes* (*L. mono*); however, Blue Bell surreptitiously removed certain contaminated product from the market but failed to recall the products or issue any formal communication to consumers until roughly one month later, following multiple hospitalizations. Around this same time, FDA inspections also revealed sanitation issues at two Blue Bell facilities.

This resolution included: (1) a $17.25 million criminal fine and forfeiture pursuant to a plea agreement in which Blue Bell pled guilty to two misdemeanor counts of distributing adulterated ice cream product; and (2) a $2.1 million civil settlement to resolve allegations that the products were manufactured under insanitary conditions and sold to federal facilities. This settlement amount is the second largest ever related to a food safety matter.

Mississippi Department of Health Services

The Mississippi Department of Health Services (MDHS) agreed to pay $5 million to resolve allegations that its administration of the U.S. Department of Agriculture's (USDA) Supplemental Nutrition Assistance Program (SNAP) violated the FCA.[20] Under SNAP, USDA provides eligible low-income individuals and families with financial assistance to purchase food. The federal government funds SNAP but relies on the states to determine an applicant's eligibility for benefits, to administer those benefits, and to perform quality control on eligibility decisions. USDA reimburses

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[19] Press Release, U.S. Dep't of Justice, Blue Bell Creameries Agreed to Plead Guilty and Pay $19.35 Million for Ice Cream Listeria Contamination – Former Company President Charged (May 1, 2020), https://www.justice.gov/opa/pr/blue-bell-creameries-agrees-plead-guilty-and-pay-1935-million-ice-cream-listeria.

[20] Press Release, U.S. Dep't of Justice, Mississippi Department of Health Services Agrees to Pay $5 Million to Resolve False Claims Act Liability in Connection with SNAP Quality Control (June 2, 2020), https://www.justice.gov/opa/pr/mississippi-department-health-services-agrees-pay-5-million-resolve-false-claims-act.

states for a portion of administrative expenses incurred in administering SNAP and awards performance bonuses to states with the lowest and most improved error rates.

The allegations stemmed primarily from concerns that third-party consultants weakened the integrity of the SNAP quality control process. Specifically, MDHS engaged a consultant, Julie Osnes Consulting, LLC (Osnes Consulting), to provide advice designed to lower its quality control error rate. The government alleged that Osnes Consulting's recommendations created bias, resulting in MDHS' submission of false quality control data to USDA and its receipt of undeserved performance bonuses.

This settlement represents the sixth settlement with a state agency for manipulating its SNAP quality control findings, following settlements in Virginia, Wisconsin, Texas, Louisiana, and Alaska. Inclusive of this settlement with MDHS, the United States has recovered over $41 million in connection with this investigation.

CONCLUSION

The 2020 settlements illustrate FDA's and DOJ's commitment to food and drug safety, even in the face of a global pandemic.

The FCA operates as the government's primary civil tool to rectify false claims of federal funds. With the availability of trillions of dollars of federal relief funds in response to COVID-19, we may expect to see an abrupt increase in the number of new investigations and/or recovery figures in the coming years. However, whether DOJ will re-align any areas of focus to those particularly implicated by our behavioral changes in response to COVID-19 (think, increases in the use of telehealth medicine and resulting cybersecurity concerns) remains to be seen.

Significant Regulatory, Policy, and Enforcement Developments: 2020
A Tale of the Three C's: COVID-19, Cannabis, and CBD

LAUREN FARRUGGIA & JONATHAN HAVENS*

To state the very obvious, the COVID-19 pandemic has had and will continue to have a profound impact on the U.S. Food and Drug Administration (FDA or agency). However, there were significant regulatory, policy, and enforcement developments in 2020 not having anything to do with the global pandemic, including in the cannabis and cannabidiol (CBD) spaces.

COVID-19

The agency published its first statement regarding the novel coronavirus on January 27, 2020, in an attempt to assure the public that FDA was acting quickly "to facilitate the development and availability of investigational medical products to help address this urgent public health situation."[1] Shortly thereafter, on January 31, 2020, then-Department of Health and Human Services (HHS) Secretary Alex M. Azar II declared a public health emergency pursuant to his authority under Section 319 of the Public Health Service Act.[2] Over one year later, after industry's unprecedented push for expanded testing, rapid manufacturing and sourcing of personal protective equipment (PPE), development of investigational therapies, and studying and securing authorization for multiple vaccine candidates, there is light at the end of the tunnel.

In spite of the fairly successful vaccine rollout to date, FDA's portfolio will continue to be dominated by COVID-19 throughout 2021. Since former Secretary Azar declared the public health emergency over a year ago, the agency has relied on its authority under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which permits the FDA Commissioner to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to

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1 Press Release, U.S. Food & Drug Admin., FDA Announces Key Actions to Advance Development of Novel Coronavirus Medical Countermeasures (Jan. 27, 2020), https://www.fda.gov/news-events/press-announcements/fda-announces-key-actions-advance-development-novel-coronavirus-medical-countermeasures.

2 Press Release, U.S. Dep't of Health & Human Servs., Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus (Jan. 31, 2020), https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html.

diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when there are no adequate, approved, and available alternatives that exist.[3] Under this Emergency Use Authorization (EUA) provision, FDA has permitted the marketing of hundreds of products that have not been subject to ordinary (*i.e.*, non-emergency) premarket review, including face masks, surgical masks, and respirators, as well as PPE and PPE decontaminants, diagnostic and serological (*i.e.*, antibody) tests, ventilators, patient monitoring devices, and, as of April 9, 2021, three safe and effective COVID-19 vaccines.[4] These products must all satisfy certain criteria in order to receive an EUA, and each authorization letter specifies, in some form, that the "EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of [the product] during the COVID-19 outbreak is terminated."[5]

While, unfortunately, the public health emergency will not be lifted any time soon, we anticipate that manufacturers of items marketed pursuant to EUA will eventually face the same dilemma: Whether to spend the necessary resources to register their establishments and pay the required registration fee, as well as apply for, and obtain, the requisite premarket clearance or approval required to market their product(s) in non-emergency settings. These expenses will prove difficult for certain firms that were not previously subject to FDA's jurisdiction but who pivoted their manufacturing operations to assist the public during the early months of the pandemic (*e.g.*, alcohol producers pivoting to making hand sanitizer, although HHS recently clarified that FDA's newly enacted over-the-counter (OTC) monograph drug facility fees will not apply to those companies that first entered the OTC drug market only to produce hand sanitizer during the COVID-19 public health emergency).[6] Beyond the burdens on industry not used to FDA compliance and related costs, the agency will also be burdened by a return to non-emergency review of products (*e.g.*, handling an influx of premarket applications).

CANNABIS

Despite COVID-19, 2020 was marked by significant cannabis sector growth, due in large part to the impact of cannabis ballot initiatives in the November 2020 elections. Given the strength of public support for cannabis legalization (currently, sixty-eight percent of Americans support legalization), it is not surprising that state cannabis policy momentum in the U.S. continued to grow last year, a trend which shows no signs of slowing down.[7] On November 4, 2020, voters in five states approved

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[3] 21 U.S.C. § 360bbb–3.

[4] *See* U.S. Food & Drug Admin., Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization (reissued Feb. 25, 2021), https://www.fda.gov/media/144412/download; U.S. Food & Drug Admin., Moderna COVID-19 Vaccine EUA Letter of Authorization (reissued Feb. 25, 2021), https://www.fda.gov/media/144636/download; U.S. Food & Drug Admin., Janssen COVID-19 Vaccine EUA Letter of Authorization (Feb. 27, 2021), https://www.fda.gov/media/146303/download.

[5] *See id.*

[6] *FDA In Brief: FDA Republishing Fee Rates under the Over-the-Counter Monograph Drug User Fee Program*, U.S. FOOD & DRUG ADMIN. (Mar. 25, 2021), https://www.fda.gov/news-events/fda-brief/fda-brief-fda-republishing-fee-rates-under-over-counter-monograph-drug-user-fee-program.

[7] Megan Brenan, *Support for Legal Marijuana Inches Up to New High of 68%*, GALLUP (Nov. 9, 2020), https://news.gallup.com/poll/323582/support-legal-marijuana-inches-new-high.aspx.

ballot measures to authorize medical and/or adult use cannabis programs.[8] At present, thirty-seven states and the District of Columbia have medical programs, or have paved the way for the same, with seventeen of those states also having adult-use (*i.e.*, recreational) programs.[9]

Mississippi and South Dakota approved measures to regulate medical cannabis, and Arizona, Montana, New Jersey, and South Dakota approved measures to regulate adult-use cannabis.[10] South Dakota became the first state to authorize medical and adult-use cannabis simultaneously.[11] The timelines in other states, such as Mississippi and South Dakota, are less clear, with program launches likely in 2022.[12]

These state developments make one thing clear: Support for cannabis does not conform with geographic or traditional political lines. Anyone who assumes that only coastal blue states will support cannabis does so at their own peril. Voters in Mississippi, Montana, and South Dakota delivered solid victories for former President Trump, but these same voters approved cannabis ballot initiatives by even wider margins.[13] Federal cannabis reform largely stalled in 2020, but given Democratic control of the House of Representatives, the Senate, and the White House, that could change moving forward. In December 2020, the U.S. House of Representatives passed (228-164, mostly, but not entirely, along party lines) the Marijuana Opportunity Reinvestment and Expungement Act (MORE Act) that, if enacted, would end the federal prohibition and criminalization of marijuana by descheduling it from the Federal Controlled Substances Act.[14] Such legislation was not taken up by the Senate, but marked the first time that Congress has ever voted on the issue. In light of the January 6, 2021 Georgia runoff elections (Sens. Raphael Warnock's and Jon Ossoff's wins have split the Senate 50-50, with Vice President Kamala Harris serving as the tiebreaker), cannabis reform legislation may receive a warmer reception under the Biden Administration.[15] The prospect of Senate approval of the MORE Act is not clear, given that Democrats could very well retain the chamber's filibuster rule, meaning that sixty votes could be required to invoke cloture (*i.e.*, end the filibustering of a bill). Approval of more modest approaches, like that in the Strengthening the Tenth Amendment Through Entrusting States (STATES) Act and/or the Secure And Fair Enforcement (SAFE) Banking Act could be more likely.[16] However, in an

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[8] *State Medical Marijuana Laws*, NAT'L CONF. OF STATE LEGS. (last updated Apr. 5, 2021), https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Mississippi Medical Marijuana Program*, MISS. STATE DEP'T OF HEALTH (last accessed Apr. 18, 2021), https://msdh.ms.gov/msdhsite/_static/30,0,425.html; S.D. Constitutional Amendment (Marijuana Legalization Initiative), https://sdsos.gov/elections-voting/assets/2020_CA_LegalizeMarijuana_AG Statement.pdf; S.D. Measure 26 (Medical Marijuana Initiative), https://sdsos.gov/elections-voting/assets/ MedMarijPetitionApproved.pdf.

[13] Alice Park, Charlie Smart, Rumsey Taylor & Miles Watkins, *An Extremely Detailed Map of the 2020 Election*, N.Y. TIMES (last accessed Apr. 18, 2021), https://www.nytimes.com/interactive/2021/ upshot/2020-election-map.html.

[14] H.R. 3884, 116th Cong. (2019–2020).

[15] *Georgia U.S. Senate Runoff Results*, THE WASHINGTON POST (Jan. 19. 2021), https://www.washingtonpost.com/elections/election-results/georgia-senate-runoffs-2021/.

[16] *See* H.R. 2093, 116th Cong. (2019–2020); H.R. 1595, 116th Cong. (2019–2020).

interview in early April, Senate Majority Leader Chuck Schumer (D-N.Y.)—who is drafting new federal marijuana reform legislation with Sens. Cory Booker (D-N.J.) and Ron Wyden (D-Ore.)—indicated that the U.S. Senate will act on marijuana legalization with or without President Biden's support.[17]

CBD

Similarly, 2021 could see further progress related to FDA's regulation of hemp-derived cannabidiol (CBD) in consumer products, but it may be too soon to tell.

On July 22, 2020, FDA sent to the White House Office of Management and Budget (OMB) for review a draft guidance, "Cannabidiol Enforcement Policy."[18] As the document was still pending review when former President Trump left office, it was subject to a regulatory "freeze" instituted by President Biden. Just a day after President Biden was inaugurated, on January 21, 2020, FDA withdrew the enforcement policy; it is not yet clear if/when the agency will release the policy (and whether it needs to go back to OMB or if FDA could issue it unilaterally), although some have predicted it could be released at any time.[19] Despite many predictions about what the document might contain—including by the authors—it appears that no one outside of the agency or OMB has yet seen the guidance.[20]

Also on July 22nd, FDA announced the availability of a draft guidance for industry, "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research," which may provide some insight into how the agency will regulate CBD products in the future.[21] On November 19, 2020, FDA held a public hearing regarding sex and gender differences in CBD use and responses, which made clear that, although the agency has made some progress in its research and assessment of CBD products across user groups, the agency still has many unanswered questions about the science, safety, and quality of products containing CBD.[22]

On the enforcement side, on December 17, 2020, the Federal Trade Commission (FTC) took action against six sellers of CBD-containing products for allegedly making a wide range of scientifically unsupported claims about their ability to treat serious

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[17] Natalie Fertig, *Schumer: Senate Will Act on Marijuana Legalization With or Without Biden*, POLITICO (Apr. 3, 2021), https://www.politico.com/news/2021/04/03/schumer-senate-marijuana-legalization-478963.

[18] *See* Office of Info. & Reg. Affs., Office of Mgmt. & Budget, Cannabidiol Enforcement Policy; Draft Guidance for Industry; Availability (received July 22, 2020; concluded date Jan. 21, 2021), https://www.reginfo.gov/public/do/eoDetails?rrid=130911.

[19] *Id.*

[20] Laura Drotleff, *FDA Submits CBD Enforcement Policy Draft Guidance to White House*, HEMP INDUSTRY DAILY (July 23, 2020), https://hempindustrydaily.com/fda-submits-cbd-enforcement-policy-draft-guidance-to-white-house/.

[21] CANNABIS AND CANNABIS-DERIVED COMPOUNDS: QUALITY CONSIDERATIONS FOR CLINICAL RESEARCH GUIDANCE FOR INDUSTRY, DRAFT GUIDANCE FOR INDUSTRY, U.S. FOOD & DRUG ADMIN. (July 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cannabis-and-cannabis-derived-compounds-quality-considerations-clinical-research-guidance-industry.

[22] *Scientific Conference: CBD and Other Cannabinoids: Sex and Gender Differences in Use and Responses*, U.S. FOOD & DRUG ADMIN. (Nov. 19, 2020), https://www.fda.gov/science-research/womens-health-research/scientific-conference-cbd-and-other-cannabinoids-sex-and-gender-differences-use-and-responses.

health conditions.[23] FDA took similar action on December 22, 2020, issuing five Warning Letters to companies for making similar impermissible, aggressive health claims.[24] These enforcement measures largely mirror FTC and FDA's prior concerns with unlawfully marketed CBD products that pose the greatest risk of harm to the public.

Although President Biden has yet to name his pick for FDA Commissioner as this book goes to press—something with which several former commissioners have taken issue—Janet Woodcock, M.D., an agency veteran who most recently served as the Director of FDA's Center for Drug Evaluation and Research (CDER) is currently serving as Acting Commissioner.[25] If she is nominated by President Biden to serve as Commissioner of the agency, which some have predicted, we expect—given her background and portfolio at the agency related to drug products—that FDA's protracted review of CBD could continue. One has to wonder, though: If federal and state cannabis reform efforts continue, will FDA's approach to CBD remain the same? With that said, the agency's position on CBD has nothing to do with its derivation from hemp, a cannabis varietal, and everything to do with CBD being studied and approved as a drug before it was marketed as an ingredient in foods.

As industry and Congress grow increasingly impatient with FDA related to the agency's relative inaction on CBD, we expect a renewed legislative push in 2021 for hemp-derived CBD to be permitted as a dietary ingredient for use in supplements. H.R. 8179 was the legislative vehicle in the 116th Congress; it will need to be reintroduced in the 117th Congress.[26] While Reps. Kurt Schrader (D-Ore.) and Morgan Griffith (R-Va.) will likely reintroduce their legislation early this year, some in Congress might wait to see if FDA's enforcement policy addresses the legislation's goals (spoiler alert: it will not, at least not nearly to the same degree as the legislation would). Regarding the bill, it will be interesting to see how much Congress listens to FDA's "technical comments" related to the same.[27] The agency's recent comments on the bill differ greatly from the approach some members of Congress are pursuing.

At any rate, CBD and cannabis remain topics of great interest to stakeholders and the public, and we expect to see more federal and state legislative and regulatory action in 2021.

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[23] Press Release, Fed. Trade Comm'n, FTC Announces Crackdown on Deceptively Marketed CBD Products (Dec. 17, 2020), https://www.ftc.gov/news-events/press-releases/2020/12/ftc-announces-crackdown-deceptively-marketed-cbd-products.

[24] Press Release, U.S. Food & Drug Admin., FDA Warns Companies Illegally Selling CBD Products (Dec. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-cbd-products.

[25] Beth Snyder Bulik, *Former FDA Chiefs Pressure Biden to Nominate a New Commissioner—And Quickly*, FIERCE PHARMA (Mar. 11, 2021), https://www.fiercepharma.com/marketing/former-fda-chiefs-pressure-biden-to-nominate-a-new-commissioner.

[26] H.R. 8179, 116th Cong. (2019–2020).

[27] Josh Long, *FDA, Congress Differ on How CBD Should be Regulated in Supplements*, NATURAL PRODUCTS INSIDER (Nov. 24, 2020), https://www.naturalproductsinsider.com/regulatory/fda-congress-differ-how-cbd-should-be-regulated-supplements.

Cases to Watch

JAMES BECK, AUGUST T. HORVATH, WILLIAM JANSSEN, SARA KOBLITZ, LYNN C. TYLER & ANNE WALSH**

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

GENUS MEDICAL TECHNOLOGIES V. FDA[1]

This case, as explained in our 2020 Cases to Watch, asks the D.C. Circuit to limit FDA's discretion in deciding whether to regulate a medical product—one that meets the statutory definition of a medical device—as a drug rather than a device. Looking at barium sulfate, which FDA does not dispute constitutes a device under the relevant statutory definition, FDA took the position that it could choose whether to regulate the device as a drug at will based on an overlap in their statutory definitions. Here, FDA did so in an effort to regulate all contrast agents, regardless of their mechanism of action, the same.

After undertaking the required regulatory process, Genus sued FDA arguing that the plain language of the statute, when analyzed in context and in accordance with the widely accepted tools of statutory interpretation, requires FDA to regulate any product that meets the definition of a device as a device. The district court held that FDA's claimed discretion would render superfluous the device definition in the statute. FDA appealed, and the D.C. Circuit affirmed the district court's decision relying on the long-accepted adage that specific statutory language supersedes general statutory provision. Thus, the D.C. Circuit directed FDA to treat products as devices if they meet the statutory definition of a device. This decision limits FDA's typically broad discretion and precludes the agency from imposing significant regulatory hurdles and costs based on policy positions rather than the congressionally imposed risk-based regulatory scheme.

As of April 2021, the Department of Justice, on FDA's behalf, is considering petitioning for a rehearing *en banc*. Given the significant implications of the case—specifically the limits on FDA discretion—the Department of Justice could also file a Petition for Certiori.

** 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 Docket No. 20-5026 (D.C. Cir. 2021).

JUDGE ROTENBERG EDUCATION CENTER V. FDA[2]

Can FDA use its banning authority to restrict the practice of medicine? Although FDA has long had the power to ban certain medical devices, the agency has only used its statutory banning authority three times. The first two bans were not challenged in court, but in *Judge Rotenberg Education Center v. FDA*, petitioners sued FDA to overturn its ban of electrostimulation devices when used to treat aggressive or self-injurious behaviors. On April 23, 2021, a three-judge panel from the U.S. Court of Appeals for the D.C. Circuit heard oral arguments from the parties. The court was focused on understanding why FDA's action to ban the device when used for one purpose but not another did not run afoul of Congress's prohibition against FDA doing anything to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship," in other words, the practice of medicine. In the banning regulation, FDA explicitly permitted the banned devices to be used for other purposes, like smoking cessation. The court questioned how a ban of a specific use did not fall squarely into a restriction of a health care practitioner's decision-making for how to treat a patient. This case is notable because of the novelty of FDA's use of its banning authority and the implications on FDA's ability to regulate the practice of medicine.

IN RE ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION[3]

In *In re Zantac (Ranitidine) Products Liability Litigation*,[4] the court held, first, that none of thirty-five jurisdictions would recognize innovator liability, the theory that seeks to hold branded drug manufacturers liable for defects in generic drug labeling where claims against the generic manufacturer are preempted. Second, with respect to the two jurisdictions, California and Massachusetts, that have recognized some variant of innovator liability, the court held that residents of those states were unable to obtain personal jurisdiction over the branded manufacturer because that manufacturer had no jurisdictional contacts in either state, since they were not alleged to have sold anything to plaintiff. *In re Zantac* has been appealed to the Eleventh Circuit, which can be expected to rule on these issues sometime in 2021.

JOHNSON & JOHNSON V. INGHAM[5]

This is a series of lawsuits alleging ovarian cancer from the use of Johnson's Baby Powder. Separate complaints filed by twenty-two different plaintiffs were consolidated for trial, at their request, before a common jury in Missouri State court. The claims that were to be tried together varied markedly, from patients in remission to patients who had died. Nonetheless, after the consolidated presentation, the common

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2 No. 20-1087 (D. C. Cir.).

3 __ (11th Cir.).

4 MDL No. 2924, __ F. Supp.3d __, 2020 WL 7866660 (S.D. Fla. Dec. 31, 2020).

5 No. 20-1223 (Sup. Ct.).

jury awarded each plaintiff $25 million in compensatory damages and imposed an additional $1.6 billion in punitive damages.

Defendant Johnson & Johnson sought review in a certiorari petition filed in March 2021. A decision on the petition is unlikely before Fall 2021. The appeal seeks review on three issues, including the constitutionality of both the punitive award and the exercise of personal jurisdiction. The lead issue, however, is what merits special attention by products litigators because of its potentially far-reaching effects across the inventory of products cases pending in both federal and state courts—does consolidation of different products liability claims pressed by different injured plaintiffs before a single jury implicate due process concerns under the federal Constitution, and if so, what is the proper analysis for assessing that constitutional fitness?

CLARK V. WESTBRAE NATURAL, INC.[6]

As reported in a chapter earlier in this volume, several U.S. district courts in the Second and Ninth Circuits have considered food labeling suits alleging that applying the flavor designator "vanilla" to a food such as ice cream or non-dairy milk, sometimes with additional material such as images of a vanilla flower or seed pod, implies to consumers that all of the vanilla flavoring in the product is derived from the vanilla plant, as opposed to some of it being from other flavors. One of the California cases, *Clark v. Westbrae Natural, Inc.*,[7] has been appealed to the Ninth Circuit Court of Appeals. Plaintiffs contest the district court's findings that they did not adequately plead facts in support of their allegations that a reasonable consumer would conclude from viewing a typical vanilla product package that all of the flavoring in the product must come from the vanilla plant, and further contest the finding that they did not adequately plead a violation of FDA regulations.

In their arguments at the district court level in the various vanilla and related flavoring cases, plaintiffs have argued for a permissive interpretation of *Williams v. Gerber Products Co.*,[8] essentially maintaining that almost any allegation about consumer perceptions of advertising or of food labeling must be taken as true for purposes of a Rule 12 motion to dismiss. This interpretation has been undercut by more recent Ninth Circuit decisions such as *Becerra v. Dr Pepper/Seven Up, Inc.*,[9] which supported a district court's duty to examine the plausibility of such allegations critically and with attention to context, even at the pleading stage. The outcome of this appeal will have implications for the approach that courts in the Ninth Circuit take to reviewing the plausibility of allegations of deceptive food labeling and other marketing materials at this stage of the case.

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6 No. 21-15749 (9th Cir.).

7 No. 3:20-cv-03221-JSC (N.D. Cal.).

8 552 F.3d 934 (9th Cir. 2008).

9 945 F.3d 1225 (9th Cir. 2019).

SEIFE V. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES[10]

In *Seife v. U.S. Dep't of Health and Human Servs.*, the district court entered summary judgment in favor of FDA and Sarepta Pharmaceuticals ("Sarepta") that certain information from clinical trials sponsored by Sarepta was exempt from disclosure under the Freedom of Information Act as "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[11] Four categories of information from two studies were at issue: (1) clinical study procedures; (2) clinical study results; (3) exploratory endpoints; and (4) unrelated adverse events.

The court applied the Supreme Court's recent decision in *Food Marketing Institute v. Argus Leader Media*[12] that "confidential" in § 552(b)(4) means "customarily [and actually] kept private, or at least closely held, by the person imparting it."[13] The Supreme Court also noted, but did not decide, that for this exemption to apply, it may be necessary that the information "was provided to the government under an assurance of privacy."[14] In *Seife*, the district court found that both conditions were satisfied. Seife argued that the information was not "confidential" because Sarepta publicized it when submitting an application for market approval of the relevant drug to the European Medicines Agency (EMA) knowing that, regardless of the outcome, the EMA would publish the data." The district court rejected this argument, however, stating that Seife provided no evidence that the EMA published information identical to the withholdings at issue.

The district court noted that Congress amended FOIA in 2016 to add an additional "foreseeable harm" requirement. Specifically, FOIA now provides that an agency "shall . . . withhold information . . . only if . . . (I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption . . . ; or (II) disclosure is prohibited by law."[15] The court found disclosure of the clinical trial information at issue was "prohibited by law," namely, 21 C.F.R. §§ 20.61 and 314.430. The court also applied the "foreseeable harm" prong to some of the information at issue and found that it was satisfied. It noted that the pharmaceutical industry is highly competitive, that Sarepta's competitors were attempting to develop a competing drug, and that disclosure of the information would help its competitors and harm Sarepta.

Seife has appealed the district court's decision to the Second Circuit, where the case is pending under appeal number 20-4072.

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10 No. 20-4072 (2d Cir.).

11 5 U.S.C. § 552(b)(4).

12 139 S. Ct. 915 (2019).

13 *Id.* at 2363.

14 *Id.*

15 5 U.S.C. § 552(a)(8)(A)(i).